HEALTH INFORMATION AND PATIENT SAFETY BILL

Revised General Scheme

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PART 1: PRELIMINARY MATTERS

Short title and commencement
1. Provide that:
(1) This Act may be cited as the Health Information and Patient Safety Act 201x.

(2) This Act shall come into operation on such day or days as may be appointed by order or orders made by the Minister, either generally or with reference to a particular purpose or provision, and different days may be so appointed for different purposes and different provisions.

Explanatory Note
This is a standard provision.

Interpretation -General
2. Provide that:
In this Act-

"*Act of 1988*" means the Data Protection Act 1988 as amended by the Data Protection (Amendment) Act 2003;

"Act of 2007" means the Health Act 2007;

"Act of 2014" means the Freedom of Information Act 2014;

"*Authority*" means the Health Information and Quality Authority established by the Health Act 2007;

"Commissioner" has the meaning assigned to it by section 9 of the Act of 1988;

"*data controller*" has the same meaning as in the Act of 1988;

"*data set*" means a collection of records that contains data about more than one individual that includes–

(a) personal data,

(b) personal health data,

(c) data that are not personal data or personal health data but are associated with personal health data;

"*disclosure*" has the same meaning as in the Act of 1988;

"*Executive*" means the Health Service Executive established by the Health Act 2004;

"health practitioner" means-

(a) a registered medical practitioner within the meaning of section 2 of the Medical Practitioners Act 2007 or a medical practitioner practising medicine pursuant to section 50 of that Act,

(b) a registered dentist within the meaning of section 2 of the Dentists Act 1985,

(c) a registered pharmacist or registered pharmaceutical assistant within the meaning of the Pharmacy Act 2007,

(d) a registered nurse or registered midwife within the meaning of section 2(1) of the Nurses and Midwives Act 2011,

(e) a registered optometrist or registered dispensing optician within the meaning of section 2 of the Opticians Act 1956,

(f) a registrant within the meaning of section 3(1) of the Health and Social Care Professionals Act 2005,

(g) a person whose name is entered in the register of pre-hospital emergency care practitioners established under the Pre-Hospital Emergency Care Council (Establishment) Order 2000 (S.I. No. 109 of 2000), or

(h) a person who falls within a class of persons, being a class of persons who provide a health service, prescribed for the purposes of this paragraph;

"*health services provider*" means-

(a) a body corporate, or an unincorporated body of persons, through which or in connection with which (whether by reason of employment or otherwise) a health practitioner provides a health service, or

(b) a health practitioner where the practitioner is not providing a health service through or in connection with (whether by reason of employment or otherwise) a body referred to in paragraph *(a);*

"health service" means a health or personal social service (including personal care and any administrative service or other ancillary matter relating to the health or personal social service) provided by or under the direction of a health services provider for-

(a) the screening, preservation or improvement of health, or

(b) the prevention, diagnosis, treatment or care of an illness or injury;

"*Minister*" means the Minister for Health;

"*personal data*" has the same meaning as in the Act of 1988;

"*personal health data*" means personal data that-

(a) relates to the physical or mental health or condition of the individual,

(b) relates to or is or was collected in connection with the provision of health services to the individual,

(c) relates to or is or was collected in connection with the donation by the individual of a body part or bodily substance, including information derived from any testing or examination of the body part or bodily substance in connection with the donation,

(d) relates to or is or was collected in connection with the promotion of patient safety,

(e) relates to or is or was collected in connection with the identification or prevention of a threat to public health,

(f) relates to or is or was collected in connection with the management of health services, including-

(i) the planning, monitoring, delivery, improvement, auditing and evaluation of health services,

(ii) the investigation and resolution of complaints relating to health services, and

(iii) the management of national health structures,

(g) relates to or is or was collected in connection with the carrying out of health research,

(h) relates to or is or was collected in connection with the provision of a scheme of health or health-related insurance operated by an undertaking authorised to so do under the Health Insurance Act 1994 or otherwise provided for in an enactment,

(i) relates to or is or was collected in connection with the genetic testing of an individual, or

(j) is any other personal data relating to or collected in connection with the health of an individual or the population that the Minister prescribes after consultation with the Commissioner;

"*prescribed*" means prescribed by the Minister by regulations made under this Act;

"*processing*", in relation to data, has the same meaning as in the Act of 1988.

Explanatory Note
This is a definitions Head. Some other Parts of the Bill also have definitions Heads with definitions applicable to those particular Parts.

The key definitions here are “personal data”, “personal health data”, “health services” and “health services provider”.

“Personal data” has the same meaning as in the Data Protection Acts and means data relating to a living individual who can be identified either from the data or from the data in conjunction with other information in the possession of the data controller. The Bill also uses the term “personal health data”. The term is not found in the Data Protection Acts but it is a specific category of personal data, as defined for the purposes of this Bill: namely, personal data that-

(a) relates to the physical or mental health or condition of the individual,

(b) relates to or is or was collected in connection with the provision of health services to the individual,

(c) relates to or is or was collected in connection with the donation by the individual of a body part or bodily substance, including information derived from any testing or examination of the body part or bodily substance in connection with the donation,

(d) relates to or is or was collected in connection with the promotion of patient safety,

(e) relates to or is or was collected in connection with the identification or prevention of a threat to public health,

(f) relates to or is or was collected in connection with the management of health services, including-

(i) the planning, monitoring, delivery, improvement, auditing and evaluation of health services,

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(i) relates to or is or was collected in connection with the genetic testing of an individual, or

(j) is any other personal data relating to or collected in connection with the health of an individual or the population that the Minister prescribes after consultation with the Commissioner.

“Health service” is broadly defined.

"Health services provider" is intended to cover public and private health services and those who operate in both the private and public sides whether providing health services through a company, partnership or on their own. For example, it includes the HSE, section 38 service providers, private hospitals and a general practitioner with an exclusively private practice or a mix of private and public patients.

Regulations
3. Provide that:
(1) The Minister may by regulations provide for any matter referred to in this Act as prescribed or to be prescribed.

(2) Regulations under this Act may contain such incidental, supplementary and consequential provisions as appear to the Minister to be necessary or expedient for the purposes of the regulations.

(3) Every regulation made under this Act shall be laid before each House of the Oireachtas as soon as may be after it is made and, if a resolution annulling the regulation is passed by either such House within the next 21 days on which that House has sat after the regulation is laid before it, the regulation shall be annulled accordingly, but without prejudice to the validity of anything previously done under the regulation.

Explanatory Note
This is a standard provision.

Expenses
4. Provide that:
The expenses incurred by the Minister in the administration of this Act shall, to such extent as may be sanctioned by the Minister for Public Expenditure, be paid out of moneys provided by the Oireachtas.

Explanatory Note
This is a standard provision.

2: PERSONAL DATA, PERSONAL HEALTH DATA AND PERSONAL HEALTH INFORMATION

Processing of personal data and personal health data
5. Provide that:
(1) Nothing in this Act shall be construed as permitting the processing of personal data and personal health data in contravention of the Act of 1988 except to the extent provided by any provision of this Act.

(2) The Commissioner shall have such powers in relation to personal health information under *Head 9* and data sets under Parts 4 and 5 as he or she has-

(a) under the Act of 1988, and

(b) as provided for in this Bill.

Explanatory Note
The purpose of this Head is to make clear that the provisions of the Data Protection Acts apply to the processing of personal data and personal health data except to any extent that they may be modified by this Bill: for example, in the areas of prescribed data matching programmes and prescribed health information resources.

The provision also makes clear that the Data Protection Commissioner will have such powers under this Bill in relation to personal health information (which arises under Head 9) and data sets (under Parts 4 and 5) as he or she has under the Data Protection Acts (that is, for example, he or she can issue enforcement notices etc) as well as any additional powers expressly given under this Bill.

Copies of medical and other records to be furnished at patient's request
6. Provide that:
(1) An individual may, by notice in writing, request a health services provider who is providing or has provided health services to the individual to furnish a copy of any health records that the provider holds in relation to the individual to a person who is the provider of a similar health service to the individual specified in the request.

(2) A request made under this Head shall be accompanied by such information as the health services provider to whom the request is made may reasonably require-

(a) in order to be satisfied as to the identity of the individual and to locate the records concerned, and

(b) in order to be satisfied as to the identity of the person specified by the individual in the request, and that that person has agreed to receive a copy of the health records concerned.

(3) A health services provider who receives a request from an individual that complies with this Head shall, within 40 days of receiving the request-

(a) furnish a copy of the health records concerned to the person specified in the request, and on or as soon as reasonably practicable after so furnishing the copy, advise the individual, by notice in writing, that the copy has been furnished to that person, or

(b) provide written reasons to the individual as to why he or she has not so furnished the copy.

(4) A health services provider who is required to furnish a copy of any health records to a person under this Head shall furnish the copy in permanent form unless-

(a) the person agrees otherwise,

(b) the copying of the health records in permanent form is not possible or would be physically detrimental to them, or

(c) the furnishing of the health records in permanent form is not possible.

(5) Nothing in this Head shall be construed as requiring a health services provider to furnish to a person a copy of any health records the subject of a request under this Head if any of the following circumstances apply-

(a) the individual has, by notice in writing to the health services provider, withdrawn the request,

(b) the person concerned has, by notice in writing to the health services provider, withdrawn his or her agreement to receive the copy of the health records,

(c) the copying of the health records is not possible or would be physically detrimental to them,

(d) the furnishing of the health records by the health services provider would conflict with a legal duty or legal obligation of the health services provider,

(e) the health services provider has already furnished a copy of the health records concerned (whether or not under this Head) to the person concerned.

(6) This Head is without prejudice to the exercise of any rights of access to, or in connection with, health records conferred by the Act of 1988 or the Act of 2014.

(7) A health services provider who fails, without reasonable excuse, to furnish health records as required by this Head is guilty of an offence and is liable-

(a) on summary conviction, to a class B fine not exceeding €4,000, or

(b) on conviction on indictment, to a fine not exceeding €100,000.

(8) In this Head, "health record", in relation to an individual means any personal health data relating to the provision of a health service to the individual and kept by a health services provider, but does not include any record or part of a record of an administrative nature.

Explanatory Note
At present, there is no legal obligation on a health services provider to forward a patient's health record to another health services provider on request from the patient. This can be problematic where a patient, for example, changes his or her GP for whatever reason. This Head addresses that issue by creating such an obligation.

A health services provider who fails, without reasonable excuse, to forward the relevant health record, as required by this Head, will be guilty of an offence.

The right conferred by this Head is without prejudice to any rights of subject access conferred on individuals under the Data Protection Acts and the Freedom of Information Act.

Notification of cessation of provision of health services
7. Provide that:
(1) A health services provider of a prescribed category who decides to cease to provide such health services in essentially the same location where he or she provided them, or who is ceasing to provide such health services at all, shall take all reasonable steps to notify, within 30 days of making such decision or such longer period as may be prescribed by the Minister, each individual whose personal health data the health services provider holds, (unless the health services provider believes on reasonable grounds that that individual is deceased) of the following matters-

> (a) the date on which it is likely that such services will cease to be provided or cease to be provided in essentially the same location,
>
> (b) the arrangements that the health services provider is proposing for ensuring that the personal health data are available to another health services provider who will be providing such services.

(2) Where the health services provider referred to in *subhead (1)* is a company to which the Companies Act 1963 applies and the reason for its ceasing to provide health services is that it is being wound up under that Act, the liquidator appointed for the purposes of the winding-up shall perform the functions under *subhead (1)*, or such portion of those functions, as the health services provider concerned has not performed before the appointment of the liquidator.

(3) Where the health services provider referred to in *subhead (1)* is an individual, the following persons shall perform the functions under *subhead (1)*-

> (a) where the reason for the cessation of the provision of health services is that the health services provider has died-
>
> > (i) a personal representative of the health services provider acting in due course of administration of his or her estate or any person acting with the consent of a personal representative so acting, or

(ii) a person on whom a function is conferred by law in relation to the health services provider or his or her estate, acting in the performance of the function,

(b) where the reason for the cessation of the provision of health services is that the health services provider has become a person of unsound mind or incapable of managing his or her affairs, the legal guardian of the provider,

(c) where the reason for the cessation of the provision of health services is that the health services provider is under a legal disability other than one referred to in *paragraph (b)*, the person entitled in law to administer the property of the provider.

(4) In a case other than one to which *subhead (2)* or *(3)* applies, the health services provider referred to in *subhead (1)* may authorise another person to perform the functions under *subhead (1)* on his or her behalf.

Explanatory Note

This provision sets out what is to happen to the personal health data held by a health services provider belonging to a category of provider prescribed by the Minister when the provider decides to cease to provide those health services or wishes to provide them in another location. The main purpose of the provision is to ensure the individuals whose personal health data is kept are advised of the cessation of health services or change of location by the health services provider and the measures being taken in relation to their information to ensure that it will be available to another health services provider who will be providing such services.

Under the Data Protection Acts, data controllers are responsible for the personal data they hold. If a data controller has collected personal data for the purposes of his or her business or profession then if they are retiring or otherwise ceasing to engage that business or profession (for example, by selling it) they can no longer keep such data (subject to any requirements to retain it for legal, insurance, tax or other like purposes). This has implications for patient records in the health care sector and was one of the matters covered, back in 2004, in A Guide to Data Protection Legislation for Irish General Practice (updated in April 2011) (see www.icgp.ie) prepared by the Irish College of General Practitioners, the Irish Medical Organisation and the National GPIT Group. The 2011 version provides-

> "6.8 Retirement, Death or Closure of a GP Practice
> When a single handed GP ceases practice due to retirement or death and no GP is due to take over the practice, the retiring GP (or executor in the case of the medical practitioner being deceased) should take prompt and reasonable steps to notify patients and allow them the opportunity to transfer their medical records to another provider. If any patient cannot be contacted or does not respond, within a reasonable period, the medical practitioner (or executor) should maintain the records with due safeguards for a period of eight years and then securely destroy them.
> In the case of GMS patients, the HSE will appoint a replacement GP to take over the "panel" of patients and the records can then be transferred to the new GP.
>
> In some cases the patient list will be "frozen" until a replacement GP is found so that it will not be possible for a patient to move to a new practice until this occurs.

In the case of a retirement or death within a partnership or group practice, the practice should inform the patients of the general practitioner involved of the retirement or death and advise that their medical record is being retained within the practice for their continuing care. Where the patient advises that he or she wishes to transfer to another practice then this request should be facilitated in the normal way.

6.9 Sale of a GP Practice
Where a practice has been sold to another practitioner, all patients should be notified as soon as possible after the sale is agreed but before the practice changes ownership so that patients have the opportunity to move from the practice to another provider if they wish.
Notification should ideally be by means of a letter which offers the patient the choice to remain with the practice or have their records sent to another GP of their choosing. In the event of the patient not responding within one month of being so advised, it can be presumed that he or she is satisfied that their records should remain with the practice and the new general practitioner."

In Britain, the Association of Optometrists states on its website (www.aop.org.uk) that with a change of ownership in a practice-

"B. Patients should be written to advise them of the change in ownership of their records. The Information Commissioner's Office, which is the official body overseeing the Data Protection Act 1988, has said that an advertisement, e.g. in a local newspaper, in the practice window or on the practice website, would not be sufficient to inform patients as to who has their records, they should be written to individually. They may be written to by post, e-mail or text message, to fulfil this requirement.

Record to be kept of disclosures
8. Provide that:
(1) A data controller shall keep a record of the following particulars in relation to any disclosure of personal health data by the data controller-

(a) the name of the person to whom the data controller makes the disclosure,

(b) the name of the individual to whom the personal health data disclosed relate,

(c) a description of the data,

(d) the purpose of the disclosure,

(e) the date of the disclosure.

(2) A record under this Head shall be retained by a data controller for a period of not less than 6 years after the date on which the disclosure to which the record relates was made.

Explanatory Note
This Head ensures that all disclosures of personal health data are properly recorded which is important for protecting confidentiality and the privacy of the individual especially if the information released proves to be inaccurate and all parties to which it was disclosed have to be so informed.

Data controllers are already obliged to ensure that any disclosure of personal data is permissible under the Data Protection Acts and they must take reasonable steps to satisfy themselves of the identity of any persons to whom they disclose personal data. As personal health data is sensitive data under the Data Protection Acts, those obligations in relation to disclosure are stronger than with non-sensitive personal data. This Head builds on that obligation by ensuring that individuals will be able to discover who precisely their personal health data has been and is being disclosed to.

Unlike Heads 6 and 7, this Head applies not only to health services providers but to any data controllers having and disclosing personal health data, which would include insurance companies, employers, etc.

Offence – buying or selling of personal health information
9. Provide that:

(1) A person who, for financial or other gain, knowingly or recklessly, sells or offers for sale personal health information about an individual that the person has obtained in a professional capacity, or in the course of employment or business, commits an offence.

(2) A person commits an offence if he or she, knowingly or recklessly, purchases or otherwise attempts to obtain, through the offer of financial or other gain, personal health information about an individual from any person who has obtained the information in a professional capacity, or in the course of employment or business.

(3) A person who commits an offence under *subhead (1)* or *(2)* is liable-

(a) on summary conviction, to a class A fine, or

(b) on conviction on indictment to a fine not exceeding €200,000.

(4) Nothing in this Head shall be construed as prohibiting an individual from selling his or her own personal health information except where such information-

(a) is or contains any genetic data, or

(b) contains or otherwise reveals personal health information about another individual.

(5) In this Head, "personal health information" means information, whether recorded or otherwise, about an individual, living or deceased, that-

(a) relates to the physical or mental health or condition of the individual,

(b) is or was collected in connection with the provision of health services to the individual,

(c) is or was collected in connection with the donation by the individual of a body part or bodily substance, including information derived from any testing or examination of the body part or bodily substance in connection with the donation,

(d) is or was collected in connection with the promotion of patient safety,

(e) is or was collected in connection with the identification or prevention of a threat to public health, or

(f) is or was collected in connection with the genetic testing of an individual.

Explanatory Note
This Head creates a criminal offence for-

(a) the buying or attempt to buy personal health information (as defined in the Head) from a person who has obtained the information in a professional capacity or in the course of employment or business, or

(b) the selling or offer for sale of personal health information where buying and selling encompass not just direct financial gain but other benefit.

It is not the intention that consent by a data subject would allow a person who had obtained personal health information in a professional capacity or in the course of employment or business to sell personal health information or similarly allow someone to buy such information from such a person.

It is not intended to prevent an individual selling his or her own personal health information or a company buying it from him or her. However, subhead (4) prohibits this where the personal health information contains any genetic data or otherwise reveals information about another individual.

It will be noted that the term "personal health information" is used in this Head rather than "personal health data". The definition of "personal health information" means information about an individual, whether living or deceased. The definition of personal health information is also designed to catch information that is or is not formally recorded (that is electronically or in a relevant filing system).

Disclosure of personal data by statutory regulatory bodies
10. Provide that:
(1) Notwithstanding any provision in any enactment or rule of law, where a prescribed health regulatory body collects or otherwise obtains personal data that it reasonably believes to be relevant to the performance of functions by another prescribed health regulatory body, it may disclose that personal data to that other body.

(2) Notwithstanding any provision in any enactment or rule of law, where a prescribed health regulatory body collects or otherwise obtains personal data that it reasonably believes to be relevant to the performance of functions by a prescribed regulatory body, it may disclose that personal data to that other body.

(3) Any disclosure of personal data for the purposes of this Head shall go no further than is reasonably necessary for the attainment of the relevant purpose.

(4) Personal data obtained by a person as a result of a disclosure made under this Head shall for the purposes of section 2(1)(a) of the Act of 1988 be regarded as having been obtained fairly.

(5) A decision to disclose personal data under this Head shall be made by the person who holds the title, or performs the functions, of the Chief Executive Officer (by whatever name called) of the health regulatory body concerned.

(6) In this Head–

(a)"body" means a body established by or under any enactment,

(b) "prescribed health regulatory body" means a body prescribed by the Minister for the purposes of this Head, having functions relating to the regulation of health services or the regulation of health services providers, and

(c) "prescribed regulatory body" means a body having regulatory functions and prescribed by the Minister for the purposes of this Head, in agreement with another Minister, where that body reports to that Minister.

(7) For the avoidance of doubt, this Head is without prejudice to any other rights to disclose or otherwise supply the information in question.

Explanatory Note
This provision is about facilitating the sharing of (personal) information by statutory regulatory bodies where the health body initiating the sharing (disclosure in data protection terms) has a reasonable belief that information involved will be relevant to the performance by another statutory regulatory body of its functions.

Standards for electronic exchange of health information
11. Provide that:
(1) The Minister may set standards for the efficient and effective electronic exchange of health information.

(2) Where the Minister is proposing to set a standard under *subhead (1)*, he or she may request the Authority to prepare a draft standard in accordance with any directions that he or she may give.

(3) Where the Authority has been so requested under *subhead (2)*, it shall for the purposes of preparing the draft standard-

(a) consult with the Executive and any other persons that it considers appropriate,

(b) following such consultations, publish the draft standard for public comment, on its website, for a period of 30 days,

(c) consider any comments received and make any amendments to the draft standard that it considers appropriate,

(d) forward the draft standard to the Minister.

(4) The Minister may, before setting the standard, revise the draft standard received under *subhead (3)(d)* after consulting with the Authority and the Executive.

(5) The Minister shall publish on a website maintained by him or her a standard set under this Head and take such other measures as he or she considers appropriate to promote awareness of the standard and encourage its use.

(6) The Executive shall report to the Minister (in its annual report under section 37 of the Health Act 2004) respecting the extent to which standards approved under this Head have been used by it during the period covered by the annual report and the actions it has taken to encourage use of the standard.

Explanatory Note
Interoperability is the term used to describe computer systems' ability to "talk" to each other. In the health services, there are many different computer systems. It is considered that the best way to address this legacy issue is to proceed incrementally, using a standards-based approach, to facilitating interoperability between different systems holding personal healthcare information. Accordingly, this Head is concerned with promoting standards on electronic interoperability (for example, languages that allow computer systems to talk to each other).

Standards will be set by the Minister but he or she may request HIQA to prepare the draft standard. HIQA will consult with the HSE where HIQA is preparing draft standards under this Head.

The standards will be of interest to persons involved in the development of ICT as the standards are intended to indicate the direction that is being taken in relation to the application of internationally accepted standards, such as Health Level 7 (HL7), to ICT in the Irish healthcare service. There is no express monitoring or enforcement element as the intention is to promote a positive attitude among software developers and others to the standards.

However, the HSE is being required to report to the Minister (in its Annual Report under section 37 of the Health Act 2004) about the extent to which standards approved under this Head have been used by it during the period covered by the Annual Report. This is important because the HSE should, itself, follow the standards and as the biggest healthcare entity in the State its use and promotion of the standards has the potential to greatly influence the adoption of the standards throughout the entire health service.

Standards for management of health data
12. Provide that:
(1) The Authority may, at the request of the Minister, set such standards for the processing of personal data as it considers appropriate for data controllers who are health services providers in relation to the provision and management of health services.

(2) Without prejudice to the generality of *subhead (1*), standards may address matters relating to the privacy of data subjects, confidentiality, quality assurance, security, storage and destruction of such data.

(3) Before setting standards under this Head, the Authority may consult with any person, or invite representations from any person, as it considers appropriate.

(4) After considering any representations made under *subhead (3)* in relation to any standards proposed by the Authority and after making any changes the Authority thinks fit, it shall submit the proposed standards to the Minister for approval.

(5) Before approving any standards submitted to him under *subhead (4)*, the Minister shall consult with the Data Protection Commissioner on any such standards.

(6) Where a standard under this Head is approved by the Minister, the Authority shall publish the standard on its website and in accordance with such other arrangements as may be specified by the Minister.

Explanatory Note
This provision will allow HIQA, at the request of the Minister, to set standards for the management of personal data used in the health service. The intention is that these will be "best practice" standards that data controllers will aspire to meet because they represent a quality approach to data management.

Given that standards will deal with personal data, the Minister will, consult with the Data Protection Commissioner prior to a decision to approve. The standards will apply to all data controllers but there is no express monitoring or enforcement element.

The intention is that this standards setting power will be separate to and distinct from the standards setting power in section 8 of the Health Act 2007 and it is also separate from the

standards setting power for prescribed Data Matching Programmes (see Part 4) and Health Information Resources (see Part 5).

PART 3: RESEARCH ETHICS APPROVAL

Part 3 provides for a voluntary, national, streamlined research ethics approval structure for health research not already governed by other legislation. This Part does not apply to clinical trials of medicinal products or medical devices as these are already governed under other legislation. A major benefit for health researchers in this Part will be the creation of a single point of contact via HIQA (which will be the supervisory body for approved research ethics committees (ARECs) under this Part) as well as obtaining a single ethical approval for national or regional health research. It will also provide an avenue for researchers to apply for a data protection consent exemption in certain limited and restricted circumstances.

Interpretation - Part 3
13. Provide that:
In this Part-

"*appointing authority*" means the Executive, a hospital, an institution of higher education within the meaning of section 1 (inserted by section 52 of the Institutes of Technology Act 2006) of the Higher Education Act 1971, an institution that otherwise provides continuing healthcare education or a prescribed body, that establishes, or establishes in conjunction with one or more other appointing authorities, a research ethics committee;

"*approved research ethics committee*" means a committee established by an appointing authority and approved by the Authority under this Part, which approval has not been revoked;

"*ethical conduct*" refers to conduct relating to the matters referred to in *paragraphs (b) to (h)* of *Head 29(2)*;

"*expert member*", in relation to an approved research ethics committee, means a member of the committee who–

(a) is a practising or retired health practitioner,

(b) has qualifications or experience relating to the conduct of health research (other than as a member of a research ethics committee),

(c) has qualifications or experience in the area of ethics, statistics, social sciences, philosophy or theology,

(d) is a practising or retired barrister or solicitor, or

(e) belongs to a class or category of persons prescribed by the Minister for the purposes of this definition;

"*health research*" means human health research but does not include otherwise governed health research;

"*lay member*", in relation to an approved research ethics committee, means a member of the committee who is not an expert member;

"*member*", in relation to an approved research ethics committee, means a person who is appointed to the committee in accordance with *Head 24;*

"*otherwise governed health research*" means human health research other than health research that is required to be the subject of another research ethics approval process provided for in an enactment or an European Act.

Explanatory Note
The key definitions here are:
"appointing authority" This is the body that establishes, either on its own or in conjunction with one or more other appointing authorities, a research ethics committee (REC). The Bill allows appointing authorities to apply for HIQA approval in relation to a REC. In the Bill, appointing authorities are the HSE, a hospital, third level college, provider of continuing healthcare education or prescribed bodies.

"approved research ethics committee" means a research ethics committee established by an appointing authority and which has been approved by HIQA under this Part. An approved research ethics committee (AREC) must include both lay and expert members and Head 24 (dealing with membership of ARECs) is relevant in this regard.

"health research" for the purposes of this Part is very broad. However, it excludes health research that is required to be the subject of an research ethics approval process that is provided for under another enactment or an European Act, prescribed for the purposes of this Part of the Bill. For example, it would exclude clinical trials regulated by EU law or transposing national domestic legislation as it is subject to its own research ethics approval process. However, see also Head 28(10)(b) which deals with applications for ethical approval for health research below doctoral level in third level institutions. ARECs will deal with all health research covered by this Bill and it will not be open to them to be approved only in respect of particular research areas: for example, only for paediatrics. However, when applying under Head 14, the appointing authority may seek for its REC to be approved in respect of the State generally or part of the State (that is, regionally).

Approval of research ethics committee by Authority
14. Provide that:
(1) An appointing authority seeking to have an research ethics committee established by it approved by the Authority shall make an application to the Authority.

(2) An application under *subhead (1)* may request that the approval of the research ethics committee be in relation to the State generally or part of the State.

(3) An application under *subhead (1)* shall be made in the form and manner specified by the Authority.

(4) Where an application under this Head is not made in full compliance with requirements under this Head, the Authority shall notify the appointing authority of a final date for the receipt of the completed application and the Authority shall not be obliged to consider the application further if the full application is not received on or before that date.

(5) Subject to *subhead (6),* where the application has been made in accordance with the requirements of *subhead (3),* the Authority shall consider the application and shall, not later than 40 days after receiving the application, make a decision in accordance with *subhead (8).*

(6)Where the Authority determines that additional information is required to make a decision on the application-

> (a) it shall notify the appointing authority of the information required and the period within which such information must be provided and the period specified in *subhead (5)* for the consideration of the application shall be suspended from the time the Authority makes the request up until the time the Authority is provided with the additional information, and
>
> (b) if the information requested in *paragraph (a)* is not provided within the period specified in that paragraph the application will be deemed to be withdrawn and the applicant will be so notified unless before that period expires, the Authority, at the request of the applicant, agrees to extend the period and so notifies the applicant.

(7) The Authority shall-

> (a) approve, with or without conditions, the committee as an approved research ethics committee, and notify the appointing authority accordingly, if it is satisfied that the committee concerned would be able to perform, in an effective manner, the functions of an approved research ethics committee, or
>
> (b) not approve the committee as an approved research ethics committee, and notify the applicant of the reasons why its application has not been approved, if it is not satisfied that the committee concerned would be able to perform, in an effective manner, the functions of an approved research ethics committee.

(8) Where the Authority is notifying an appointing authority under *subhead (7)(a),* the notification shall specify-

> (a) whether the approved research committee may act in respect of the State generally or part of the State, and
>
> (b) any conditions that apply to that committee and the reasons for those conditions.

(9) The Authority shall establish criteria on which a decision under *subhead (7)* is to be made and shall publish the criteria on its website.

(10) An appointing authority which receives a notification under this Head or *Heads 16 or 17* shall provide, without delay, a copy of the notification to the research ethics committee concerned.

Explanatory Note

This Head sets out the process for applying to become an AREC. It is the appointing authority that applies on behalf of its REC for approval and the principal relationship is,

therefore, between HIQA and the appointing authority rather than between HIQA and the AREC.

Under subhead (1), an appointing authority may apply to the Authority for approval of its REC as an approved research ethics committee. It must be willing to deal with research proposals covering all of the types of health research covered by this Part rather than seeking to specialise in any particular area of health research. However, under subhead (2), an application under subhead (1) may contain a request that the approval of the research ethics committee is in relation to the State generally or part of the State (that is on a regional basis).

Subhead (3) refers to the form and manner in which the application must be made.
Subhead (4) provides that HIQA will only consider an application under this Head where it has been made in accordance with the requirements of subhead (3).

Under subhead (5), where the application has been properly made in accordance with the requirements of subhead (3), HIQA will make a decision on the application within 40 days unless additional information is required as per subhead (6).

Subhead (7) provides that HIQA will approve an application, with or without conditions (and notify the appointing authority accordingly) if it is satisfied that the committee concerned is able to perform, in an effective manner, the functions of an approved research ethics committee under this Part. If it is not so satisfied, it will refuse the application.

Subhead (8) provides that where the application is successful that HIQA in notifying the appointing authority will specify-

(a) whether the approved research committee may act in respect of the State generally or part of the State, and

(b) any conditions that apply to that committee and the reasons for those conditions.

Specifying the reasons for the conditions is important as it will allow the appointing authority to decide whether to seek to have them removed or varied under Head 17.

Subhead (9) requires HIQA to establish and publish the criteria on how it will decide whether to grant an application or refuse an application and in regard to conditions attached to approval. This is so that those applying will be well informed in making their applications.

Subhead (10) states that an appointing authority which receives a notification under this Head or Heads 16 or 17 must provide, without delay, a copy of the notification to the research ethics committee.

Appointing authority may request that approval of approved research ethics committee be withdrawn

15. Provide that:

An appointing authority may, at any time, in relation to an approved research ethics committee established by it, request the Authority to withdraw its approval of the research ethics committee and the Authority shall give effect to that decision within 21 days of receiving the request.

Explanatory Note
Importantly, since a REC only becomes an AREC as a result of an application by its appointing authority, it is appropriate and necessary to expressly provide that the appointing authority can equally apply to have that approval withdrawn. Where that happens, arrangements will need to be made in relation to applications or appeals being considered by the AREC involved and research (approved under this Part) being monitored by it. That is provided for in other Heads.

Varying or removing a condition or attaching a new condition
16. Provide that:
(1) The Authority may vary or revoke any conditions that apply to the approval of an approved research ethics committee, where the Authority is of the opinion that to do so would enable the committee to perform its functions under this Part in a more effective manner.

(2) If the Authority proposes to vary or revoke a condition under *subhead (1)*, the Authority shall notify the appointing authority concerned describing the proposed variation or revocation and the reasons for it.

(3) The Authority shall afford the appointing authority not more than 21 days, or such shorter period as the appointing authority and the Authority may agree, in which to make written submissions on the proposal to the Authority.

(4) The Authority shall consider any submissions received under *subhead (3)* before making a decision.

(5) The Authority shall notify the appointing authority in writing of the decision made under *subhead (4)*.

Explanatory Note
This Head deals with the varying or revoking of any conditions imposed by HIQA on an AREC where the Authority is of the opinion that to do so would enable the committee to perform its functions in a more effective manner. Head 17 deals with applications by appointing authorities for removal or variation of conditions imposed by HIQA on their RECs.

Subhead (1) provides that the Authority may vary or revoke these conditions if it is of the opinion that to do so would permit the committee to more effectively perform its functions. In coming to its opinion, HIQA will have regard to Guidelines issued by it under Head 18. Subhead (2) states that the Authority must provide written notification to the appointing authority outlining the variation or revocation and the reasons for it. Subhead (3) allows the appointing authority an opportunity to make a submission in relation to the proposed variations or revocations to the Authority. Subhead (4) ensures that the Authority will consider the proposal before coming to a decision and subhead (5) provides that HIQA shall advise the appointing authority in writing of its decision.

Applications by appointing authorities for removal or variation of conditions
17. Provide that:
(1) An appointing authority may apply to the Authority for the variation or removal of any condition that applies to an approved research ethics committee appointed by that authority.

(2) In making an application under *subhead (1)* the appointing authority shall provide such information as it considers relevant to a consideration of the application.

(3) The Authority may seek such additional information from the appointing authority which made the request under *subhead (1)* as it considers necessary to make a decision on the application.

(4) The Authority may grant an application under *subhead (1)* if is satisfied that the variation or removal of the condition will enable the approved research ethics committee to perform its functions, under this Part, in a more effective manner and if not so satisfied shall refuse the application.

(5) The Authority shall notify the appointing authority of its decision under *subhead (4)* and shall give reasons for its decision.

Explanatory Note
This is similar to Head 16 but covers the situation where it is the appointing authority that makes the application to HIQA for removal or variation of conditions imposed on their AREC.

Guidelines for appointing authorities and approved research ethics committees
18. Provide that:
(1) The Authority may prepare and issue such guidelines as it considers appropriate in relation to the operation of-

(a) appointing authorities of approved research ethics committees and in relation to the operation of approved research ethics committees generally, or

(b) a particular appointing authority or approved research ethics committee.

(2) The purpose of any guidelines issued under this Head is to assist an-

(a) appointing authority of an approved research ethics committee, or

(b) approved research ethics committee,

perform their function under this Part in an effective manner.

(3) Before issuing guidelines under this Head, the Authority shall consult with any person and invite representations from any person, as it considers appropriate.

(4) After considering any representations made in relation to any guidelines proposed under this Head, and making any changes deemed necessary by it, the Authority shall publish the guidelines on its website.

(5) The Authority shall have regard to the guidelines issued when considering whether-

(a) an appointing authority, or

(b) an approved research ethics committee,

has or is performing its functions in an effective manner.

Explanatory Note
The purpose of this Head is to require the Authority to prepare and issue guidelines that will help appointing authorities and approved research ethics committees perform their functions in an effective manner. The Head provides that HIQA will have regard to the guidelines when considering whether an appointing authority or an AREC has been or is performing its functions in an effective manner.

It is envisaged that the guidelines would include-

- how to deal with research proposals involving vulnerable groups generally or specific vulnerable groups: for example, prisoners, asylum seekers and children;
- the role of subcommittees;
- role of expert advisors;
- matters relevant to Head 29(2)(h).

Monitoring by Authority of appointing authorities
19. Provide that:
(1) The Authority shall monitor the performance by appointing authorities of approved research ethics committees of their functions under this Part.

(2) An appointing authority referred to in *subhead (1)* shall co-operate with the Authority in the carrying out by the Authority of its monitoring functions under *subhead (1)*.

(3) An appointing authority referred to in *subhead (1)* shall notify the Authority in writing of-

(a) any change in a material fact or of a material circumstance which relates to any research ethics committee established by it and approved under *Head 14*,

(b) any proposed change in the information referred to in *Head 27(2)(a), (b), (f)* or (g),

(c) any change in respect of any other matter that is relevant to the performance of functions of an appointing authority under this Part.

(4) A notification under *subhead (3)* shall be made as soon as reasonably practicable and, in any event, not more than 21 days after the appointing authority concerned becomes aware that the change has been made or is proposed to be made.

Explanatory Note
This Head provides that HIQA will monitor the effective performance by appointing authorities of their functions under this Part. Under subhead (2), an appointing authority of an AREC must co-operate with HIQA in the performance by HIQA of its monitoring functions of the appointing authority.

As per subhead (3), an appointing authority of an AREC must notify the Authority in writing of-

(a) any change in a material fact or of a material circumstance which relates to any research ethics committee established by it and approved under Head 14,

(b) any change in the information referred to in Head 27(2)(a), (b), (f) or (g),

(c) any change in respect to any other matter that is relevant to the performance of its functions under this Part.

Subhead (4) requires that a notification under subhead (3) must be made as soon as reasonably practicable and, in any event, not more than 21 days after the appointing authority concerned becomes aware that the change has been made.

Monitoring of approved research ethics committee by appointing authority
20. Provide that:
(1) An appointing authority shall monitor the performance of the functions under this Part by an approved research ethics committee established by it and approved under *Head 14*.

(2) An approved research ethics committee referred to in *subhead (1)* shall co-operate with the appointing authority that established it, in the performance by that appointing authority of its monitoring functions under *subhead (1)*.

(3) An approved research ethics committee referred to in *subhead (1)* shall notify the appointing authority that established it, in writing, of any change in a material fact or of a material circumstance which relates to it or to the performance of any of its functions under this Part after it is approved.

(4) A notification under *subhead (3)* shall be made as soon as reasonably practicable and, in any event, not more than 7 days after the change has been made.

(5) Where an approved research ethics committee does not perform a function assigned to it under this Act, the appointing authority may direct the committee-

(a) to perform such function, and

(b) for that purpose, to do any other thing that is ancillary or incidental to the function.

(6) Where an approved research ethics committee does not comply with a direction under *subhead (5)*, the appointing authority may remove from office any or all of the members by notifying them in writing of their removal and the reason for it.

Explanatory Note
Appointing authorities are responsible for their ARECs. Accordingly, this Head provides that an appointing authority must monitor the effective performance of the functions of its approved research ethics committees. An approved research ethics committee must co-operate with the appointing authority that established it in the performance by that appointing authority of its monitoring functions.

The approved research ethics committee shall notify the appointing authority that established it, in writing, of any change in a material fact or of a material circumstance which relates to it or to the performance of any of its functions. This notification must be made as soon as reasonably practicable and, in any event, not more than 7 days after the change has been made.

If an approved research ethics committee does not perform a function assigned to it, the appointing authority can direct it to do so. If the approved research ethics committee does not comply with this direction, the appointing authority can remove from membership any or all of the members of the committee by notifying them in writing of their removal and the reason for it. HIQA's power to revoke the approved status is set out in Head 22.

Requests by Authority for information etc.
21. Provide that:
(1) The Authority may request, in writing, that an appointing authority which has had a research ethics committee established by it approved under *Head 14*, provide to the Authority any information the Authority considers necessary for the performance of the Authority's functions under this Part.

(2) An appointing authority which receives a request in accordance with *subhead (1)* shall provide the information within the period specified by the Authority.

Explanatory Note
This Head gives HIQA the power to require relevant information from appointing authorities of ARECs.

Revocation of approval of approved research ethics committees
22. Provide that:
(1) The Authority may revoke the approval of an approved research ethics committee.

(2) The Authority may take the action referred to in *subhead (1)* where-

(a) it is satisfied that the appointing authority of an approved research ethics committee-

(i) is not performing its functions under this Part in an effective manner in relation to the research ethics committee,

(ii) has failed to properly investigate a complaint received under *Head 40(3)* or has failed to take the actions notified to it under *Head 40(10)*,

(b) it is satisfied that the approved research ethics committee is failing to perform its functions under this Part in an effective manner.

(3) Where the Authority proposes to take the action under *subhead (1)*, it shall send a notice, in writing, to the appointing authority concerned and copy that notice to the approved research ethics committee concerned.

(4) A notice under *subhead (3)* shall set out-

(a) the Authority's intention to revoke its approval of the committee,

(b) the grounds upon which the revocation is proposed to be made, and

(c) a statement that the appointing authority concerned may make written representations to the Authority, not more than 28 days after the date on which it is sent, as to why the committee should not have its approval revoked.

(5) Subject to *subhead (6)*, where a notice has been sent under *subhead (3)*, the Authority shall not decide the matter that is the subject of the proposal until the later of-

(a) the day on which the appointing authority has notified the Authority in writing that it does not intend to make representations, or

(b) the day on which the number of days referred to in *subhead (4)(c)* has expired.

(6) Where, following a notice under *subhead (3)*, the Authority receives written representations, it shall consider those written representations before deciding whether or not to take the action concerned.

(7) Where the Authority decides to take the action referred to in *subhead (1)*, it shall notify in writing the appointing authority concerned.

Explanatory Note
There has to be some sanction where an appointing authority is not performing its functions under this Part in an effective manner in relation to its approved research ethics committee. It is not appropriate that such sanction should include either the abolition of the REC – as the REC was not created by HIQA- or the removal of any or all of its members –as that is a matter for its appointing authority.

Consequently, in the case of an approved research ethics committee, HIQA may revoke its approval if it is not satisfied that an appointing authority is fulfilling its functions in an effective manner in relation to the committee or if the appointing authority has not (a) caused an investigation into a complaint to be carried out properly under Head 40(3) or (b) complied with the requirements to take action under Head 40(10).

HIQA may also revoke the approval if it is satisfied that the approved research ethics committee is failing to perform its functions in an effective manner.

An AREC that has had its approval withdrawn can, of course, continue to act as a local/institutional REC outside of the Bill but the provisions of Heads 29 or 33 will not apply

to research ethics approved by it. Instead, the scope of its ethical approval will be limited to research proposed to be carried out at the institution concerned.

Arrangements where approval of a research ethics committee has been withdrawn or revoked

23. Provide that:

Subject to *Head 38(6)* and *Head 38(7)*, where an appointing authority applies for approval of an approved research ethics committee to be withdrawn under *Head 15* or where approval has been revoked under *Head 22(1)*, the Authority shall make arrangements for anything commenced but not completed by that committee under *Head 28, Head 29, Head 32, Head 38* or *Head 41* before the withdrawal or revocation of approval to be completed by an appropriate approved research ethics committee.

Explanatory Note

This Head deals with the implications of withdrawing or revoking approval of an AREC where a decision on an application or appeal on a research proposal is pending before it. It also covers the scenario where research ethics approval had already been given by that AREC and the research had not yet been completed and monitoring is, therefore, still required. Further, it addresses the situation in relation to complaints investigations outstanding by that AREC. In those scenarios, HIQA is being required to make suitable arrangements for another AREC to essentially take over.

Membership of approved research ethics committee

24. Provide that:

(1) An approved research ethics committee shall consist of expert members and lay members to be appointed in accordance with the provisions of this Head by its appointing authority.

(2) There shall be no more than 21 persons and no less than 12 persons appointed to be members of an approved research ethics committee and at least one quarter of members shall be lay members.

(3) The appointing authority shall appoint an expert member as chairperson and a lay member as deputy chairperson of the approved research ethics committee.

(4) A person is not eligible for appointment as a member of an approved research ethics committee if the person is not a fit and proper person.

Explanatory Note

This Head is about the membership and size of an AREC. An approved research ethics committee shall consist of expert members and lay members to be appointed by the establishing appointing authority. In terms of numbers, ARECs must have not less than 12 and not more than 21 members and at least one quarter of those members must be lay members. The chairperson will be an expert member and the deputy chairperson will be a lay member.

It is also provided that a person will not be eligible for appointment as a member of an approved research ethics committee unless the person is a fit and proper person.

Sub-committees of approved research ethics committees
25. Provide that:
(1) An approved research ethics committee may appoint one or more sub-committees to provide advice and assistance to it.

(2) Subject to *subhead (5)*, the acts of a sub-committee are subject to confirmation by the committee unless the approved research ethics committee dispenses with the necessity for confirmation.

(3) An approved research ethics committee may, at any time, dissolve a sub-committee.

(4) A sub-committee may consider one or more matters as requested by its approved research ethics committee when it is considering a proposal under *Head 29(2)* and report to that committee before that committee makes its decision.

(5) A decision under *Head 29* may not be made by a sub-committee of an approved research ethics committee.

Explanatory Note
This Head deals with sub committees which may be appointed by an approved research ethics committee. As per subhead (2), the acts of the sub-committee are subject to confirmation by the committee unless the committee decides the confirmation is not necessary.

Subhead (3) states that the committee may at any time dissolve a sub-committee. This may be appropriate if the purpose for which the sub-committee was set up is no longer required.

Subhead (4) provides for the situation where a sub-committee has been asked to assist in the consideration of a health research proposal submitted to the approved research ethics committee for decision. It is expressly provided, in subhead (5), that a sub-committee is not empowered to make a decision on the ethics of a health research proposal on behalf of the approved research ethics committee.

Annual reports of approved research ethics committees
26. Provide that:
(1) An approved research ethics committee shall, not later than 31 March in any year or such later date as may be specified by the Authority, submit a report in accordance with this Head on the performance by it of its functions under this Part during the previous year and on such related matters as the Authority may specify.

(2) A report under this Head, in respect of an approved research ethics committee, shall include-

(a) the names of the members of the committee and their identification as expert members or lay members,

(b) the decisions made by the committee in relation to health research proposals referred to it,

(c) the number and type of complaints received, and

(d) any other matters as may be specified by the Authority.

(3) The report shall be submitted–

(a) by the approved research ethics committee to the appointing authority that established it, and

(b) as soon as may be after it has been submitted under *paragraph (a)*, by that appointing authority to the Authority.

(4) As soon as reasonably practicable after a report is submitted to it, the Authority shall publish the report on its website and in accordance with such other arrangements as the Minister may prescribe.

Explanatory Note
An approved research ethics committee must submit an annual report not later than 31 March in any year or such later date as may be specified by HIQA.

This report will cover matters specified by HIQA which must include the following: the names of the members of the committee and their identification as expert members or lay members, the decisions made by the committee in relation to research proposals referred to it by HIQA, information on complaints received and information on any other matters specified by HIQA.

ARECs must submit their reports to the relevant appointing authority which must then send the report on to HIQA. After a report is submitted to it, HIQA will publish the report on its website or in accordance with such other arrangements as the Minister may prescribe.

Information available on Internet
27. Provide that:
(1) The Authority shall establish and maintain a register of approved research ethics committees and it shall publish the register on its website and in accordance with such other arrangements as the Minister may prescribe.

(2) A register established under *subhead (1)* shall contain the following information-

(a) the name of the approved research ethics committee,

(b) the address for correspondence,

(c) the date of approval under *Head 14*,

(d) details on whether the committee may act for the State generally or part of the State,

(e) the conditions, if any, attached to the committee and the date they were attached,

(f) the names of the members of the committee and an indication whether they are lay or expert members, and

(g) any other information the Authority considers appropriate.

(3) The Authority shall publish on its website or in accordance with such other arrangements as the Minister may prescribe the following information in relation to applications approved under *Head 29*-

(a) the name and business address of the person who made the application,

(b) a brief description of the research proposal,

(c) the name of the approved research ethics committee which approved the proposal under *Head 29* or *32*, as appropriate,

(d) whether the person referred to in *paragraph (a)* included in his or her application under *Head 28* a request for a decision by the Commissioner under *Head 33* and, where he or she did so include such a request, the decision of the Commissioner under that Head.

(4) The Authority shall not publish-

(a) the residential addresses, home telephone numbers or personal e-mail addresses of any person referred to in this Head, or

(b) any other similar details that, in its opinion, should, in the interests of the security of those persons, be protected from disclosure.

Explanatory Note
This provision is about transparency and making certain information about ARECs and research proposals publicly available.

HIQA will establish, maintain and publish a register of currently approved research ethics committees. This register must contain the following information:

- the name of the approved research ethics committee,
- the address for correspondence,
- the date of its approval,
- whether the committee may act for the State generally or part of the State,
- the part or parts of the State in respect of which the committee may act,

- conditions, if any, attached to the approval,

- the names of the members of the committee and an indication whether they are lay or expert members, and

- any other information the Authority considers appropriate.

HIQA will also publish on its website or in accordance with such other arrangements as the Minister may prescribe the following information in relation to research proposals which are approved:

- the name and business address of the person who made the application,

- a brief description of the research proposal,

- the name of the approved research ethics committee which considered and approved the proposal and where the proposal was subject to an appeal the name of the approved research ethics committee that heard the appeal and its decision, and

- where the applicant included in his or her application under Head 28 a request for a decision by the Commissioner under Head 33 the decision of the Commissioner on that request.

For security reasons, it is provided that HIQA will not publish the residential addresses, home telephone numbers or personal e-mail addresses of any person covered by the Head or any other similar details that, in its opinion, should, in the interests of the security of those persons, also be protected from disclosure.

Application to Authority for referral of a research proposal to an approved research ethics committee

28. Provide that:

(1) A person proposing to carry out health research may apply to the Authority for his or her proposal to be considered by an approved research ethics committee for a decision on the ethics of the proposed research.

(2) An application under *subhead (1)* shall be-

(a) made in the form and manner specified by the Authority, and

(b) accompanied by the prescribed fee, if any, where the application includes a request for a decision from the Commissioner under *Head 33*.

(3) An application under this Head in respect of a proposal that intends for the research to be carried out-

(a) in the State generally may only be considered by an approved research ethics committee approved for the State generally,

(b) in part of the State may be considered by an approved research ethics committee approved for the part of the State that the research is intended to be carried out in or an approved research ethics committee approved for the State generally.

(4) The Authority shall put in place such procedures as it considers appropriate to facilitate the transmission of a proposal for consideration by an approved research ethics committee.

(5) An approved research ethics committee to which the proposal is transmitted shall, as a preliminary matter, decide whether the proposal is-

(a) one to which this Part applies, or

(b) one to which this Part does not apply,

and notify the Authority and the applicant accordingly.

(6) Where an approved research ethics committee makes a decision referred to in *subhead (5)(b),* it shall notify the applicant of their right of appeal under *Head 32*.

(7) Where the Authority is notified-

(a) of a decision referred to in *subhead (5)(a)* and the application includes a request for a decision from the Commissioner under *Head 33*, it shall-

(i) transmit the health research proposal to the Commissioner together with the prescribed fee,

(ii) inform the Commissioner of the approved research ethics committee that is considering the proposal,

(iii) notify the approved research ethics committee considering the proposal that it has done the matters referred to in *subparagraphs (i)* and *(ii),*

(b) of a decision referred to in *subhead (5)(b)* and the application includes a request for a decision from the Commissioner under *Head 33*, it shall return the fee that accompanied the application to the applicant.

(8) An approved research ethics committee may, at any time, before or during its consideration of a proposal transmitted under *subhead (4)* or received under *Head 23* request any information from the person making the application that it considers relevant to determining-

(a) whether the proposal is one to which this Part applies, and

(b) whether to grant approval to the proposal under *Head 29.*

(9) Where the information requested under *subhead (8)* is not forwarded within the time specified or agreed with the approved research ethics committee the application will be deemed to have been withdrawn and the committee shall so notify-

(a) the Authority,

(b) the applicant, and

(c) the Commissioner where the application includes a request under *Head 33*.

(10) (a) An approved research ethics committee may only consider proposals that the Authority has transmitted to it under *subhead (4)*,

(b) Notwithstanding *paragraph (a)*, an approved research ethics committee may consider health research proposals where such health research is below doctoral level undertaken-

(i) in an institution of higher education within the meaning of section 1 (inserted by section 52 of the Institutes of Technology Act 2006) of the Higher Education Act 1971,

(ii) in an institution that otherwise provides continuing healthcare education, or

(iii) in a prescribed body,

but in considering such research it shall not do so as an approved research ethics committee under this Part and any ethical approval given is not given under this Part.

Explanatory Note
As per subhead (1), applications by researchers for research ethics approval, under this Part, are made to HIQA. To ensure consistency, subhead (2) requires the application be made in the form and manner specified by the Authority.

Some ARECs will be national ones, others may be regional ones. Accordingly, subhead (3) makes it clear that an application under this Head in respect of a proposal that intends for the research to be carried out-

(a) in the State generally may only be considered by an approved research ethics committee approved for the State generally,

(b) in part of the State may only be considered by an approved research ethics committee approved for the part of the State that the research is intended to be carried out in.

Subhead (4) requires that HIQA put in place appropriate procedures to facilitate the transmission of the research proposal for consideration by an AREC. This is likely to be web based. No fee is payable to HIQA with the application but a fee will be payable where the applicant is seeking a data protection consent exemption under this Part.

Subhead (5) requires the AREC to which the proposal is transmitted to determine, as a preliminary matter, whether the proposal is-

(a) one to which this Part applies and, where it is, it will notify HIQA and the applicant, or

(b) not one to which the Part applies and, where it is, it will notify the HIQA and the applicant. In this situation, the applicant will be able to appeal under Head 32 should he or she so wish.

Under subhead (6), an AREC must notify an applicant of the right to appeal a decision referred to in subhead (5). This appeal on the preliminary matter of whether the research proposal falls within the scope of Part 3 will be heard by another AREC which is the same arrangement as will be in place for appeals from the substantive decisions of an AREC on ethical approval.

Subhead (7) provides that where HIQA is notified of the decision referred to in subhead 5(a) and the application includes a request for a decision from the Commissioner under Head 33, it shall-

(a) transmit the proposal to the Commissioner together with the prescribed fee,

(b) inform the Commissioner of the approved research ethics committee that is considering the proposal,

(c) notify the approved research ethics committee considering the proposal that it has done (a) and (b).

It also provides for the return of a Head 33 fee by HIQA where the health research proposal is not one covered by this Part of the Bill.

The rationale with subhead (7) is that there is no point involving the Data Protection Commissioner in considering the proposal until it has been considered by an AREC to establish that it is a proposal to which Part applies.

Subheads (8) and (9) are about giving the AREC the power to require relevant information from the applicant and the consequences for the applicant of not responding.

Subhead (10) deals with a major matter. An AREC may have been an institutional or local REC whose appointing authority has applied for HIQA approval under the Bill. In such a scenario, the position is that the REC should, after approval, deal only with research proposals that come through HIQA via the research application process set out in this Part. However, an AREC may be associated with a University or a hospital. If so, the University or hospital may have students or employees doing health research at undergraduate and masters level which lie outside the scope of "otherwise governed health research". Such students can continue to go to "their" REC. However, where they do so, it will not be under this part of the Bill and the AREC will not be sitting as an AREC.

Decision on ethics of proposed health research proposal
29. **Provide that:**
(1) An approved research ethics committee to which a proposal is transmitted for consideration under *Head 28(4)* or received under *Head 23* shall–

(a) consider the ethics of the proposed health research on the basis of the matters referred to in *subhead (2),* and

(b) after doing so, make a decision on the ethics of the proposed health research, under *subheads (3)* or *(4).*

(2) An approved research ethics committee shall, in considering any proposal, consider the following matters to the extent that they are relevant to the proposal concerned-

(a) whether the health research is likely to assist in–

(i) the advancement or protection of human health, whether of the population as a whole or of any part of the population,

(ii) the scientific understanding of human health,

(iii) the understanding of social factors affecting human health,

(iv) the identification, prevention or treatment of illness, disease or other medical impairment, or

(v) the effective management of health services, including improvements in the delivery of those services,

(b) whether the person making the proposal has identified and assessed the potential benefits and risks associated with the carrying out of the health research,

(c) whether the person making the proposal will make every effort to ensure that the participation of individuals in the health research will be informed and voluntary,

(d) whether the person making the proposal is qualified to carry out the health research concerned,

(e) whether there are adequate safeguards in place to protect the privacy of individuals participating in the health research and the confidentiality of their personal data, including, where appropriate, that any conditions imposed by the Commissioner under *Head 33* have been complied with as required,

(f) whether there is anything in the health research concerned that will undermine or decrease public confidence in health research generally,

(g) whether the research methodology proposed is appropriate,

(h) any guidelines issued by the Authority under *Head 18.*

(3) If an approved research ethics committee is not satisfied with one or more relevant matters relating to the proposal, referred to in *subhead (2),* the committee shall refuse to give its ethical approval to the proposal.

(4) If an approved research ethics committee is satisfied with the relevant matters relating to the proposal, referred to in *subhead (2)*, the committee shall give its ethical approval to the proposal with or without conditions.

(5) Subject to *subhead (6)* and *Head 33(9)*, an approved research ethics committee shall, not more than 40 days after receiving the proposal under *Head 28*, notify the person proposing to carry out the health research in writing of its decision.

(6) Where an approved research ethics committee makes a request under *Head 28(8)*, the number of days specified in *subhead (5)* for the consideration of the proposal shall be suspended from the time the approved research ethics committee makes the request up until the time the information is provided within a period specified by the approved research ethics committee or agreed with the person making the application.

(7) If the decision of the approved research ethics committee is that the proposal is approved, the notification under *subhead (5)* shall include a statement of-

(a) conditions, if any, to which the health research is to be subject,

(b) whether the research may be carried out in the State generally or in part of the State only, and

(c) matters identified as possible adverse events that must be reported by the person to the approved research ethics committee should they occur in the carrying out of the research.

(8) Where a report of adverse events is made to an approved research ethics committee, the approved research ethics committee shall notify its appointing authority in every case-

(a) of the report, and

(b) any actions it proposes to take in relation to the report.

(9) If the decision of the approved research ethics committee is that the proposal is refused or approved with conditions, the notification under *subhead (5)* shall include-

(a) the reasons for the refusal or the conditions, and

(b) a statement that the person may appeal the refusal or the conditions to the Authority for consideration under *Head 32*.

Explanatory Note
Subhead (1) provides that an approved research ethics committee to which a health research proposal is transmitted by HIQA (under Head 28) or received by the Committee (under Head 23) will consider the ethics of the proposed research on the basis of the factors outlined below and make a decision to give (with or without conditions) or refuse ethical approval.

As per subhead (2), the committee will, in considering a research proposal**,** consider the following matters to the extent that they are relevant to the proposal concerned-

(a) whether the health research is likely to assist in–

(i) the advancement or protection of human health, whether of the population as a whole or of any part of the population,

(ii) the scientific understanding of human health,

(iii) the understanding of social factors affecting human health,

(iv) the identification, prevention or treatment of illness, disease or other medical impairment, or

(v) the effective management of health services, including improvements in the delivery of those services,

(b) whether the person making the proposal has identified and assessed the potential benefits and risks associated with the carrying out of the health research,

(c) whether the person making the proposal will make every effort to ensure that the participation of individuals in the health research will be informed and voluntary,

(d) whether the person making the proposal is qualified to carry out the health research concerned,

(e) whether there are adequate safeguards in place to protect the privacy of individuals participating in the health research and the confidentiality of their personal data, including that the conditions where a request was made to process personal data without consent, are satisfied as required,

(f) whether there is anything in the health research concerned that will undermine or decrease public confidence in health research generally,

(g) whether the research methodology proposed is appropriate,

(h) any guidelines issued by the HIQA under Head 18.

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Subhead (3) makes clear that if the committee is not satisfied with one or more of the relevant matters enumerated in subhead (2), it must refuse to give its ethical approval to the proposal. However, under subhead (4), where the committee is satisfied with the relevant matters relating to the proposal, it will give its ethical approval to the proposal. That approval can be with or without conditions.

Subhead (5) is about the time for a decision on a proposal to be made. Subject to subhead (6) and Head 33 (data protection consent exemption), the approved research ethics committee must, not more than 40 days after receiving the proposal, notify the person proposing to carry out the health research in writing of its decision. The information to be included in such notifications in set out in subheads (7) and (9).

Subhead (6) relates back to Head 28(8) and provides that where the committee makes a request for more information the number of days specified for the consideration of the proposal is suspended from the time the approved research ethics committee makes the request up until the time such information is provided.

Subhead (7) covers where the decision of the approved research ethics committee is to approve the proposal under subhead (4). It provides that the notification (of approval) to the applicant will include a statement of any-

> (a) conditions, if any, to which the health research is to be subject,
>
> (b) whether the research may be carried out in the State generally or part of the State only, and
>
> (c) matters identified as possible adverse events that must be reported by the person to the approved research ethics committee should they occur in the carrying out of the research.

Subhead (8) deals with the situation where a report of adverse events is made to an approved research ethics committee. In such a case, the committee will notify its appointing authority of the report, and any actions it proposes to take in relation to the report.

Subhead (9) sets out the information to be provided in a notification refusing ethical approval or approving it with conditions. The notification will include-

- the reasons for the refusal or the conditions attached to the approval, and
- a statement that the person may appeal the refusal of the application or conditions attached to the approval to HIQA for consideration.

Effect of approval under *Head 29* or *Head 32*
30. Provide that:
(1) Where a proposal to do health research is approved under *Head 29* or *Head 32* in relation to the State generally-

> (a) no other approved research ethics committee established by an appointing authority, and
>
> (b) no other research ethics committee established by an appointing authority that is in receipt of any funding from the State,

shall require, as a condition of the research being carried out, that any examination of the matters referred to in *Head 29(2)* be done.

(2) Where a proposal to do health research is approved under *Head 29* or *Head 32* in relation to part of the State-

(a) no other approved research ethics committee established by an appointing authority within that part of the State, and

(b) no other research ethics committee established by an appointing authority within that part of the State that is in receipt of any funding from the State,

shall require, as a condition of the research being carried out, that any examination of the matters referred to in *Head 29(2)* be done.

(3) Where a proposal to do health research is approved under *Head 29* or *Head 32* in relation to part of the State, that approval is applicable to the carrying out of the research concerned only in that part of the State.

(4) Where a proposal to do health research is approved under *Head 29* or *Head 32* in relation to the State generally, that approval is applicable to the carrying out of the research concerned in the whole of the State.

Explanatory Note
This Head is very important to the success of the ethical approval structure provided for under this Part of the Bill. Consistent with the objective to have ARECs that can give national or regional ethical approval, its purpose is to prevent that national or regional approval, as appropriate, being re-opened by another AREC or by a REC where the appointing authority of the REC is in in receipt of State funding.

Accordingly, under subhead (1), where a proposal to do health research is approved by an AREC in relation to the State generally-

(a) no other approved research ethics committee established by an appointing authority, and

(b) no other research ethics committee established by an appointing authority that is in receipt of any funding from the State,

can require, as a condition of the research being carried out, that any examination of the ethical matters specified in Head 29(2) be undertaken.

Subhead (2) mirrors subhead (1), as appropriate, in relation to a regional ethical approval by an AREC.

Subhead (3) makes it clear that where a proposal to do health research is approved under Head 29 or Head 32 in relation to part of the State the approval is valid only for that part of the State. If a researcher initially sought regional ethical approval because he or she was planning that the research would only be carried out within a particular region but subsequently decided to extend the research beyond that region they would have to make a fresh application under Head 28 for approval for the parts of the State it was now intended to extend the research to.

Similarly, subhead (4) makes clear where a proposal to do health research is approved under Head 29 or Head 32 in relation to the State generally that approval is applicable to carrying out the research concerned in the whole of the State.

Decision-making
31. Provide that:
(1) In considering the matter or matters under *Heads 29(1)* and *(2)*, an approved research ethics committee may consult with a person who is not a member of the committee, where it considers that that person has an expertise required by the committee.

(2) A member of an approved research ethics committee shall not, in any manner, directly or indirectly, participate in the consideration of any proposal in which the member, or a person with whom the member is connected, has any interest and, accordingly, a member shall withdraw from any meeting at which such a proposal is to be considered or decided.

(3) A decision under *Head 29* shall not be made by an approved research ethics committee unless it is made by a quorum of its members which for the purposes of *Head 29* means-

(a) more than half the membership of the committee, and

(b) at least one quarter of the membership making the decision have to be lay members.

Explanatory Note
When considering research applications, subhead (1) allows the AREC to consult with other persons who are not members of the AREC but who may have expertise in the research area under consideration.

The provision in subhead (2) addresses the conflict of interest question. A member of an approved research ethics committee cannot participate in the consideration of any research proposal in which the member, or a person with whom the member is connected, has any interest. The member must withdraw from any meeting at which such a proposal is to be considered.

Subhead (3) also outlines the requirements in relation to a quorum for decision-making on a research proposal including the number of expert and lay members.

Appeal from a decision under *Heads 28(5), 29(3)* and *38*
32. Provide that:
(1) A person who has made an application to the Authority under *Head 28* and has received a decision on the proposal referred to in *Head 28(5)* or in *Head 29(3)* may appeal that decision.

(2) A person who is notified under *Head 38* by an approved research ethics committee may appeal the decision in the notification.

(3) An application for an appeal under *subheads (1)* or *(2)* shall be made to the Authority-

(a) in the specified form and manner,

(b) shall set out the grounds for the appeal,

(c) be accompanied by the prescribed fee.

(4) Subject to *subheads (5)* and *(6)*, the Authority shall refer an appeal under this Head to an approved research ethics committee, other than the one from whose decision the appeal is made, for consideration.

(5) Where the proposal was approved by a research ethics committee approved for the State generally, the Authority shall refer the appeal under *subhead (4)* to another research ethics committee approved for the State generally and that committee shall hear the appeal.

(6) Where the proposal was approved by a research ethics committee approved for part of the State, the Authority shall refer the appeal under *subhead (4)* to another research ethics committee approved either for the same part of the State or the State generally and that committee shall hear the appeal.

(7) An appeal under this Head shall be considered and decided on by an approved research committee in the manner provided in *Head 29(2)* to *(6)*.

(8) An appellant when notified of the decision by the approved research ethics committee that considered the appeal under this Head shall notify within 21 days-

(a) that approved research ethics committee, as appropriate, and

(b) the Authority,

of his or her acceptance or not of the decision.

(9) The Authority shall notify the Commissioner of-

(a) any appeal made under this Head where the application made under *Head 28* included a request for a decision from the Commissioner,

(b) the decision of any such appeal under this Head, and

the notification by the appellant under *subhead (8*).

Explanatory Note
It is considered desirable that there should be an appeals process for researchers in respect of decisions made on applications: including preliminary decisions made under Head 28(5). A separate appeals process, consistent with the Data Protection Acts, will apply in relation to the data protection consent exemption element, see Head 34.

Subheads (1) and (2) provide for the researcher to make an appeal to HIQA. Under subhead (3), the appeal application must be made in the specified form and manner and set out the grounds for the appeal. It is intended that there should be a (prescribed) fee for an appeal which must be paid at the time the appeal is being made.

Subhead (4) provides that an appeal will be referred by HIQA to an approved research ethics committee, other than the one from whose decision the appeal is made, for consideration. Subheads (5) and (6) tease out this principle.

Specifically, subhead (5) provides that where the research proposal was approved by a research ethics committee approved for the State generally, the Authority must refer the appeal to another research ethics committee approved for the State generally. That is because it would be inappropriate to have a regional AREC consider a project that was a national one.

Subhead (6) covers the situation where the research proposal was refused by a regional research ethics committee. In that case, HIQA will refer the appeal to another research ethics committee approved either for the same part of the State or the State generally.

Subhead (7) makes sure that the same criteria are applied when considering the appeal as were applied when considering the original application.

Subhead (8) requires the appellant to advise the AREC that heard the appeal and HIQA of his or her acceptance or not of the appeal decision.

Subhead (9) has regard to the need to keep the Data Protection Commissioner advised where the researcher has applied for a consent exemption under Head 33.

Processing of personal data without consent
33. Provide that:
(1) A person proposing to carry out health research may include in their application under *Head 28* a request for a decision from the Commissioner permitting the collection and use, by the person, of personal data that relate to one or more individuals without the consent of those individuals.

(2) (a) Where such a request is included in the application the person must as part of the application provide written information demonstrating that–

(i) the research requires that personal data of the type specified be obtained and used rather than anonymised or pseudo-anonymised data,

(ii) the proposed research, and the need to collect and use such personal data as is specified in *subparagraph (i)* is of sufficient importance that the public interest in it outweighs to a substantial degree the public interest in protecting the confidentiality of the personal data concerned,

(iii) the personal data will not be used in such a way that damage or distress is, or is likely to be, caused to the individuals to whom the data relate,

(iv) the collecting and use of the personal data will go no further than is necessary for the attainment of the research objective,

(v) there will be no further disclosure of the personal data unless required under an enactment or rule of law or to the data subject,

(vi) adequate safeguards will be in place at the time the research is to be carried out to protect the security of the personal data concerned,

(vii) appropriate arrangements will be in place after the research has been completed to secure, archive or destroy that data,

(viii) the duration for which the personal data concerned may be kept in a manner that identifies any individual is no longer than necessary for the proper conduct of the research, and

(ix) the number of individuals whose personal data is intended to be collected and used is such that obtaining the consent referred to in *subparagraph (i)* is unreasonable, impractical or not feasible.

(b) The Commissioner shall publish on his or her website, the criteria on which a decision under this Head is to be made.

(3) (a) A person including a request under *subhead (1)* shall, if so required by the Commissioner, provide any additional information requested relevant to any of the matters in *subhead (2)* within a time specified or agreed with the Commissioner and if such information is not provided within that time the request shall be deemed to have been withdrawn.

(b) The Commissioner shall inform, in writing, the Authority and the approved research ethics committee considering the proposal that the request has been withdrawn due to failure by the applicant to comply with the requirement to provide the information sought.

(4) The Commissioner shall, not more than 30 days after receiving the proposal under *Head 28(7)*, subject to any requirement for additional information under *subhead (3)* which shall suspend the 30 day period until the information required is provided, make a decision–

(a) if not satisfied that all the grounds set out in *subhead (2)* have been met, refusing the request, or

(b) (i) if satisfied that the grounds set out in *subhead (2)* have been met, granting the request, subject to such conditions as he or she considers necessary to protect the interests of data subjects likely to be affected by the granting of the request, and

(ii) without limiting the generality of the conditions that might be imposed particular regard shall be had to the following-

(A) ensuring that the personal data are not used in such a way that damage or distress is, or is likely to be, caused to the data subjects to whom the data relate,

(B) requiring that the collecting and use of the personal data involved goes no further than is necessary for the attainment of the research objective,

(C) specifying the duration for which the personal data concerned may be kept in a manner that identifies any data subject,

(D) limiting the further processing of the personal data concerned,

(E) setting out the security arrangements that should apply to the personal data.

(5) The Commissioner may consult with such other persons as he or she considers appropriate for the making of the decision under this Head.

(6) Where the Commissioner receives an application under this Head, the Commission shall publish a notice on his or her website-

(a) advising that the application has been made,

(b) giving a brief description of the research proposal, and

(c) advising that any person may make, until a date specified, representations concerning the request for an exemption under this Head.

(7) The Commissioner shall consider any representations received under *subhead (6)(c)* in reaching a decision under this Head.

(8) After making a decision under this Head, the Commissioner shall-

(a) send written notice of the decision and the reasons for it to-

(i) the person who made the proposal,

(ii) the approved research ethics committee concerned, and

(iii) the Authority, and

(b) display on his or her website the decision and the reasons for it.

(9) An approved research ethics committee shall not make a decision under *Head 29* in respect of a proposal that includes a request under *subhead (1)* until the day on which the decision under *subhead (4)* has become final by virtue of-

(a) the person has not appealed it under section 26 of the Act of 1988 and the time for taking the appeal has expired or he or she has notified, in writing, the Authority, the approved research ethics committee and Commissioner of his or her decision not to appeal, or

(b) all rights of appeal under that Act have been exhausted.

(10) The Commissioner and the Authority shall review the operation of this Head at least once per year and shall report to the Minister, not later than 31 March of every year, on the operation of this Head during the previous year.

(11) A reference in this Head to the consent of an individual to whom personal data relate is a reference to consent obtained from, or on behalf of, the individual in accordance with the Act of 1988.

Explanatory Note

This Head provides a mechanism for a person proposing to carry out health research to apply for a data protection consent exemption in certain strict and limited circumstances. Where the exemption is being sought, the request must be made as part of the application to be made under Head 28. The decision on the request will be made by the Data Protection Commissioner who may consult with other appropriate persons before reaching a decision. There will be a fee payable to the Office of the Data Protection Commissioner where the researcher seeks this exemption.

Subhead (1) provides that a person proposing to carry out health research may include in the application (under Head 28) a request for a decision from the Data Protection Commissioner permitting the collection and use, by the person, of personal data that relate to one or more individuals without the consent of those individuals.

Subhead (2) (a) provides that where such a request is included in the application the person must as part of the application provide written information demonstrating that–

(i) the research requires that personal data of the type specified be obtained and used,

(ii) the proposed research, and the need to collect and use such personal data as is specified in subparagraph (i) is of sufficient importance that the public interest in it outweighs to a substantial degree the public interest in protecting the confidentiality of the personal data concerned,

(iii) the personal data will not be used in such a way that damage or distress is, or is likely to be, caused to the individuals to whom the data relate,

(iv) the collecting and use of the personal data will go no further than is necessary for the attainment of the research objective,

(v) there will be no disclosure of the personal data unless required under an enactment or rule of law or to the data subject,

(vi) adequate safeguards will be in place at the time the research is to be carried out to protect the security of the personal data concerned,

(vii) appropriate arrangements will be in place after the research has been completed to secure, archive or destroy that data,

(viii) the duration for which the personal data concerned may be kept in a manner that identifies any individual is no longer than necessary for the proper conduct of the research, and

(ix) the number of individuals whose personal data is intended to be collected and used is such that obtaining the consent referred to in subparagraph (i) is unreasonable, impractical or not feasible

Subhead (2) (b) states that that Commissioner shall publish the criteria on which a decision under this Head is to be made on his or her website.

Subhead (3) allows the Commissioner to require -and the applicant to provide- any additional information relevant to any of the matters in subhead (2). Failure to provide the information sought within the relevant timeframe will mean that the request for the consent exemption has been deemed to have been withdrawn.

Subhead (4) deals with timeframes and decisions by the Commissioner. Essentially, the request will be rejected where the Commissioner is not satisfied that all the grounds set out in subhead (2) have been met. Where the Commissioner is so satisfied, he or she may grant the request, subject to such conditions as he or she considers necessary to protect the interests of data subjects likely to be affected by the granting of the request.

Subhead (5) allows the Commissioner to consult with such other persons as he or she considers appropriate in making the decision.

Subhead (6) is about transparency. It helps ensure that there is a public awareness of the application made for a consent exemption and an opportunity to make representations.

Subhead (7) requires the Commissioner to consider any representations received in making a decision.

Subhead (8) is about informing the relevant parties of the decision made.

Subhead (9) requires that an approved research ethics committee will not make a decision under Head 29 until the day on which the decision under subhead (4) has become final.

Subhead (10) provides for a review, annually or more frequently, of the operation of this Head. That review will be carried out by the Data Protection Commissioner in conjunction with HIQA.

Subhead (11) makes clear that the reference, in this Head, to the consent of an individual to whom personal data relate to consent obtained from, or on behalf of, the individual in accordance with the Data Protection Acts.

Appeal from a decision of the Commissioner
34. Provide that:
(1) An appeal from the decision of the Commissioner under *Head 33* to the Circuit Court shall be open to the applicant under *Head 28* and any individual whose personal data would be affected by the decision.

Explanatory Note
The Data Protection Acts provide for an appeal from the decisions of the Commissioner to the Circuit Court and this Head provides, accordingly for an appeal, in relation to decisions under Head 33. The appeal will be open both to the researcher concerned and any individual whose personal data would be affected by the decision.

Relationship with Data Protection Acts
35. Provide that:
(1) Section 2(1)(c)(ii) of the Act of 1988 shall not be construed as preventing a data controller disclosing personal data to another person for the purposes of health research that has been approved under this Part, so long as the disclosure is in accordance with a decision of the Commissioner under *Head 33*.

(2) Personal data obtained by a person as the result of a disclosure by a data controller pursuant to a decision under *Head 33* shall not be regarded, for the purposes of section 2(1)(a) of the Act of 1988, as having been obtained unfairly by reason only that its use for the purposes of health research that has been approved under this Part was not disclosed when it was obtained by the data controller.

(3) A data controller who processes personal data for the purposes of health research that has been approved under this Part, and does so in accordance with a decision of the Commissioner under *Head 33*, shall be deemed to comply with section 2A and, in the case of data that are sensitive personal data, section 2B, of the Act of 1988.

(4) Nothing in this Head shall be construed as limiting the application of any provisions of the Act of 1988, other than sections 2(1)(a) and (c)(ii), 2A and 2B of that Act, to the processing of personal data for the purposes of health research that has been approved under this Part.

Explanatory Note
This Head is related to Head 33 (which deals with applications by health researchers under Head 28 where those applications includes request for a consent exemption as provided for in Head 33) and links that Head with certain relevant provisions in the Data Protection Acts as set out below.

Subhead (1) provides that section 2(1)(c)(ii) of the Data Protection Act 1988 will not be construed as preventing a data controller disclosing personal data to another person for the purposes of health research that has been approved under this Part so long as the disclosure is in accordance with a decision of the Data Protection Commissioner under Head 33. Section 2(1)(c)(ii) provides that a data controller cannot, as respects personal data kept by him or her, further process (including disclosing) such data in a manner incompatible with the purpose for which it was collected by him or her. This would normally prevent a hospital, GP etc disclosing information to a health researcher as they collected the information for patient care. Subhead (2) is the inverse of subhead (1) as it addresses the issue from the point of view of the health researcher by making the receipt of such information "fair" within the meaning of section 2(1)(a) of the Data Protection Acts.

Subhead (3) makes it clear that a data controller who processes personal data for the purposes of health research that has been approved under this Part, and does so in accordance with a decision of the Data Protection Commissioner under Head 33, will be deemed to be compliant with section 2A and, in the case of data that are sensitive personal data, section 2B, of the Data Protection Act 1988. Sections 2A and 2B set out the grounds on which processing of personal data may be carried out under the Data Protection Acts.

Subhead (4) makes clear that nothing in this Head shall be construed as limiting the application of any provisions of the Data Protection Acts other than the ones expressly referred to in this Head: for example, the requirement in relation to data security will apply.

No requirement to provide personal data
36. Provide that:
Nothing in this Part shall be construed as requiring any person to provide personal data to a person whose-

(a) proposal has been approved under *Head 29* by an approved research ethics committee or *Head 32* by an approved research ethics committee,

(b) request for a decision under *Head 33* has been approved by the Commissioner or on appeal by the Circuit Court.

Explanatory Note
The purpose of this provision is to make clear that ethical approval by an approved research ethics committee, in itself, or even such ethical approval with a consent exemption from the Data Protection Commissioner does not create any obligations on any person to release personal data to the researcher.

Notification of acceptance of decision or intention to appeal a decision
37. Provide that:
Where a person who has been notified of a decision under *Head 29(3) or (4)* he or she shall notify the approved research ethics committee that made the decision, in writing, not later than 10 days after the notification is sent, that he or she-

(a) accepts the decision,

(b) does not accept the decision but does not intend either to appeal it under *Head 32* or make a complaint under *Head 40*, or

(c) does not accept the decision and intends either to appeal it under *Head 32* or make a complaint under *Head 40*.

Explanatory Note
Where a person has been notified of a decision that his or her proposal to carry out health research has been ethically approved, with or without conditions, or has not been approved, he or she must notify the approved research ethics committee, in writing, no later than 10 days after the notification is sent, that he or she-

(a) accepts the decision,
(b) does not accept the decision but does not intend either to appeal it or make a complaint in relation to it, or
(c) does not accept the decision and intends either to appeal it or make a complaint in relation to it.

An appeal can be made against either a decision either in relation to a refusal or the conditions attached to an approval.

Monitoring of health research
38. Provide that:
(1) (a) An approved research ethics committee shall monitor, in terms of its ethical conduct, the carrying out of research that has been approved by it under this Part.

(b) A person whose research has been approved under this Part shall notify the approved research ethics committee that approved the research of the date on which the carrying out of the research commences and the date on which it finishes.

(c) For the purposes of monitoring under *paragraph (a)*, an approved research ethics committee shall have the power to request such-

(i) information, and

(ii) interim and final reports,

as it considers necessary from a person whose proposal has been approved by it under this Part.

(2) (a) A person whose proposal has been approved under this Part shall co-operate with the approved research ethics committee that approved the proposal when it is carrying out its monitoring under *subhead (1)*.

(b) A failure to co-operate in accordance with *paragraph (a)* may lead to approval under this Part being withdrawn by the approved research ethics committee.

(3) (a) A person whose proposal has been approved under this Part shall notify the approved research ethics committee that approved the proposal in writing of any proposed change in a material fact or of a material circumstance which relates to him or her or to the carrying out of the health research concerned.

(b) A failure to comply with *paragraph (a)* may lead to ethical approval under this Part being withdrawn by the approved research ethics committee.

(4)The approved research ethics committee shall consider the change notified under *subhead (3)* and, not more than 21 days after receiving that notification, shall–

(a) if it decides that no amendment to the approval or to any condition of the approval is warranted, so advise the person by notice in writing, or

(b) if it decides that the approval shall be withdrawn or that the approval shall have conditions added to it, removed or otherwise varied so advise the person by notice in writing.

(5) (a) A person who receives a notice under *subhead (4)* shall acknowledge receipt of the notice to the approved research ethics committee within 10 days and shall state that he or she-

(i) accepts the decision in the notice,

(ii) intends to appeal, under *Head 32*, the decision in the notice, or

(iii) intends to make a complaint under *Head 40* in relation to the procedures followed by the approved research ethics committee in considering and deciding upon the matter under *subhead (4)*.

(b) A failure to comply with *paragraph (a)* may lead to ethical approval under this Part being withdrawn by the approved research ethics committee.

(6) Where the approved research ethics committee that approved the proposal has had, while the research is being carried out, its approval revoked by the Authority under *Head 22* or its appointing authority has applied for the approval to be withdrawn under *Head 15*, the Authority shall where the proposal was approved by a research ethics committee approved for the State generally assign another research ethics committee approved for the State generally to carry out the monitoring under this Head as if it were the committee that had approved the research and that committee shall so monitor.

(7) Where the approved research ethics committee that approved the proposal has had, while the research is being carried out, its approval revoked by the Authority under *Head 22* or its appointing authority has applied for the approval to be withdrawn under *Head 15*, the Authority shall where the proposal was approved by a research ethics committee approved for part of the State assign another research ethics committee approved either for the same part of the State or the State generally to carry out the monitoring under this Head as if it were the committee that had approved the research and that committee shall so monitor.

Explanatory Note

It is considered important that the carrying out of health research ethically approved under this Part of the Bill by an approved research ethics committee should be monitored by the committee. This is provided for in this Head. This is in keeping with Helsinki Declaration (World Medical Association Declaration of Helsinki - Ethical Principles for Medical Research Involving Human Subjects) which states that

> "The [research ethics] committee must have the right to monitor ongoing studies. The researcher must provide monitoring information to the committee, especially information about any serious adverse events. No amendment to the protocol may be made without consideration and approval by the committee. After the end of the study, the researchers must submit a final report to the committee containing a summary of the study's findings and conclusions."

Subhead (1) provides that an approved research ethics committee will monitor, in terms of its ethical conduct, the carrying out of health research that has been approved by it under this

Part. For that purpose, an approved research ethics committee shall have the power to request such-

(a) information, and

(b) interim and final reports,

as it considers necessary from a person whose proposal has been approved by it under this Part.

The subhead also provides that a person whose research has been approved under this Part must notify the approved research ethics committee that approved the research when the carrying out of the research commences and finishes. This will provide clarity for monitoring purposes.

Subhead (2) places an obligation on the researcher concerned to co-operate with the AREC in its monitoring. A failure to co-operate could lead to approval under this Part being withdrawn by the AREC.

Subhead (3) places obligations on the researcher to notify the AREC in writing of any proposed change in a material fact or of a material circumstance which relates to him or her or to the carrying out of the health research concerned. A failure to do so could lead to ethical approval under this Part being withdrawn by the AREC.

Under subhead (4), the AREC will consider the material change notified and, not more than 21 days after receiving that notification, will take one of the following two courses of action: namely, it will-

(a) if it decides that no amendment to the approval or to any condition of the approval is warranted, so advise the person by notice in writing, or

(b) if it decides that the approval should be withdrawn or that the approval should have conditions added, removed or otherwise varied so advise the person by notice in writing.

Subhead (5) addresses sets out what a person who receives a notice under subhead (4) must do and the potential consequence of not doing so.

Subheads (6) and (7) cover the scenario where the AREC that approved the research proposal has had its approval revoked (either at the request of its appointing authority or by HIQA.

Offence - false or misleading statements or representations
39. Provide that:
(1) A person is guilty of an offence if, for the purposes of an application under *Head 28*, an appeal under *Head 32* or a complaint under *Head 40* or *Head 41*, he or she–

(a) makes any statement or representation, whether oral or written, that he or she knows to be false or misleading in any material respect, or

(b) knowingly conceals any material fact.

(2) A person is guilty of an offence if, in relation to the monitoring of health research under *Head 38*, he or she–

(a) makes any statement or representation, whether oral or written, that he or she knows to be false or misleading in any material respect, or

(b) knowingly conceals any material fact.

(3) A person is guilty of an offence if he or she-

(a) makes any statement or representation, whether oral or written, that health research that he or she is carrying out, or is planning to carry out or has carried out, has been approved by an approved research ethics committee if he or she knows the statement or representation to be false or misleading, or

(b) makes any statement or representation, whether oral or written, about the terms of an approval under this Part that he or she knows to be false or misleading in any material respect.

(4) A person guilty of an offence under this Head is liable-

(a) on summary conviction, to a class B fine, or

(b) on conviction on indictment, to a fine not exceeding €100,000.

(5) (a) Subject to *paragraph (b)*, summary proceedings for an offence under this Head may be brought and prosecuted by the Authority.

(b) Where the false or misleading statement or representation or the concealment of material facts relates, in whole or in part, to a matter that falls under *Head 33*, summary proceedings may be brought by the Authority only after consulting with the Commissioner.

Explanatory Note
Head 39 provides for offences where false or misleading statements or representations are made with persons convicted of an offence being subject to a fine. While the system of research ethics approval being put in place under this Part of the Bill is voluntary it is nonetheless important (given the value of health research and the need to maintain public confidence in it) that there are penalties with regard to the system.

Complaints to the Authority
40. Provide that:
(1) An applicant under *Head 28* or an appellant under *Head 32* who is of the view that he or she has been affected by the procedural conduct of an approved research ethics committee, or a member of an approved research ethics committee, in the performance of its or his or her functions under this Part may, in accordance with *subhead (2)*, make a complaint to the Authority about that conduct not later than 6 months after the date of the conduct to which the complaint relates.

(2) Any person making a complaint under this Head shall do so-

(a) in the form and manner specified by the Authority, and

(b) set out the grounds for the complaint.

(3) Where the Authority receives a complaint under *subhead (1)* it shall (where the prescribed fee, if any, has accompanied the complaint), without delay, refer the complaint to the appointing authority for the approved research ethics committee concerned for investigation and-

(a) the complainant, and

(b) the approved research ethics committee and members of the approved research ethics committee,

shall co-operate with the appointing authority carrying out an investigation under this Head.

(4) An appointing authority carrying out an investigation under this Head may, after such consideration as appears necessary-

(a) dismiss a complaint if it considers it frivolous or vexatious, or

(b) seek to resolve the complaint through informal resolution.

(5) Where the appointing authority carrying out an investigation under this Head dismisses a complaint under *subhead (4)(a)* it shall notify-

(a) the complainant,

(b) the approved research ethics committee and members of the approved research ethics committee, and

(c) the Authority,

of the decision and the reasons for it.

(6) Where the appointing authority carrying out an investigation under this Head seeks to resolve the complaint under *subhead (4)(b*), it shall notify-

(a) the complainant,

(b) the approved research ethics committee and members of the approved research ethics committee, and

(c) the Authority,

of the decision to do so.

(7) The complainant, the approved research ethics committee and members of the approved research ethics committee notified under *subhead (6)* shall co-operate with the informal resolution under *subhead (4)(b*).

(8) Where the appointing authority does not dismiss a complaint or resolve it through informal resolution under *subhead (4)*, the appointing authority shall notify the persons referred to in *subhead (6)* and continue to investigate the complaint under this Head.

(9) The appointing authority investigating the complaint under *subhead (1)* shall conclude its investigation and report to the Authority on its findings and with its recommendations within such period as the Authority may specify.

(10) The Authority shall consider the report and recommendations made to it under *subhead (9)* and shall notify the appointing authority of the actions, if any, it wishes the appointing authority to take and the period within which those actions must be taken.

(11) The appointing authority shall notify the Authority, within the time specified by the Authority, when it has taken any actions notified to it under *subhead (10)*.

(12) A failure by the appointing authority to-

(a) investigate, under *subhead (3),* a complaint made under this Head, or

(b) take any actions notified under *subhead (8),*

may lead to the revocation by the Authority, under *Head 22*, of the approval of the research ethics committee.

(13) An appointing authority shall provide the Authority with a report on complaints investigated under this Head in such form and at such times as the Authority may specify.

Explanatory Note
This Head deals with the making and investigation of complaints against approved research ethics committees or its members. This is separate from the appeals process provided for under Head 32.

Under subhead (1) an applicant under Head 28 or an appellant under Head 32 who is of the opinion that he or she has been affected by the procedural conduct of an approved research ethics committee or a member of an approved research ethics committee in the performance of its or his or her functions under this Part can make a complaint to HIQA about that conduct but only up until such time as the carrying out of the research is concluded. Subhead (2) provides that it must be made in the form and manner specified by the Authority.

Under subhead (3) the Authority, when it receives a complaint in accordance with subhead (1), shall cause the appointing authority to undertake the investigation and the approved research ethics committee and its members as well as the complainant shall co-operate with the investigation.

Under subhead (4), the appointing authority can dismiss a complaint if it considers it frivolous or vexatious or it may seek to resolve the complaint through informal resolution.

Subhead (5) states that where a complaint is dismissed under subhead (4)(a), the appointing authority will notify the relevant parties.

Subheads (6) to (8) deal with information resolution which is provided for under subhead (4)(b), If informal resolution is not successful, the appointing authority will resume investigating the complaint formally.

Subheads (9) (10) and (11) deal with the report made by the appointing authority on the investigation and will outline its findings and recommendations. Subhead (9) provides that the appointing authority makes its report to HIQA. Subhead (10) states that HIQA will consider the report and any recommendations made by the appointing authority. Subhead (11) provides that HIQA will notify the appointing authority of the actions, if any, it wishes it to take and the period within which those actions must be taken. Subhead (12) provides that failure to take the actions specified may lead to the revocation by the Authority of the approval of the research ethics committee concerned. It also provides that failure to investigate the complaint in line with subhead (3) may also lead to revocation.

Finally, as per subhead (13), an appointing authority shall provide the Authority with a report on complaints investigated under this Head in such form and at such times as the Authority may specify.

Complaints to an approved research ethics committee
41. Provide that:
(1) A person affected by the ethical conduct of a person carrying out research approved under this Part may, in accordance with *subhead (2)*, make a complaint in writing to the approved research ethics committee that approved the research, not later than the date on which the researcher notifies the approved research ethics committee, under *Head 38(1)(b)*, that the carrying out of the research has finished.

(2) Any person making a complaint under this Head shall-

(a) do so in the form and manner specified by the Authority, and

(b) set out the grounds for the complaint.

(3) Where the approved research ethics committee receives a complaint under *subhead (1)* it shall, without delay, notify-

(a) the Authority,

(b) its appointing authority, and

(c) the researcher who is the subject of the complaint,

that a complaint has been made and is being investigated by it.

(4) An approved research ethics committee carrying out an investigation under this Head may, after such consideration as appears necessary-

(a) dismiss a complaint if it considers it frivolous or vexatious, or

(b) seek to resolve the complaint through informal resolution.

(5) Where the approved research ethics committee carrying out an investigation under this Head dismisses a complaint under *subhead (4)(a)* it shall notify-

(a) the complainant,

(b) the researcher who is the subject of the complaint, and

(c) its appointing authority,

of the decision.

(6) Where the approved research ethics committee carrying out an investigation under this Head seeks to resolve the complaint under *subhead (4)(b*), it shall notify-

(a) the complainant,

(b) the researcher who is the subject of the complaint, and

(c) its appointing authority,

of the decision.

(7) The complainant and the researcher who are notified under *subhead (6)* shall co-operate with the informal resolution under *subhead (4)(b*).

(8) Where informal resolution under *subhead (4)(b*) is unsuccessful, the approved research ethics committee shall notify the parties referred to in *subhead (6)* and continue to investigate the complaint under this Head.

(9) Where an approved research ethics committee is investigating a complaint under this Head the-

(a) complainant, and

(b) the researcher who is the subject of the complaint,

shall co-operate with the approved research ethics committee.

(10) The approved research ethics committee shall, on concluding its investigation, report to-

(a) the Authority,

(b) its appointing authority,

(c) the complainant, and

(d) the researcher who is the subject of the complaint,

with its findings, the action it proposes to take and the period within which those actions will be taken.

(11) The actions that an approved research ethics committee may take under *subhead (10)* are to-

(a) withdraw the approval given under *Head 29* or *32*,

(b) vary the conditions under which the approval was given under *Head 29* or *32*,

(c) direct that the researcher who is the subject of the complaint take such other measures as are specified within a specified timeframe and report when those measures have been taken and where no report is made or the approved research ethics committee is not satisfied with the measures taken it may withdraw the approval given under *Head 29* or *32*.

(12) An approved research ethics committee shall provide its appointing authority with a report on complaints investigated under this Head in such form and at such times as the appointing authority may specify and the appointing authority shall forward that report, when received, to the Authority.

Explanatory Note
This Head deals with the making and investigation of complaints against researchers carrying out health research ethically approved under this Part.

It covers complaints that may be made by a person affected by the ethical conduct of a person carrying out research ethically approved under this Part of the Bill. A complaint can only be made, during the monitoring period (that is the period during which the research is being carried out). In such instances, the complaints are made to and investigated by the AREC that approved the research proposal. (Head 23 includes provision for another committee to investigate where the AREC has had its approval withdrawn or revoked).

In every case, any person making a complaint under this Head must do so-

(a) in the specified form and manner, and

(b) set out the grounds for the complaint.

When the AREC has finished its investigation, it reports to-

(a) the Authority,

(b) its appointing authority,

(c) the complainant, and

(d) the researcher who is the subject of the complaint,

with its findings, the action it proposes to take and the period within which those actions will be taken.

The actions that an approved research ethics committee can take are to-

(a) withdraw the approval given under Head 29 or on appeal under Head 32,

(b) vary the conditions under which the approval was given under Head 31,

(c) direct that the person takes such other measures as are specified within a specified timeframe and report when those measures have been taken and where no report is made or the approved research ethics committee is not satisfied with the action taken it shall withdraw the approval given under Head 29 or 32.

As with Head 40, there is also provision for informal resolution of complaints. Where the informal resolution is unsuccessful the complaint will continue to be investigated.

Finally, an approved research ethics committee shall provide its appointing authority with a report on complaints investigated under this Head in such form and at such times as the Authority may specify.

Advice and training
42. Provide that:
The Authority may-

(a) in relation to approved research ethics committees provide such advice and training as it considers appropriate for such committees in the performance of their functions, and

(b) in relation to research ethics committees that are not approved research committees under this Part, provide advice and training as the Authority considers appropriate for the promotion, maintenance and development of health research ethics in the State.

Explanatory Note
This Head is about allowing HIQA to provide advice and training to approved and other research ethics committees with a view to raising the overall operational and decision-making quality of all RECs operating in the State.

Fees
43. Provide that:
(1) (a) The Minister may make regulations prescribing fees for-

(i) applications made under *Head 28* that include in the application a request for a decision from the Commissioner under *Head 33,*

(ii) appeals made under *Head 32,*

(iii) complaints made under *Head 40(1)*.

(b) The Minister shall consult with-

(i) the Commissioner when proposing to make regulations under *paragraph (a)(i)*,

(ii) the Authority when proposing to make regulations under *paragraph (a)(ii) and (iii)*,

(2) Subject to *subhead (4)*, fees paid to the Authority under this Part shall be recorded as and deemed to be income.

(3) In making regulations under this Act in relation to fees payable to the Authority under this Part the regulations shall specify the proportion or amount of any such fee that shall be forwarded to an appointing authority whose approved research ethics committee is considering an appeal made under *Head 32* or a complaint under *Head 40.*

(4) Amounts forwarded under *subhead (3)* shall be regarded as reducing the income of the Authority.

(5) The Authority or the Commissioner may recover, as a simple contract debt in any court of competent jurisdiction, from the person by whom it is payable any amount due and owing to it as a result of a fee payable under this Part.

(6) No appointing authority or approved research ethics committee may seek or receive any payment, fee, financial or other benefit from a person in respect of any proposal under *Head 28* being considered by the approved research ethics committee.

(7) Where an appointing authority or approved research ethics committee receives any payment, fee, financial or other benefit from a person in respect of any proposal under *Head 28* being considered by the approved research ethics committee it shall return it to the person concerned and advise the Authority accordingly.

(8) Any fee payable by virtue of *subhead (1)(a)(ii)* and *(iii)* shall be returned if the appeal is successful or the complaint is upheld, as the case may be.

Explanatory Note
It is not intended that an appointing authority seeking to have its REC approved will have to pay an application fee. Similarly, it not intended that a researcher making an application to have his or her research project considered by an AREC will have to pay a fee. However, fees may be payable in the following circumstances-

(a) a researcher seeking to secure a data protection consent exemption as part of the ethical approval process will have to pay a fee to go to the Data Protection Commissioner,

(b) a researcher who wishes to appeal the decision of an AREC will have to pay a fee (but the fee will be returned if the appeal is successful), and

(c) a researcher who wishes to complain about an AREC will have to pay a fee (but the fee will be returned if the complaint is successful).

There will be no fees for persons making a complaint to an AREC about a health researcher under Head 41.

PART 4: DATA MATCHING PROGRAMMES

Even though they cover different matters there is considerable similarity in terms of objectives, principles and provisions between Part 4 (Data Matching Programmes) and Part 5 (Health Information Resources) of the Bill.

Interpretation – Part 4
44. Provide that:
In this Part–

"data matching" means, in relation to data relating to an individual whose personal data are contained in a data set, comparing that data set with one or more than one other data set in order –

(a) where there are personal data in the other data set or data sets that relate to that individual, to identify, and produce information about that individual, or

(b) to establish that there are no personal data about that individual contained in the other data sets;

"prescribed data matching programme" means a data matching programme, to be carried out at national level by a person other than the Minister, prescribed under *Head 50*;

"results" means any information or data produced by a prescribed data matching programme;

"standards" mean standards set by the Authority under *Head* 5*2.*

Explanatory Note
"Data matching" is essentially about taking information (collected for different purposes) from either within the same organisation or between organisations and comparing/contrasting the information in the different data sets to identify common characteristics and the people having those characteristics. This has the potential to be valuable in a number of health service areas (including management, prevention and screening of diseases and public health) where information already collected for one purpose can be reused and associated with other information for a different purpose. However, there are privacy issues to be considered. One of the policy goals of the Health Information and Patient Safety Bill therefore is to allow for data matching (sometimes called data linking) in the health service and to regulate it so that the privacy considerations of data subjects are addressed. This Part of the Bill sets out the provisions for prescribed data matching programmes.

Part 4 allows the Minister to prescribe a data matching programme and requires data controllers to provide information to a prescribed programme. The arrangements will be tightly controlled, with a number of safeguarding measures designed to ensure that the amount and type of personal data or personal health data that would be kept in a prescribed data matching programme will be protected and not be excessive or unjustified. The Minister will consult the Data Protection Commissioner and HIQA on regulations providing for each intended prescribed data matching programme. HIQA will also set standards for prescribed programmes and monitor compliance with standards and will advise the Minister and the Commissioner where there is a failure by a person carrying out a data matching programme to co-operate with HIQA in its monitoring of standards. Transparency is also addressed.

The Minister must publish a notice in relation to every data matching programme prescribed, giving specified particulars about the programme.

It is important to emphasise that the prescribing of a data matching programme under this Part is intended to be at the discretion of the Minister where he or she identifies a need for a prescribed programme, rather than an application based tick box exercise. That is why there is no formal application process provided for in this Part. Neither is it intended that the Minister should prescribe a programme under his or her control.

It is, of course, always open to a data controller, under the Data Protection Acts, to seek the consent of individuals to participate in a data matching programme that is not prescribed.

The term data set is used in this Part and in Part 5 (Health Information Resources). The definition of "*data set"* (which is set out in Head 2) covers both manual and electronic records and any combination thereof. It means a collection of records that contains data about more than one individual that includes-

(a) personal data,

(b) personal health data, and

(c) data that are not personal data or personal health data but are associated with personal health data;

Results from data matching programmes may sometimes be published so as to better inform decision-making or public awareness on particular issues. Results are defined to mean any information or data produced by a prescribed data matching programme. This is separate from the core information in the programme. Head 49 deals with the publication of results from prescribed programmes.

Requirement to provide data
45. Provide that:
(1) A person carrying out a prescribed data matching programme may request a data controller to provide to him or her one or more than one data sets in the possession or control of that data controller that relate to the programme.

(2) A request under *subhead (1)* shall be made in writing and dated and, where the Minister has prescribed the format in which the information is to be provided, shall indicate that format.

(3) Notwithstanding-

(a) the Act of 1988,

(b) a rule of law which would require obtaining the consent of a person for the disclosure of personal data, or

(c) a rule of law relating to the non-disclosure or confidentiality of personal data,

a data controller who receives a request under *subhead (1)* shall comply as soon as reasonably practicable but not later than the end of any prescribed period.

(4) A data controller who discloses personal data or personal health data, as part of a data set, under this Head to a person carrying out a prescribed data matching programme shall not be regarded as having disclosed that personal data or personal health data unfairly in contravention of section 2(1)(c)(ii) of the Act of 1988.

(5) Where, on application to the High Court by a person carrying out a prescribed data matching programme, and the Court is satisfied that a data controller to whom a request has been made under *subhead (1)* has failed to comply with the request, it may by order direct the data controller concerned to comply.

(6) In considering an application under *subhead (5)*, the High Court shall have regard to the public interest, and in particular to–

(a) the purpose of the prescribed data matching programme concerned, as specified in regulations made under *Head 50*, and

(b) the probable effect on the effectiveness of that programme if the data set or data sets concerned are not provided,

and it shall make the order unless it is satisfied that there is good and sufficient reason not to so do.

(7) An application under *subhead (6)* shall be by motion, and the High Court when considering the matter may make such interim or interlocutory order as it considers appropriate.

(8) A person commits an offence if a person requests that a data controller provide a data set to the person, if–

(a) the person falsely represents himself or herself as a person carrying out a prescribed data matching programme, or

(b) the person is a person carrying out a prescribed data matching programme but the request is not made only for the purpose of carrying out of the prescribed data matching programme concerned.

(9) A person who knowingly or recklessly contravenes *subhead (9)* is guilty of an offence and is liable–

(a) on summary conviction, to a Class A fine, or

(b) on conviction on indictment, to a fine not exceeding €200,000.

Explanatory Note
This provision creates the requirement to provide information to a prescribed data matching programme so that it can be carried out effectively. Subhead (1) allows a person carrying out

a prescribed data matching programme to request information from data controllers. The request can be made only for the purposes of a prescribed data matching programme.

Under subhead (2), a request for information made under subhead (1) must be made in writing and dated and, where the Minister has prescribed the format in which the information is to be provided, will indicate that format.

Subhead (3) provides the legal exemptions necessary to facilitate a data controller in complying with a request. Subhead (3) also provides that a data controller who receives a request under subhead (1) must comply with a request as soon as reasonably practicable but not later than the end of any prescribed period.

Subhead (4) ensures that a data controller who discloses personal data or personal health data, as part of a data set, under this Head to a person carrying out a prescribed data matching programme shall not be regarded as having disclosed that personal data unfairly in contravention of section 2(1)(c)(ii) of the Data Protection Acts. That provision provides that personal data obtained by a data controller should not be further processed (which includes disclosure) in a manner incompatible with the purpose(s) for which the personal data was initially obtained.

While no criminal sanctions are being provided for non-compliance with a request to provide information under subhead (1), subheads (5), (6) and (7) do provide for the person carrying out a prescribed data matching programme to seek injunctive relief in the High Court where a data controller has not provided the information sought.

Subhead (8) is important and provides that a person commits an offence if he or she falsely represents himself or herself as a person carrying out a prescribed data matching programme, or is a person carrying out a prescribed data matching programme but the request is not made only for the purpose of carrying out the prescribed data matching programme.

Subhead (9) provides for penalties.

Use of data sets provided under *Head 45*
46. Provide that:
(1) No data set, part of a data set, or data contained in a data set that is provided, under *Head 45*, to a person carrying out a prescribed data matching programme shall be used by that person for any purpose other than the purpose of the programme as specified in regulations made under *Head 50*.

(2) A person carrying out a prescribed data matching programme who obtains personal data or personal health data, as part of a data set, provided under *Head 45* shall not be regarded as having obtained that personal data or personal health data unfairly in contravention of section 2(1)(a) of the Act of 1988.

(3) A person who knowingly or recklessly contravenes *subhead (1)* is guilty of an offence and is liable–

(a) on summary conviction, to a Class A fine, or

(b) on conviction on indictment, to a fine not exceeding €200,000.

Explanatory Note
This Head is about using the data sets provided under Head 45. It complements the provision on offences under Head 45(9).

Subhead (1) provides that no data set, part of a data set, or data contained in a data set that is provided under Head 45 to a person carrying out a prescribed data matching programme can be used for any purpose other than the purpose of the programme. This is in recognition of the fact that the powers to require data sets under this Part of the Bill – and the related use of those data sets - need to be strictly controlled. In that regard, Head 50 and the regulations to be made thereunder are particularly important. Public confidence in the arrangements governing prescribed data matching programmes will be enhanced where there is certainty that information provided under Head 45 cannot be used for any other purpose other than the one specified in the Head 50 regulation that prescribes the data matching programme concerned. Head 47 which deals with disclosure of data sets provided under Head 45 is similarly motivated.

Subhead (2) addresses the requirement in the Data Protection Acts to obtain personal data fairly. It provides that a person carrying out a prescribed data matching programme who obtains personal data or personal health data, as part of a data set, provided under Head 45 shall not be regarded as having obtained that personal data unfairly in contravention of section 2(1)(a) of the Acts.

Subhead (3) creates a criminal offence and penalties where a person knowingly or recklessly contravenes subhead (1).

Disclosure of data sets provided under *Head 45*
47. Provide that:
(1) No data set, part of a data set, or data contained in a data set, that is provided under *Head 45* to a person carrying out a prescribed data matching programme shall be disclosed by that person except where it is personal data or personal health data and is disclosed only where it is-

(a) made to the data subject concerned,

(b) made at the request or with the consent of the data subject or to a person acting on his behalf,

(c) required urgently to prevent injury or other damage to the health of a person or serious loss of or damage to property,

(d) required by or under any enactment or by a rule of law or order of a court,

(e) required for the purposes of obtaining legal advice or for the purposes of, or in the course of, legal proceedings in which the person making the processing is a party or a witness.

(2) A person who knowingly or recklessly contravenes *subhead (1)* is guilty of an offence and is liable–

(a) on summary conviction, to a Class A fine, or

(b) on conviction on indictment, to a fine not exceeding €200,000.

Explanatory Note
This Head prohibits persons carrying out prescribed data matching programmes from disclosing information received under Head 45. There is an exception where the disclosure is personal data or personal health data and the circumstances are that the disclosure is-

(a) made to the data subject concerned,

(b) made at the request or with the consent of the data subject or to a person acting on his behalf,

(c) required urgently to prevent injury or other damage to the health of a person or serious loss of or damage to property,

(d) required by or under any enactment or by a rule of law or order of a court,

(e) required for the purposes of obtaining legal advice or for the purposes of, or in the course of, legal proceedings in which the person making the processing is a party or a witness.

Subhead (2) creates a criminal offence and penalties where a person knowingly or recklessly contravenes subhead (1).

Use of data already held by the person carrying out the prescribed data matching programme
48. Provide that:
A person carrying out a prescribed data matching programme may, for the purposes of carrying out that programme, use personal data and personal health data that are included in one or more than one data set that the person already holds.

Explanatory Note
This Head covers the situation where the person carrying out the prescribed data matching programme may need to use some personal data/personal health data that he or she has already collected for another purpose (for example, individual patient care) for the separate subsequent purpose of the prescribed programme (notwithstanding any restrictions in the Data Protection Acts).

Publication of results from data matching programme
49. Provide that:
(1) Subject to *subhead (2)*, a person carrying out a prescribed data matching programme may publish results only in accordance with regulations made under *Head 50* except to the extent that those results reveal-

(a) personal data, or

(b) personal health data.

(2) *Subhead (1)* does not apply if the publication is a disclosure of personal data or personal health data-

(a) made to the data subject concerned,

(b) made at the request or with the consent of the data subject or to a person acting on his behalf,

(c) required urgently to prevent injury or other damage to the health of a person or serious loss of or damage to property,

(d) required by or under any enactment or by a rule of law or order of a court,

(e) required for the purposes of obtaining legal advice or for the purposes of, or in the course of, legal proceedings in which the person making the processing is a party or a witness.

(3) A person who knowingly or recklessly contravenes *subhead (1)* is guilty of an offence and is liable-

(a) on summary conviction, to a class A fine, or

(b) on conviction on indictment, to a fine not exceeding €200,000.

Explanatory Note

The purpose of a prescribed data matching programme is to generate information in the form of results for a particular purpose that is considered important enough to justify prescribing the programme. There may be good reasons to publish the results of the programme and subhead (1) allows the publication of results only in accordance with regulations made under Head 50. This will ensure that the nature of the publication to be permitted, in any case, will be determined by reference to the particular data matching programme concerned.

It is not considered appropriate that information generated from a prescribed data matching programme should be published in a way that identifies individual data subjects unless, as per subhead (2), that publication is a disclosure of personal data or personal health data-

(a) made to the data subject concerned,

(b) made at the request or with the consent of the data subject or to a person acting on his behalf,

(c) required urgently to prevent injury or other damage to the health of a person or serious loss of or damage to property,

(d) required by or under any enactment or by a rule of law or order of a court,

(e) required for the purposes of obtaining legal advice or for the purposes of, or in the course of, legal proceedings in which the person making the processing is a party or a witness.

Subhead (3) provides for criminal sanctions where a person knowingly or recklessly contravenes subhead (1).

Prescribed data matching programmes
50. Provide that:
(1)(a) The Minister may, after consultation with-

(i) the Commissioner on matters regarding the protection of personal data, and

(ii) the Authority on matters relating to the likelihood of a person complying with standards,

make regulations prescribing a data matching programme to be carried out on a national basis.

(b) Where the Minister makes or amends any regulations under *paragraph (a),* he or she shall notify the Authority and the Commissioner of the making or amending.

(2) The Minister may prescribe a data matching programme under this Head only if he or she is satisfied that–

(a) the purpose of the programme relates to a matter of significant health importance, including-

(i) the improvement of patient safety,

(ii) the screening for, or prevention of, a particular disease, illness, disability or other health condition,

(iii) the identification or prevention of a threat to public health,

(iv) the monitoring or control of a particular disease, illness, disability or other health condition or a threat to public health,

(v) the care or treatment of persons with a particular disease, illness, disability or other health condition, or

(vi) the effective management of resources as they relate to the delivery of health and personal social services,

(b) the benefit that is likely to accrue to persons in the State from the data matching concerned justifies the prescription of the data matching programme concerned,

(c) to obtain the consent of each individual concerned to the inclusion of his or her personal data or personal health data would-

(i) be impracticable,

(ii) involve unreasonable expense, or

(iii) be likely to have a significant adverse effect on the quality of the data matching programme concerned,

(d) the amount and type of personal data or personal health data that would be kept in the data matching programme concerned would not be excessive or unjustified, having regard to the objective of that programme,

(e) the person who will carry out the data matching programme will not directly or indirectly benefit from the operation of the programme, and

(f) the person who will carry out the data matching programme has appropriate security and other arrangements in place to protect the personal data and personal health data concerned.

(3) Regulations made under this Head shall provide for the manner in which the data matching under the prescribed data matching programme is to be carried out, having regard to the purpose of the data matching programme and the need for processing data sets in a way that protects the privacy of individuals and the confidentiality of their personal data and personal health data.

(4) Regulations made under this Head-

(a) shall specify the purpose of the data matching programme,

(b) shall specify the name of the person carrying out the data matching programme and the name, title, business address and email address of the employee or agent of that person who is to be contacted for further information in relation to the programme concerned,

(c) shall ensure that the person carrying out the data matching programme will not directly or indirectly benefit from the operation of the programme,

(d) may make different provisions in respect of different data matching programmes or classes of data matching programmes, in relation to-

(i) the purpose of the data matching programme or classes of data matching programmes,

(ii) the types of personal data and personal health data to be kept for the carrying out of data matching programmes,

(iii) the duration of the data matching programmes,

(iv) the duration for which the data obtained for the purposes of the data matching data programme may be kept,

(v) the categories of data controllers who shall provide data sets in respect of data matching programmes,

(vi) the prescribed format for the purposes of *Head 45(2)* and the period for the purposes of *Head 45(3)*,

(vii) conditions to be complied with by the person carrying out the data matching programme in relation to-

(A) the publicising of the programme,

(B) the publication of results from the programme under *Head 49*,

(C) the retention, archiving or destruction of any data sets provided under *Head 45*, and

(D) the protection of the confidentiality of data sets in data matching programmes and the safeguarding of the privacy of individuals whose personal data or personal health data is included in those data sets,

(e) may provide that any identifier assigned under the Health Identifiers Act 2014 be used in relation to a data matching programme, including by a data controller who provides one or more than one data set under *Head 45*, if the Minister, having obtained the agreement of any other Minister as appropriate, is satisfied that to do so is necessary for the effective operation of data matching programmes, and

(f) may include such incidental and supplementary provisions as the Minister considers expedient from time to time.

(5) The Minister shall publish, on an Internet website that he or she maintains, a notice in relation to every data matching programme prescribed under this Head, containing the following particulars-

(a) the purpose of the data matching programme concerned,

(b) the name of the person carrying out the data matching programme concerned, and the name, title, business address and email address of the employee or agent of that person who may be contacted for further information in relation to the programme concerned,

(c) a description of the types of data to be kept for the carrying out of the data matching under the data matching programme concerned,

(d) the duration of the data matching programme concerned,

(e) the duration for which the data obtained for the purposes of the data matching data programme may be kept,

(f) the categories of data controllers who shall provide data sets in respect of the data matching programme concerned,

(g) the format prescribed for the purposes of *Head 45(2)* and the period prescribed for the purposes of *Head 45(3)*,

(h) conditions to be complied with by the person carrying out the data matching programme in relation to-

(i) the publicising of the programme,
(ii) the publication of results from the programme under *Head 49*,
(iii) the retention, archiving or destruction of any data sets provided under *Head 45*, and
(iv) the protection of the confidentiality of data sets in data matching programmes and the safeguarding of the privacy of individuals whose personal data or personal health data is included in those data sets.

(6) A person carrying out a prescribed data matching programme shall ensure that any change in any of the information referred to in s*ubhead (5)(b)* relating to the person who may be contacted for further information is notified to the Minister as soon as may be but not later than the end of any prescribed period.

Explanatory Note
This Head sets out the principles and rules that will apply to the prescribing of a data matching programme by the Minister.

A significant consultative role is given to the Data Protection Commissioner and HIQA when the Minister proposes to prescribe a data matching programme. In that regard, subhead (1) provides that the Minister must consult the Commissioner and the Authority on any regulations, including consulting on each intended prescribed data matching programme.

It will be noted that, under subhead (2), the Minister needs to be satisfied on a number of matters before prescribing: namely, that the purpose of the programme relates to a matter of significant health importance; that it has significant justifiable benefit; that obtaining

individual consent would be impracticable, involve unreasonable expense or be likely to significantly adversely affect the quality of the programme; that the amount of information proposed to be held is not excessive or unjustified; and that the person carrying out a prescribed data matching programme has adequate security and other arrangements in place to protect the data.

Subhead (3) requires that regulations made under this Head which will provide for the manner in which the data matching under the prescribed programme concerned is to be carried out must have regard to the need for processing data sets in a way that protects the privacy of individuals and the confidentiality of their personal data and personal health data.

Subhead (4) sets out what must be addressed in the regulations including the conditions to be complied with by the person carrying out the data matching programme in relation to-

(a) the publicising of the programme which is important for transparency and public awareness,

(b) the publication of results from the programme under Head 49, which can help the public see the values and benefits of these programmes.

(c) the retention, archiving or destruction of any data sets provided under Head 45 which will ensure that data sets are not kept for longer than is necessary before being archived securely or destroyed in a specified manner, and

(d) the protection of the confidentiality of data sets in data matching programmes and the safeguarding of the privacy of individuals whose personal data or personal health data is included in those data sets. Like the matters referred to in (i), (ii) and (iii), this is important in helping to ensure that there can be public confidence in prescribed data matching programmes.

Subhead (5) is about transparency. It provides that the Minister must publish, on an Internet website that he or she maintains, a notice in relation to every data matching programme prescribed under this Head containing specified particulars about the programme. Subhead (6) places an obligation on the person carrying out the programme to update the Minister on contact details for employees or agents carrying out the prescribed programme.

Revocation or amendment of regulations
51. Provide that:
(1) The Minister may amend or revoke regulations prescribing one or more than one data matching programme made under *Head 50* where-

(a) the purpose of the programme has been achieved,

(b) the Authority advises the Minister under *Head 53* of its opinion that the person carrying out a prescribed data matching programme has-

(i) failed to co-operate with the monitoring of the standards,

(ii) failed to comply with the standards, or

(iii) contravened a provision of this Part, regulations made under *Head 50* or a provision of the Act of 1988, or

(c) the Commissioner informs the Minister of the findings of an investigation under *Head 54* or otherwise where the findings indicate that the person carrying out a prescribed data matching programme has-

(i) failed to comply with the standards, or

(ii) contravened a provision of this Part, regulations made under *Head 50* or a provision of the Act of 1988.

(2) Before proceeding to amend or revoke regulations in relation to a prescribed data matching programme the Minister shall send a notice to the person carrying out the prescribed data matching programme, the Authority and the Commissioner that sets out–

(a) the Minister's intention to amend or revoke the regulations, and, in the case of a proposed amendment, the changes that would be made to the regulations concerned,

(b) the reasons for the proposed amendment or revocation, and

(c) a statement that the person carrying out the prescribed data matching programme may make written representations to the Minister, not later than 28 days after the date on which it is sent, as to why or how the regulations should or should not be amended or revoked.

(3) Where the Minister is of the opinion that it is necessary as a matter of urgency for reasons of public importance or public concern to do so, the Minister may order the person carrying out a prescribed data matching programme not to-

(a) make any requests under *Head 45*,

(b) use or further use any data sets already provided under *Head 45*,

(c) use or further use, under *Head 48*, any personal data already held,

unless a notice under *subhead (6)(c)* is sent to that person and, if the Minister makes such an order, he or she shall include a reference to that order in the notice under *subhead (2)*.

(4) Where a notice has been sent under *subhead (2)*, the Minister shall not amend or revoke the regulations concerned until the later of-

(a) the day on which the person carrying out the prescribed data matching programme has-

(i) made written representations to the Minister concerning the proposal, or

(ii) notified the Minister in writing that he or she does not intend to make representations,

and

(b) the day on which the 28 days referred to in *subhead (2)(c)* have expired.

(5) Where the Minister receives written representations under *subhead (4)(a)(i),* he or she shall consider those written representations before deciding whether or not to amend or revoke the regulations concerned.

(6) The Minister shall, as soon as may be after he or she decides whether or not to amend or revoke the regulations concerned, send a notice to the person carrying out the prescribed data matching programme, the Authority and the Commissioner of that decision, and–

(a) if the decision is to revoke the regulations concerned, of the date on which the revocation will take effect,

(b) if the decision is to amend the regulations concerned, of the tenor of the amendments and the date on which they will take effect, or

(c) if the decision is to neither revoke nor amend the regulations concerned but the Minister has ordered, in accordance with *subhead (3),* the person carrying out the prescribed data matching programme not to make requests under *Head 45,* of the termination of the effect of that order as of the date on which the notice under this subhead is sent.

Explanatory Note

This Head empowers the Minister to amend or revoke the regulations prescribing a data matching programme made under Head 50 where the Minister is of the opinion that-

(a) the purpose of the programme has been achieved,

(b) HIQA advises the Minister under Head 53 of its opinion that the person carrying out a prescribed data matching programme has-

(i) failed to co-operate with the monitoring of the standards,

(ii) failed to comply with the standards, or

(iii) contravened a provision of this Part, regulations made under Head 50 or a provision of the Act of 1988.

(c) the Data Protection Commissioner informs the Minister of the findings of an investigation under Head 54 or otherwise where the findings indicate that the person carrying out a prescribed data matching programme has-

(i) failed to comply with the standards, or

(ii) contravened a provision of this Part, regulations made under Head 50 or a provision of the Data Protection Acts.

Subhead (2) is concerned with fairness and giving the person carrying out a prescribed data matching programme the opportunity to make representations as to why or how the regulations should or should not be amended or revoked. In that regard, it requires the Minister to notify the person setting out his intentions and the reasons involved. The person carrying out the programme has 28 days to make representations.

Subhead (3) addresses urgent situations. It provides that where the Minister is of the view that it is necessary as a matter of urgency, for reasons of public importance or public concern, he or she may order the person carrying out a prescribed data matching programme not to (a) make any requests under Head 45, (b) use or further use any data sets already provided under Head 45 or (c) use or further use, as per Head 48, any personal data already held, until a decision is made and communicated under subhead (6) not to revoke or amend the regulation.

Subheads (4) and (5) prevent the Minister from amending or revoking the regulations until the 28 day time limit for making representations has expired.

Subhead (6) provides that the Minister will, as soon as may be after he or she decides whether or not to amend or revoke the regulations concerned, notify the person carrying out a prescribed data matching programme. Under the subhead, the Minister will also notify HIQA and the Commissioner of the decision.

Standards for prescribed data matching programmes
52. Provide that:
(1) The Authority may, at the request of the Minister, set such standards for the processing of data in data sets, as it considers appropriate for the carrying out of prescribed data matching programmes.

(2) Without prejudice to the generality of *subhead (1*), standards may address matters relating to the privacy of data subjects, confidentiality, quality assurance, security, storage and destruction of such data.

(3) Before setting standards under this Head, the Authority may consult with any person, or invite representations from any person, as it considers appropriate.

(4) After considering any representations made under *subhead (3)* in relation to any standards proposed by the Authority and after making any changes the Authority thinks fit, it shall submit the proposed standards to the Minister for approval.

(5) Before approving any standards submitted to him under *subhead (4)*, the Minister shall consult with the Data Protection Commissioner on any such standards.

(6) Where a standard under this Head is approved by the Minister, the Authority shall publish the standard on its website and in accordance with such other arrangements as may be specified by the Minister.

Explanatory Note

It is proposed that HIQA will set standards in relation to the prescribed data matching programmes and health information resources. This will ensure that prescribed programmes and resources are carried out or maintained, as appropriate, to high quality levels.

Head 52 is about setting those standards for prescribed programmes. This power will be separate to and distinct from the standard setting power in section 8 of the Health Act 2007.

The provision provides, in subhead (1), that HIQA may, at the request of the Minister, set such standards, as it considers appropriate, for the carrying out prescribed data matching programmes.

Subhead (2) sets out some of the matters that may be addressed in the standards: for example, matters relating to the privacy of data subjects, confidentiality, quality assurance, security, storage and destruction of such data.

Subhead (3) provides that HIQA, before setting standards under this Head, may consult with any person, or receive representations from any person, as it considers appropriate.

As per subhead (4), HIQA after considering any representations made under subhead (3) in relation to any standards proposed by it and after making any changes it thinks fit, it shall submit the proposed standards to the Minister for approval.

Subhead (5) requires the Minister to consult with the Data Protection Commissioner on any standards submitted under subhead (4) as data matching programme data sets contain personal data and personal health data.

Subhead (6) provides that where a standard under this Head is approved by the Minister, the Authority shall publish the standard on its website and in accordance with such other arrangements as may be specified by the Minister.

Compliance with standards
53. Provide that:
(1) Where standards are set in relation to the carrying out of a prescribed data matching programme under *Head 52* a relevant person shall comply with the standards and shall co-operate with the Authority in its monitoring of compliance with those standards.

(2) If in the opinion of the Authority, there is a failure by a relevant person to co-operate with the monitoring of the standards referred to in *subhead (1)*, the Authority shall so advise the Minister and the Commissioner.

(3) If in the opinion of the Authority, there is a failure to comply by a relevant person with the standards referred to in *subhead (1)*, the Authority shall seek to engage with the person concerned to bring about compliance with the standards but if such engagement proves not possible or unsuccessful it shall so advise the Minister and the Commissioner.

(4) If the Authority becomes aware of a contravention by a relevant person of a provision of this Part, regulations made under *Head 50* or a provision of the Act of 1988, the Authority shall so advise the Minister and the Commissioner.

(5) In this Head "relevant person" means a person carrying out a prescribed data matching programme.

Explanatory Note
Persons carrying out prescribed data matching programmes will, as per subhead (1), have to comply with the standards set by HIQA.

Under subhead (2), HIQA will advise the Minister and the Data Protection Commissioner where there is a failure by the relevant person (that is the person carrying out a prescribed data matching programme) to co-operate with HIQA in its monitoring of standards.

Under subhead (3), HIQA can, if it becomes aware of a failure to comply with the standards, seek to engage with the relevant person concerned to bring about compliance with the standards but if such engagement proves not possible or unsuccessful it will advise the Minister and the Commissioner of the failure to comply.

As per subhead (4), HIQA will if it becomes aware of a contravention by the relevant person of a provision of Part 4, regulations made under Head 50 or a provision of the Data Protection Acts advise the Minister and the Commissioner of that failure.

Subhead (5) explains the use of the term "relevant person" in the Head to mean a person carrying out a prescribed data matching programme.

This Head and the one immediately below (Investigation by the Data Protection Commissioner) are designed to give important but not overlapping roles to both bodies. Head 54 reflects the role of the Commissioner as national supervisory body for the purposes of the EU Data Protection Directive.

Investigation by Commissioner
54. Provide that:
(1) Without prejudice to any other powers conferred on the Commissioner under any other Act, he or she may carry out or cause to be carried out such investigations as he or she considers appropriate in relation to the carrying out of a prescribed data matching programme-

(a) if the Minister so requests,

(b) if a complaint is made to him or her, or

(c) if he or she considers it appropriate to do so, either on foot of being advised of a failure under *Heads 53(2), (3) or (4)* or otherwise.

(2) The Commissioner shall inform the Minister of the findings of an investigation under *subhead (1)* –

(a) if the investigation was carried out on the request of the Minister,

(b) if the findings show a failure by the person carrying out a prescribed data matching programme to comply with-

(i) the standards,

(ii) a provision of this Part,

(iii) regulations made under *Head 50,* or

(iv) a provision of the Act of 1988,

or

(c) in any other case, if he or she considers it appropriate to do so.

Explanatory Note
This provision gives the Data Protection Commissioner an express investigatory role in relation to prescribed data matching programmes. This power is in addition to any other powers conferred on the Commissioner under any other Act: for example under section 10 (enforcement of data protection) and section 12 (power to require information) of the Data Protection Acts

Under subhead (1), the Minister can request the Commissioner to investigate a prescribed programme. However, the power to investigate under this Head is not limited to requests from the Minister. The Commissioner can investigate on his or her own initiative, if a complaint is made to him or her or as a result of being advised by HIQA of its opinion under Head 53 or otherwise.

Subhead (2) is about keeping the Minister informed of investigations into prescribed data matching programmes. This is important given that the findings of the Commissioner may lead the Minister to withdraw the prescribed status of the data matching programme.

Co-operation between the Authority and the Commissioner
55. Provide that:
The Commissioner and the Authority shall co-operate with each other and provide assistance to each other in the performance of their functions under this Part.

Explanatory Note
This Part of the Bill seeks to utilise the expertise of both HIQA and the Data Protection Commissioner in ensuring that prescribed data matching programmes are carried out in line with legal requirements and standards set. Head 55 is modelled on the provision in section 1(5)(b) of the Data Protection Acts which provides that the Data Protection Commissioner and the Information Commissioner shall, in the performance of their functions, co-operate with and provide assistance to each other.

PART 5: HEALTH INFORMATION RESOURCES

Interpretation – Part 5
56. Provide that:
In this Part–

"health information resource" means a register, index, database or other collection of records that contains data about more than one individual;

"prescribed health information resource" means a health information resource to be maintained at national level by a person other than the Minister, prescribed under *Head 62*;

"results" means any information or data produced from an analysis of the information and data in a prescribed health information resource;

"standards" mean standards set under *Head 64*.

Explanatory Note
In a practical sense, a *register* can be regarded as a repository of information dealing with a particular issue. *Registers* are not, however, always called registers. The terms *index* (for example, the National Drug-Related Deaths Index operated by the Health Research Board) or *database* are also used. In British Columbia, the E-Health (Personal Health Information Access and Protection of Privacy) Act 2008 provides that the Minister for Health may by order establish or designate a *database* containing personal health information as a *Health Information Bank*. More important than the term is the purpose for which the information is collected and the organisation of the information to allow it to be used effectively for that purpose.

The Data Protection Acts do not refer to *registers*. In that regard, a data controller that establishes a *register* containing personal data may be viewed as simply organising the collection, keeping, using and disclosing of such data for a particular purpose or purposes in line with the provisions of the Data Protection Acts. The data controller is therefore the *registry*.

It is not intended, therefore, in this Bill to define registers, databases, indexes or to introduce specific requirements in relation to them. Instead, the term health information resource is used in this Part. Further, the intention is only to establish a framework that will, like Part 4 (Data Matching Programmes), allow the Minister for health to prescribe, in specified circumstances, certain health information resources kept by particular data controllers. A person maintaining such a prescribed health information resource will be able to require a data controller to provide information for the purpose of the effective operation of the prescribed health information resource so that there will be the necessary high coverage for these important information resources.

"data set" as used in Parts 4 and 5 is defined in Head 2.

Results from prescribed health information resources, may sometimes be published so as to better inform decision-making or public awareness on particular issues. Results are defined to mean any information or data produced from an analysis of the information and data in a

prescribed health information resource. This is separate from the core information in the resource. Head 61 deals with the publication of results from prescribed health information resources.

Requirement to provide data
57. Provide that:
(1) A person maintaining a prescribed health information resource may request a data controller to provide to him or her, one or more than one data set in the possession of that data controller that relate to the resource.

(2) A request under *subhead (1)* shall be made in writing and dated, and, where the Minister has prescribed the format in which the information is to be provided, shall indicate that format.

(3) Notwithstanding-

(a) the Act of 1988,

(b) a rule of law which would require obtaining the consent of a person for the disclosure of personal data, or

(c) a rule of law relating to the non-disclosure or confidentiality of personal data,

a data controller who receives a request under *subhead (1)* shall comply as soon as reasonably practicable but not later than the end of any prescribed period.

(4) A data controller who discloses personal data or personal health data, as part of a data set, under this Head to a person maintaining a prescribed health information resource shall not be regarded as having disclosed that personal data or personal health data unfairly in contravention of section 2(1)(c)(ii) of the Act of 1988.

(5) Where, on application to the High Court by a person maintaining a prescribed health information resource and the Court is satisfied that a data controller to whom the request has been made under *subhead (1)* has failed to comply with the request, it may by order direct the data controller concerned to comply.

(6) In considering an application under *subhead (6)*, the High Court shall have regard to the public interest, and in particular to–

(a) the purpose of the prescribed health information resource concerned, as specified in regulations made under *Head 62*, and

(b) the probable effect on the effectiveness of that resource if the data set or data sets concerned are not provided,

and it shall make the order unless it is satisfied that there is good and sufficient reason not to so do.

(7) An application under *subhead (6)* shall be by motion and the High Court when considering the matter may make such interim or interlocutory order as it considers appropriate.

(8) A person commits an offence if the person requests that a data controller provide a data set to the person if–

(a) the person falsely represents himself or herself as a person maintaining a prescribed health information resource, or

(b) the person is a person maintaining a prescribed health information resource, but the request is not made for the purpose of the operation of the prescribed health information resource.

(9) A person who knowingly or recklessly contravenes *subhead (9)* is guilty of an offence and is liable-

(a) on summary conviction, to a class A fine, or

(b) on conviction on indictment, to a fine not exceeding €200,000.

Explanatory Note

This is similar to Head 45. This provision creates the requirement to provide information to a prescribed health information resource so that it can operate effectively.

Under subhead (2), a request for information made under subhead (1) must be made in writing, dated and where the Minister has prescribed the format in which the information is to be provided, it will indicate that format.

Subhead (3) provides the legal exemptions necessary to facilitate a data controller in complying with a request. Subhead (3) also provides that a data controller who receives a request under subhead (1) must comply with a request as soon as reasonably practicable but not later than the end of any prescribed period.

Subhead (4) ensures that a data controller who discloses personal data or personal health data as part of a data set, under this Head for the purposes of the maintenance of a health information resource shall not be regarded as having disclosed that personal data unfairly in contravention of section 2(1)(c)(ii) of the Act of 1988.

While no criminal sanctions are being provided for non-compliance with a request to provide information under subhead (1), subheads (5), (6) and (7) do provide for the person maintaining the prescribed health information resource to seek injunctive relief in the High Court where a data controller has not provided the information sought.

Subhead (8) is important. It provides that a person commits an offence if he or she falsely represents himself or herself as a person maintaining a health information resource or is a person maintaining a prescribed health information resource but the request is not made for the purpose of the carrying out of the prescribed health information resource. Subhead (9) provides for penalties.

Use of data sets provided under *Head 57*
58. Provide that:
(1) No data set, part of a data set, or data contained in a data set, that is provided under *Head 57* to a person maintaining a prescribed health information resource shall be used by that person for any other purpose other than the purpose of the resource as specified in regulations made under *Head 62*.

(2) A person maintaining a prescribed health information resource who obtains personal data or personal health data, as part of a data set, provided under *Head 57* shall not be regarded as having obtained that personal data or personal health data unfairly in contravention of section 2(1)(a) of the Act of 1988.

(3) A person who knowingly or recklessly contravenes *subhead (1)* is guilty of an offence and is liable-

(a) on summary conviction, to a class A fine, or

(b) on conviction on indictment, to a fine not exceeding €200,000.

Explanatory Note
This is similar to Head 46. Subhead (1) provides that no data set, part of a data set or data contained in a data set that is provided under Head 57 to a person maintaining a health information resource can be used for any purpose other than the purpose of the health information resource. It complements the provision on offences under Head 57 (9).

Subhead (2) addresses the requirement in the Data Protection Acts to obtain personal data fairly. It provides that a person maintaining a prescribed health information resource who obtains personal data or personal health data as part of a data set provided under Head 57 shall not be regarded as having obtained that personal data unfairly in contravention of section 2(1)(a) of the Acts. Subhead (3) creates a criminal offence and penalties where a person knowingly or recklessly contravenes subhead (1).

Disclosure of data sets provided under *Head 57*
59. Provide that:
(1) No data set, part of a data set, or data contained in a data set, that is provided, under Head 57, to a person maintaining a prescribed health information resource shall be disclosed by that person except where it is personal data or personal health data and is disclosed only where it is-

(a) made to the data subject concerned,

(b) made at the request or with the consent of the data subject or to a person acting on his behalf,

(c) required urgently to prevent injury or other damage to the health of a person or serious loss of or damage to property,

(d) required by or under any enactment or by a rule of law or order of a court,

(e) required for the purposes of obtaining legal advice or for the purposes of, or in the course of, legal proceedings in which the person making the processing is a party or a witness.

(2) A person who knowingly or recklessly contravenes *subhead (1)* is guilty of an offence and is liable–

(a) on summary conviction, to a Class A fine, or

(b) on conviction on indictment, to a fine not exceeding €200,000.

Explanatory Note
This is similar to Head 47. This Head prohibits the persons maintaining a prescribed health information resource from disclosing information received under Head 57. However, under subhead (1), there is an exception. There is where the disclosure is personal data or personal health data and the circumstances are that the disclosure is-

(a) made to the data subject concerned,

(b) made at the request or with the consent of the data subject or to a person acting on his behalf,

(c) required urgently to prevent injury or other damage to the health of a person or serious loss of or damage to property,

(d) required by or under any enactment or by a rule of law or order of a court,

(e) required for the purposes of obtaining legal advice or for the purposes of, or in the course of, legal proceedings in which the person making the processing is a party or a witness.

Subhead (2) creates a criminal offence and penalties where a person knowingly or recklessly contravenes subhead (1).

Use of data already held by the person maintaining a prescribed health information resource
60. Provide that:
A person maintaining a prescribed health information resource may, for the purposes of maintaining that resource, use personal data and personal health data that are included in one or more than one data set that the person already holds.

Explanatory Note
This is similar to Head 48. This Head covers the situation where the person maintaining the health information resource may need to use some personal data/personal health data that he or she has already collected for another purpose (for example, individual patient care) for the separate subsequent purpose of the maintenance of the resource.

Publication of information held in a prescribed health information resource
61. Provide that:
(1) Subject to *subhead (2)*, a person maintaining a prescribed health information resource may publish any information or data included in a prescribed health information resource only in accordance with regulations made under *Head 62*, except to the extent that those results reveal-

(a) personal data, or

(b) personal health data.

(2) *Subhead (1)* does not apply if the publication is a disclosure of personal data or personal health data-

(a) made to the data subject concerned,

(b) made at the request or with the consent of the data subject or to a person acting on his behalf,

(c) required urgently to prevent injury or other damage to the health of a person or serious loss of or damage to property,

(d) required by or under any enactment or by a rule of law or order of a court,

(e) required for the purposes of obtaining legal advice or for the purposes of, or in the course of, legal proceedings in which the person making the processing is a party or a witness.

(3) A person who knowingly or recklessly contravenes *subhead (1)* is guilty of an offence and is liable-

(a) on summary conviction, to a class A fine, or

(b) on conviction on indictment, to a fine not exceeding €200,000.

Explanatory Note
This is similar to Head 49. The purpose of a prescribed Health Information Resource is to generate information for a purpose set out in Head 62. For example**,** currently the National Cancer Registry (www.ncri.ie/publications) publishes a series of papers including ones dealing with cancer trends & projections, statistical reports, cancer atlases, research reports and infographics. This Head, therefore, provides for publication in relation to prescribed Resources. Information generated from a prescribed Health Information Resource cannot be published in a way that identifies individual data subjects unless such publication is to the data subject concerned, made at the request or with the consent of the data subject or to a person acting on his behalf, required urgently to prevent injury or other damage to the health of a person or serious loss of or damage to property, required by or under any enactment or by a rule of law or order of a court, or required for the purposes of obtaining legal advice or for the purposes of, or in the course of, legal proceedings in which the person making the processing is a party or a witness.

Subhead (3) provides for criminal sanctions where a person knowingly or recklessly contravenes subhead (1).

Prescribed health information resources
62. Provide that:
(1)(a) The Minister may, after consultation with-

(i) the Commissioner on matters regarding the protection of personal data, and

(ii) the Authority on matters relating to the likelihood of a data controller complying with standards,

make regulations prescribing a health information resource maintained at a national level.

(b) Where the Minister makes or amends any regulations under *paragraph (a)*, he or she shall notify the Authority and the Commissioner of the making or amending.

(2) The Minister may prescribe a health information resource under this Head only if he or she is satisfied that–

(a) the purpose of the health information resource relates to a matter of significant health importance, including-

(i) the improvement of patient safety,

(ii) the screening for, or prevention of, a particular disease, illness, disability or other health condition,

(iii) the identification or prevention of a threat to public health,

(iv) the monitoring or control of a particular disease, illness, disability or other health condition or a threat to public health,

(v) the care or treatment of persons with a particular disease, illness, disability or other health condition,

(vi) the effective management of resources as they relate to the delivery of health and personal social services, or

(vii) an international health data agreement to which the State is a party,

(b) the benefit that is likely to accrue to persons in the State from the maintenance of the health information resource concerned justifies the prescription of the health information resource concerned,

(c) to obtain the consent of each individual concerned to the inclusion of his or her personal data or personal health data in the health information resource would-

(i) be impracticable,

(ii) involve unreasonable expense, or

(iii) be likely to have a significant adverse effect on the quality of the health information resource concerned,

(d) the amount and type of personal data or personal health data that would be kept in the health information resource concerned would not be excessive or unjustified, having regard to the objective of that resource,

(e) the person maintaining the health information resource will not directly or indirectly benefit financially from the operation of the resource, and

(f) the person who will maintain the health information resource concerned has appropriate security and other arrangements in place to protect the personal data and personal health data concerned.

(3) Regulations made under this Head shall provide for the manner in which the prescribed health information resource is to be maintained, having regard to the purpose of the health information resource concerned and the need for processing data sets in a way that protects the privacy of individuals and the confidentiality of their personal data and personal health data.

(4) Regulations made under this Head–

(a) shall specify the purpose of the prescribed health information resource,

(b) shall specify the name of the person maintaining a prescribed health information resource and the name, title, business address and email address of the employee or agent of the person who is to be contacted for further information in relation to the health information resource concerned,

(c) shall ensure that the person maintaining the health information resource will not directly or indirectly benefit financially from the operation of the resource,

(d) may make different provisions in respect of different prescribed health information resources or classes of prescribed health information resources, in relation to-

(i) the purpose of the health information resources or classes of health information resources,

(ii) the types of personal data and personal health data to be kept in the health information resource concerned,

(iii) the duration of the health information resource concerned,

(iv) the duration for which the data obtained for the purposes of the health information resource may be kept,

(v) the categories of data controllers who shall provide data sets in respect of health information resources,

(vi) the prescribed format for the purposes of *Head 57(2)* and the period prescribed for the purposes of *Head 57(3)*,

(vii) conditions to be complied with by the person maintaining the health information resource in relation to-

(A) the publicising of the resource,
(B) the publication of information from the resource under *Head 61*,
(C) the retention, archiving or destruction of any data sets provided under *Head 57*, and
(D) the protection of the confidentiality of data sets kept in health information resources and the safeguarding of the privacy of individuals whose personal data or personal health data are included in those resources,

(e) may provide that any identifier assigned under the Health Identifiers Act 2014 be used in relation to a prescribed health information resource, including by a data controller who provides one or more than one data set under *Head 57,* if the Minister, having obtained the agreement of any other Minister as appropriate, is satisfied that to do so is necessary for the effective maintenance of the health information resource, and

(f) may include such incidental and supplementary provisions as the Minister considers expedient from time to time.

(5) The Minister shall publish, on an Internet website that he or she maintains, a notice in relation to every health information resource prescribed under this Head, containing the following particulars-

(a) the purpose of the health information resource,

(b) the name of the person maintaining the health information resource and the name, title, business address and email address of the employee or agent of the person who may be contacted for further information in relation to the resource.

(c) a description of the type of personal data and personal health data included in the data sets kept in the health information resource,

(d) the duration of the health information resource concerned,

(e) the duration for which the data obtained for the purposes of the health information resource may be kept,

(f) the categories of data controllers who shall provide data sets in respect of the health information resource,

(g) the prescribed format for the purposes of *Head 57(2)* and the period prescribed for the purposes of *Head 57(3)*,

(h) conditions to be complied with by the person maintaining the health information resource in relation to-
(i) the publicising of the resource,
(ii) the publication of information from the health information resource under *Head 61*,
(iii) the retention, archiving or destruction of any data sets provided under *Head 57* and,
(iv) the protection of the confidentiality of data sets kept in the health information resource concerned and the safeguarding of the privacy of individuals whose personal data or personal health data are included in that health information resource,

(6) A person maintaining a prescribed health information resource shall ensure that any change in any of the information referred to in s*ubhead (5)(b)* relating to the person who may be contacted for further information is notified to the Minister as soon as may be but not later than before the end of the prescribed period.

Explanatory Note
This is similar to Head 50. This Head sets out the principles and rules that will apply to prescribing a health information resource (which are similar to those applying to data matching programmes). The Minister will not be prescribing health information resources that are under his or her control.

It will also be noted that the Minister for Health needs to be satisfied on a number of matters: namely, that the purpose of the resource relates to a matter of significant health importance; that it has significant justifiable benefit; that obtaining individual consent would be impracticable, involve unreasonable expense or be likely to significantly adversely affect the quality of the resource; that the amount of information proposed to be held is not excessive or unjustified; and that the person concerned has adequate security and other arrangements in place to protect the data. The need for transparency is also addressed.

Subhead (4) sets out what must be addressed in the regulations including the conditions to be complied with by the person carrying out the health information resource in relation to-

(i) the publicising of the resource which is important for transparency and public awareness,

(ii) the publication of results from the resource under Head 61, which can help the public see the values and benefits of these resources.

(iii) the retention, archiving or destruction of any data sets provided under Head 57 which will ensure that data sets are not kept for longer than is necessary before being archived securely or destroyed in a specified manner, and

(iv) the protection of the confidentiality of data sets in health information resources and the safeguarding of the privacy of individuals whose personal data or personal health data is included in those data sets. Like the matters referred to in (i), (ii) and (iii), this is important in helping to ensure that there can be public confidence in prescribed health information resources.

This provision gives a significant role to the Data Protection Commissioner and HIQA. The Minister must consult the Commissioner and the Authority on any Regulations, including consulting on each intended prescribed Health Information Resource.

Revocation or amendment of regulations
63. Provide that:
(1) The Minister may amend or revoke regulations prescribing one or more than one health information resource made under *Head 62* where -

(a) the purpose of the resource has been achieved,

(b) HIQA advises the Minister under *Head 65* of its opinion that the person carrying out a prescribed health information resource has-

(i) failed to co-operate with the monitoring of the standards,

(ii) failed to comply with the standards, or

(iii) contravened a provision of this Part, regulations made under *Head 62* or a provision of the Act of 1988,

(c) the Data Protection Commissioner informs the Minister of the findings of an investigation under *Head 66* or otherwise where the findings indicate that the person carrying out a prescribed health information resource has-

(i) failed to comply with the standards, or

(ii) contravened a provision of this Part, regulations made under *Head 62* or a provision of the Data Protection Acts,

(d) the Minister is aware that the person maintaining the health information resource has committed a breach of the Act of 1988 other than ones referred to in *paragraph (c)* above.

(2) Before proceeding to amend or revoke regulations in relation to a prescribed health information resource the Minister shall send a notice to the person maintaining the health information resource, the Authority and the Commissioner that sets out–

(a) the Minister's intention to amend or revoke the regulations, and, in the case of a proposed amendment, the changes that would be made to the regulations concerned,

(b) the reasons for the proposed amendment or revocation, and

(c) a statement that the person concerned may make written representations to the Minister, not later than 28 days after the date on which it is sent, as to why or how the regulations should or should not be amended or revoked.

(3) Where the Minister is of the opinion that it is necessary as a matter of urgency for reasons of public importance or public concern to do so, the Minister may order the person concerned not to make any requests under *Head 57* unless a notice under *subhead (6)(c)* is sent to that person and, if the Minister makes such an order, he or she shall include a reference to that order in the notice under *subhead (2)*.

(4) Where a notice has been sent under *subhead (2)*, the Minister shall not amend or revoke the regulations concerned until the later of -

(a) the day on which the person concerned has-

(i) made written representations to the Minister concerning the proposal, or

(ii) notified the Minister in writing that he or she does not intend to make representations,

and

(b) the day on which the 28 days referred to in *subhead (2)(c)* have expired.

(5) Where the Minister receives written representations under *subhead (4)(a)(i)*, he or she shall consider those written representations before deciding whether or not to amend or revoke the regulations concerned.

(6) The Minister shall, as soon as may be after he or she decides whether or not to amend or revoke the regulations concerned, send a notice to the person, the Authority and the Commissioner of that decision, and–

(a) if the decision is to revoke the regulations concerned, of the date on which the revocation will take effect,

(b) if the decision is to amend the regulations concerned, of the tenor of the amendments and the date on which they will take effect, or

(c) if the decision is to neither revoke nor amend the regulations concerned but the Minister has ordered, in accordance with *subhead (3)*, the person concerned not to make requests under *Head 57*, of the termination of the effect of that order as of the date on which the notice under this subhead is sent.

Explanatory Note
This is similar to Head 51. This Head provides for and makes clear that the Minister may amend or revoke regulations prescribing one or more than one health information resource made under Head 62 in specified circumstances.

In the interests of fairness, it also provides that before proceeding to amend or revoke any such regulations the Minister must send a notice to the person concerned that sets out the Minister's intentions, the reasons for such intended action and a statement that the person concerned may make written representations to the Minister on the matter.

The need for urgent action by the Minister is also addressed.

Standards for prescribed health information resources
64. Provide that:
(1) The Authority may, at the request of the Minister, set such standards for the processing of data in data sets, as it considers appropriate for the maintaining of prescribed health information resources.

(2) Without prejudice to the generality of *subhead (1*), standards may address matters relating to the privacy of data subjects, confidentiality, quality assurance, security, storage and destruction of such data.

(3) Before setting standards under this Head, the Authority may consult with any person, or invite representations from any person, as it considers appropriate.

(4) After considering any representations made under *subhead (3)* in relation to any standards proposed by the Authority and after making any changes the Authority thinks fit, it shall submit the proposed standards to the Minister for approval.

(5) Before approving any standards submitted to him under *subhead (4)*, the Minister shall consult with the Data Protection Commissioner on any such standards.

(6) Where a standard under this Head is approved by the Minister, the Authority shall publish the standard on its website and in accordance with such other arrangements as may be specified by the Minister.

Explanatory Note

This Head is similar to Head 52.

Compliance with standards
65. Provide that:
(1) Where standards are set in relation to the maintaining of a prescribed health information resource under *Head 64*, a relevant person shall comply with the standards and shall co-operate with the Authority in its monitoring of compliance with those standards.

(2) If in the opinion of the Authority, there is a failure by a relevant person to co-operate with the monitoring of the standards referred to in *subhead (1)*, the Authority shall so advise the Minister and the Commissioner of that failure.

(3) If in the opinion of the Authority, there is a failure to comply by a relevant person with the standards referred to in *subhead (1)*, the Authority shall seek to engage with the person

concerned to bring about compliance with the standards but if such engagement proves not possible or unsuccessful it shall so advise the Minister and the Commissioner.

(4) If the Authority becomes aware of a contravention by a relevant person of a provision of this *Part*, regulations made under *Head 62* or a provision of the Act of 1988, the Authority shall so advise the Minister and the Commissioner.

(5) In this Head "relevant person" means a person maintaining a prescribed health information resource.

Explanatory Note
This is similar to Head 53.

Investigation by Commissioner
66. Provide that:
(1) Without prejudice to any other powers conferred on the Commissioner under any other Act, he or she may carry out or cause to be carried out such investigations as he or she considers appropriate in relation to the maintaining of a prescribed health information resource–

(a) if the Minister so requests,

(b) if a complaint is made to him or her, or

(c) if he or she considers it desirable to do so, either on foot of being advised of a failure under *Head 65* or otherwise.

(2) The Commissioner shall inform the Minister of the findings of an investigation–

(a) if the investigation was carried out on the request of the Minister,

(b) if the findings show a failure by the person carrying out a prescribed health information resource to comply with-

(i) the standards,

(ii) a provision of this Part,

(iii) regulations made under *Head 62,* or

(iv) a provision of the Act of 1988,

or

(c) in any other case, if he or she considers it desirable to do so.

Explanatory Note
This Provision gives the Data Protection Commissioner an express investigatory role in relation to prescribed health information resources and is similar to the provision in Head 54.

Co-operation between the Authority and the Commissioner

67. Provide that:

The Commissioner and the Authority shall co-operate with each other and provide assistance to each other in the performance of their functions under this Part.

Explanatory Note
This Head provides a formal basis for co-operation between the Data Protection Commissioner and HIQA in relation this Part and is similar to Head 55.

PART 6: PATIENT SAFETY INCIDENTS

This Part of the Bill is concerned with the notification of Patient Safety Incidents

Interpretation – Part 6
68. Provide that:
(1) In this Part-

"Agency" means the State Claims Agency under the National Treasury Management Agency (Amendment) Act 2000;

"*Chief Inspector of Social Services*" means the person who is appointed to the office of the Chief Inspector of Social Services in accordance with section 40 of the Act of 2007;

"*Child and Family Agency*" means the Child and Family Agency established in accordance with section 7 of the Child and Family Agency Act 2013;

"Commission" means the Mental Health Commission established under section 32 of the Mental Health Act 2001;

"designated centre" means a designated centre as defined in section 2(1) of the Act of 2007;

"mental health services" means mental health services as defined in section 2(1) of the Mental Health Act 2001;

"*patient safety incident*" in relation to a relevant provider, means-

(a) any unintended or unanticipated injury or harm to a service user that occurred during the provision of a health service,

(b) an event that occurred when providing a health service to a service user that did not result in actual injury or harm but there are reasonable grounds to believe that the event concerned placed the service user at risk of unintended or unanticipated injury or harm,

(c) an incident that was prevented from occurring due to timely intervention or chance and which there are reasonable grounds for believing could have resulted, if it had not been so prevented, in unintended or unanticipated injury or harm to a service user during the provision of a health service to that service user;

"*personal injury*" has the same meaning as it has in the Civil Liability Act 1961;

"*record*" has the same meaning as in the Act of 2014;

"registered provider" means a registered provider as defined in section 2(1) of the Act of 2007;

"relevant body" means-

(a) the Executive,

(b) the Child and Family Agency,

(c) a service provider who is a State authority under the National Treasury Management (Amendment) Act 2000;

"relevant provider" means-

(a) a relevant body,

(b) a person providing mental health services,

(c) a registered provider;

"*reportable incident*" means a patient safety incident prescribed by the Minister under this Part for the purposes of *Head 71*;

"service provider" means a service provider as defined in section 2(1) of the Act of 2007;

"service user" means a person who receives or received a health service;

"standards" means standards jointly set by the Authority and the Commission and approved by the Minister as referred to in *Head 70*;

"State authority" means a State authority as defined in section 7(1) of the National Treasury Management (Amendment) Act 2000.

Explanatory Note

The Commission on Patient Safety and Quality Assurance creates a framework for better patient safety and quality in the Irish health service. A number of recommendations focus on developing quality improvement learning systems. The Commission recommended that there should be mandatory national reporting of adverse events which result in death or serious harm and provision for (voluntary) reporting of other less serious adverse events and 'near-misses.' Many adverse events and poor outcomes in healthcare arise from several service wide factors acting together and rarely arise solely because of shortcomings or failures on the part of individuals. However, the Commission recognised that fear of litigation and damage to professional reputation presents a significant challenge for professionals in engaging with incident reporting, open disclosure and audit processes. This is supported by international experience.

To build a positive culture of participation that would benefit patients and the health services as a whole, the Commission recommended that legislation should be introduced providing for (a) exemptions from FOI legislation for records arising from these specific activities and (b) protections for these records from admissibility as evidence in civil proceedings. These protections do not preclude the taking of disciplinary or regulatory proceedings through other routes. Criminal proceedings are not affected.

Subject access by individuals, under FOI, to their own medical records is unaffected as is the use of medical records in civil liability cases.

This Part of the Bill therefore provides that public health service providers must notify serious patient incidents (reportable incidents) occurring in their services to the State Claims Agency and to HIQA or the Mental Health Commission, as appropriate. The Child and Family Agency (Tusla) will also notify the State Claims Agency of reportable incidents it becomes aware of occurring in services provided on behalf of Tusla.

Any private health service providers regulated by HIQA/the Chief Inspector of Social Services (e.g. private nursing homes) must notify the Chief Inspector of serious incidents. Private providers of mental health services will be required to notify the Mental Health Commission of serious incidents.

Less serious incidents and near misses may be reported by public providers to the State Claims Agency. In the case of Tusla, this will also include less serious incidents and near misses it becomes aware of in services provided on its behalf.

HIQA and the Mental Health Commission will jointly set standards for notifications and the intention is that notifications made in line with these standards will have the protections recommended by the Commission on Patient Safety and Quality Assurance.

Requirements in this Part of the Bill supplement existing obligations by State authorities (including the public health service) to report adverse incidents to the State Claims Agency under section 11 of the National Treasury Management (Amendment) Act 2000 and arrangements for incident reporting by providers to the Chief Inspector of Social Services or the Mental Health Commission arising from the Health Act 2007 and the Mental Health Act 2001.

Head 68 is the Interpretation Head for this Part and sets out key definitions. "Patient safety incident" in relation to a relevant provider is defined to include unintended or unanticipated injury or harm to a service user, incidents that could have caused harm, but did not (no harm incidents) and incidents that were prevented from happening due to timely intervention or chance (near misses.)

"Relevant provider" is intended to cover public and private health service providers. It means a relevant body (the public health service providers), public and private providers of mental health services regulated by the Mental Health Commission and registered providers of residential services under the Health Act 2007. These registered providers would include the HSE, voluntary bodies and providers of private nursing homes.

As outlined above, "relevant body" is designed to encompass public health service providers and means the HSE, Tusla and service providers as defined in the Health Act 2007 (i.e. persons providing services on behalf of the HSE or Tusla) but only those service providers which are also within the remit of the State Claims Agency.

The definition of "designated centre" relates to residential services for older people (including private nursing homes), children and people with disabilities. The Health Act 2007 provides for the registration and inspection of these services.

"Mental health services" has the same meaning as it does under the Mental Health Act 2001 and includes public and private providers.

Standards set by the Authority and the Commission on notification of patient safety incidents.

69. Provide that:

(1) The Authority and the Commission shall jointly set standards-

(a) for relevant bodies in relation to the notification of patient safety incidents to the Agency pursuant to *Head 71 or Head 72,*

(b) for relevant providers in relation to the notification of reportable incidents to the Authority, the chief inspector of social services and the Commission pursuant to *Head 71,*

and different standards may be set in relation to different types of incidents.

(2)Without limiting the generality of *Head 3,* the Minister may make regulations respecting procedures to be followed by the Authority and the Commission in setting standards under this Head including but not limited to regulations respecting—

(a) publication of any proposed standards,

(b) consultations in relation to the standards,

(c) the consultation period, and

(d) the publication of the standards after their approval by the Minister.

(3) After considering any representations made in relation to any standards proposed by the Authority and Commission and after making any changes the Authority and Commission think fit, they shall submit the proposed standard to the Minister for approval.

Explanatory Note

The Bill envisages that there will be two standard setting bodies for this Part of the Bill: HIQA and the Mental Health Commission. Head 69 provides for HIQA and the Mental Health Commission to jointly set standards on the notification of reportable incidents and other patient safety incidents. Standards will require Ministerial approval.

Subhead (2*)* provides that without limiting the generality of Head 3 of the Bill – the Head that deals with the making of regulations under the Health Information and Patient Safety Bill - the Minister may make regulations respecting procedures to be followed by the Authority and Commission in setting standards under this Head including but not limited to regulations respecting—

(a) publication of any proposed standards,

(b) consultations in relation to the standards,

(c) the consultation period, and

(d) the publication of the standards after their approval by the Minister.

Under subhead (3), HIQA and the Commission will submit the proposed standards to the Minister for approval after they have considered any representations made making any changes they consider appropriate.

Reportable incidents
70. Provide that:
(1) The Minister may prescribe such patient safety incidents that are comprehended by *paragraphs (a)* and *(b)* of the definition of patient safety incident in *Head 68* as he or she considers appropriate to be reportable incidents having regard to the seriousness or potential seriousness of such incidents.

Explanatory Note
The Madden Commission Report on Patient Safety and Quality Assurance considered that the system for reporting adverse events must clearly delineate the events which must be reported. This will be done through Ministerial regulations which will specify "reportable incidents" which must be reported to the relevant reporting authority. This detailed listing will make it clear what must be reported.

Head 70 gives the Minister the power to prescribe patient safety incidents to be reportable incidents. These will be actual events of a serious nature or no harm events that potentially could have been serious. They will not include near misses although as indicated earlier these may be reported to the State Claims Agency (Head 72).

Notification of reportable incidents
71. Provide that:
(1) A relevant body shall notify the Agency of a reportable incident as soon as the body becomes aware of the incident and, in any event, not later than 7 days after becoming so aware and, in the case of the Child and Family Agency, this shall include a reportable incident occurring in a service provided by a service provider on behalf of the Child and Family Agency.

(2) The Executive shall notify the Authority of a reportable incident (not being a reportable incident relating to services at a designated centre) as soon as the Executive become becomes aware of the incident and, in any event, not later than 7 days after becoming so aware.

(3) A registered provider of a designated centre shall notify the Chief Inspector of Social Services of a reportable incident relating to services at a designated centre as soon as the registered provider becomes aware of the incident and, in any event, not later than 7 days after becoming so aware.

(4) A person providing mental health services shall notify the Commission of a patient safety incident relating to mental health services as soon as the person becomes aware of the incident and, in any event, not later than 7 days after becoming so aware.

(5) A notification under this Head shall be made in accordance with standards set by the Authority and the Commission under *Head 69.*

(6) A reporting authority shall acknowledge receipt of a notification under this Head.

(7) In this Head, reporting authority means-

(a) the Agency,
(b) the Authority,
(c) the Chief Inspector of Social Services,
(d) the Commission.

Explanatory Note

Head 71 places obligations on persons to notify "reportable incidents." The authorities to which incidents must be notified are the State Claims Agency and the relevant regulator. These are HIQA, the Chief Inspector of Social Services in the case of residential services and, in the case of mental health services, the Mental Health Commission. Where a notification is received under this Head, the regulator will be in a position to take action as it considers appropriate under its own legislation.

Notifications must be made within seven days of the provider becoming aware of the incident.

Under subhead (1), the HSE, Tusla and service providers who are State authorities under the National Treasury Management (Amendment) Act 2000 must notify the State Claims Agency of a reportable incident. Tusla must also notify the State Claims Agency of reportable incidents occurring in services provided on its behalf, where it becomes aware of the incident.

Under subhead (2), the HSE must notify HIQA of reportable incidents other than reportable incidents in designated centres or in mental health services. These will be reported to the Chief Inspector of Social Services and the Mental Health Commission respectively.

Under subhead (3), registered providers of designated centres (these providers may be the HSE, service providers under the Health Act 2007 or owners of private nursing homes, must notify the Chief Inspector of Social Services of reportable incidents in designated centres.

Under subhead (4) persons providing mental health services must notify reportable incident to the Mental Health Commission.

Subhead (5) provides that notifications must be made in line with standards set by HIQA and the Commission.

Subhead (6) requires reporting authorities to acknowledge receipt of notifications under this Head.

Subhead (7) defines the reporting authorities as the State Claims Agency, HIQA, the Chief Inspector of Social Services and the Mental Health Commission.

Notification of patient safety incidents
72. Provide that:
Without prejudice to section 11 of the National Treasury Management (Amendment) Act 2000, a relevant body may notify the Agency of a patient safety incident that is not a reportable incident and, in the case of the Child and Family Agency, this may include a reportable incident occurring in a service provided by a service provider on behalf of the Child and Family Agency.

Explanatory Note
As set out earlier, in addition to events causing injury or harm, patient safety incident is defined to include near misses and no harm incidents. Learning can be gained from these. Head 72 in association with Heads 75 and 76 is designed to support notifications of these incidents to the State Claims Agency. In this way, information will be available on serious incidents, incidents that are less serious, no harm incidents and near misses.

Functions of the Agency under this Part.
73. Provide that:
(1) The functions of the Agency, under this Part, are to-

(a) promote, through such measures as it thinks appropriate, patient safety awareness in relevant bodies,

(b) compile, analyse, disseminate and publish information derived from patient safety incidents notified to it under *Head 71(1)* or *Head 72*, including extracting and analysing trends of any matter that appears relevant to patient safety,

(c) disseminate or publish, as it sees fit, information and analysis on specific or general issues of patient safety.

(2) In disseminating or publishing information under *subhead (1)*, the Agency shall not disclose personal data relating to any individual without the consent of the individual concerned.

(3) This Head is without prejudice to any functions and powers of the Agency under the National Treasury Management Agency (Amendment) Act 2000 and any other enactments.

Explanatory Note
Head 73 is concerned with ensuring that learning from patient safety incidents notified to the State Claims agency under Heads 71 and 72 is disseminated.

Subhead (1) sets out the functions of the Agency under this part. The Agency will (a) promote patient safety awareness in relevant bodies, (b) compile, analyse, disseminate and publish information derived from patient safety incidents notified to it, including extracting and analysing trends of any matter that appears relevant to patient safety and (c) disseminate

or publish, as it sees fit, information and analysis on specific or general issues of patient safety.

Subhead (2) provides that in disseminating or publishing information, under subhead (1), the Agency shall not disclose personal data relating to any individual without consent.

The Agency already has functions under section 8 of the National Treasury Management Agency (Amendment) Act 2000 in relation to advising and assisting State authorities. Subhead (3) provides that this Head is without prejudice to the State Claims Agency's functions and powers under the National Treasury Management Agency (Amendment) Act 2000 and any other enactments.

Information on the functions of the Agency under this Part
74. Provide that:
(1) Subject to *subhead (2)*, the Agency shall publish information in relation to the performance of its functions under this Part.

(2) Information on patient safety incidents notified to the Agency pursuant to *Head 71* and *Head 72* may not be published in a manner that particulars relating to any identifiable individual are ascertainable without the consent of the individual concerned.

Explanatory Note
This Head provides for the State Claims Agency to make information available on the performance of its functions. Information relating to an identifiable individual will not be published unless the individual has given his or her consent.

Freedom of Information
75. Provide that:
(1) Subject to *subhead (2)*, section 6 of the Act of 2014 shall not apply to a record that is a notification under *Head 71* or *Head 72* made in accordance with standards set under *Head 69.*

(2) *Subhead (1)* shall not apply where the request for access under section 6 is by an individual whose personal information is contained in a notification.

Explanatory Note
The provisions of the FOI legislation (including Access to Records under section 6) will apply to records created under this Part of the Bill with one exception: namely, that third party access (where it might otherwise arise), for example, the media, will not be available in respect of notifications made under Heads 71 or 72, where the notification is made in accordance with standards set under Head 70. This provision is intended to ensure that the rights of individuals to access information relating to them under FOI will continue to apply fully while at the same time incentivising, from a public interest perspective, healthcare providers to notify patient safety incidents so that greater knowledge can be gained about the number and nature of such incidents.

Patient safety incident notifications not admissible in certain civil proceedings
76. Provide that:
A notification under *Head 71* or *Head 72* made in accordance with standards set under *Head 69* is not admissible in evidence in any civil proceedings (whether by discovery or otherwise) as evidence of the liability of a health and social care provider (including any employee or agent of the provider acting in the capacity of employee or agent) in connection with any personal injury or death alleged to have been caused by the health and social care provider.

Explanatory Note
The intention here is to provide that notifications under Head 71 (reportable incidents) or Head 72 (other patient safety incidents) made in accordance with joint HIQA/MHC standards are not admissible as evidence in civil proceedings relating to liability for injury or death. They would be admissible in evidence for other civil proceedings and in criminal proceedings.

This provision has the same purpose as the FOI provision in Head 75: that is to encourage notification of patient safety incidents. Any documents or reports created in the course of investigating an incident are not covered by the exemption and will be subject to the normal rules of evidence.

Saver
77. Provide that:
(1) Nothing in this Part shall be construed as-

(a) diminishing or removing any obligations on a person who makes a notification under *Head 71* or *72* to comply with any other laws,

(b) limiting or removing any other protection available in law for the reporting of matters covered by this Part.

Explanatory Note
Provisions in this Part are not intended to interfere with other obligations by persons to notify incidents to the State Claims Agency, the Mental Health Commission or to the Chief Inspector of Social Services. Nor are they intended to interfere with obligations to make reports to any other agencies.

Head 77 is therefore intended to prevent the reduction or removal of any obligations on a person who makes a notification under Head 71 or 72 to comply with any other laws. It is also intended to prevent the limiting or removal of any other protection available in law for the reporting of matters covered by this Bill.

PART 7: CLINICAL AUDIT

Clinical Audit is a process to improve patient care and outcomes.

Interpretation – Part 7
78. Provide that:
For the purposes of this Part:

"*clinical audit*" means a process to improve patient care and outcomes-

> *(a)* involving a documented, structured and systematic review and evaluation, against clinical standards, referred to in *Head 79(3)(c)*, of clinical care, and, where necessary, actions to improve clinical care, and
> *(b)* carried out by or on behalf of or in association with one or more health services providers;

"*guidance*" means guidance issued *Head 79*;

"*record*" has the same meaning as in the Act of 2014.

Explanatory Note
Head 78 defines terms used in this Part of the Bill.

The clinical audit process is different from a review of a specific case or an information resource provided for in Part 5. Clinical audit is part of the clinical governance agenda and is intended to provide the evidence for assuring the quality of clinical care and helping to bring about improvements where necessary.
Clinical care should be interpreted in its broadest sense, providing for specific clinical circumstances across the entire clinical system. Accordingly, clinical care is not confined to the care delivered at the hospital bedside but includes, for example, diagnostic laboratory services or health promotion services provided by public health nurses in the community.
Clinical audit can look at the structures of care, the processes of delivering care (including for example clinical handover arrangements) or the outcome for individuals having received that care. Ultimately, it is about improving care or outcomes through review, evaluation and action for improvement in clinical practice, where indicated.
Clinical audit is a cyclical process, recognised as having the following elements:

- a commitment to quality improvement and learning,
- measurement - measuring a specific element of clinical practice,
- comparison - comparing results with an accepted benchmark, these are national or international standards,
- evaluation and action - reflecting the outcome of audit and where indicated, changing practice accordingly (sometimes referred to as "closing the loop").

The definition in Head 78 envisages clinical audit undertaken by a health services provider (for example, a hospital) either alone or with other providers and also envisages that the clinical audit may be carried out 'in association with' meaning by other persons on behalf of

the provider(s). Such other persons may consist, for example, of an academic partner institution or one of the professional colleges (like the Royal College of Surgeons of Ireland and Royal College of Physicians).

The definitions of health services and health services provider set out in Head 2 are applicable to this Part.

Minister shall issue guidance for the purposes of this Part
79. Provide that:
(1) The Minister shall establish a process for consulting with such persons, if any, as he or she considers appropriate, and having had due regard to those consultations, the Minister shall issue guidance applicable to clinical audit to which this Part applies.

(2) Different guidance may be issued in relation to different categories of health service providers.

(3) Without prejudice to the generality of *subhead (1)*, such guidance shall cover-

(a) the governance framework to be adopted for clinical audit,

(b) the methodology to be used in carrying out clinical audit,

(c) (i) the identification of the relevant clinical standard to be used in carrying out clinical audit, or
(ii) in the absence of such a standard in any case, the process to be followed by the persons intending to carry out the clinical audit in setting the clinical standard that should be used in carrying out the clinical audit concerned.

(4) The Minister shall establish a process for consulting with such persons, if any, as he or she considers appropriate, and having had due regard to those consultations, the Minister may amend or withdraw any guidance issued under *subhead (1)*. .

(5) The Minister, where he or she issues guidance under *subhead (1)* or amends or withdraws any guidance issued under *subhead (3)*, shall publish on an internet website that he or she maintains-

(a) the guidance issued and any amendments thereto, and

(b) where the guidance or amended guidance has been withdrawn, a notification to that effect.

Explanatory Note
Subhead (1) requires the Minister to issue guidance on carrying out clinical audit and to establish a process for consulting with such persons, if any, as he or she considers appropriate. Later Heads provide that FOI exemptions and legal protections will not apply to clinical audit which has not been carried out in accordance with Ministerial guidance and other requirements under this Part.

It is expected that the National Clinical Effectiveness Committee (NCEC) will play an important role in advising the Minister on guidance to be issued and updated. The NCEC is a group of key stakeholders which was established on a non-statutory basis as part of the Patient Safety First Initiative and its mission is to provide a framework for national endorsement of clinical guidelines and audit to optimise patient and service user care.

Under subhead (2), the Minister may issue different guidance in relation to different categories of health services provider.

While not limiting guidance that may be issued, subhead (3) provides that guidance may encompass the governance framework (see below), the methodology to be used in carrying out the audit, and the identification of relevant clinical standards (including the process for establishing such a standard where one does not exist) –the purpose of the guidance is to ensure quality and consistency of the audit.

The governance framework will detail the necessary structure, process and outcome criteria that are required for formalised oversight, accountability and compliance of the clinical audit with the guidance to achieve its objectives. The process for identifying potential clinical standards and determining the most appropriate clinical standards to use in the audit will also be explicit in the guidance. In limited cases where there is an absence of clinical standard(s) for the topic of interest, the guidance will make explicit how the clinical standard(s) can be established.

Guidance can be amended or withdrawn, in the light of experience gained with issued guidance or evolving national or international evidence – subhead (4).

Subhead (5) requires the Minister to publish any guidance and any changes to the guidance on the Internet – this will be the Department of Health website.

Publication of aggregate clinical audit results
80. Provide that:
(1) The Minister shall, after consulting with such persons, if any, as he or she considers appropriate, and having had due regard to those consultations, specify the timing, frequency, format and method of publication of aggregate results of clinical audit to which this Part applies.

(2) The timing, frequency, format or method of publication specified under *subhead (1)* may differ in relation to different categories of health service providers.

(3) A publication under this Head shall not contain personal data.

(4) The Minister may, after consulting with such persons, if any, as he or she considers appropriate, and having had due regard to those consultations, amend or withdraw a specification referred to in *subhead (1)*.

(5) The Minister, where he or she specifies a matter under *subhead (1)* or amends or withdraws any specification under *subhead (4)*, shall publish on an internet website that he or she maintains-

(a) the specification and any amendments thereto, and

(b) where the specification or amended specification has been withdrawn, a notification to that effect.

Explanatory Note
The Commission on Patient Safety and Quality Assurance said that if clinical audit is to be granted FOI exemption or legal privilege, aggregated information must be published on the results of the audit. Later Heads therefore provide for this publication requirement if the FOI exemption and legal protection are to be given.

Aggregate results are essentially findings from the clinical audit presented in a statistical format.

Subhead (1) requires the Minister to specify the timing, frequency format and method of publication of aggregate information after having consulted with such persons as he or she deems appropriate. The intention is that published information on the results could cover a number of providers, giving a national, regional or local picture of the outcome of the audit. The information would give an overview of performance and show how any deficits are addressed. However, given that clinical audit is a cyclical process, the specifications in relation to timing, frequency format and method of publication of aggregate information is to ensure that publication does occur within the cycle.

Subhead (2) allows the Minister to specify different arrangements for different categories of providers. As this Head is concerned with aggregate data, subhead (3) provides that publications under this Head cannot contain personal data. It will separately be open to a person carrying out a clinical audit to publish information in relation to a clinical audit that identifies an individual in line with the Data Protection Acts (for example, consent of the individual concerned or one of the other grounds in section 8 of the Data Protection Acts)..

Subheads (4) and (5) deal with publication by the Minister of his or her specifications on the timing, frequency and format of clinical audit aggregated data, and any amendments to those specifications.

Freedom of Information
81. Provide that:
(1) Subject to *subhead (2)*, the Act of 2014 shall not apply to a record that is created solely for the purpose of clinical audit where-

(a) the clinical audit is carried out in accordance with all elements of the guidance issued by the Minister under *Head 79,*

(b) aggregate results of the clinical audit are published in accordance with *Head 80.*

(2) This Head does not apply to a publication under *Head 80.*

Explanatory Note
The purpose of this Head is to provide for an FOI exemption for clinical audit in line with Madden Commission Report on Patient Safety and Quality Assurance.

Subhead (1) provides for a FOI exemption for a record (up to and including the audit report) created solely for the purpose of clinical audit where the following requirements are met: the clinical audit is carried out in accordance with all the elements of the guidance issued under Head 79, and the results of the clinical audit are published in accordance with Head 80.

It is envisaged that where a person makes an FOI request to a (public) health service provider in regard to a clinical audit, the provider, where he or she considers that they have carried out the audit in line with the requirements of this Part, will cite the exemption in Head 81 to the FOI requester. If the requestor wishes to pursue the matter, he or she can do so under the mechanisms set out in the FOI Act 2014 involving internal reviews (under chapter 3 of that Act) and reviews by the Information Commissioner (under chapter 4 of that Act). Documents published under Head 80 will be in the public domain so they do not need to be FOI exempted under this Head. Accordingly, subhead (2) provides that this Head does not apply to a publication under Head 80.

Evidence
82. Provide that:
(1) Subject to *subhead (2)*, a record created solely for the purposes of clinical audit will not be admissible in evidence (whether by discovery or otherwise) in civil proceedings where-

(a) the clinical audit is carried out in accordance with all elements of the guidance issued by the Minister under *Head 79,* and

(b) aggregate results of the clinical audit are published in accordance with *Head 80.*

(2) This Head does not apply to a publication under *Head 80.*

Explanatory Note
Like Head 81, this provision gives effect to a recommendation in the Madden Commission Report on Patient Safety and Quality Assurance. This Head provides that a record created solely for the purposes of a clinical audit will not be admissible as evidence (whether by discovery or otherwise) in civil proceedings.

Specifically, subhead (1) provides for the civil admissibility exemption for a record (document etc) created solely for the purpose of clinical audit where the clinical audit is carried out in accordance with all the elements of the guidance issued under Head 79 and the clinical audit are published in accordance with Head 80.

Documents published under Head 80 will be in the public domain. Subhead (2) therefore provides that this Head does not apply to a publication under Head 80.

Records created as part of a clinical audit will be admissible in evidence in criminal proceedings.

Separately, the medical records of a patient would, of course, continue to be admissible in civil proceedings including in relation to personal injury or death.

The Bill does not contain provisions on monitoring of clinical audit to assess if it is being carried out in accordance with the requirements set out in this Part. If the matter of the admissibility in evidence of clinical audit documents is raised in civil proceedings, it will be for the Court to determine, on the basis of the arguments made by the parties to the proceedings and the facts of the situation, whether the documents in question are ones that fall within the exemption in Head 82 or not.

Saver for this Part
83. Provide that:
(1) Nothing in this Part shall be construed as-

(a) diminishing or removing any obligations on health services providers to comply with any other laws,

(b) limiting or removing any protection available in law for the reporting of matters covered by this Part.

Explanatory Note
This is intended to prevent the reduction or removal of any obligations on health services providers, carrying out clinical audit to comply with any other laws e.g. arrangements for the reporting of deaths to the coroner under the Coroners Acts or statutory obligations to report to the Health and Safety Authority or the State Claims Agency. It also addresses not limiting or removing any protections available in law for the reporting of matters covered by this Part.

Part 8: AMENDMENT OF DATA PROTECTION ACTS

This Part amends certain provisions of the Data Protection Acts

Amendment of section 2B of the Act of 1988
84. Provide that:
Section 2B(4) of the Act of 1988 is amended by substituting the following for the definition of "health professional":

> "'health professional' has the same meaning as "health practitioner" in the Health Information and Patient Safety Act 201x",.

Explanatory Note
Section 2A of the Data Protection Acts sets out the grounds for the processing of non-sensitive personal data. Section 2B sets out the grounds for the processing of sensitive personal data (which includes personal health data). There is a definition of "health professional" in section 2B(4) of the Acts. This Head updates the definition of "health professional" and make it consistent with the definition of "health practitioner" in this Bill.

Amendment of section 2C of the Act of 1988
85. Provide that:
Section 2C of the Act of 1988 is amended by inserting the following subsection after subsection (3):

> "(4) This section also applies in respect of personal health information, within the meaning of section 9(5) of the Health Information and Patient Safety Act 201x, of an individual"

Explanatory Note
Section 2C of the Data Protection Acts deals with the technical and physical security of personal data. The term "personal data" (as defined in the Data Protection Acts) is used throughout this Bill. However, in Head 9 (Offence –buying or selling of personal health information), the term "personal health information" is used and it protects information of living and deceased persons from purchase and sale.

Accordingly, this Head has the objective of ensuring that security measures are applied by data controllers and data processors in relation to personal health information of both living and deceased individuals. This seems appropriate and is consistent with good practice. An individual's health information should not be subjected to lesser security standards by a data controller or data processor just because the individual is deceased.

Amendment of Section 14 of the Act of 1988
86. Provide that:
Section 14(1)(e) of the Act of 1988 is amended by substituting "activities under the Health Information and Patient Safety Act 201x, the European Communities (Electronic Communications Networks and Services) (Data Protection and Privacy) Regulations 2003

and this Act" for "activities under the European Communities (Electronic Communications Networks and Services) (Data Protection and Privacy) Regulations 2003 and this Act".

Explanatory Note
Section 14 of the Data Protection Acts provides for an Annual Report by the Commissioner on his or her activities under those Acts and the European Communities (Electronic Communications Networks and Services) (Data Protection and Privacy) Regulations 2003 in the preceding year. This Head amends section 14 to provide for the Annual Report by the Commissioner to reference this Bill.

Amendment of section 26 of the Act of 1988
87. Provide that:
Section 26(1) of the Acts is amended –

(a) in paragraph *(c)*, by substituting "under that section," for "under that section, and",

(b) in paragraph *(d*), by substituting "of this Act, and" for "of this Act,"

and

(c) by inserting the following paragraph after paragraph *(d*):
"*(e)* a decision of the Commissioner under Part 3 of the Health Information and Patient Safety Act 201x,".

Explanatory Note
These are technical amendments to section 26 of the Data Protection Acts arising from the appeals provision in Head 34 which allows an appeal from the Data Protection Commissioner where he or she refuses a consent exemption request made under Part 3.

Part 9: AMENDMENT OF HEALTH ACT 2007
(Extending HIQA's remit to the private health service)

Amendment of section 2 of the Act of 2007
88. Provide that:

Section 2 of the Act of 2007 is amended in subsection (1) –

(a) by inserting the following after the definition of "local authority":

> ""medical speciality" for the purposes of the definition of private hospital means a medical speciality recognised by the Medical Council under section 89 of the Medical Practitioners Act 2007;",

(b) by inserting the following definitions after the definition of "prescribed":

> ""prescribed private health service" means a private health service prescribed by the Minister under section 98A;
>
> "private hospital" means an establishment carried on by a person other than the Executive or a service provider at which medical or surgical treatment for illness, injury, or palliative or obstetric care is provided to an individual under the direction of registered medical practitioners from at least 3 medical specialties and which is being held out by the person carrying on the business of the private hospital as being capable of accommodating one or more such individuals for continuous periods of 24 hours or longer but does not include any part of the institution that is a centre registered by the Mental Health Commission or a designated centre.

Explanatory note
Section 2 of the Health Act 2007 is the Interpretation section for that Act. This Head amends section 2 to include new terms.

The definition of private hospital and related definition of "medical specialty" is intended to describe private hospitals where medical or surgical treatment for illness or injury, palliative care or obstetric care is provided under the direction of registered medical practitioners from at least 3 of the specialties recognised by the Medical Council in accordance with section 89 of the Medical Practitioners Act 2007. Current recognised medical specialities are:

- anaesthesia
- emergency medicine
- general practice
- medicine
  - cardiology
  - clinical genetics
  - clinical neurophysiology
  - clinical pharmacology and therapeutics
  - dermatology
  - endocrinology and diabetes mellitus
  - gastroenterology
  - general (internal) medicine
  - genito-urinary medicine

    - geriatric medicine
    - infectious diseases
    - medical oncology
    - nephrology
    - neurology
    - palliative medicine
    - pharmaceutical medicine
    - respiratory medicine
    - rheumatology
    - tropical medicine
- obstetrics and gynaecology
- ophthalmology
- paediatrics
    - paediatric cardiology
    - paediatrics
- pathology
    - chemical pathology
    - haematology (clinical and laboratory)
    - histopathology
    - immunology (clinical and laboratory
    - microbiology
    - neuropathology
- psychiatry,
    - child and adolescent psychiatry
    - psychiatry
    - psychiatry of learning disability
    - psychiatry of old age
- public health medicine
- radiology
    - radiation oncology
    - radiology
- sports and exercise medicine
- surgery
    - cardiothoracic surgery
    - general surgery
    - ophthalmic surgery
    - oral and maxilla-facial surgery
    - otolaryngology
    - paediatric surgery
    - plastic, reconstructive and aesthetic surgery
    - trauma and orthopaedic surgery
    - urology.

For the avoidance of any doubt, the definition of "private hospital" excludes residential centres for children, older people and people with disabilities and also excludes psychiatric hospitals and units.

Other private health services
As indicated earlier, the intention is that HIQA's functions on setting standards, monitoring compliance with standards and undertaking investigations will also extend to other private

services in addition to private hospitals. Information on this is in Head 96 which inserts a new regulation making provision in the Health Act 2007 – section 98A – to enable the Minister to prescribe a private health service to come within HIQA's remit. Also as mentioned earlier, if a service is prescribed by the Minister, HIQA's functions will apply to all private providers of that service. A prescribed service is intended to include particular high risk services currently provided in the private health service where the use of a general anaesthetic is required to be administered to the patient.

Amendment of section 8 of the Act of 2007 (Functions of HIQA)
89. Provide that:
(1) Section 8 of the Act of 2007 is amended in subsection (1)–

(a) by inserting the following after paragraph (b):

"(bb) to set standards on safety and quality in relation to—

(i) private hospitals,

(ii) prescribed private health services,

and advise the Minister accordingly;",

(b) in paragraph (c), by deleting " referred to in paragraph (b)" and substituting "referred to in paragraph (b) and paragraph (bb)",

(c) in paragraph (g), by inserting "or services referred to in paragraph (bb) " after "the services".

(2) Section 8 of the Act of 2007 is amended by the insertion of the following after subsection (2):

"(2A) (a) The Authority, in setting standards under subsection (1)(b)or subsection (1)(bb), may set different standards in relation to different categories of services.".

Explanatory note
HIQA's current functions are set out in section 8 of the Health Act 2007. This Head amends section 8 of the Health Act 2007 to allow for HIQA standards to apply to both the public and private healthcare services. The standards will apply to services provided by private hospitals and to such other services as prescribed by the Minister. HIQA also operates schemes aimed at ensuring safety and quality in the provision of public services and this function is now extended to the private hospitals and prescribed private services.

It is not expected that HIQA will set standards specifically for private hospitals or prescribed private health services but is instead envisaged that HIQA will instead apply existing standards e.g. the Safer Better Healthcare Standards to those services. However, to provide flexibility generally in regard to different categories of services, both public and private, a new subsection - subsection (2A) - provides that HIQA may set different standards for different categories of services. Where services are provided in the private health service and not in the public health service, HIQA may set specific standards relevant to that service. In the event that the service should be provided by the public health service in the future the same standards will apply.

Currently, HIQA standards must be approved by the Minister and this will not change.

Amendment of section 9 of the Act of 2007 (Investigations by the Authority)
90. Provide that:

Section 9 of the Act of 2007 is amended by substituting the following for subsections (1), (2) and (2A):

"(1) Subject to subsection (1A), the Authority may undertake an investigation as to the safety, quality and standards of the services described in section 8 (1)(b) or 8 (1)(bb) if the Authority believes on reasonable grounds that-

(a) there is a serious risk-

(i) to the health or welfare of a person receiving those services, or

(ii) of a failure to comply with the provisions of the Act of 2013, and

(b) the risk may be the result of any act, failure to act or negligence on the part of—

(i) the Executive,
(ii) the Agency,
(iii) a service provider to which paragraphs (a) or (b) of the definition of service provider applies,
(iv) a service provider to which paragraph *(c)* of the definition of service provider applies,
(v) the registered provider of a designated centre to which paragraphs (a)(ii), (iii) or (c) of the definition of designated centre applies,
(vi) the registered provider of a designated centre to which paragraphs (a)(i) or (b) of the definition of designated centre applies,
(vii) the person in charge of a designated centre referred to in subparagraph (v), if other than its registered provider,
(viii) the person in charge of a designated centre referred to in subparagraph (vi), if other than its registered provider,
(ix) a person carrying on the business of a private hospital,
(x) a person carrying on the business of a prescribed private health service.";

(1A) The Authority shall notify the Minister before undertaking an investigation under subsection (1).

(2) The Minister may, if he or she believes on reasonable grounds that—

(a) there is a serious risk of the kind mentioned in paragraph *(a)* of subsection (1), and

(b) the risk may be the result of any act, failure or negligence of the kind mentioned in paragraphs (b)(i), (iii), (v), (vii), (ix) or (x) of subsection (1),

require the Authority to undertake an investigation in accordance with this section.

(2A) The Minister for Children and Youth Affairs may, if he or she believes on reasonable grounds that-

(a) there is a serious risk of the kind mentioned in paragraph (a) (i) of subsection (1), and

(b) the risk may be the result of any act, failure or negligence mentioned in paragraph (b)(ii), (iv), (vi) or (viii) of subsection (1),

require the Authority to undertake an investigation in accordance with this section.

(2AB) On undertaking an investigation, the Authority shall–

(a) give notice in writing to the person providing the service to which the investigation relates of the matters to which the investigation relates, and

(b) give the person referred to in paragraph (a) copies of any documents relevant to the investigation.".

Explanatory note

Section 9 of the Health Act 2007 deals with investigations by HIQA where HIQA believes there is a serious risk to the health or welfare of people receiving a particular service. Investigations under section 9 may be carried out by HIQA on its own initiative or when required by the Minister or the Minister for Children and Youth Affairs as the case may be. Currently, section 9(1)(b) applies to the HSE, the Child and Family Agency, service providers under the Act, registered providers of designated centres and persons in charge of designated centres. This Head amends section 9 to take account of investigations into services provided by other healthcare providers. It also provides for HIQA to notify the Minister in advance where it proposes to undertake an investigation. Head 90 also includes a new subsection in section 9 (subsection (2AB) in regard to procedures to be followed. HIQA must give written notification to the public or private provider concerned when undertaking the investigation and give relevant documentation to the provider.

Amendment of section 10 of the Act of 2007

91. Provide that:

The Act of 2007 is amended by substituting the following for section 10:

""Standards set by Authority"

10. (1) In this section, "standards" means standards set by the Authority under section 8(1).

(2) Subject to subsection (4), before submitting a draft standard to the Minister for approval the Authority shall-

(a) publish the proposed draft on the Internet website of the Authority and in such other manner as the Authority may determine, and

(b) issue a notice on the Internet website of the Authority to the public seeking written comment on the draft before a date as specified by the Authority in the

notice, and in accordance with any requirement prescribed by the Minister for this purpose.

(3) The Authority shall consult with such other persons on the draft standard referred to in subsection (2) in accordance with any requirements prescribed for this purpose by the Minister.

(4) The Authority shall notify the Minister before undertaking a consultation under this section.

(5) Following consideration of any comments received under subsection (2) and consultation under subsection (3), and where the Authority proposes to proceed with the draft standard, the Authority shall submit to the Minister for approval the draft standard either in the form in which it was published or with such other changes as the Authority may determine.

(6) Where the standards referred to in subsection (5) relate to services provided under the Child and Family Agency Act 2013, the Minister shall not approve the proposed standards without the consent of the Minister for Children and Youth Affairs.

(7) As soon as practicable after a standard is approved by the Minister, the Authority shall publish the standard on the Internet website of the Authority and in any other manner as may be prescribed by the Minister, and shall publish a note on the standard in Iris Oifigiuil.

(8) A note referred to in subsection (7) shall identify the standard and specify the date on which the standard comes into operation.".

Explanatory note

Section 10 of the Health Act 2007 sets out arrangements in relation to standard setting. Currently, after considering any representation made during consultation on a proposed standard, and after making any changes HIQA thinks fit, HIQA submits the proposed standard to the Minister for approval. If a proposed standard relates to a function of the Child and Family Agency, the Minister cannot approve the proposed standard without the consent of the Minister for Children and Youth Affairs. This Head amends section 10 and sets out requirements for publishing and consulting on draft standards.

Under subhead (2), before submitting a standard to the Minister for approval, HIQA must publish a draft standard on the Internet and by any other means that HIQA thinks appropriate and invite written comment from the public on the draft before a date as specified by HIQA in the notice and in line with any requirements prescribed by the Minister.

Under subhead (3), HIQA must also consult with other persons in accordance with requirements prescribed by the Minister. These for example could be the HSE, organisations representing private providers and organisations representing service users.

Subhead (4), requires HIQA to notify the Minister prior to undertaking a consultation.

Following consideration of any comments received under subhead (2) and consultation under subhead (3), and where HIQA decides to proceed with the draft standard, it shall submit it to the Minister for approval in its published form or with other changes as HIQA consider necessary - Subhead (5).

Subhead (6) replicates the current role of the Minister for Children and Youth Affairs.

Under subhead (7), once a standard is approved by the Minister, HIQA must publish the standard on the Internet and in any other form the Minister may prescribe. HIQA must also publish a note on the standard in Iris Oifigiuil. Subhead (8) provides that this note must identify the standard and indicate the date on which the standard comes into operation.

Amendment of section 12 of the Act of 2007

92. Provide that:

The Act of 2007 is amended by substituting the following for section 12:

""Provision of information to Authority"
12.-The Authority may require -

(a) the Executive,
(b) the Agency,
(c) a service provider,
(d) a person carrying on the business of a private hospital, and
(e) a person carrying on the business of a prescribed private health service

to provide it with any information or statistics the Authority needs in order to determine the level of compliance by-

(i) the Executive,
(ii) the Agency,
(iii) a service provider,
(iv)a person carrying on the business of a private hospital, and
(v) a person carrying on the business of a prescribed private health service

with the standards set by the Authority in accordance with section 8(1).".

Explanatory note
Section 12 of the Health Act 2007 provides that HIQA may require the HSE, the Child and Family Agency, or a service provider to give HIQA any information or statistics HIQA needs in order to determine the level of compliance by these organisations with standards set by HIQA. Head 92 amends section 12 to include private healthcare providers. Detailed powers in relation to monitoring compliance and investigations are in Part 9 of the Health Act 2007.

Amendment of section 73 of the Act of 2007
93. Provide that:

(1) Section 73 (1) of the Act of 2007 is substituted by the following:

"**73**. (1) If an authorised person considers it necessary or expedient for the purposes of-
(a) monitoring compliance with standards in accordance with section 8(1)(c), or

(b) an investigation referred to in section 8 (1)(d),

the authorised person may enter and inspect at any time any premises-

(i) owned or controlled by-
(A) the Executive,
(B) the Agency,
(C) a service provider,
(D) a person carrying on the business of a private hospital or
(E) a person carrying on the business of a prescribed private health service, or

(ii) used or proposed to be used, for any purpose connected with the provision of services described in section 8 (1)(b) or (bb).

(2) Section 73 of the Act of 2007 is amended in paragraph (a) of subsection (4) by inserting-

"a person carrying on the business of a private hospital, or a person carrying on the business of a prescribed private health service" after "service provider".

Explanatory note
Section 73 provides for the right of entry and inspection by authorised person or chief inspector for the purposes of monitoring compliance with HIQA standards and investigations.

Currently, section 73(1) provides that where an authorised person considers it necessary for the purposes of monitoring compliance of HIQA standards or an investigation as referred to under section 8 of the Act, he or she may enter and inspect premises owned by the HSE, the Child and Family Agency, or a service provider or used or proposed to be used for the purposes of providing services described in section 8 (1) (c).

This Head amends subsection (1) of section 73 to also apply to premises owned, used or proposed to be used by persons carrying on a private hospital or a prescribed private health service.

Subparagraph (a) of subsection (4) is also amended under this Head to take account of private hospitals or prescribed private health services.

Amendment of section 74 of the Act of 2007
94. Provide that:

The Act of 2007 is amended by substituting the following for section 74:
""Requirement for consent of occupier or District Court warrant to enter dwelling"
74. (1) In this section, "dwelling" includes any part of a designated centre, private hospital, or premises used to carry on the business of a prescribed private health service occupied as a private residence.

(2) Notwithstanding section 73, an authorised person or the chief inspector, in the performance of functions under that section, may not enter a dwelling other than—

(a) with the consent of the occupier, or
(b) in accordance with a warrant from the District Court issued under section 75(2) authorising the entry.".

Explanatory note
Section 74 of the Health Act 2007 provides that, notwithstanding the right of entry under section 73 of that Act, the Chief Inspector of Social Services or an authorised person cannot enter a dwelling other than with the consent of the occupier, or in accordance with a warrant from the District Court authorising such an entry. "Dwelling" includes any part of a designated centre occupied as a private residence by the registered provider of the designated centre or by a member of staff of the registered provider. Head 94 amends the definition of "dwelling" in subsection (1) to include any part of a private hospital or premises used to carry on a prescribed health service that is used as a private residence.

Amendment of section 78 of the Act of 2007
95. Provide that:
The Act of 2007 is amended by substituting the following for section 78:

""Reports of Authority, authorised persons, the chief inspector and inspectors.
78.—(1) The Authority and the chief inspector may prepare and may publish reports related to activities and functions of the Authority or the chief inspector as the case may be, including reports–

(a) on compliance by a person with standards monitored in accordance with section 8(1)(c),
(b) on investigations referred to in section 8(1)(d),
(c) arising from the performance by the chief inspector of his or her functions under section 41,
(d) arising from the performance of functions under section 43 by an inspector appointed under that section, or
(e) arising from the performance of functions under section 70 by an authorised person or other person appointed under that section.

(2). Where the Authority or the chief inspector proposes to prepare a report referred to in subsection (1) and the report is in relation to compliance by a person with standards set under *section 8*, regulations applicable to designated centres or investigations under section 8(1)(d), the Authority or the chief inspector, as the case may be, shall—

(a) prepare a draft of the report, and

(b) give to the person concerned—

(i) a copy of the draft of the report, and

(ii) a notice in writing stating that the person concerned may, not later than 21 days from the date on which the notice was received by him or her, or such further period as the Authority allows, make submissions in writing to the Authority on the draft.

(3) The Authority shall, as soon as is practicable after—

(a) the expiration of the period referred to in subsection (2)(b)(ii), and

(b) having—

(i) considered the submissions (if any) referred to in subsection (2)(b)(ii) made before the expiration of that period on the draft report concerned, and

(ii) made any revisions to the draft of the investigation report which, in the opinion of the Authority, are warranted following such consideration,

prepare the final form of the report.

(4) The Authority shall give a copy of the final report to the person referred to in subsection (2)(b) before publishing the report.

(5) The Authority, an authorised person, the chief inspector, an inspector or a person appointed under section 72 is not liable in damages arising from any—

(a) report or other document prepared, or

(b) report published, or

(c) communication made,

in good faith.

Explanatory note

Section 78 is about reports of HIQA, authorised persons and the Chief Inspector. It currently provides that HIQA, authorised persons, the Chief Inspector or people appointed to assist the Chief Inspector are not liable in damages arising from reports or other documents prepared or communications made in good faith for the purposes of or in connection with monitoring compliance with standards, investigations or, in the case of the Chief Inspector, inspections. This Head amends section 78 by including procedures to be followed by HIQA in preparing reports.

Subhead (1) provides that HIQA and the Chief Inspector may prepare and may publish reports related to their activities and functions including reports on compliance with standards or investigations and reports arising from the performance of their functions and the functions of authorised persons.

Subhead (2) provides for a situation where HIQA or the Chief Inspector proposes to prepare a report on monitoring compliance or on an investigation, HIQA or the Chief Inspector, as applicable, must prepare a draft report and give a copy of it to the provider concerned, together with a notice stating that submissions can be made on the draft within a stated time

period. The intention is that the provider will have the opportunity to correct any factual statements or clarify an issue by giving additional information. It is not intended that submissions would challenge any regulatory judgements by HIQA or the Chief Inspector.

Subhead (3) provides that HIQA prepares the final draft having considered any submissions made. Subhead(4) requires HIQA to provide the final version to the provider before publication. Subhead (5) deals with qualified privilege.

Insertion of section 98A in the Act of 2007

96. Provide that:

The Act of 2007 is amended by inserting the following section after section 98:
"**98A**. (1) Without limiting the generality of section 98, the Minister, after consultation with the Authority and any other person whom the Minister considers appropriate, may make regulations for the purposes of *section 8* prescribing a private health service.
(2) A private health service may be prescribed under this section only if the service falls within the definition of a private health service set out in subsection (3).
(3) In this section, "private health service" means–

(a) a service offered or provided by a person other than the Executive or a service provider for-

(i) the screening, preservation or improvement of health and wellbeing,

or

(ii) the prevention, diagnosis, treatment or care of illness or injury, or

(b) any procedure offered or provided by a person other than the Executive or a service provider that is similar to forms of medical or surgical care but is not provided in connection with a medical condition,

but does not include any of the following-

(i) services provided at a centre registered by the Mental Health Commission or any other service regulated by the Mental Health Commission under the Mental Health Act 2001,
(ii) services provided at a designated centre,
(iii) a retail pharmacy business, or
(iv) complementary and alternative medicine;

"retail pharmacy business" has the meaning assigned to it by *section 2 (1)* of the Pharmacy Act 2007.".

Explanatory note
Regulations under the Health Act 2007 are provided for in Part 13 of the Act – sections 98 to 102. Head 96 inserts a new section in the Act, section 98A, allowing the Minister to prescribe private health services for the purposes of the Act. HIQA may then set standards for these services, can monitor compliance with standards set and can, if necessary, undertake investigations into these services. The Minister will make a regulation prescribing a health

service only after consultation with HIQA and any other person or group the Minister thinks appropriate.

For a service to be prescribed by regulation it must be a service coming within the definition of private health service. Private health service is defined in subhead (3) as:

> (a) a service offered or provided by a person other than the Executive or a service provider for-
>
> (i) the screening, preservation or improvement of health and wellbeing, or
>
> (ii) the prevention, diagnosis, treatment or care of illness or injury, or
>
> (b) any procedure offered or provided by a person other than the Executive or a service provider that is similar to forms of medical or surgical care but is not provided in connection with a medical condition.

As set out earlier, prescribed services are likely to be those higher risk services sometimes provided outside of a hospital setting, for example the provision of services involving the use of a general anaesthetic. The necessary related services associated with the prescribed service would also be encompassed.

For the avoidance of any doubt, the definition of private health service in subhead (3) excludes services that are already regulated. The definition also excludes alternative and complementary therapies.

Part 10: ENFORCEMENT

Most breaches of the Bill's provisions dealing with personal data and personal health data will be dealt with by the Data Protection Commissioner through his or her power to issue enforcement, information and prohibition notices (as per the Data Protection Acts). Under the Data Protection Acts, failure to comply with such notices may constitute an offence. In addition, there are other contraventions in the Data Protection Acts that lead directly to the committing of an offence.

However, this Bill also creates certain new information and data related offences in Parts 2, 4 and 5. It is proposed (under this Part) that where they are prosecuted by way of summary proceedings that the Data Protection Commissioner should bring those proceedings. Separately, Head 39 (in Part 3) provides for an offence in relation to false or misleading statements and provides that summary proceedings for an offence under that Head may be brought and prosecuted by HIQA (subject to prior consultation with the Data Protection Commissioner where the offence relates, in whole or in part, to a matter that falls under Head 33).

Specifically, Head 97 provides the whole or any part of proceedings under this Act may, at the discretion of the court, be heard otherwise than in public. Head 98 provides that, subject to Head 39, summary proceedings for an offence under this Act may be brought and prosecuted by the Commissioner. Summery proceeding for Head 39 offences will be brought by HIQA. Head 99 deals with offences by bodies corporate and directors and Head 100 deals with the possible forfeiture or destruction of data where a person is convicted of an offence under this Act. Head 101 deals with costs in proceedings.

Hearing of proceedings
97. Provide that:
The whole or any part of proceedings under this Act may, at the discretion of the court, be heard otherwise than in public.

Explanatory Note
This is a provision relating to the hearing of proceedings.

Proceedings for offences
98. Provide that:
(1) Subject to *Head 39*, summary proceedings for an offence under this Act may be brought and prosecuted by the Commissioner.

(2) Notwithstanding section 10(4) of the Petty Sessions (Ireland) Act, 1851, summary proceedings for an offence under this Act may be instituted within two years from the date of the offence.

Explanatory Note
This provision relates to the summary prosecution of offences by the Data Protection Commissioner. This is similar to section 28 of the Data Protection Acts except that the period in subhead (2) is two years rather than one year. The reference to Head 39 is because that

Head deals with certain offences (relating to false or misleading statements) that will be prosecuted by HIQA after consulting with the Commissioner.

Offences - directors and others of bodies corporate
99. Provide that:
(1) Where an offence under this Act has been committed by a body corporate and it is proved that the offence was committed with the consent or connivance, or was attributable to any wilful neglect, of a person who, when the offence was committed, was a director, manager, secretary or other officer of the body corporate, or a person purporting to act in that capacity, that person, as well as the body corporate, is guilty of an offence and may be proceeded against and punished as if he or she were guilty of the first-mentioned offence.

(2) Where the affairs of a body corporate are managed by its members, *subsection (1)* applies in relation to the acts and defaults of a member in connection with his or her functions of management as if he or she were a director or manager of the body corporate.

Explanatory Note
This is a standard provision. (This is similar to section 30 of the Data Protection Acts.)

Forfeiture or destruction of data
100. Provide that:
(1) Where a person is convicted of an offence under this Act, the court may order any data material which appears to the court to be connected with the commission of the offence to be forfeited or destroyed and any relevant data to be erased.

(2) The court shall not make an order under *subhead (1)* in relation to data material or data where it considers that some person other than the person convicted of the offence concerned may be the owner of, or otherwise interested in, the data unless such steps as are reasonably practicable have been taken for notifying that person and giving him an opportunity to show cause why the order should not be made.

(3) In this Head, "data" and "data material" have the same meanings as they have in the Act of 1988.

Explanatory Note
Section 31 of the Data Protection Acts deals with penalties for offences under that Act: including the forfeiture and destruction of data and data material. Where there are offences in this Bill, the penalty (a fine) is specified in each relevant Head. However, we propose to allow for the possibility of forfeiture or destruction of data and data material in certain cases where offences have been committed. This Head mirrors section 31 of the Data Protection Acts in that regard.

Costs in proceedings
101. Provide that:
(1) On convicting a person of an offence under this Act, the court shall, unless satisfied that there are special and substantial reasons for not so doing, order the person to pay to the

Commissioner or Authority, as appropriate, the costs and expenses, measured by the court, incurred by the Commissioner or Authority in relation to the investigation, detection and prosecution of the offence.

(2) An order for costs and expenses under *subhead (1)* is in addition to and not instead of any fine or penalty the court may impose.

Explanatory Note
This provision is similar to section 80 of the Consumer Protection Act 2007. It will help ensure that the Data Protection Commissioner and HIQA, as appropriate, can recoup costs and expenses incurred in relation to the investigation, detection and prosecution of the offences under this Bill.