NATIONAL OFFICE FOR RESEARCH ETHICS COMMITTEES

National Irish COVID-19 Biobank Research Ethics Committee (NICB-REC)

Operational Framework

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1. Overview

The National Action Plan for Ireland's response to COVID-19 was published on 16 March 2020[1]. The Government's *'Resilience and Recovery 2020-2021 Plan for Living with Covid-19'*[2] further sets out how research and innovation have been crucial in informing and shaping the public health and policy response to Covid-19 to date, and the specific reference to the need for investment in '*infrastructure to support biobank studies.*' This need has been affirmed in recent health research developments more broadly, mainly through the government's involvement in the EU Health Emergency Preparedness and Response Authority (HERA)[3] and the launch of the National Genetics and Genomics Strategy.[4]

In direct response to this need, the Department of Health has invested in the National Irish COVID-19 Biobank (NICB)[5]. The NICB is a national integrated biorepository of human biological samples with linked sociodemographic and clinical data provided by individuals with COVID-19. The NICB aims to enable a harmonised, shared platform for COVID-19 research that strengthens national research infrastructure and supports Irish and international research to address the challenges presented by COVID-19.

The NICB is under the co-direction of University College Dublin (UCD; Professor Patrick Mallon) and Trinity College Dublin (TCD; Professor Colm Bergin) and is managed by a leadership team which includes individuals from six universities across Ireland, as well as The Irish Platform for Patient Organisations, Science and Industry (IPPOSI), The Health Protection Surveillance Centre (HPSC) and Children's Health Ireland (CHI).

It is crucial that the collection, storage and use of COVID-19 biological samples and associated data is underpinned by the highest standards in ethics, governance and codes of practices. The use of the NICB for health and social care research purposes comes with a significant responsibility to protect the dignity, autonomy, and well-being of the individuals who give their biological samples and data to the NICB, including the needs to safeguard their data protection and privacy rights.

Given the significance of the establishment of this national asset and the scale of COVID-19 biological samples and associated data to be safeguarded and governed, there is a critical need to ensure a consistent, robust and transparent ethical oversight of all aspects associated with the NICB as a multisite, multi legal entity, biobanking infrastructure. The NICB requires a dedicated ethics review mechanism to ensure its establishment, governance and operational harmonisation across all sites meets the highest ethical standards in accordance with national and international practice and legislation and to provide assurance to the public that these standards are being met.

To this end, the Department of Health mandated the National Office[6] to support the establishment of a single, dedicated research ethics committee (REC) for the NICB. The NICB-REC reviews ethics applications submitted by the NICB and delivers opinions on the ethical robustness of its establishment, governance, operational harmonisation, and scope of access rights. It is imperative that the ethical decision-making process of the NICB-REC engenders and sustains the trust of the research community, research participants and wider public. As Ireland's biobanking infrastructure expands, national leadership in ethical standards will be required. The NICB-REC will help provide guidance and leadership in this area.

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[1] https://www.gov.ie/en/publication/47b727-government-publishes-national-action-plan-on-covid-19/

[2] https://www.gov.ie/en/publication/e5175-resilience-and-recovery-2020-2021-plan-for-living-with-covid-19/

[3] https://commission.europa.eu/about-european-commission/departments-and-executive-agencies/health-emergency-preparedness-and-response-authority_en

[4] https://www.hse.ie/eng/about/who/strategic-programmes-office-overviewnational-strategy-for-accelerating-genetic-and-genomic-medicine-in-ireland/national-strategy-for-accelerating-genetic-and-genomic-medicine-in-ireland.pdf

[5] https://www.hrb.ie/news/news-story/article/a-national-biobank-for-covid-19-research/

[6] www.nrecoffice.ie

Member selection is based on a diversity of suitable skills, qualifications, interests, backgrounds and lived experiences required to deliver ethics decisions on the NICB application(s).

The NICB-REC is supported in its work by the National Office for Research Ethics Committees (located in the Health Research Board). The NICB-REC will be independent in the exercise of its function. The National Office is responsible for all administrative actions associated with the Committee.

Any queries in relation to the Committee must be directed to the National Office. Queries must not be directed to the Committee or an individual member of the Committee. The email address for the National Office is nicbrec@nrec.ie.

2. Role of NICB-REC

The purpose of the National Irish COVID-19 Biobank REC (NICB-REC) is to assess, in accordance with best national and international practices and under necessary legislative frameworks, all ethical aspects of the establishment, governance, operational harmonisation across biobank sites, maintenance of, and criteria for access rights to the NICB as a multisite, multi legal entity biobanking infrastructure.

The ethical assessments carried out by the NICB-REC will include compliance of the NICB with the Declaration of Helsinki[7], (first adopted by the World Medical Assembly in 1964, and updated in 2013) and the Declaration of Taipei[8] on-ethical-considerations-regarding-health-databases-and-biobanks (Adopted by the 53rd WMA General Assembly, Washington, DC, USA, October 2002 and revised by the 67th WMA General Assembly, Taipei, Taiwan, October 2016). It will further seek assurance that the NICB is established in accordance with the '*European Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine 1997*'[9], more commonly known as the "*Oviedo Convention*".

The NICB-REC will assess from an ethical perspective, all data protection and governance safeguards to ensure compliance with the General Data Protection Regulations[10] and Health Research Regulations 2018[11], such that the fundamental rights and freedoms of individuals who provide the biobank with samples can be exercised and are protected.

The NICB-REC will make ethical assessments on the application(s) submitted to it, including an application for approval of the NICB as a multisite, multi legal entity, infrastructure, plus subsequent applications for ethics approval for any additions or amendments to the initial NICB-REC opinion.

The prevailing role of the Committee will be the protection of the rights, safety, dignity, and well-being of biobank participants.

To support it in its purpose and operation, the NICB-REC shall, where and to the extent it considers appropriate, with the support of the National Office, engage with other persons and bodies involved in the regulation, safeguarding and practice of health research[12], personal data protection, biological sample collection and biobanking. Such bodies may include but are not limited to the Health Research Consent Declaration Committee (HRCDC)[13], the Irish National Accreditation Board (INAB)[14]

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[7] https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/

[8] https://www.wma.net/policies-post/wma-declaration-of-taipei-on-ethical-considerations-regarding-health-databases-and-biobanks/

[9] https://rm.coe.int/168007cf98

[10] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016R0679&from=EN

[11] https://www.irishstatutebook.ie/eli/2018/si/314/made/en/pdf

[12] Health research has the meaning ascribed to it under Regulation 3(2) of the Health Research Regulations 2018

[13] https://hrcdc.ie/

[14] https://www.inab.ie/

, the Biobanking and Biomolecular Research Infrastructure – European Research Infrastructure Consortium (BBMRI-ERIC)[15] and the International Society for Biological and Environmental Repositories (ISBER)[16]. Operating under the National Office, the NICB-REC will also constitute an important part of Ireland's national ethical research infrastructure. When appropriate, the NICB-REC will work collaboratively with the NREC-CTs and NREC-MDs to improve Ireland's health research ethical infrastructure.

The Committee, with the support of the National Office, shall determine its own procedures.

The NICB-REC will deliver a single national ethics opinion for the NICB. To ensure consistency of ethical standards across all NICB sites, as of the date of issuance of the NICB-REC opinion to the NICB, only this single national opinion, and all associated, approved documents, are valid.

3. Out of scope

The NICB-REC will not review ethics applications for any independent research studies that seek to use biological samples and associated data from the NICB. All research studies must have ethical approval, from a local institutional research ethics committee to access the biological samples and associated data. While biobank access procedures will be ethically assessed by the NICB-REC, the NICB will manage the application process for researchers accessing the biobank.

4. Membership

It is important that the decisions of the Committee are informed by a diversity of skills, experiences, interests and backgrounds that are reflective of Irish society as a whole, including those in Irish society affected by COVID-19. The membership of the committee will therefore comprise of individuals with wide-ranging lived and professional experiences to enable the Members to make an informed consensus-based ethical assessment of all NICB applications.

The Committee comprises of members with professional qualifications, expertise and/or experience in the provision of health and social care, research, epidemiology, genetics and genomics, pathology, virology, immunology, gerontology, respiratory medicine, pharmaceutical bioethics and the ethical, legal and societal aspects of both biobanking and use of biological samples and associated data in health and social care research.

PPI representation on the Committee is integral to any robust ethics review system, to ensure the perspective of patients, carers and the public are reflected in the decision-making process of the Committee.

The NICB-REC will comprise of no fewer than 10 members and no more than 15 members, inclusive of a Chairperson and a Deputy Chairperson.

These members will consist of expert and lay members. A minimum of two lay members will be patient, public and carer (PPI) representatives.

The members of the NICB-REC are appointed by the Minister for Health.

All members will hold office for an initial period of two years, or such shorter or longer period as may be determined by the Minister, from the date of the establishment of the Committee by the Minister, irrespective of the date of their appointment.

[15] BBMRI (https://www.bbmri-eric.eu/) is a research infrastructure under the ERIC legal framework that establishes, operates and develops a pan-European distributed research infrastructure of biobanks and biomolecular resources in order to facilitate the access to resources as well as facilities and to support high quality biomolecular and medical research

[16] ISBER

Decisions on membership beyond that initial period will be made by the Minister at the appropriate time and all members will be so advised.

5. Ethical review process

A bespoke ethical review process has been designed to ensure a robust assessment of the NICB as a national, multisite, multi legal entity, biobanking infrastructure. A specifically designed ethics application form ensures all information required for this ethical assessment is captured. All NICB-REC members are asked to submit written comments pertaining to the application under the following categories:

1. **Operations, governance and access rights**. This section includes requests specific information regarding harmonised NICB site processes including but not limited to all operations, governance and access rights.
2. **Biological samples, associated data and research scope**. This section includes s information relating to collection/recruitment/inclusion of prospective and retrospective biological samples & data and all associated processes including data protection. This section also includes information on research scope including specific information regarding genetics and genomics research.
3. **Biobank participants and Informed consent**. This section includes all information regarding biobank participants and informed consent and assent.
4. **Public engagement, patient and public involvement (PPI), sustainability and societal impact.** This section includes information regarding public engagement, Patient, Public and Carer Involvement, economical sustainability, pathway to commercialisation and biobank impact on society and research.
5. **Local Approvals.** This section includes information regarding all local REC approvals in place, the associated conditions of those approvals and the NICB responses to those conditions.
6. **Documentation** (Governance Structure, Patient information leaflets & Informed Consent forms (PIL/ICFs), Protocol, DPIA**,** Co-Director CVs**,** Sample and data access policy and GP Letter etc)

The ethical assessment process is managed as follows:

1. Issuance of bespoke biobank application form to Applicants
2. Submission of biobank ethics application form and additional documentation to National Office
3. Validation of application and submitted documentation including a request for clarification or further information if required.
4. Issuance of documentation for ethical review to NICB-REC via a secure reading room:
    I. Application form,
    II. Submitted documentation,
    III. Validation notification with request for further documentation and information
    IV. Documentation submitted post validation to the NICB-REC
5. Issuance of ethical review form to NICB-REC members
6. Submission of written ethical review comments
7. Issuance of compiled ethical review comments to all committee members, prior to the meeting
8. Ethical review meeting for deliberation of any ethical considerations as raised
9. Issuance of either final ethical opinion OR request for further information (RFI) to the NICB Co-Directors.

10. RFI submitted by Applicants.
11. Validation of submitted further information.
12. Issuance of submitted further information to NICB-REC (including any additional validation documentation if applicable)
13. Issuance of RFI specific ethical review comment form to NICB-REC members
14. Submission of committee members' RFI based ethical review comments.
15. Issue of compiled, ethical review comments to all committee members, prior to the RFI meeting
16. RFI discussion meeting
17. Issuance of single national ethical opinion to NICB Co-Directors

6. Meetings

In is envisaged that the Committee may convene every four to six weeks for the purpose of reviewing ethics applications submitted by the Co-Directors of the NICB (the 'Applicants').

It is envisaged that not that more than 10 meetings will be convened in a 12-month period. The meetings will be scheduled as agreed by the Chairperson, Deputy Chairperson and Ordinary Members, in accordance with an agreed schedule of prospective cut off dates for submission of new application or substantial modification requests.

The quorum for a meeting, other than a sub-committee thereof, will be seven members, one of which must be the Chairperson or Deputy Chairperson, and one of which must be a PPI member.

Where neither the Chairperson nor Deputy Chairperson of the NICB-REC, is available to chair a meeting, another member of the NICB-REC may be designated by the Chairperson to chair that meeting.

Subject to the above requirements for a quorum, the NICB-REC will not be invalidated by any vacancy among its members.

The Chairperson shall ensure the Committee can discharge its functions efficiently and effectively, particularly as regards making a consensus-based decision on an application being assessed.

The operations and administration associated with all meetings will be co-ordinated and supported by the National Office.

Ethics applications and accompanying documentation shall be validated by the National Office and uploaded to a secure reading room no less than 10 business days in advance of a scheduled meeting.

All meetings will be conducted remotely, unless otherwise required to be convened in person as agreed in advance by the Chairperson and members.

7. Decision-making

The Committee shall be objective in considering issues and weighing-up conflicting opinions. All Members' opinions are given equal weight in the decision-making process. All decisions are made by consensus.

For the purposes of the effective and efficient consideration of applications and operations of the NICB-REC, the Chairperson, in consultation with the Deputy Chairperson, the Head of the National Office and the NICB-REC Programme Manager, shall determine procedures for the organisation and prioritisation of the work.

NICB-REC phased and partitioned ethical opinion model

A phased and partitioned ethical opinion model enables the NICB-REC to facilitate NICB operations in a time expedient and ethically robust way and in line with the NICB's expected establishment

milestones. This enables an ethical opinion to be delivered on aspects where all required information is available for ethical review while allowing the NICB-REC to reserve an ethical opinion on aspects yet to be fully established (and for which the required information is currently unavailable for ethical review). A phased and partitioned opinion model allows for the issue of an ethical opinion on different aspects of biobank operations by:

1. issuing a **favourable opinion** on aspects of NICB operations found to be ethically robust,
2. issuing an opinion of **favourable subject to conditions** on aspects of NICB operations found to be ethically robust subject to the fulfilment of conditions,
3. issuing an **opinion reserved** outcome on aspects for which insufficient information was available to enable an ethical assessment. All biobank operational aspects receiving an **opinion reserved** outcome are subject to submission of a new application for full ethical assessment.

The breakdown of biobank elements ethically assessed by the NICB-REC to facilitate a phased and partitioned opinion model are as follows:

1. **Governance:** Governance and oversight
2. **Participant recruitment**: Identification of potential participants; participant facing information and consent protocols.
3. **Biological sample and data**: collection, storage, processing, cataloguing, general curation, and security aspects.
4. **Researcher Access**, downstream impact and commercialisation.

The Committee may request additional information from the Applicant(s) to enable it to make its decision.

The Committee may consult with an external expert who it believes can assist it in its deliberations on the application, if the necessary expertise is not available on the committee. Any such engagement is subject to a duty of confidence. Where an external person is consulted to assist in deliberations, they shall not be counted for the purpose of a quorum.

In the event of an unfavourable ethical opinion, no appeal option is available. The Applicants will, have the option to re-submit a new application for full ethical assessment by the Committee.

In the event of a split committee decision, which cannot be resolved through further discussion or additional information, the Chairperson will decide the outcome.

A decision letter will be issued and will include, if relevant, a statement of conditions and recommendations. The National Office will aim to inform the Applicant of the outcome of the ethics review within ten working days of the meeting being held where possible. Applicants will be asked to acknowledge receipt and acceptance of the outcome and the associated conditions.

The National Office will ensure that that the minutes clearly record the decisions taken by the Committee, but specific comments will not be attributable to individual members.

The NICB-REC will, when compiling minutes, have regard to matters of commercial sensitivity and will ensure that minutes published on its website comply with the Data Protection Acts 1998 to 2018.

The names of all members present at a meeting of a the NICB-REC will be recorded in the minutes of the meeting.

The final decision will be made publicly available on the National Office website.

8. Current Local REC opinions

All current ethical opinions that have been delivered by the local RECs regarding the NICB remain valid until such time as the NICB-REC has delivered a national ethics opinion to the NICB.

Upon delivery of the NICB-REC ethical opinion of the NICB:

- Ethical opinions that have been delivered by the local RECs, will be automatically superseded by NICB-REC opinions, upon notification to the NICB by the National Office. Local RECs should be notified of all NICB-REC opinions, by the NICB.
- Local RECs do not have authority to request any changes to the NICB-REC opinion as it may relate to documents, processes, operations, governance, or any other item assessed by the NICB-REC. Any and all NICB requested, modifications to NICB documents, processes, operations and governance will be submitted to and assessed by the NICB-REC.
- Local RECs will have responsibility for the ethical assessment of all health research studies seeking to access and utilise NICB biological samples and associated data.

9. Modifications

The Applicants may request ethical approval for modifications, including substantial modifications, to the NICB infrastructure through this process. All requested modifications will be assessed by the NICB-REC.

The modification application form will include additional sections for the required information for aspects of the biobank operations and governance which were not included for ethical review in the initial application.

10. Conflicts of Interest

Where a member of the NICB-REC has a material interest in any matter which falls to be considered by the NICB-REC, they will:

a. disclose to the Chairperson of the National REC and the National Office 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.

A person is regarded as having a material interest if:

a. they, their connected relative, or a nominee of either of them is a member of a company or any other body which has a beneficial interest in, or material to, a matter to be considered by the committee.

b. they or their connected relative is in partnership with or is in the employment of a person who has a beneficial interest in, or material to, any such matter,

c. they or their connected relative is a party to any arrangement or agreement (whether or not enforceable) concerning land to which any such matter relates, or

d. a connected relative has a beneficial interest in, or material to, any such matter.

For the purposes of the above, a “connected relative” means a spouse, civil partner, parent, brother, sister, child or the spouse or civil partner of a child of the person.

Where a material interest is disclosed, it will be recorded in the minutes of the meeting concerned.

Where the Minister is satisfied that a member of the NICB-REC has not complied with the requirements regarding declaring conflicts of interest, the Minister may remove that member from office.

11. Sub-Committees

The National Office, in consultation with the chairperson of the NICB-REC, may establish one or more sub-committees of the NICB-REC to provide assistance to the Committee in the carrying out of its work.

Each member of a sub-committee will be a member of the NICB-REC.

The National Office may, after consulting with the Chairperson of the NICB-REC, at any time, dissolve an NICB-REC sub-committee.

An NICB-REC sub-committee may consider and make a decision only where the sub-committee concerned is chaired by the Chairperson or the Deputy Chairperson of the NICB-REC, or, where neither the chairperson nor the deputy chairperson is available, another member of the NICB-REC who is designated by the Chairperson to chair that meeting.

12. Training

The Committee will be provided with appropriate training as necessary to ensure it is facilitated to conduct an informed ethical review of the NICB ethics application and any subsequent amendments. Training will initially be by way of an online induction seminar and will cover appropriate areas of importance which may include:

a. Ethical, legal and societal aspects of biobanking
b. Data protection and consent
c. Health Research Regulations and other legislative frameworks

Committee members will also be invited to attend monthly 'lunch and learn' webinars organised by the National Office on relevant topics during their tenure as an NICB-REC member.

13. Transparency

The National Office for Research Ethics Committees shall publish on its website the following information in relation to the NICB-REC:

a. the names of its members and their professional details, where appropriate,
b. information on its processes and procedures,
c. summary information about the NICB application for consideration by the committee,
d. minutes of its meetings,
e. decisions on applications made,
f. guidance and other material that relates to its work, and
g. such other information that the Chairperson considers appropriate.

Link to National Office webpage: National Irish Covid Biobank REC - NREC (nrecoffice.ie)

14. Contact

All queries regarding the NICB-REC or any opinion delivered by it, should be directed to the NICB-REC Programme Manager, Dr Anne Costello at nicbrec@nrec.ie.

NATIONAL OFFICE FOR RESEARCH ETHICS COMMITTEES

Appendix one: NICB-REC Application form

NATIONAL OFFICE FOR RESEARCH ETHICS COMMITTEES

National Irish COVID-19 Biobank - Research Ethics Committee (NICB-REC)

Application form for the Ethical Review of the National Irish COVID-19 Biobank

Instructions

- This application form is specifically for seeking ethics approval for the National Irish Covid-19 Biobank only.
- **Section One** requests specific information regarding harmonised NICB site processes including but not limited to all operations, governance and access rights.
- **Section Two** requests information relating to collection/recruitment/inclusion of prospective and retrospective biological samples & data and all associated processes including data protection. This section also requests information on research scope including specific information regarding genetics and genomics research.
- **Section Three** requests all information regarding biobank participants and informed consent and assent.
- **Section Four** requests information regarding public engagement, Patient, Public and Carer Involvement and economical sustainability.
- **Section Five** requests information regarding all local REC approvals in place, the associated conditions of those approvals, the responses to those conditions, and any requests for NICB-REC approval of future amendments to these documents.

- **Section Six** - Declaration of National Principal Investigators, Host institution Data protection officers and Host institution authorised signatories.
- For the purposes of this document the term 'biobank' will be used in reference to the NICB from this point forwards.
- All sections of the application form must be completed. Please do not alter the layout of the application form.
- Ensure all answers are in plain English comprehensible to a lay person.
- Information on this form will remain confidential, however, the NICB-REC may seek an external expert to provide advice on any aspect of the application which lies beyond the expertise of the members.
- Respond to each question carefully and succinctly. Please contact the National Office (nicbrec@nrec.ie) in the event of queries which may arise during the completion of this form.
- It is advisable to ensure the biobank is compliant and aligned where appropriate with, for example
  - General Data Protection Regulation
  - Data Protection Act 2018 (section 36 (2) (Health Research) regulations
  - HSE National Consent Policy for Health Research (hseresearch.ie)
  - WMA Declaration of Taipei on Ethical Considerations regarding Health Databases and Biobanks – WMA – The World Medical Association
  - WMA Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjects – WMA – The World Medical Association
- Please do not provide surplus documentation not requested in this form.
- Digital signatures are acceptable and encouraged.
- Please do not alter the structure of the form other than to add or delete table rows as needed.
- Please ensure all added text is standard (not bold).
- Please submit the completed, signed, non-scanned, PDF application form and ancillary documents to nicbrec@nrec.ie

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Lay Summary

The lay summary will be used for the purpose of National Office public records. Please do not use overly technical language or commercially sensitive information. **Limit is 300 words**.

Please click here to provide a brief, non-confidential, summary of the application in lay terms, including definition and purpose

Document list: For approval

List in bullet points all documents provided for reference with this application:

Click or tap here to enter text.

Document list: For reference **List in bullet points all documents provided for reference with this application:**
Click or tap here to enter text.

Section One - Operations, governance and access rights

Section one requests specific information regarding harmonised biobank multisite processes including but not limited to all operations, governance and access rights, individuals involved and general Information.

1.1 Title

Click or tap here to enter text.

1.2 Lay title (if different)

Click or tap here to enter text.

1.3 Scientific justification for, and aims and objectives of, the biobank

Limit is 500 words

Click or tap here to enter text.

1.4 Co-Directors and team

1.4.1 National Co-Director	
Title:	Click or tap here to enter text.
Name:	Click or tap here to enter text.
Employing institution:	Click or tap here to enter text.
Other affiliate institution:	Click or tap here to enter text.
Position:	Click or tap here to enter text.
Biobank role & responsibility:	Click or tap here to enter text.
1.4.2 National Co-Director	
Title:	Click or tap here to enter text.

Name:	Click or tap here to enter text.
Employing institution:	Click or tap here to enter text.
Other affiliate institution:	Click or tap here to enter text.
Position:	Click or tap here to enter text.
Biobank role & responsibility:	Click or tap here to enter text.

1.4.3 Lead point of contact person for correspondence/ queries for this application	
Name:	Click or tap here to enter text.
Position	Click or tap here to enter text.
Department	Click or tap here to enter text.
Organisation	Click or tap here to enter text.
Telephone (work)	Click or tap here to enter text.
Telephone (mobile)	Click or tap here to enter text.
E-mail:	Click or tap here to enter text.

1.4.4 Team members involved in the operations and governance of the biobank.

Table 1: Leadership and scientific team members

Name	Affiliation	Biobank role and responsibility
Click or tap here to enter text.	Click or tap here to enter text.	Click or tap here to enter text.
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Table 2: Operational team members

Name	Affiliation	Biobank role and responsibility
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Click or tap here to enter text.	Click or tap here to enter text.	Click or tap here to enter text.

1.4.5 Lead Data Controller details

(Ref Art. 4 GDPR)

The Data Controller determines how and why personal data is being collected and used (processed) for the health research study. Please include the principal business of the Data Controller eg higher education institute, voluntary hospital, single GP, health service provider.

Organisation	Click or tap here to enter text.
General role undertaken by Lead Controller:	Click or tap here to enter text.
DPO contact:	Click or tap here to enter text.

1.4.6 Joint Data Controller details if applicable Ref Art. 26 GDPR e.g. consider organisations of co-investigators collaborators etc and others that may also be determining how and why personal data is being used (processed).	
Not applicable	☐
Organisation	Click or tap here to enter text.
General role undertaken by Joint – Data Controller:	Click or tap here to enter text.
Name of DPO representative	Click or tap here to enter text.
Please outline what arrangements are in place between the Joint-Data Controllers to reflect the roles and responsibilities (Ref Art. 26 GDPR) if applicable. Example arrangements maybe data transfer agreements, inter-institutional agreements, contractual arrangements etc	
☐ Not applicable	
Click or tap here to enter text.	

1.5 Biobank sites

Table 3: Biobank sites and site leads Submit site suitability and agreement documentation for each site listed. To inform governance structures, please indicate which sites are designated Data Controllers and/or Data Processors and whether the sites retain custodianship of their samples.		
Biobank site (name/location) and data controller/ processor/ custodian designation	**Site lead (name)**	**Site lead role and responsibility**
Click here to enter site name and location. ☐ Data controller ☐ Data Processor	Click or tap here to enter text.	Click or tap here to enter text.

☐ Sample and data custodian		
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Table 4: Data processors
List all data processors involved in the biobank, not indicated in Table 3 above.

Name of organisation	affiliation	Role and responsibility
Click or tap here to enter text.	Click or tap here to enter text.	Click or tap here to enter text.
Click or tap here to enter text.	Click or tap here to enter text.	Click or tap here to enter text.
Click or tap here to enter text.	Click or tap here to enter text.	Click or tap here to enter text.
Click or tap here to enter text.	Click or tap here to enter text.	Click or tap here to enter text.
Click or tap here to enter text.	Click or tap here to enter text.	Click or tap here to enter text.

1.5.1 Specify any person/third party other than the named data controller, joint controllers or processors with whom it is intended to share any of the participant data collected and the purpose of such sharing, and format of data (eg anonymised/ pseudonymised/identifiable).

Click or tap here to enter text.

1.5.2 Controller-Processors: Please outline what legal agreements or legal acts are in place between the Controller(s) and Processor (Ref: Art. 28 GDPR).

☐ Not applicable

Click or tap here to enter text.

1.6 Governance

1.6.1 Governance Structures

Provide a comprehensive description of the governance structures which underpin the management and safeguarding of the biobank as a whole, and separately at each site. Submit all relevant governance documentation such as, but not limited to legal agreements, site agreements, contractual arrangements between lead sites, access policies, access committees, steering/advisory groups etc
Click or tap here to enter text.

1.6.2 Biobank Accreditation

Please list all accreditation(s) secured and/or planned for? For example; Biobanking accreditation which can be sought from the Irish National Accreditation Board under ISO 20387
Click or tap here to enter text.

1.6.3 Biobank access

(a) List organisations that are expected to access the biobank.	
Academic/Higher education institutions	☐ Yes ☐ No
Clinical research organisations	☐ Yes ☐ No
Non-for-profit agencies	☐ Yes ☐ No
Government agencies	☐ Yes ☐ No
Commercial agencies/Industry	☐ Yes ☐ No
International organisations	☐ Yes ☐ No
Other (list below)	☐ Yes ☐ No
Click or tap here to enter text.	
(b) Detail the assessment and approval process for third parties accessing biological samples and data from the biobank.	
Click or tap here to enter text.	
(c) Describe areas of research or research organisations that are excluded from accessing the biobank and provide rationale for such exclusion, if applicable.	
Click or tap here to enter text.	

(d)	**Does the biobank have a template material transfer and data sharing agreement or other such contractual arrangement between the biobank and the recipient institution(s) to which the biological samples and data will be sent? Please comment on the terms and conditions that will be applied.**
Click or tap here to enter text.	

1.6.4 Biological sample and data return and/or retention

(a)	**What arrangements will be made with recipient institution for the return, disposal or further storage of biological samples when studies are completed?**
Click or tap here to enter text.	

(b)	**What arrangements will be made with recipient institution to anonymise, archive or destroy personal data when studies are completed.**
Click or tap here to enter text.	

(c)	**What is the biobank's policy regarding recipient institutions retention of participant data and associated biological samples for studies supported by the biobank?** For example, after data analysis has taken place, will participant data be retained? If yes, who will have access, for how long, for what purpose, and where will it be retained?
Click or tap here to enter text.	

1.6.5 Engagement with International Bodies

(a)	**What plans, if any, are in place to engage with the biobanking and biomolecular resources research Infrastructures – European research infrastructure consortium** (BBMRI-ERIC) now or in the future? Outline the rationale for any such engagement, if applicable. Ref: Home - BBMRI-ERIC: Making New Treatments Possible
Click or tap here to enter text.	

(b)	What plans, if any, are in place to engage with the International Society for Biological and Environmental Repositories (ISBER) now or in the future? Outline the rationale for any such engagement, if applicable. Ref: ISBER
Click or tap here to enter text.	

(c) What plans, if any, are in place to engage with any other international bodies now or in the future? Please list, and outline the rationale for any such engagement, if applicable.
Click or tap here to enter text.

1.7 Biobank Duration

1.7.1 Anticipated full biobank operations commencement date:
Click or tap here to enter text.

1.7.2 Anticipated term of the biobank:
Click or tap here to enter text.

1.7.3 What is the biobank storage period for biological samples and retention period for associated data?
Click or tap here to enter text.

1.7.4 What changes to biobank operations are anticipated, if any, when the term of the biobank expires?
Click or tap here to enter text.

1.7.5 In the event that the biobank must cease all operations in the future, will biological samples and data be destroyed?
☐ Yes ☐ No
If No, how and where will the biological samples and associated data be stored/archived, and for how long?
Click or tap here to enter text.
If Yes, detail how will the biobank ensure that the destruction of biological samples and associated data is line with best practice and applicable legislation.
Click or tap here to enter text.

Section Two – Biological samples, associated data and research scope

Section two requests specific information regarding collection/recruitment/inclusion of prospective and retrospective biological samples and associated data, all associated processes and research scope including genetic and genomic research.

2.1 Access to healthcare records and participant pre-screening

2.1.1 Will the identification of prospective participants involve reviewing or screening medical records or other such records for identifiable personal information of patients, service users or any other person?
☐ Yes ☐ No
If answer is No, please skip the remaining questions in 'Access to healthcare records and participant pre-screening'.
If yes, **1. Describe the data sources from which the data is being collected - eg hospital medical records, GP records etc** **2. Describe what measures will be in place to confirm that access to this data for pre-screening purposes will be processed in compliance with Data Protection Act 2018 (Section 36(2)) (Health Research) Regulations 2018. Please outline who will access the data and any other measures taken to ensure lawful access.**
1. Click or tap here to enter text.
2. Click or tap here to enter text.

2.2 Biological samples and associated participant data

2.2.1 Detail the types of biological samples to be included in the biobank (both retrospective and prospectively collected and stored samples). Eg: blood, stool, urine, saliva swabs, biopsies etc
Click or tap here to enter text.

2.2.2 Detail the types of participant data to be collected and linked with the biological samples. Eg: name, age, sex, ethnicity, health and clinical data etc
Click or tap here to enter text.

2.2.3 What formats of data will be collected?	
Paper-based	☐ Yes ☐ No
Electronic/Digital	☐ Yes ☐ No
Audio	☐ Yes ☐ No
Video	☐ Yes ☐ No
Photography	☐ Yes ☐ No
Other	☐ Yes ☐ No
If 'Other' please comment:	Click or tap here to enter text.

2.2.4 Will biological samples and associated data be collected, for biobanking, as part of routine clinical care and treatment?
☐ Yes ☐ No
If yes, confirm that separate, unbundled consent from participants will be sought for their biological samples and data to be included in the biobank
Click or tap here to enter text.

2.2.5 Will biological samples and associated data be collected specifically for the purposes of donating to the biobank?
☐ Yes ☐ No

2.2.6 Will post-mortem biological samples and associated data be collected and stored in the biobank?
☐ Yes ☐ No
If yes: Describe what consents and approvals are in place for the use of post-mortem biological samples and associated data Link: HSE National Consent Policy for Health Research (hseresearch.ie)
Click or tap here to enter text.

2.2.7	Will the biobank include retrospectively collected samples and data previously obtained at any biobank site?
☐ Yes ☐ No	
If yes, please note information related to informed consent associated with retrospectively collected samples is requested in section three.	

2.2.8	Will the biobank seek to include samples and data from sites in countries outside of the Republic of Ireland
☐ Yes ☐ No	
If yes, provide a list of site countries outside of the Republic of Ireland.	
Click or tap here to enter text.	

2.2.9	Detail what arrangements will be place regarding the governance and access to samples from international sites
Click or tap here to enter text.	

2.3 Biological sample and participant data transfer

2.3.1	Specify arrangements for the physical transfer of biological samples from the biobank to a research organisation and comment on the safeguards in place to protect the viability of the biological samples in transit.
Click or tap here to enter text.	

2.3.2	Specify the technical and security processes and safeguards for sharing of data associated with transferred biological samples.
Click or tap here to enter text.	

2.3.3	Will biological samples and associated data be shared with other national and/or international biobanks? If Yes, set out the proposed governance arrangements (eg: transfer agreements, legal arrangements, joint-controller/controller-processor agreements etc).
Click or tap here to enter text.	

2.3.4 Will biological samples be transferred outside of the State?

☐ Yes ☐ No

If yes specify the recipient countries.

☐ Non-EEA

☐ EEA

If non-EEA, specify arrangements for transfer of samples and comment on the safeguards in place to protect the viability of the biological samples in transit.

Click or tap here to enter text.

2.3.5 Will personal data be transferred outside of the State?

Link: Transfers of Personal Data to Third Countries or International Organisations | Data Protection Commissioner

Link: Chapter 5 – Transfers of personal data to third countries or international organisations - General Data Protection Regulation (GDPR) (gdpr-info.eu)

☐ Yes ☐ No

If yes specify the recipient countries.

☐ Non-EEA

☐ EEA

If Non-EEA please identify the legal basis for the transfer of personal data below

☐ on the basis of an Adequacy Decision

☐ using the safeguard of Standard Data Protection clauses

☐ using the safeguard of Binding Corporate Rules,

☐ on the basis of approved Codes of Conduct,

☐ on the basis of approved Certification Mechanisms,

☐ on the basis of a legally binding and enforceable instrument between public authorities or bodies,

If a legal basis for transfer of personal data outside the EEA has been identified above, please name the country(ies) of transfer and outline what arrangements are in place governing the transfer:

Click or tap here to enter text.

2.4 Data confidentiality and privacy

2.4.1 Will the data collected be processed as anonymous, pseudonymous, coded or identifiable data?

Click or tap here to enter text.

If pseudonymised, please confirm who will retain the 'key'/masterlist to re-identify the data?

Click or tap here to enter text.

Outline the process for re-identifying pseudonymised participant data.

Click or tap here to enter text.

2.4.2 Describe how personal data will be irrevocably anonymised or pseudonymised to protect the confidentiality of participants. What measures will be taken to prevent possible re-identification of participants, by linking to other databases?

Click or tap here to enter text.

2.4.3 What measures will be taken to prevent possible re-identification of participants, by linking to other databases?

Click or tap here to enter text.

2.5 Data protection safeguards

2.5.1 Describe the processing activities of biological samples and associated data that will be carried out during the term of the biobank. A simple flow diagram of an individual biological sample and data life cycle should be provided if possible.

Art. 4 GDPR

Consider activities such as: accessing, collecting, recording, storing, adapting, pseudonymisation, anonymisation, analysis, linking, combining, sharing, transfers, archiving and destruction.

Click or tap here to enter text.

2.5.2 Comment on how participant data will be processed as is necessary to ensure that it shall not be processed in such a way that may cause damage or distress to the data subject

Click or tap here to enter text.

2.5.3 Specify the controls and security measures in place to prevent unauthorised consultation, access, dissemination, alteration, disclosure, erasure, or loss of information and/or participant data.

Click or tap here to enter text.

2.5.4 Specify the controls in place to log whether and by whom participant data has been consulted, altered, disclosed or erased.

Click or tap here to enter text.

2.5.5 Specify other technical and organisational measures designed to ensure that processing is carried out in accordance with the Data Protection Act 2018 (Section 36(2)) (Health Research) Regulations 2018, together with processes for testing and evaluating the effectiveness of such measures.

Link**:** Ref Recital 78/GDPR, Art 32/GDPR

Click or tap here to enter text.

2.5.6 Describe the measures that will be implemented in the case of a participant data security breach in order to mitigate the possible adverse effects.

Click or tap here to enter text.

2.5.7 Specify the measures in place that demonstrate compliance with the data minimisation principle.

Is collected data adequate, relevant and limited to what is necessary?

Click or tap here to enter text.

2.5.8 Specify the transparency arrangements that are/will be in place to ensure that biological samples and associated data are used in a transparent manner.

Art. 5 GDPR

Transparency is an important data protection principle and safeguard for biobanking practices, Consider what transparency measures will be implemented to inform participants/public about the biobank and how biological samples and associated data will be used under the framework of biobank. Eg data protection policies, public notices, publicity campaigns, information leaflets, websites, engagement with representative patient/advocacy groups etc. Please provide supporting documentation where possible.

Click or tap here to enter text.

2.5.9 Has each site Data Protection Officer (as applicable) reviewed the data protection risk assessment and mitigating actions set out in the DPIA?

☐ Yes ☐ No

Provide evidence of the DPO engagement and feedback.

DPO 1: Click or tap here to enter text.

DPO 2: Click or tap here to enter text.

Other DPO: Click or tap here to enter text.

2.6 Research scope (general)

2.6.1 What types of research will be undertaken and in what field(s) of biomedicine

Click or tap here to enter text.

2.7 Genetic and Genomic Research

2.7.1 Will the biobank support studies conducting Genetic and Genomic research?

☐ Yes ☐ No

If yes, outline the nature and purpose of the genetic and genomic research.

Click or tap here to enter text.

2.7.2 Will participant consent be sought for genetic and genomic research at the time of initial consent for biobank participation?

☐ Yes ☐ No

If Yes, detail how you will ensure that consent is in line with broad explicit consent as mandated under in the Data protection act 2018 (section 36 (2) Health Research) regulations 2018.

Click or tap here to enter text.

2.7.3 What policy and process will be in place to ensure that research findings specific to the participant will be linked with the stored biological samples and participant data?

Click or tap here to enter text.

2.7.4 Will participants be entitled to important incidental findings (unexpected clinically or socially relevant data) or secondary findings (results that are actively sought in addition to the primary target of a test or procedure) which arise from a research study?

Ref 1: HSE National Consent Policy for Health Research (hseresearch.ie)

Ref 2: ACMG SF v3.0 list for reporting of secondary findings in clinical exome and genome sequencing: a policy statement of the American College of Medical Genetics and Genomics (ACMG) - Genetics in Medicine (gimjournal.org)

☐ Yes ☐ No

If No, please outline how this will be communicated to participants and comment on the obligations of researchers, and the biobank, regarding non-disclosure of important incidental findings and/or secondary findings to the participants.

Click or tap here to enter text.

If Yes,

1. Please consider whether consent may be required from a legally designated representative (an individual who is legally authorised to make a decision on behalf of another person) or legal guardian (person with parental responsibility) for the disclosure of this information. If so, ensure that this is captured in the information leaflet(s) and the consent/assent form.
2. Set out the steps that will be taken and the information that will be provided to participants prior to the conduct of the genetic and genomic research and processing of genetic data in relation to any potential implications for the health of participants, which may become known as a result of the research.

3. Set out the arrangements that will be in place to address and inform the biobank participant of any significant results or information arising from the processing of genetic data. **4.** In the event that genetic and genomic research leads to information regarding a genetic predisposition for medical conditions and/or diseases which are generally considered to be untreatable, set out the arrangements in place to notify the individual concerned and to ensure they have access to appropriate counselling.
1) Click or tap here to enter text.
2) Click or tap here to enter text.
3) Click or tap here to enter text.
4) Click or tap here to enter text.

2.7.5 Set out the arrangements which will be in place to ensure the privacy and confidentiality of participant's genetic data throughout the life cycle of the biological sample and participant personal data.
Click or tap here to enter text.

2.7.6 What strategy/arrangements will be in place regarding third party disclosure, in particular, to family members or others. Please consider whether consent may be required from the participant for this disclosure. If so, please ensure that this is captured in the patient leaflet and consent form.
Click or tap here to enter text.

Section Three – Biobank participants and informed consent

Section three includes all information related to biobank participants and Informed consent and assent.

3.1 Biobank Participants

3.1.1 How many participants are to be recruited in total in Ireland? Please include numbers for participants with COVID-19 and controls (no COVID-19)

Click or tap here to enter text.

3.1.2 Justify the number of prospective participants to be recruited to the biobank

Click or tap here to enter text.

3.1.3 Outline and justify the inclusion criteria for participants.

Click or tap here to enter text.

3.1.4 How will the participants be identified, recruited, and selected?

Click or tap here to enter text.

3.1.5 What resources will be used for recruitment?

Describe the format of the resources, e.g. paper or electronic and how these will be presented to potential participants e.g. via the post, in the clinic / hospital, through social media, radio etc. If recruitment includes advertisements or written correspondence, please provide copies and/or TV/radio scripts and letters and all relevant participant facing material

Click or tap here to enter text.

3.1.6 Will there be any further contact with participants to collect additional biological samples or data following their initial donation?

Click or tap here to enter text.

3.1.7 Will healthcare and treatment be withheld from participants as a result of their participation in the biobank?

☐ Yes ☐ No ☐ N/A

If yes, provide details.

Click or tap here to enter text.

3.1.8 What activities, procedures or interventions (if any) are participants asked to undergo or engage in for the purposes of participating in the biobank??

Click or tap here to enter text.

3.1.9 What are the potential adverse effects, risks, or hazards for participants of the biobank, either from giving or withholding medications, devices, ionising radiation, or from other interventions, which may cause inconvenience or changes to lifestyle?

Click or tap here to enter text.

3.1.10 What are the potential benefits for participants?

Click or tap here to enter text.

3.1.11 Will participants be from any of the following groups?

This question is to gauge demographics as well as to identify the inclusion of vulnerable groups.

Children under 16 years of age	☐	Adults with learning disabilities	☐
Children under 18 years of age	☐	Adults who have a terminal illness	☐
Adults who are unconscious	☐	Adults with mental illness	☐
Adults in emergency situations	☐	Prisoners	☐
Pregnant or breastfeeding individuals	☐	Healthy volunteers	☐
Adults with dementia	☐	Those who could be considered to be vulnerable or have a particularly dependent relationship with the investigator, e.g. those in care homes, medical students.	☐

Other	☐	Click or tap here to enter text.

If yes, justify the inclusion of all vulnerable groups, outlining how the biobank is expected to benefit participants.

Click or tap here to enter text.

3.2 Informed Consent

NOTE: Explicit consent (informed consent that is recorded) to process personal data for research purposes is specified as one of the necessary safeguards under the Data Protection Act 2018 (Section 36 (2)) (Health Research) Regulations. If explicit consent cannot be obtained for donation to the biobank, a consent declaration from the HRCDC may be required. For more information, visit – www.hrcdc.ie

3.2.1 Will informed consent be obtained from participants

☐ Yes ☐ No

If no,

a) please justify:

Click or tap here to enter text.

b) will deferred consent from the participants be sought at any stage?

Click or tap here to enter text.

3.2.2 Will a tiered approach to obtaining consent be used to facilitate option selection?

Ref HSE National Consent Policy for Health Research (hseresearch.ie) Section 2.2.2.1

☐ Yes ☐ No

If no,

a) please justify:

Click or tap here to enter text.

3.2.3 Will participants be invited to provide consent to be contacted for future purposes and circumstances under which recontact or reconsent may arise?

Ref HSE National Consent Policy for Health Research (hseresearch.ie)

☐ Yes ☐ No

If participants do not consent to be contacted in the future detail how the biobank will ensure that consent is in line with broad explicit consent as mandated under in the Data protection act 2018 (section 36 (2) Health Research) regulations 2018

Click or tap here to enter text.

3.2.4 Describe the model of consent being implemented.

Comment as to whether informed consent being sought is, for example, layered, tiered, dynamic etc.

Click or tap here to enter text.

3.2.5 Who will be approaching potential biobank participants and who will be obtaining informed consent, if different.

Describe the professional role and whether there is a prior clinical relationship with potential participants

Click or tap here to enter text.

3.2.6 When will informed consent be obtained?

Describe when and where informed consent will be obtained, what the timeframe to allow participants to review and consider the information and how privacy during the consenting process will be ensured

Click or tap here to enter text.

3.2.7 How will it be assured that biobank participants have understood the information and that consent is informed and freely given?

This should include how the informational needs of individuals will be identified and addressed

Click or tap here to enter text.

3.2.8 What arrangements are in place to obtain informed consent from participants who do not speak English?

Click or tap here to enter text.

3.2.9 Provide any further information, in relation to the procedure for recruitment of participants and seeking informed consent, which has not been provided elsewhere in this document.

Click or tap here to enter text.

3.3 Participants lacking decisionmaking capacity

NOTE: Explicit consent (informed consent that is recorded) to process personal data for research purposes is specified as one of the necessary safeguards under the Data Protection Act 2018 (Section 36 (2)) (Health Research) Regulations. If explicit consent cannot be obtained for participation in the biobank, a consent declaration from the HRCDC may be required. For more information, visit – www.hrcdc.ie

3.3.1 Will all participants have the decision-making capacity to give informed consent?

☐ Yes ☐ No

If answer is Yes, please skip the remaining questions in Section 3.3.

3.3.2 Outline how the decision-making capacity of participant(s) is determined, and by whom.

Click or tap here to enter text.

3.3.3 Where capacity to consent may fluctuate or is deemed borderline, how will participants be involved in the decision to donate to the biobank?

This should include how information will be tailored to ensure participants are accommodated and assisted to understand the information and how participants who regain decision-making capacity will be re-consented to continue their participation in the biobank.

Click or tap here to enter text.

3.3.4 What arrangements have been made for participants who might not adequately understand verbal or written information?

Click or tap here to enter text.

3.3.5 Will the biobank support research which has the potential to benefit participants who lack decision-making capacity to consent for themselves?

Click or tap here to enter text.

3.3.6	Will the biobank itself, or the research it supports, involve any foreseeable risk or burden for these participants or interfere in any way with their fundamental rights and freedoms.
Click or tap here to enter text.	

3.3.7	What arrangements will be made to continue to consult these participants during the course of the research where necessary?
Click or tap here to enter text.	

3.3.8	Where participants are individuals who lack decision-making capacity, will a consent declaration be applied for from the HRCDC?
☐ Yes ☐ No	
If no, please provide justification	
Click or tap here to enter text.	

3.4 Minors

3.4.1	Will any participants be minors?
☐ Yes ☐ No	

If answer is No, please skip remaining questions in Section 3.4

3.4.2	Specify the potential age ranges of minors under 18 who will be recruited to participate in the biobank.
Click or tap here to enter text.	

3.4.3	Indicate the numbers of minors with COVID-19 and number of controls.
Click or tap here to enter text.	

3.4.4	Describe the arrangements for seeking informed consent from a person with parental responsibility

Click or tap here to enter text.

3.4.5 How will minors be involved and accommodated in an age-appropriate way, to seek their assent to participate in the biobank?

Describe arrangements for obtaining and recording assent of the minor, including who will be obtaining consent from parent/legal guardian and details of their training and experience with children.

Click or tap here to enter text.

3.4.6 How will minors be consented when they reach the age of legal competence?

Click or tap here to enter text.

3.5 Consent related to retrospectively collected samples and data

3.5.1 List the biobank sites providing retrospectively collected biological samples and data.

Click or tap here to enter text.

Address, comprehensively and separately, all of the following points, for each site listed above:

- whether the consent previously given matches that required by the biobank,
- whether participants will be re-consented for the purposes of the biobank, and
- the re-consenting process through which this will be obtained,
- whether a consent declaration from the HRCDC is required, and
- why a HRCDC consent declaration is or is not required.

Click or tap here to enter text.

3.6 Withdrawal of consent and/or assent

Ref: HSE-National-Policy-for-Consent-in-Health-and-Social-Care-Research Section 3.6 – Withdrawal of consent

3.6.1 Describe the processes to enable participants to withdraw their personal data and biological samples from the biobank.

This should include how potential consequences of consent withdrawal will be communicated to participants and managed

Click or tap here to enter text.

3.6.2 Outline in detail specific protocols for managing the withdrawal of consent and assent.

Click or tap here to enter text.

3.6.3 What will happen to the biological samples and associated data if 1) the participant does not provide deferred consent, or 2) proxy assent is not provided or is withdrawn.

If there are specific protocols for managing the withdrawal of consent and assent, please outline in detail.

1) Click or tap here to enter text.

2) Click or tap here to enter text.

3.6.4 It may not be possible to withdraw from a research study when:

- Personal data and results have been irrevocably anonymised, preventing them from being identified for removal.
- The results from such study have already been published.
- Research results have been disseminated in other ways, such as being deposited in a publicly accessible database, where subsequent usage could not be withdrawn.
- Analysis has been conducted and the data withdrawal may impact on the statistical validity of the result.
- Data have to be retained for safety and regulatory purposes.

Ref HSE National Consent Policy for Health Research (hseresearch.ie)

Explain how this will be managed and communicated to participants during the consent withdrawal process.

Click or tap here to enter text.

Section Four - Public engagement, PPI, sustainability and societal impact.

4.1 Public engagement and outreach

4.1.1 How will the impact of the biobank on society, health and social care research and innovation be measured, reported and disseminated to the public and participants during the life of the biobank?

e.g. peer-reviewed journal publications, research participants, public engagement

Click or tap here to enter text.

4.2 Public, patient and carer involvement activity

4.2.1 What public, patient and carer involvement activity (PPI) has been, or will be, undertaken with focus groups, advocacy groups, patient and/or representative participants regarding:

PPI activity is considered an important ethical and data protection safeguarding activity, to gain representative perspectives and opinions from representatives. PPI activity also provides a valuable and meaningful way of seeking views on the support for and development of the research. This PPI engagement can further inform what transparency measures can be implemented and how, which itself is an important data protection principle.

a) **The consent process:**

Click or tap here to enter text.

☐ **None**. If none explain why:

Click or tap here to enter text.

b) **Support for, and development of the biobank:**

Click or tap here to enter text.

☐ **None**. If none explain why:

Click or tap here to enter text.

c) **Any other comments:**

Click or tap here to enter text.

4.3 Commercialisation and translational impact

4.3.1 Please describe the anticipated societal and population health impact of the biobank.

Limit is 300 words
Click or tap here to enter text.

4.3.2 Describe the anticipated pathway towards translation and commercialisation of research outputs.
Click or tap here to enter text.

4.3.3 Where research is commercialised, will participants receive any benefits? Please explain.
Click or tap here to enter text.

4.4 Indemnity and insurance

4.4.1 What arrangements have been made for compensation in the event of a claim made by or on behalf of a participant?
Click or tap here to enter text.

4.4.2 Please confirm and provide evidence that appropriate insurance / indemnity is in place for the biobank at each site, if applicable.
Click or tap here to enter text.

4.4.3 Do the National Principal Investigators (Co-Directors) or any of the biobank investigators (scientific or governance team) have any direct or indirect involvement in the potential outcomes or commercialisation of biobank associated research that could in any way be regarded as a possible conflict of interest?
☐ Yes ☐ No
If yes, please provide further detail
Click or tap here to enter text.

4.5 Biobank costs and funding

4.5.1 Give details of funding organisation(s), amount of funding secured and duration of funding:	
Organisation (s):	Click or tap here to enter text.
Amounts (s)	Click or tap here to enter text.
Duration	Click or tap here to enter text.

4.5.2 What arrangements have been/will be made to cover the cost of the biobank when funding ends?
Click or tap here to enter text.

4.6 Payments to participants

4.6.1 Will participants be reimbursed for expenses?
Participants may be reimbursed for lost earnings, travel costs and other expenses incurred. Compensation for the time and inconvenience involved in participation (e.g. payment at minimum wage level) might also be permissible as research participants/ should not be expected to bear the costs that relate to donating a biobanking unit. However, it is important to note that compensation is understood to mean a recompense for losses incurred e.g. time away from work. **Any reimbursements or compensation that might be offered to participants, should be measurable and not reflect any undue inducement by encouraging people to act against their better judgment or take unnecessary risks.**
☐ Yes ☐ No
If yes, please provide further detail
Click or tap here to enter text.

4.6.2 Will participants receive any incentives?
☐ Yes ☐ No
If yes, please provide further detail
Click or tap here to enter text.

Section Five - Local approvals

Part five requests information regarding all local REC approvals in place, all associated conditions of those approvals and all responses to those conditions.

The inclusion of this information is for posterity, to inform the NICB-REC of all previous communications and approvals related to ethics at a local level.

Please note it is understood that all documents previously approved at a local level will be superseded by a harmonised set of documents, approved at a national level by the NICB-REC. The use of a harmonised set of documents across all biobank sites will ensure standardisation of process', procedures and consent.

5.1 Local REC approvals

This section covers all decisions which have been made by local RECs, as well as biobank responses, and actions taken, regarding decisions made and any associated conditions.

List all documents previously approved by Local RECs, any conditions associated with these approved documents and whether or not these conditions have been met.

NB: All listed documentation must be submitted as part of this application.

Document and date of issue	Local REC	Conditions of approval	Responses and actions taken
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Section Six – Declarations

Declaration of the biobank Directors/Custodians, Data protection officer(s) (DPO) and Authorised authority at each host institution.

This declaration must be signed and sent to the NICB-REC. Digital signatures are acceptable.

I certify that the information in this form is accurate to the best of my knowledge, and I take full responsibility for it.	☐ Yes ☐ No
I undertake to abide by the ethical principles outlined in the Declaration of Helsinki, the Declaration of Taipei and my obligations as set out in the relevant Good Clinical Practice Guidelines, (International Conference on Harmonisation's Good Clinical Practice Guidelines (ICH GCP).	☐ Yes ☐ No
If the biobank receives a favourable opinion, I undertake to adhere to the approved operations and governance and to comply with any conditions set out in the letter of approval sent by the NICB-REC.	☐ Yes ☐ No
I am aware of my responsibility to be up to date and comply with the requirements of the law relating to security and confidentiality of participant or other personal data as regulated under the General Data Protection Regulation and the Data Protection Act 2018 (Section 36(2)) (Health Research) Regulations.	☐ Yes ☐ No

Signature – Biobank Co-Director:	Add signature
Print Name:	Type name
Date:	dd/mm/yy
Signature – Biobank Co-Director:	Add signature
Print Name:	Type name
Date:	dd/mm/yy

I hereby declare that I am the duly authorised Data Protection Officer, and I am duly authorised by my organisation (Data Controller) to submit this application to the NICB-REC. To the best of my knowledge all the information provided herein is correct. I hereby understand that any decision made by the NICB-REC is based on the accuracy of the information provided herein, or any subsequent information provided to the NICB-REC.

Signature – UCD DPO:	Add signature
Print Name:	Type name
Date:	dd/mm/yy

Signature – TCD DPO:	Add signature
Print Name:	Type name
Date:	dd/mm/yy
I hereby declare that I am an authorised institutional signatory and I am duly authorised to submit this application to the NICB-REC.	
Signature – UCD Authorised institutional signatory	Add signature
Print Name:	Type name
Date:	dd/mm/yy
Signature – TCD Authorised institutional signatory	Add signature
Print Name:	Type name
Date:	dd/mm/yy