

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

Terms of Reference

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1. Overview

The National Action Plan for Ireland's response to COVID-19 was published on 16 March 2020¹. 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 biobank. The NICB requires a dedicated ethics review mechanism to ensure its establishment and governance 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. 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.

To this end, the Department of Health has mandated the National Office⁶ to support the establishment of a single, dedicated research ethics committee (REC) for the NICB. The NICB-REC will review ethics applications submitted by the NICB and deliver opinions on the ethical robustness of its establishment, governance 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.

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 will be 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 will be 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 will be 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, maintenance of and criteria for access rights to the NICB as a research infrastructure.

The ethical assessments carried out by the NICB-REC will include compliance of the NICB with the Declaration of Helsinki⁷, (first adopted by the World Medical Assembly in 1964, and updated in 2013) and the Declaration of Taipei⁸ 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 Regulations¹⁰ and Health Research Regulations 2018¹¹, 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 an infrastructure, plus subsequent applications for ethics approval for any amendments to the NICB.

The prevailing role of the Committee will be the protection of the rights, safety, dignity, and well-being of research 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 research¹², personal data protection biological samples collection and biobanking. Such bodies may include but not limited to the Health Research Consent Declaration Committee (HRCDC)¹³, the Irish National Accreditation Board (INAB)¹⁴ and the Biobanking and Biomolecular Research Infrastructure - European Research Infrastructure

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/>

Consortium (BBMRI-ERIC)¹⁵. 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.

3. Out of scope

The NICB-REC will not review ethics applications for any independent research studies that seek to use biological samples and associate data from the NICB. All research studies must have ethical approval, from a local institutional research ethics committee, in place, in advance of approaching the NICB to access the biological samples and associated data. The NICB will manage the application process for accessing the biobank.

4. Membership

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.

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 Committee shall comprise of members with professional qualifications or experience in the provision of health and social care, and ethical, legal and societal aspects of both biobanking and use of biological samples and clinical data in health and social care research.

The members of the NICB-REC will be appointed by the Minister of Health.

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.

5. Conduct of Members

The Committee will at all times in discharging their duties, act in good faith and maintain proper standards of integrity. During the course of the ethical review the members of the Committee shall adhere to these Terms of Reference for the NICB- REC provided by the National Office as follows:

- a. Actively participate in the all of the scheduled meetings each year, confirming attendance and any foreseen absences in advance,
- b. Comply with all relevant legislative requirements and have due regard to principles of best practice,
- c. Prepare ahead of committee meetings including review of applications, and documentation of any preliminary comments,
- d. Maintain impartiality in consideration of applications,

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

- e. Commit to a consensus-based approach to decision-making under the direction of the Chairperson or deputy chairperson as applicable, contributing opinions in line with member's capacity and comfort,
- f. Respect the opinions of all fellow Committee members,
- g. Work collaboratively with the Chairperson, fellow Committee members and National Office staff to ensure the highest standards of ethics review and efficiency in the process,
- h. Maintain the strictest confidentiality on proprietary information,
- i. Declare all affiliations and any conflicts of interest,
- j. Attend and complete the requisite training provided,
- k. Use IT tools provided by the National Office that facilitate the Committee's work,
- l. Uphold the National Office's values of trust and transparency in the Committee's work.

While conducting its ethical reviews, the Committee, shall have due regard to accepted principles of good governance and best practice as outlined in the NREC operational framework¹⁶ of the National Office. This includes where any conflict of interest arises in relation to an application. In such a case, the member must immediately declare the conflict of interest and remove themselves from any further consideration of the application. Members will also be required to complete an annual declaration of interest.

Where the Minister is satisfied that a member of a National REC has not complied with the aforementioned principles of conduct, the Minister may remove that member from office and that person shall then be disqualified from being a member from this or any other National REC.

6. Tenure

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.

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

Any Member of the Committee may resign by written notice (electronic or other written means, to the Minister/Chairperson and Head of National Office. This letter should be forwarded through the National Office for Research Ethics Committees:

By email: nicbrec@nrec.ie
 Or by post: Attn: Programme Manager, NICB-REC
 Grattan House,
 67-72 Lower Mount Street,
 Dublin 2, D02 H638

Once written notice of resignation is received by the Minister/Chairperson and Head of National Office the resignation will take effect on the date of the next meeting of the NICB-REC.

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

- a. the member has become incapable through ill-health of performing their functions,
- b. the member has committed stated misbehaviour of a type that would make them unsuitable for membership of the National REC,
- c. the removal of the member appears to the Minister to be necessary for the NICB-REC to

¹⁶ <https://www.nrecoffice.ie/wp-content/uploads/NREC-Operational-Framework-v1.1-Final.pdf>

perform its functions effectively and with public confidence.

If a member of a NICB-REC resigns, ceases to be qualified for office and ceases to hold office, or is removed from office, or dies, the Minister may appoint another a member to fill the vacancy for a duration determined by the Minister.

7. Meetings

The Committee will convene every four to six weeks for the purpose of reviewing the ethics application 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.

The duration of the meetings will be scheduled for two hours at a time as agreed by the Chairperson, Deputy Chairperson and ordinary members.

Further meetings may be scheduled, rescheduled or cancelled as determined by the Chairperson depending on the volume of applications received by the National Office over any one period.

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.

At least 5 working days before a meeting of the NICB-REC, the agenda, approved by or on behalf of the chairperson of the NICB-REC, or in the absence of the chairperson, by or on behalf of a deputy chairperson, will be sent by the National Office to every member of the NICB-REC scheduled to attend the meeting.

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.

At a meeting of the NICB-REC, the Chairperson of the NICB-REC will chair the meeting. Where the Chairperson is unavailable for a meeting the Deputy Chairperson will chair that meeting. Where the Deputy Chairperson is not available, another member of the NICB-REC shall be designated by the Head of the National Office in consultation with the Chairperson or Deputy Chairperson to chair that meeting.

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

8. 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.

Every question arising at a meeting of a NICB-REC will be collectively determined by the members present. A decision on an application can only be made at a meeting where there is a quorum present.

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

The NICB-REC shall make any of the following decisions:

- a. to give a favourable opinion in relation to the application,
- b. to give a favourable opinion in relation to the application, subject to certain conditions, or
- c. to refuse to give a favourable opinion in relation to the application.

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 should be 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, however, have the option to re-submit the 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. 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 minutes shall be distributed to all members with the agenda for the following meeting of the Committee for formal approval.

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.

9. 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, he or she will-

- a. disclose to the chairman 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.

For the purposes of the following points, but without prejudice to the generality of the points concerning conflicts of interest above, 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.

A person is not regarded as having a material interest in any matter if they, or any company or other body or person mentioned, has an interest which is so remote or insignificant that it cannot reasonably be regarded as likely to influence them in any way. The NICB-REC will also have due regard to the likelihood of a perception of a material interest.

Where a material interest is disclosed, the disclosure will be recorded in the minutes of the meeting concerned and the member of the NICB-REC by whom the disclosure is made will not be counted in the quorum for that meeting.

Where, at a meeting of the NICB-REC, a question arises as to whether or not a course of conduct, if pursued by a member of the NICB-REC, would constitute a failure by them to comply with the requirements regarding conflicts of interest, the chairperson will decide, and their decision will be final. Where such a question arises, particulars of the chairperson’s decision shall be recorded in the minutes of the meeting.

Where, at a meeting of the NICB-REC the chairperson of the meeting declares a conflict of interest the Deputy Chairperson will chair the meeting. Where both the Chairperson and the Deputy chairperson have a conflict of interest the other members of the NICB-REC attending the meeting will choose one of their number to be chairperson of the meeting.

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 and that person will then be disqualified from being a member of the NICB-REC concerned or any National REC.

10. Sub-Committees

The Head of 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 Head of 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.

11. 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 REC member.

12. 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.

13. Indemnity

Members will have legal indemnity in relation to their work on the committee where any action taken, or decision made is taken or made in good faith.

14. Expenses

Committee members shall be re-imbursed for all reasonable vouched expenses incurred by them in connection with the work of the committee.

In recognising that NICB-REC work will clearly fall outside of typical responsibilities and experiences for public, patient and carer involvement (PPI) members, these members will be offered an annual payment of €2.5K.