Proposal for a national Covid-19 biobank infrastructure.

Most European countries, including UK, Spain, France, Italy, Demark, Finland and Norway among many others, have an established national biobanking infrastructure that has been leveraged for the Covid-19 pandemic. The Research Subgroup of the EAG recommends the **urgent establishment of national biobanking infrastructure in Ireland** with an initial focus on Covid-19 but with potential application to other priority research issues in the future. A national Covid-19 biobank- is needed to support core clinical and public health research on the treatment and prevention of the infection. A biobank would greatly enhance our preparedness for further waves of Covid-19 infection and future pandemics and it will help ensure that Ireland participates in international collaborative studies and contributes to the global body of emerging knowledge on Covid-19, at a level commensurate with an agile, knowledge-based economy.

A timely decision on the establishment of a biobank is of particular importance at the current stage of the Covid-19 pandemic in Ireland, as the first wave of infection recedes and we prepare for a possible second wave in late 2020. The infrastructure needs to be ready to develop biobanking arms to future national projects, including, for example, sero-prevalence studies of healthy adults, children, pregnant women and other designated groups of interest (such as health care staff) among many others.

A Covid-19 biobank based on samples derived from Covid-19 antibody sero-prevalence studies or a biobank developed in the context of a longitudinal cohort study of patients with confirmed Covid-19 infection, would provide an especially valuable resource for research on clinical and immunological outcomes of Covid-19 infection. This includes work on medium- and long-term sequelae of infection (at different levels of severity and in different patient sub-groups), assessment of prognostic markers, trends in antibody titres over time and susceptibility to recurrent infection. Biobank samples will also support work on the assessment of screening and diagnostic tests for current and prior Covid-19 infection.

The establishment of the proposed biobank will clearly require detailed planning, informed by scientific, practical/ logistical and ethical considerations. It is suggested that **the DoH, with support from the HSE, the HRB and others, will establish a national steering group to lead** on the development of the Covid-19 biobanking infrastructure drawing on the relevant expertise as required, including expertise in biobanking, study design, sampling, health informatics, ethics, immunology and relevant clinical disciplines. It is recommended that core funding to be routed via the existing national HRB Clinical Research Facility (CRF) network with all CRF's (including linked network hospitals) involved and with involvement of the Chief Academic Officers. We will need an agreed core minimum dataset for all study participants providing biobank samples and standard operating procedures for data collection, sample handling, barcoding and storage at a level compliant with the current internationally agreed standard for biobanking (ISO 20387).

The Steering Group will need to consider the Governance arrangements for the biobanking infrastructure together with issues of consent, data access, security and record linkage including the arrangements required to ensure accurate and timely follow-up for morbidity and mortality. The Covid-19 biobank should be established as **a national resource with agreed, transparent processes for both ethical review (in collaboration with NREC) and access to the data and samples**. In particular, given the finite nature of the Covid-19 bio-banked collection, the Steering Group will also need to devise a mechanism to prioritise access to samples. Access should exclusively be granted for Covid-19 related research and priority should be given to high quality studies likely to yield maximum impact.

The Health Research Regulations 2018 will provide the legal framework for compliance with data protection legislation for research. In the absence of specific national legislation for biobanking, the Recommendation (2016)6 on Biobanking, a legal instrument by the Council of Europe of which Ireland is a member will provide an appropriate legal framework. In addition, further guidance in relation to biobanking is available nationally (CRDI) and internationally (WHO, EU BBMRI).

The scale of this undertaking should not be underestimated. Although there is significant capacity within the HRB Clinical Research Facility (CRF) network, dedicated funding will be required.