

NATIONAL RESEARCH ETHICS COMMITTEES BILL

GENERAL SCHEME

July 2019

NATIONAL RESEARCH ETHICS COMMITTEES BILL

DRAFT GENERAL SCHEME

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Part 1: Preliminary and General

Head 1

Short title and commencement

Provide that-

1. (1) This Act may be cited as the National Research Ethics Committees Act 2019.
- (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 providing for the short title of the Act and commencement provisions.

General Note

It is important to note at the outset of reading this General Scheme that a particular legislative approach is being adopted to bring about the desired outcome of a unified National Research Ethics Committee framework for all health research.

Given the need for urgent reform of the current REC system for clinical trials of medicinal products and the need to be ready for the full entry into force of the new EU Clinical Trials of Medicinal Product Regulation 2014, it will be necessary to set up the National Clinical Trials of Medicinal Products REC as soon as possible. That will be done by amending the current statutory instrument (SI no 190 of 2004) and future proofing it against the Regulation.

This National Research Ethics Committee Bill provides for the establishment of all other National RECs.

The same National Office for Research Ethics Committee will be responsible for all of the National RECs.

This approach is designed to ensure consistency between all National RECs in all relevant matters except where, for example, the Clinical Trials Regulation provide specifically for something to be done in particular way or by a particular date –for example, timelines in relation to making decisions or the making of applications through the Clinical Trials Information System.

Head 2

Interpretation

Provide that-

“*appeals panel*” means a panel established under head 26;

“*Board*” means the Health Research Board;

“*expert member*”, in relation to an National REC, 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, or
- (d) belongs to a class or category of persons prescribed by the Minister for the purposes of this definition for the purpose of membership of a particular National REC;

“*health research*” means any of the following types of scientific research for the purpose of human health:

- (i) research with the goal of understanding normal and abnormal functioning, at molecular, cellular, organ system and whole body levels;
 - (ii) research that is specifically concerned with innovative strategies, devices, products or services for the diagnosis, treatment or prevention of human disease or injury;
 - (iii) research with the goal of improving the diagnosis and treatment (including the rehabilitation and palliation) of human disease and injury and of improving the health and quality of life of individuals;
 - (iv) research with the goal of improving the efficiency and effectiveness of health professionals and the health care system;
 - (v) research with the goal of improving the health of the population as a whole or any part of the population through a better understanding of the ways in which social, cultural, environmental, occupational and economic factors determine health status;
- and

includes action taken to establish whether an individual may be suitable for inclusion in the research;

“*lay member*”, in relation to a National REC, means a member of the committee who is not an expert member;

"*member*", in relation to an National REC, means a person who is appointed to the committee in accordance with *Head 16 and the Schedule*;

"*Minister*" means the Minister for Health;

"*National Office*" means the Office of National Research Ethics Committees established under *Head 6*;

"*National REC*" means a National Research Ethics Committee established under *Head 15*.

Explanatory Note

This head sets out the key definitions. The most important of which is the wide-ranging definition of health research which is drawn from the definition used in the Health Research Regulations (SI 314 of 2018) which itself is based on the definition that is applicable to the Health Research Board.

The other key definitions relate to the (new) National Research Ethics Committees (see Part 4 and 5) which will make decisions on the ethical dimension of health research projects that come to them and the (also new) National Office for Research Ethics Committees (see Parts 2 and 3) which will support, develop and oversee the new national REC framework.

The National Office will be located as a separate statutory office within the Health Research Board. This is based on Part 7 of the Health Act 2007. That Act established the Health Information and Quality Authority and Part 7 established the Office of the Chief Inspector of Social Services as a distinct statutory office within the Authority.

In order to ensure the independence of the National RECs and avoid potential conflicts of interests, the role of the Health Research Board is effectively limited to employing the staff of the National Office and related general operational oversight of the National Office. The Board will have no role in relation to the work of the National RECs or decisions made by the National RECs (or the Appeals Panels set up to hear appeals from decisions of the National RECs). The Minister will appoint the members of the National REC and the Appeals Panels. The National Office will prepare its Corporate Plan and Business Plan for approval by the Minister and establish National RECs with the approval of the Minister. These matters are addressed fully in Parts 2, 3, 4 and 5.

The right membership, in terms of skills, expertise and general backgrounds, of the new National RECs will be essential to their success. Given the nature of the work of health research ethics committees and the matters they consider it is a longstanding principle that the composition of such committees should be made up of expert and lay members.

Accordingly, one important element of all research ethics committees is that they should be broadly based in terms of membership. There has always been a difficulty in recruiting lay members. That difficulty can be compounded by having an over-expansive definition of "expert member" especially today where so many people have academic or professional qualifications. For example, should a person with a legal qualification be best regarded as an

expert or lay member? Consequently, the approach adopted in the definition of expert member is to define it narrowly but with scope for the Minister to make Regulations to expand it either generally or with reference to a particular National REC.

Recital 18 of the EU Clinical Trials Regulations 2014, as well as providing that it should be left to individual Member States to determine the appropriate body or bodies to be involved in the assessment of the application to conduct a clinical trial and to organise the involvement of ethics committees, has this to say about the membership of research ethics committees-

“Member States should ensure the involvement of laypersons, in particular patients or patients' organisations. They should also ensure that the necessary expertise is available. In accordance with international guidelines, the assessment should be done jointly by a reasonable number of persons who collectively have the necessary qualifications and experience.”

Another point about membership of National RECs is that some administrative or professional incentives, but not payment, will be important to ensure optimal participation by specialist clinicians. For example, consideration is being given to mechanisms deployed by other countries to ensure that the time spent by clinicians on such National Committees is recognised as critical to performance of their day-to-day healthcare role. It is not considered that this needs to be addressed in the Bill unless at the drafting stage it becomes essential to do so.

However, it is important to recognise that the work of the Chairperson (and Deputy Chairpersons) of the National RECs will, given the inevitable workload involved with those positions, require some remuneration if the right persons are to be attracted. This will be subject to discussion with the Department of Public Expenditure and Reform.

It will also be necessary to provide, in the usual way, for indemnity for non-public servants carrying out, in good faith, their bona fides duties as members of National RECs.

Head 3 Regulations

Provide that-

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

(2) Without prejudice to any provision of this Act, 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 sits 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.

Head 4 Expenses

Provide that-

4. The expenses incurred by the Minister or any other Minister of the Government in the administration of this Act shall, to such extent as may be sanctioned by the Minister for Public Expenditure and Reform, be paid out of moneys provided by the Oireachtas.

Explanatory Note

This is a standard provision.

Head 5 Review of operation of Act

Provide that-

5. (1) The Minister shall, not later than 5 years after the passing of this Act, commence a review of the operation of this Act.

(2) The Minister shall, not later than one year after the commencement of the review, make a report to each House of the Oireachtas of the Minister's findings and conclusions resulting from the review.

(3) In undertaking a review under this head, the Minister shall consult with such other Ministers of the Government as he or she considers appropriate and such other persons or bodies as he or she considers appropriate.

Explanatory Note

This is a standard provision to ensure that the legislation is working as intended and meeting its objectives. However, it is worth noting that the Minister will be concerned to ensure from the outset that the new framework is embedded quickly.

Part 2: National Office for Research Ethics Committees

Head 6 Establishment of the National Office

Provide that-

(1) The National Office for Research Ethics Committees is established as a statutory office within the Board.

(2) The National Office shall be headed by a person, known in this Act as the Head of the National Office, appointed by the Board and shall hold office and be paid such remuneration and any allowances for expenses that the Board may determine with the approval of the Minister given with the consent of the Minister for Public Expenditure and Reform.

(3) The Board may dismiss the Head of the National Office from his or her office if satisfied that the Head of the National Office-

(a) has become incapable through ill health of effectively performing the functions of the office,

(b) is adjudicated bankrupt,

(c) is convicted of a criminal offence,

(d) has without reasonable excuse failed to discharge his or her functions for a continuous period of 3 months beginning not earlier than 6 months before the day of dismissal, or

(e) should be dismissed for any other stated reason.

(4) The other employees of the National Office shall also be employees of the Board which shall determine their conditions of employment and duties and they shall report to the Head of the National Office in relation to the performance of those duties.

Explanatory Note

In terms of providing a “home” for the new National Office, the Minister has considered that creating a new statutory body for that purpose should only be proposed if existing bodies cannot be adapted and utilised. Conscious generally of limited resources, it is proposed that the National REC Office should be located as a statutory office (with specified functions as set out in the Bill) within the Health Research Board (HRB) in a way broadly similar to that of the Office of the Chief Inspector of Social Services within HIQA under the Health Act 2007.

The National Office rather than the Health Research Board will be responsible for the National RECs and the Board will have no role whatsoever in applications coming before the National RECs or appeals made to the Appeals Panel. Further, it will be the Minister who

appoints the members of the National RECs (see Head 16) and approves the Corporate Plan and Business Plan of the National Office (see Head 7).

The employees of the National Office will be employees of the Board and the Board will provide an operational infrastructure for the National Office and have a related operational oversight (as per head 7).

That approach will avoid potential conflict of interest possibilities that might arise from the HRBs other functions as the Office will be distinct from the funding side of the HRB. This approach also helps build on the existing well-established Health Research Board brand and expertise.

Head 7 Governance of National Office

Provide that-

- (1) The Board shall be responsible for providing infrastructural support and routine operational oversight of the National Office established under this Act.
- (2) Where the Board is concerned about any matter of infrastructural support or routine operational oversight concerning the National Office it shall investigate or cause the matter to be investigated and prepare and forward a report to the Minister on the findings from the investigations with recommendations, if any, for actions to be taken.
- (3) The Minister, where he or she considers it necessary for maintaining public confidence in the National Office, may investigate or otherwise arrange for the investigation of the National Office.

Explanatory Note

This head provides that the Health Research Board is responsible for providing infrastructural support and routine operational oversight of the National Office. Where the Board is concerned about any matter of infrastructural support or routine operational oversight concerning the National Office, it can investigate the matter and forward a report to the Minister on the findings from the investigations with recommendations, if applicable, for actions to be taken. None of this gives the Board any role in relation to the operation of the National RECs.

There is also provision for the Minister, where he or she considers it necessary for maintaining public confidence in the National Office to investigate or otherwise arrange for the investigation of the National Office.

Part 3: Functions of National Office

Head 8 Functions of National Office

Provide that-

(1) The functions of the National Office are those set out in this Act and include such incidental, supplementary and consequential actions as are necessary or expedient for the purposes of carrying out those functions.

(2) Subject to any directions that may be given by the Minister, the Head of the National Office shall prepare—

(a) the corporate plan for the National Office, and

(b) the business plan for the National Office,

to be approved by the Minister.

(3) A corporate plan covering a period of three years prepared under *subhead (2)* shall be approved by the Minister within six months after the establishment of the National Office and shall set out-

(a) the key objectives of the National Office for the period concerned and the strategies for achieving those objectives, and

(b) the uses to which the National Office proposes to apply its resources.

(4) A business plan prepared under *subhead (2)* shall be in the in the form and manner specified by the Minister and shall—

(a) indicate the National Office's activities for the period to which the business plan relates, and

(b) have regard to the corporate plan in operation at that time

(5) Whenever requested by the Minister, the Head of the National Office shall furnish information in relation to such matters pertaining to the implementation of the Corporate Plan and Business Plan as the Minister may specify.

Explanatory Note

This head provides that the functions of the National Office are those set out in this Act.

The head also provides for preparation of a Corporate and Business Plan for the National Office, to be approved by the Minister, to guide its work and that whenever requested by the Minister, the Head of the National Office must furnish information in relation to such matters

relating to the implementation of the Corporate Plan and Business Plan as the Minister may specify.

Head 9: Information on the internet in relation to National Office

Provide that-

The National Office shall provide, and update in a timely manner, on a website maintained by it-

- (a) contact details for the National Office,
 - (b) the name of each National REC established under *head 15* and a description of the area of health research covered by it,
 - (c) the names of the members of each National REC and their identification as expert members or lay members,
 - (d) the decisions made by each National REC in relation to health research proposals referred to it,
 - (e) the names of the persons on appeal panels established under *head 26* and their identification as expert members or lay members,
 - (f) the decisions made by appeals panels in relation to health research proposals referred to it,
 - (h) the number and type of complaints received about the National Office and National RECs and the outcomes of such complaints.
- (d) any other matters that the National Office considers appropriate.

Explanatory Note

This is a transparency measure to ensure openness about the work of the National Office and the National RECs.

Head 10 Development and support of National RECs

Provide that-

- (1) The Head of the National Office shall subject to any general directions by the Minister-
 - (a) take such actions and initiatives as are appropriate to develop a high performing system of National RECs,

(b) provide such administrative and other support as is necessary to enable the National RECs to perform their functions efficiently and effectively.

Explanatory Note

This head provides for the development and support functions of the National Office in relation to the National RECs. These will be critical to the success of the new National REC structure.

Head 11 Preparation and Issuing of Guidelines

Provide that-

(1) The National Office may prepare and issue such guidelines as it considers appropriate in relation to the operation of a National REC either with regard to a particular National REC or more generally.

(2) The purpose of any guidelines issued under this head is to assist a National REC to perform its function under this Part in an effective and efficient manner.

(3) Before issuing guidelines under this head, the National Office 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 National Office shall publish the guidelines on its website.

(5) A National REC shall have regard to the guidelines issued when performing its functions.

(6) Where the National Office is of the view that the guidelines are not adhered to it shall take such actions as it considers appropriate.

Explanatory Note

This head provides that the National Office may prepare and issue guidelines in relation to the operation of the National RECs either with regard to a particular National REC or more generally. The scope for such guidelines is wide-ranging but is likely to include, for example, standard operational procedures, how to deal with research proposals involving vulnerable groups generally or specific vulnerable group.

The head also sets out the consultative procedure to be used when it comes to issuing Guidelines under this head.

Given the direct relationship between the National Office and the National RECs it is not considered appropriate or necessary that the guidelines should be mandatory with penalties for non-observance. If the guidelines are not being adhered to, the National Office will be aware and can take such actions as it considers appropriate. That could include talking to the

Chairperson of the Committee (see Head 12) about the matter or making a report to the Minister (also Head 12).

Head 12 Monitoring and oversight by National Office of National RECs

(1) The National Office shall monitor the performance of a National REC and in doing so shall have particular regard to the guidelines issued under *head 11*.

(2) Where the National Office forms a view that a National REC is not performing its functions properly it shall notify the Chairperson of the National REC concerned setting out its concerns and the reasons for those concerns.

(3) A chairperson of a National REC who receives a notification under *subhead (2)* shall reply to that notification within 30 days of receiving it.

(4) The National Office shall consider the reply received under *subhead (3)* and may seek additional information from the chairperson which the chairperson shall provide as soon as practicable.

(5) When such additional information has been received or if it has not been received within 30 days of the request for information under *subhead (4)* the National Office shall, having considered all the information it has available to it, make one of the following decisions-

(a) take no further action on the basis that it is now satisfied,

(b) write to the chairperson of the National REC concerned and advise that certain specified actions need to be taken within a specified timeframe,

(c) refer the matter to the Minister with a recommendation for action, including the removal of the chairperson and or other members of the National REC.

(6) When the Minister has considered a matter referred to him or her under *subhead (5) (c)*, he or she shall take no action or such action as he or she considers appropriate and necessary, including the removal of the chairperson and other members of the National REC.

Explanatory Note

This head is concerned with the monitoring and oversight role that the National Office has in relation to National RECs and the actions it can take where it is concerned. It is likely, in reality, that informal engagement will take place between the National Office and a National REC where a problem is perceived or uncovered. The formal provisions in this head may, therefore, be seen as being applicable where the informal approach has failed.

The ultimate sanction is for the Minister to remove the chairperson and or other members of the National REC.

Head 13 Monitoring and oversight by National Office of health research approved under *Part 5*

Provide that:

(1) The National Office shall monitor, in terms of ethical considerations, the carrying out of research that has been approved by a National REC under *Part 5*.

(2) A person whose research has been approved under *Part 5* shall notify the National Office of the date on which the carrying out of the research commences and the date on which it finishes.

(3) (a) For the purposes of this head, the National Office shall have the power to request a person referred to in *subhead (2)* to provide such -

(i) information, and

(ii) interim and final reports,

as it considers necessary to determine that the research is being carried out in line with the application made and approved under *Part 5*.

(b) Where there is a failure to co-operate with the National Office in accordance with *paragraph (a)*, the National Office shall advise the National REC which gave the approval and the National REC may withdraw its approval.

(4) (a) A person whose proposal has been approved under *Part 5* shall notify the National Office 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) Where there is a failure to comply with *paragraph (a)*, the National Office shall advise the National REC which gave the approval and the National REC may withdraw its approval.

(5) (a) A person whose proposal has been approved under *Part 5* shall notify the National Office of an adverse event which arose from or is connected with the carrying out of the health research concerned.

(b) The notification under *paragraph (a)* shall also specify any actions the person proposes to take in relation to the adverse event.

(c) Where there is a failure to comply with *paragraph (a)* and (b), the National Office shall advise the National REC which gave the approval and the National REC may withdraw its approval.

Explanatory Note

It is important to the success of the framework proposed in the Bill that the carrying out of health research ethically approved by a National REC under Part 5 should be monitored by the National Office and that is provided for in this Head. Monitoring was considered central in the 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.”

It is considered that the National Office with its full time staff is better suited to the monitoring process than the part-time National REC that gave the ethical approval under Part 5.

For the purposes of being effective, the National Office will have certain powers to request information and reports and a failure by a National REC to co-operate with the National Office may lead to the ethical approval granted under *Part 5* being withdrawn.

The provisions in subheads (4) and (5) place an onus on a person whose research proposal has been approved under Part 5 to notify the National Office in writing of any proposed change in a material fact or of a material circumstance which relates to the carrying out of the health research concerned. Similarly with adverse events that arise from or are connected with the carrying out of the health research concerned. A failure to comply with those requirements may lead to ethical approval being withdrawn by the National REC.

Head 14: Advice, educational outreach and training for RECs

Provide that-

The National Office may-

- (a) in relation to National RECs 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 Act, provide educational outreach and training as the National Office considers appropriate for the promotion, maintenance and development of health research ethics in the State.

Explanatory Note

This Head is about allowing the National Office to provide advice and training to National RECs and educational outreach and training to other research ethics committees with a view to raising the overall operational and decision-making quality of all RECs operating in the State. This is a necessary and desirable provision given that local/ institutional RECs will remain part of the overall REC framework in Ireland.

Part 4: National Research Ethics Committees

Head 15 Establishment of National Research Ethics Committees

(1) A National REC is a research ethics committee established, with the approval of the Minister after he or she has consulted with the Board, by the Head of the National Office, for the purposes of giving an ethical decision with effect throughout the State on proposals for health research transmitted to it by the National Office under *head 19*.

(2) The Minister shall prescribe the descriptions, categories or types of health research that may be considered under Part 5 by a National REC.

(3) The Head of the National Office shall in establishing a National REC under *subhead (1)* have regard to ensuring that there are so many National RECs as he or she considers necessary and appropriate for-

(a) the proper consideration of different descriptions, categories or types of health research that have been prescribed by the Minister for the purposes of this Act to be considered by a National REC, and

(b) the efficient and effective consideration of proposals likely to be considered by the National RECs.

(4) The Minister may, after consulting with the Board, direct the Head of the National Office to establish a National REC in a specified area of health research.

Explanatory Note

This is a key provision in the Bill in that it provides for the establishment of a system of National RECs. Unlike an institutional REC which can only give ethical approval in relation to health research in its own institution, a National REC will be able to give a decision on ethical approval that will have effect throughout the State on the health research proposals concerned (see Head 25).

As per subhead (1), the establishment of a National REC by the Head of the National Office requires the approval of the Minister who will consult with the Health Research Board. Consulting with the Board seems appropriate and desirable given its role in and its knowledge of the health research scene in Ireland.

Subhead (2) provides that it will be the Minister who will prescribe the descriptions, categories or types of health research that may be considered under Part 5 by a National REC. This is to ensure that the National RECs are concerned with research projects of significant importance and complexity. Further, head 19(5) provides that a National REC may only consider proposals that the National Office has transmitted to it.

More than one National REC will be required and that is provided for in subhead (3) which provides that the Head of the National Office can establish so many National RECs as are considered necessary and appropriate for the efficient and effective consideration of proposals likely to be considered by the National RECs.

For completeness and in case of necessity, it is also being provided that the Minister may, after consulting with the Health Research Board, direct the Head of the National Office to establish a National REC in a specified area of health research.

Head 16 Membership and operation of National RECs

Provide that-

(1) The Minister shall appoint the members of a National REC subject to the provisions of this head.

(2) A National REC shall consist of expert and lay persons who having regard to the functions of the National REC are suitably qualified in terms of diversity of skills, qualifications, interests and backgrounds to make decisions on applications likely to be made to the National REC under *Part 5*.

(3) The provisions of the Schedule shall apply to the membership and operation of a National REC.

(4) The Head of the National Office shall

(a) take whatever measures he or she considers appropriate to publicly invite expressions of interests from persons who may be interested in being appointed to a National REC.

(b) set a deadline for the receipt of expression of interests under *subhead (4) (a)*.

(5) (a) Where, after consideration of the expressions of interest made under *subhead (3)*, the Head of the National Office is of the view that it is necessary, in relation to having the appropriate membership composition on a National REC, to invite one or more other persons having particular skills, qualifications, interest or background to be considered by the Minister for membership of a National REC, he or she shall make such arrangements.

(b) The Head of the National Office shall set a deadline for a response to any invitations issued under *subhead (5)(a)*.

(6) When the processes provided for in both *subhead (4)* and *(5)* have been completed, the Head of the National Office shall forward to the Minister for consideration for appointment to a National REC the relevant details of persons who

(a) expressed an interest under *subhead (4)* or

(b) accepted an invitation under *subhead (5)*

that are suitably qualified in terms of diversity of skills, qualifications, interests and backgrounds to make decisions on applications likely to be made to the National REC

(7) No person shall be appointed to a National REC by the Minister unless he or she is a fit and proper person.

Explanatory Note

Subhead (1) provides the Minister will appoint the members of a National REC.

Subhead (2) provides that a National REC shall consist of expert and lay persons who having regard to the functions of the National REC are suitably qualified in terms of diversity of skills, qualifications, interests and backgrounds to make decisions on applications likely to be made to the National REC

Subhead (3) provides that the provisions of the Schedule apply to the membership and operational aspects of the National RECs.

Subheads (4), (5) and (6) concern the recruitment of members of National RECs. Subhead (4) provides for public expressions of interest. Subhead (5) is designed to ensure that the required skills set for the membership of a National REC can be realised by allowing the National Office to invite persons with the requisite skills, interests, qualifications or background where the expressions of interests process has not yielded the appropriate membership mix and needs to be supplemented. Subhead (6) provides that when the processes provided for in both subhead (4) and (5) have been completed, the Head of the National Office will forward to the Minister for consideration for appointment to a National REC the relevant details of persons who expressed an interest under subhead (4) or accepted an invitation under subhead (5). that are suitably qualified I terms of interests, qualifications and experience.

Subhead (7) is a standard provision regarding appointing fit and proper persons.

Head 17 Sub-committees of National RECs

Provide that-

(1) A National REC may appoint, after advising the National Office, one or more sub-committees to provide advice and assistance to it with its work.

(2) The acts of a sub-committee are subject to confirmation by the National REC unless the National REC dispenses with the necessity for confirmation.

(3) A National REC may, at any time, dissolve a sub-committee.

(4) A decision under *Part 5* may not be made by a sub-committee of a National REC.

Explanatory Note

This Head deals with sub-committees which may be appointed by a National REC to help it with its work. 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) makes it expressly clear that a sub-committee is not empowered to make a decision on any matter arising for decision under Part 5.

Head 18 Functions of National RECs

Provide that-

The functions of a National REC are those set out in *Part 5* and include such incidental, supplementary and consequential actions as are necessary or expedient for the purposes of carrying out those functions.

Explanatory Note

This is a self-explanatory provision. For clarity, the specific functions of National RECs are set out in Part 5.

Part 5: Applications to and decisions of National Research Ethics Committees

Head 19 Application to National Office for referral of a research proposal to a National REC

Provide that-

(1) A person proposing to carry out health research to which this Act applies may apply to the National Office for his or her proposal to be considered by a National REC 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 National Office, and

(b) accompanied by the prescribed fee, if any.

(3) The National Office shall, as a preliminary matter, decide whether the proposal is-

(a) one to which this Act applies, or

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

and shall notify the applicant accordingly.

(4) The National Office shall put in place such procedures as it considers appropriate to facilitate the transmission of a proposal for consideration by a national REC.

(5) A National REC may only consider proposals that the National Office has transmitted to it under *subhead (4)* or that another national or EU enactment provides for it to consider.

Explanatory Note

This head sets out the procedure for a person making an application to the National Office for his or her proposal to be considered by a National REC for a decision on the ethics of the health research.

To ensure uniformity in applications, they must be made in the form and manner specified by the National Office and accompanied by the prescribed fee, if any.

When an application is received by the National Office, the Office must as a preliminary matter, decide whether the proposal is one to which this Act applies or not, as the case may be. This is covered in Head 19. Where it decides the proposed research does not fall under the Act, it must advise the applicant of that fact.

It is the National Office that will forward the application to an appropriate National REC for consideration. For example, if the area of research is genomics and a specialist genomic

National REC has been established then the National office will forward the application to that National REC.

A National REC may only consider proposals that the National Office has transmitted to it under this head.

Head 20 Proposals for health research to which this Act applies

Provide that-

The National Office shall specify on its website, health research prescribed by the Minister under *head 15*, in relation to which applications can be made under *Head 19*.

Explanatory Note

Given the number of health research projects undertaken in the State every year, it is important that the National RECs are not overwhelmed with applications and that has been addressed in head 15. This information head requires the National Office to set out publicly on its website health research in relation to which applications can be made for consideration by National RECs.

Head 21 Consultation by a National REC

Provide that-

(1) In considering the matter or matters under *Heads 22(2)*, a National REC 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) The views of a person consulted under *subhead (1)* shall be recorded by the Committee in the minutes of the meeting where the proposal concerned was considered

(3) A person who is consulted under *subhead (2)* shall, as soon as he or she becomes aware of it, advise the National REC of his or interest in or association with the proposal being considered.

(4) A person who is consulted under *subhead (2)* may be paid a fee by the National REC where this is agreed by the National Office.

Explanatory Note

When considering research applications, subhead (1) allows the National REC to consult with other persons who may have expertise in the research area under consideration.

Transparency is addressed under subhead (2) which provides that the views of a person consulted under subhead (1) shall be recorded by the Committee in the minutes of the meeting where the proposal concerned was considered

Subhead (3) deals with matters of material interest between the research and the expert being consulted. Subhead (4) allows for the possibility of a fee to be paid.

Head 22 Ethical Matters to be considered by National REC

Provide that-

A National REC to which a proposal is transmitted for consideration under *Head 19* shall consider the ethics of the health research on the basis of 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,
- (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 on ethical consideration issued by the National Office under *Head 11*.

Explanatory Note

This head identifies the matters to be considered by a National REC in making its decision on ethical approval.

Head 23 Decisions on applications

Provide that-

(1) Where a National REC has considered the relevant matters in *Head 22*, the National REC may refuse to give its ethical approval to the proposal if it is not satisfied that one or more of those matters has not been met.

(2) Where a National REC has considered the relevant matters in *Head 22*, the National REC shall give its ethical approval to the proposal if it is satisfied that those matters have been met.

(3) Subject to *subhead (4)*, a National REC shall, not more than

(a) 40 days, or

(b) a period for ethical consideration of health research specified in a national or European Union enactment,

after receiving the proposal under *Head 19*, notify the person proposing to carry out the health research in writing of its decision.

(4) Where an National REC makes a request for additional information, the number of days specified in *subhead (3)* for the consideration of the proposal shall be suspended from the time the National REC makes the request up until the time the information is provided within a period specified by the National REC or agreed with the person making the application.

(5) If the decision of the National REC is that the proposal is approved (with or without conditions), the notification under *subhead (3)* shall include a statement of-

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

(b) matters identified as possible adverse events that must be reported by the person to the National Office should they occur in the carrying out of the research.

(6) If the decision of the National REC is that the proposal is refused the notification under *subhead (3)* shall include-

(a) the reasons for the refusal, and

(b) a statement that the person may appeal the refusal under *Head 27*.

Explanatory Note

This head directly follows on from *head 22* which sets out the ethical matters to be considered by a National REC in making a decision.

It makes clear that where a National REC has considered the relevant matters in *head 22*, it may refuse to give its ethical approval to the proposal if it is not satisfied that one or more of those matters has not been met. Where a National REC is satisfied that the relevant matters in *head 22*, have been met it must give its ethical approval to the proposal.

Where the decision is to refuse ethical approval to the health research concerned, the applicant must be provided with the reasons for the refusal and be informed that an appeal can be made.

Head 24 Notification of acceptance of decision or intention to appeal a decision

Provide that-

Where a person who has been notified of a decision under *Head 24*, he or she shall notify the National REC 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 27* or make a complaint under *Head 34*, or
- (c) does not accept the decision and intends either to appeal it under *Head 27* or make a complaint under *Head 34*.

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 National REC, 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 the National REC, or
- (c) does not accept the decision and intends either to appeal it or make a complaint in relation to the National REC.

Head 25 Effect of approval under *Head 23* or *Head 27*

Provide that-

(1) Where a proposal to carry out health research is approved under *Head 23* or *Head 27* no institution that is in receipt of any funding from the State or research ethics committee established or jointly established by such an institution shall request or require, as a condition of the research being carried out in that institution, that any examination of the matters referred to in *Head 22* be done.

(2) Where an institution or research ethics committee referred to in *subhead (1)* makes a request or imposes a requirement of the nature specified in *subhead (1)*, the person whose research has been approved under *Head 23* or *Head 27* shall notify the National Office of the request or the requirement.

(3) Upon receipt of a notification under *subhead (2)*, the National Office shall write to the institution or research ethics committee concerned and the institution or research ethics committee shall co-operate with any request for information made by the National Office under this subhead.

Explanatory Note

This Head is very important to the success of the ethical approval structure provided for under this Part of the Bill in terms of ensuring that a decision by a National REC to grant ethical approval cannot be revisited by institutions or other RECs.

Head 26 Appeals Panel

(1) The Minister shall, subject to the provisions of this head, establish an appeals panel to hear appeals from the decisions of a National REC under this *Part*.

(2) The provisions of *subheads (4) to (7)* of *head 16* shall apply, as appropriate, to the appointment of persons to an appeals panel.

(3) An appeals panel established under *subhead (1)* shall consist of 7 persons, one of whom shall be appointed by the Minister to be the chairperson and another to be the deputy chairperson, who in the opinion of the Minister and having regard to the functions of the appeals panel are suitably qualified in terms of diversity of skills, qualifications, interests and backgrounds to make decisions on appeals likely to be made under *head 27*.

(3) At least two of the members of an appeals panel shall be lay persons.

(4) None of the persons appointed to an appeals panel to hear an appeal shall have been a member of the National REC against which the appeal is made.

(5) An appeal panel shall determine its own procedure.

(6) An appeal made under *subhead (1)* shall be considered by an appeals panel within 40 days or such other period that may be set out in a national or European Union enactment in relation to the type of research concerned.

(7) Having considered an appeal under this head the appeal panel shall—

- (a) confirm the decision,
- (b) vary the decision, or
- (c) allow the appeal,

and shall notify the appellant and the National Office of the decision and the reasons for the decision.

(8) The National Office shall provide such administrative and other support as is necessary for the appeal panel to perform its functions under this head in an efficient and effective manner.

(9) There may be paid by the National Office to the members of an appeals panel such allowances in respect of reasonable expenses properly incurred by them in the performance of their duties and responsibilities.

(10) (a) An appeal on a point of law may be made by the appellant from a decision of the appeals panel to the Circuit Court within 30 days of having being notified of the decision.

(b) The person making the appeal under *subhead 10 (a)* shall inform the National Office that an appeal has been made.

Explanatory Note

In the interests of fairness, there needs to be an appeals process where an application for ethical approval is refused by a National REC. This head provides the mechanism –an appeals panel- and head 27 sets out the appeals procedure and decision making process. The head also provides, again in the interests of fairness, that an appeal, on a point of law, may be made to the Circuit Court from a decision of the appeals panel.

Head 27 Appeal from a decision under *Head 23*

Provide that-

(1) An application for an appeal to an appeals panel established under *head 26* shall be made to the National Office-

- (a) in the specified form and manner,
- (b) shall set out the grounds for the appeal,

(c) be accompanied by the prescribed fee, if any.

(2) The National Office shall refer an appeal under this head to an appeals panel for consideration.

(3) An appeal under this Head shall be considered and decided on by an appeals panel in the manner provided in *Heads 22 and 23(1) and (2)*.

Explanatory Note

Appeals must be made to the National Office which will refer them to an appeals panel established under Head 26. Under subheads (1), 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 but will be refunded if successful.

Subhead (2) makes sure that the same criteria are applied when considering the appeal as should be applied when considering an initial application.

Part 6: Offences

Head 28 Offence - False or misleading statements or representations

Provide that-

(1) A person is guilty of an offence if, for the purposes of an application under *Head 19*, an appeal under *Head 27* or a complaint under *Head 34* or *Head 35*, 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 13*, 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 a National REC 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 *Part 5* 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) Summary proceedings for an offence under this head may be brought and prosecuted by the Head of the National Office.

Explanatory Note

This head 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 deliberate actions that undermine the system.

Head 29 Offences by bodies corporate

Provide that-

(1) Where an offence under this Act is 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 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, shall be 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 in an offences section where a body corporate may have been involved in the offence concerned.

Head 30 Hearing of proceedings

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 standard provision relating to the hearing of proceedings.

Head 31 Proceedings for offences

Provide that-

Summary proceedings for an offence under this Act may be brought and prosecuted by the National Office.

Explanatory Note

This is a standard provision relating to the summary prosecution of offences.

Head 32 Destruction, erasure or forfeiture of data or other material

Provide that-

(1) Where a person is convicted of an offence under this Act, the court may order any data or material, including bodily samples, which appears to the court to be associated with or arise from the commission of the offence to be destroyed, erased or forfeited.

(2) The court shall not make an order under *subhead (1)* in relation to data or material 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 or her an opportunity to show cause why the order should not be made.

Explanatory Note

This provision allows for the possibility of any samples or data associated with or arising from the research where an offence has been committed to be destroyed, erased or forfeited by way of a court order. It also provides for a situation where the court order may not make such an order.

Part 7 Miscellaneous Provisions

Head 33 No requirement to provide personal data

Provide that-

Nothing in this Act shall be construed as

- (a) requiring any person to provide personal data to a person whose proposal has been approved under *Part 5*.
- (b) authorising any person to disclose personal data to a person whose proposal has been approved under *Part 5* where such disclosure would otherwise not be authorised in law.

Explanatory Note

The purpose of this provision is to make clear that ethical approval by a National REC or an Appeals Panel does not create any obligations on any person to release personal data to the researcher or to permit a disclosure that would otherwise be unlawful.

Head 34 Complaints to the National Office about a National REC

Provide that-

(1) An applicant under *Head 19* or an appellant under *Head 27* who is of the view that he or she has been affected by the procedural conduct of an National REC or a member of a National REC, in the performance of its or his or her functions under this Act may, in accordance with *subhead (2)*, make a complaint to the National Office 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 National Office, and
- (b) set out the grounds for the complaint.

(3) Where the National Office receives a complaint under *subhead (1)* it shall (where the prescribed fee, if any, has accompanied the complaint), without delay, investigate the complaint and-

- (a) the complainant, and
- (b) the National REC and members of the National REC concerned,

shall co-operate with the National Office in carrying out the investigation under this head.

(4) The National Office 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 National Office carrying out an investigation under this head dismisses a complaint under *subhead (4)(a)* it shall notify-

- (a) the complainant, and
- (b) the National REC and members of the National REC

of the decision and the reasons for it.

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

- (a) the complainant, and
- (b) the National REC and members of the National REC,

of the decision to do so.

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

(8) The National Office investigating the complaint under *subhead (1)* shall on concluding its investigation report to the Minister on its findings and with its recommendations.

(9) The Minister shall consider the report and recommendations made to it under *subhead (8)* and shall notify the National Office of the actions, if any, it wishes the National Office to take in relation to the matter and the period within which those actions must be taken.

Explanatory Note

This Head deals with the making and investigation of complaints against National RECs or its members. This is separate from the appeals process provided for under Head 27.

Head 35 Complaints about the ethical conduct of a person carrying out research

Provide that-

(1) A person affected by the ethical conduct of a person carrying out research approved under *Part 5* may, in accordance with *subhead (2)*, make a complaint in writing to the National Office.

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

- (a) do so in the form and manner specified by the National Office, and
- (b) set out the grounds for the complaint.

(3) Where the National Office receives a complaint under *subhead (1)* it shall, without delay, notify-

- (a) the National REC which approved the application, and
- (b) the researcher who is the subject of the complaint,

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

(4) The National Office, in 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 otherwise without merit, or
- (b) seek to resolve the complaint through informal resolution.

(5) Where the National Office carrying out an investigation under this head dismisses a complaint under *subhead (4)(a)* it shall notify-

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

of the decision.

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

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

of the decision to do so.

(7) Where informal resolution under *subhead (4)(b)* is unsuccessful, the National Office shall notify the parties referred to in *subhead (6)* and continue to investigate the complaint under this head.

(8) Where the National Office 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 National Office

(9) The National Office shall, on concluding its investigation, report to-

- (a) the National REC concerned,
- (b) the complainant, and
- (d) the researcher who is the subject of the complaint,

with its findings and the actions it recommends that the National REC concerned should take.

(10) The actions that a National REC may take under *subhead (9)* are to-

- (a) withdraw the approval given under *Part 5*,
- (b) vary the conditions under which the approval was given under *Part 5*,
- (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 National REC is not satisfied with the measures taken it may withdraw the approval given under *Part 5*.

Explanatory Note

This Head deals with the making and investigation of complaints against researchers carrying out health research ethically approved under Part 5. It covers complaints that may be made by a person affected by the ethical conduct of a person carrying out the approved research.

Head 36 Annual Report

Provide that:

(1) The National Office shall make an Annual Report to the Minister on such date as the Minister may determine and covering such matters as the Minister may specify and that report should be made available on the website of the National Office.

(2) The annual report of the Board shall report on such matters related to the National Office as are considered appropriate by the Board.

Explanatory Note

This provision ensures that the operation of the National Office and National RECs are subject to annual reporting.

Head 37: Power of National Office to specify the form of documents

Provide that-

33. (1) The National Office may specify the form of any documents (including in relation to application and appeals under *Part 5*) required for the purposes of this Act as it thinks fit.

(2) The power of the National Office under *subhead (1)* may be exercised in such a way as to include in the specified form of any document referred to in that subsection a statutory declaration—

(i) to be made by the person completing the form, and

(ii) as to whether the particulars contained in the form are true and correct to the best of that person's knowledge and belief.

(3) The form of a document specified under this head shall be—

(a) completed in accordance with such directions and instructions as are specified in the document, and

(b) accompanied by such other documents as are specified in the document.

so provided in the manner (if any) specified in the document.

Explanatory Note

This gives the National Office the power to specify forms. This will allow information to be provided in a manner that meets the needs of the National Office. It complements other provisions such as head 19 dealing with applications.

Head 38 Power of National Office to extend time

Provide that-

Where—

(a) a provision of this Act specifies a period not later than which a person is required to provide any information to the National Office or a National REC, and

(b) the National Office is satisfied, on the basis of a submission made to it by that person in that regard, that it is not reasonably practicable for the person to provide that information to the National Office or National REC within that period, the National Office may, by a notice in writing given to the person, extend that period by such further period as the National Office is satisfied is a period within which it is reasonably practicable for the person to provide that information.

Explanatory Note

This provision gives some flexibility in relation to timelines for providing information to the National Office and National RECs.

Head 39 Fees

Provide that-

(1) The Minister may, after consulting with the Minister for Business, Enterprise and Innovation and any other Minister of the Government that he or she thinks is necessary, make regulations prescribing fees to be paid to the National Office for-

(i) applications made under *Head 19*,

(ii) appeals made under *Head 27* any fee payable for an appeal shall be returned if the appeal is successful.

(2) The Regulations made under *subhead (1)* may prescribe for different fees in relation to different areas of research and different classes of persons.

(3) Fees forwarded under this head shall be regarded as reducing the income of the National Office.

(4) The National Office 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.

Explanatory Note

While it is not intended that a researcher making an application to have his or her research project considered by a National REC under this Act will have to pay a fee, it is nonetheless considered prudent to have that possibility provided for in the Act. Further, the head provides that different fees may be payable in relation to different areas of research or by different classes of persons. This could, for example, be used where the application is made by a not for profit applicant. It is likely that a fee may be payable in relation to an appeal against the decision of a National REC but refunded where the appeal is successful.

Head 40 Prohibition on seeking or receiving payments or benefits

Provide that-

(1) No member of a National REC or an appeal panel may seek or receive any payment, fee, financial or other benefit from a person in respect of any application or appeal made under *Part 5*.

(2) Where a member of a National REC or appeal panel receives any payment, fee, financial or other benefit from a person in respect of any application or appeal under *Part 5* he or she shall return it to the person concerned and advise the National Office accordingly.

Explanatory Note

This head is intended to ensure that no undue influence is exercised on members of National RECs or appeal panels and that where such influence is sought to be brought to bear that it is reported to the National Office.

Head 41 Application for Consent Declaration

Provide that-

A person making an application under *head 19* shall indicate, as part of the application, whether it is intended to make an application for a consent declaration to the Health Research Consent Declaration Committee established by the Minister under the Data Protection Act 2018 (Section 36(2)) (Health Research) Regulations 2018 (Statutory Instrument Number 314 of 2018).

Explanatory Note

As consent is a very significant ethical issue, it is considered important that where it is not intended to seek consent for the processing of personal data for health research and to seek instead a consent declaration under the Health Research Regulations (SI 314 of 2018) that that matter is highlighted in the application made under head 19. It may well also be that the Consent Declaration Committee which makes such declarations may become part of the National REC framework at some future date (as an integrated regulatory research infrastructure and accompanying application process is developed) and this head is considered useful in that regard.

SCHEDULE

**MEMBERSHIP AND OPERATION OF NATIONAL RESEARCH ETHICS
COMMITTEE**

Membership

1. (1) A National REC shall consist of expert and lay persons who in the opinion of the Minister and having regard to the functions of the National REC are suitably qualified in terms of diversity of skills, qualifications, interests and backgrounds to make decisions on applications likely to be made to the National REC.

(2) A person is not eligible for appointment as a member of a National REC if the person is not a fit and proper person.

2. (1) A National REC shall have not fewer than 11 persons and not more than 21 persons, including a chairperson and 2 deputy chairpersons and at least one quarter of members shall be lay members.

(2) The chairperson, deputy chairpersons and ordinary members of the National REC shall be appointed by the Minister.

(3) (a) The chairperson and the deputy chairpersons of a National REC shall each hold office for the period of 4 years from the date of his or her appointment.

(b) An ordinary member of the National REC shall hold office for the period of 3 years from the date of his or her appointment.

(4) A member of the National REC whose term of office expires by the efflux of time shall be eligible for reappointment to the National REC.

(5) A person who is reappointed to the National REC in accordance with paragraph (5) shall not hold office for more than 2 consecutive terms.

3. (1) A member of the National REC may resign by written notice of resignation signed by him or her to the Minister and the resignation shall take effect on the date of the National REC meeting next held after written notice of resignation is received by the Minister.

(2) The Minister may at any time remove from office a member of the National REC if, in the Minister's opinion—

(a) the member has become incapable through ill-health of performing his or her functions,

(b) the member has committed stated misbehaviour of a type that would make him or her unsuitable for membership of the National REC,

(c) the removal of the member appears to the Minister to be necessary for the National REC to perform its functions effectively and with public confidence.

(3) If a casual vacancy occurs among the members, the Minister shall appoint a person to fill the vacancy and the person so appointed shall hold office for that period of the term of office of the member who occasioned the casual vacancy concerned that remains unexpired at the date of his or her appointment or such other period not exceeding 3 years as the Minister may specify.

Meetings

4. (1) The quorum for a meeting of the National REC shall be 7, and at least one of those present shall be the chairperson or a deputy chairperson.

(2) Subject to subparagraph (1), the proceedings of the National REC shall not be invalidated by any vacancy among its members.

5. (1) The chairperson or, in the absence of the chairperson, a deputy chairperson of the National REC, shall convene a meeting of the National REC as

(a) required to efficiently and effectively dispatch the work of the National REC in terms of proposals referred to it, or

(b) requested by the Head of the National Office.

(2) At least 5 working days before a meeting of the National REC, a notice in writing, signed by or on behalf of the chairperson of the National REC, or in the absence of the chairperson, by or on behalf of a deputy chairperson, shall be sent to every member of the National REC which shall specify the agenda for that meeting.

(3) At a meeting of the National REC-

(a) the chairperson of the National REC shall, if present, be the chairperson of the meeting,

(b) if and so long as the chairperson of the National REC is not present, or if that office is vacant, a deputy chairperson shall be the chairperson of the meeting.

Decision Making

6. (1) Every question arising at a meeting of the National REC duly convened shall be determined by a majority of the votes of the members of the National REC present and voting on the question at a meeting of the National REC.

(2) In the case of an equal division of votes on any question arising at a meeting of the National REC, the chairperson of the meeting shall have a second or casting vote.

(3) Where a member of the National REC has a material interest in any matter which falls to be considered by the National REC he or she shall-

- (a) disclose to the National REC the nature of the interest in advance of any consideration of the matter,
- (b) neither influence nor seek to influence a decision relating to the matter,
- (c) withdraw from a meeting or that part of a meeting at which the matter is being discussed or considered, and
- (d) take no part in any deliberation or decision relating to the matter.

(4) Where a material interest is disclosed under paragraph (3), the disclosure shall be recorded in the minutes of the meeting concerned and, for so long as the matter to which the disclosure relates is being dealt with by the meeting, the member of the National REC by whom the disclosure is made shall not be counted in the quorum for the meeting.

(5) Where, at a meeting of the National REC, a question arises as to whether or not a course of conduct, if pursued by a member of the National REC, would constitute a failure by him or her to comply with the requirements of subparagraph (3), the question may, subject to subparagraph (6), be determined by the chairperson of the meeting, whose decision shall be final, and where such a question is so determined, particulars of the determination shall be recorded in the minutes of the meeting.

(6) Where, at a meeting of the National REC the chairperson of the meeting is the person in respect of whom a matter to which subparagraph (3) applies falls to be determined, the other members of the National REC attending the meeting shall choose one of their number to be chairperson of the meeting for the purposes of subparagraph (5).

(7) Where the Minister is satisfied that a member of the National REC has not complied with subparagraph (3), the Minister may remove that member from office and that person shall then be disqualified from being a member of the National REC.

Minutes

7. (1) The chairperson of the meeting shall cause proper minutes of each meeting to be prepared which shall be approved by the National REC at the next National REC meeting and, after they are approved, published on the website of the National Office.

(2) The names of all members present at a meeting of the National REC shall be recorded in the minutes of the meeting.

Payments and Expenses

8. There may be paid by the National Office to the chairperson, deputy chairpersons and the members of the National REC such allowances in respect of reasonable expenses properly incurred by them in the carrying out of their duties and responsibilities as chairperson, deputy chairperson or members with the consent of the Minister for Health and the approval of the Minister for Public Expenditure and Reform.

Procedures

9. Subject to the provisions of this Schedule, a National REC shall determine its own procedures.