NATIONAL OFFICE FOR RESEARCH ETHICS COMMITTEES

National Irish COVID-19 Biobank – REC

Meeting minutes

Time: 09:00 to 11:00

Date: 01 July 2024

Location: Zoom meeting

Table of Contents

Attendance

Name	Role
Dr Georgina Flood	Chairperson, NICB-REC
Prof. Kathleen Bennett	Committee Member, NICB-REC
Mr John Culliney	Committee Member, NICB-REC
Dr Aisling de Paor	Committee Member, NICB-REC
Ms Joan Jordan	Committee Member, NICB-REC
Prof. Sean Hynes	Committee Member, NICB-REC
Dr Sonja Khan	Committee Member, NICB-REC
Prof Shaun O'Keeffe	Committee Member, NICB-REC
Prof. Cathal Seoighe	Committee Member, NICB-REC
Prof Anthony Staines	Committee Member, NICB-REC
Dr Emily Vereker	Head of Office, National Office for RECs
Dr Anne Costello	Programme Manager, National Office for RECs

Apologies

Name	Role
Dr Anne Moore	Deputy Chairperson, NICB-REC
Dr Brian Clark	Committee Member, NICB-REC
Dr Patrick Manning	Committee Member, NICB-REC
Dr Kevin May	Committee Member, NICB-REC
Dr Ciara Staunton	Committee Member, NICB-REC

Agenda

09:00 – 09:10 Welcome and notification of apologies

09:10 – 11:00 Discussion of NICB Access application. Section by section discussion followed by discussion of each submitted document.

Deliberations

Chairperson, Dr Georgina Flood, opened the meeting, welcomed the Committee, noted apologies and confirmed with the members that there were no conflicts of interest.

The Chairperson gave an overview of the structure of the meeting, such that the NICB access application would be discussed section by section, including the submitted documentation as follows:

- Template material and data transfer agreement
- Access Committee terms of reference;
- NICB Conflict of interest policy;
- NICB Recognition policy;
- NICB Sample and data access policy, and
- NICB Sustainability and cost recovery plan.

1. Researcher Access

- The Committee agreed that the criteria for approval or decline of applications for biobank access should be formally stated and transparent to applicants.
- The Committee commented that the NICB Access Committee should make provisions within the assessment process, to enable a rejection of access for a COVID-19 based research project which is not considered to be in the public interest.
- The Committee recommended that FAIR data principles are appropriately referenced in the access agreement template, the sample and data access policy and the NICB access application form to ensure that researchers accessing the biobank will adopt FAIR principles in relation to the research data generated and returned to the biobank. This is in line with the NICB's previously stated commitment to FAIR data principles.
- It was unclear to the Committee what collective expertise the Access Committee has to perform access assessments. It was noted that the membership of the Access Committee comprises a representative from each academic institution plus a Data Protection Officer and PPI members. The Committee noted that the applicant's made no reference to the required expertise the access committee members should bring, as a whole. The NICB should define a required skillset to ensure the appropriate expertise is included on the Access Committee, to appropriately assess the applications. This information should be included in the Access Committee terms of reference.
- The Committee noted that the researcher access application process includes various steps as follows:
  - Registration of applicant on the NICB online system (14-day turnaround for registration acceptance by the biobank operational team);
  - Researcher submission of access application;
  - NICB operations team check (14-day turnaround);
    - It was unclear to the Committee whether the operations teams are involved in solely validating the access application Or whether the operations team check determines if the application meets the criteria for '**access**'. The sample and data access policy states "All applications will undergo an initial check by the NICB Operations Team to ensure the application is accurate and complete and meets the criteria for access." The Committee recommend that the NICB Access Committee should be wholly responsible for determining whether an access application is approved or not.
  - Review by access committee (14-day turnaround);

- It was unclear to the Committee what assessment criteria will be used to determine whether an access application is approved or not, to ensure a fair process which will assure each application is assessed according to the same criteria. The Committee requested further information defining the formal criteria which will be used to assess applications for access to the biobank.
- The applicants stated that the access assessment process includes an assessment of whether adequate funding is in place for a study applying to the NICB; The Committee noted, however, that the amount of funding is not requested in the application form. The Committee recommended that the amount of funding available to carry out the research is requested in the access application form.
- The Committee queried the feasibility of a 14 day turn around for Access Committee assessment. However, the Committee accepted that this is an operational rather than an ethical matter which is best determined by the NICB.

– Local REC approval:

- The Committee noted that a successful access application must have local REC approval, to progress;

– NICB-REC involvement in assessing access applications:

- The Committee noted the reference to the NICB-REC as part of the NICB access assessment process and agreed this is not within the remit of the NICB-REC, which only provides ethical oversight for the NICB itself and not third-party research studies.
- The Committee recommended that the NICB Access Committee should include appropriate and independent ethics expertise to determine whether applications fall within the research scope of the NICB.
- The Committee noted that the ethics of the research projects drawing down from the biobank is a separate item to be determined and approved through the local REC system.

The Committee suggested that the access process should be appropriately streamlined and facilitative to enable progress of research projects, in line with the research scope of the biobank.

- The Committee noted that the terms of reference for the Access Committee do not include information relating to quorum or what may or may not constitute a quorum for decision making on access requests at a committee meeting. Further information on the quorum required for decision making was requested.
- The Committee considered that potential member conflict of interest should be assessed prior to appointment to the Access Committee.
- The Committee agreed that maximising the use of participants' donated data and bio-samples for research is an important ethical consideration. From a patient perspective it was suggested that when a participants' data and bio-samples are used for research that the participant receives a notification that their bio-samples and data have been accessed, for transparency of the use of the contribution they have made to the biobank.
- Data return vs IP generation: The type of IP generated in each research project would be case-by-case. The Committee considered that it may be difficult for the NICB to be wholly

prescriptive regarding the terms and conditions surrounding return and reuse of research findings. It was recommended that the NICB consider which terms and conditions may or may not be negotiable regarding the NICB's use of returned research findings. This is separate to terms and conditions related to return of research generated raw data.

- It is widely understood that third parties who may have an interest in an individual's personal health data, such as private insurance companies or employers, cannot under any circumstances, legally access an individual's banked data. The Committee recommended that, for the benefit of the participants, the assured protection of their personal health data under GDPR and the Irish Health Research Regulations is transparent and clearly communicated.
- The Committee considered that the NICB should keep the policy of non-return of incidental and/or secondary findings under review and ensure that this policy is updated in line with any related legislation and/or any future, compelling ethics guidelines.
- The Committee commented on the GDPR requirement of a Transfer Impact Assessment to be carried out for each access application received from outside the EEA. Where no local policy exists, which appropriately safeguards citizens bio-samples and data while overseas, then no transfer should occur.
- The Committee considered that inclusion of a section in the access application form, specific to applicants from outside the EEA, is required. This section should include a request for information regarding the legal basis for transfer of EEA citizen biosamples and data outside of the EEA.
- Access clauses for genetic and genomic research:
  - It was unclear to the Committee whether or not full genome sequencing would be permitted as part of an access agreement for a genetic or genomic research project.
  - It was unclear to the Committee what limits, if any, will be applicable to researchers' future use of generated genomic data.

  Access clauses which will ensure the confidentially requirements surrounding participants' personal data are required to be included in the access agreement and kept in line with the scope of the participant's consent.

2. Biological sample and data transfer

- The Committee considered that the NICB have appropriately managed data minimisation and purpose limitation as required under the GDPR article 5 purpose limitation principle.
- Generation of Genomic data:
  - While the Committee considered that non-disclosure of genetic information to 'at risk' family members is currently appropriate, it was recommended that the NICB should keep this under review. This approach to non-disclosure should be updated in line with any relevant future legislation or the publication of compelling ethics guidelines which address the legal duty of care and the individuals' rights of access to genetic risk information.
  - It was unclear to the Committee whether generated research data, including genomic data, would be destroyed when the project has concluded. Where generated data is

retained after the conclusion of the project the appropriate safeguards surrounding retention should be transparent and sufficient to protect the confidentiality and rights of the participant. Any future use of generated genomic data is required to be transparent.

  - In the interests of public health and public interest, the Committee considered that it would be appropriate for researchers who perform genomic sequencing in line with any appropriate consents from the participant(s), to ensure this the data is available at the conclusion of the research project, through public repositories and/or platforms such as the EU Genome archive. Transparency in this area is ethically imperative.

- The Committee suggested that an infographic which provides a clear visualisation of data protection requirements would be useful for applicants, particularly those outside the EEA.
- The Committee considered that access agreements between the NICB and organisations in receipt of samples and data for projects outside of the EEA, should be safeguarded with appropriate and robust legal terms and conditions, with clear authorised signatories.
- From a PPI perspective the Committee commented that participants' bio-samples and data should be used in line with participants expectations. That is, for participant data and biosamples to be distributed and used by researchers as much as possible, as safely as possible and as securely as possible.

3. Public engagement, PPI, sustainability and societal impact.

- The Committee considered that patient engagement as outlined was lacking substantive detail.
- The Committee recommended that a survey for biobank participants may be useful to gather general feedback.
- The Committee suggested that a survey for researchers accessing the biobank may inform the accessibility of the process itself, once it has been established.
- From a PPI perspective the Committee suggested a public social media video focussing on biobanking in general would raise public awareness and potentially contribute to increased participant understanding of what a biobank is and how it works to support health research. Raising public awareness in this way may lay the groundwork for improved participant understanding when these individuals are approached for informed consent in a hospital setting, when they may be very ill.
- The Committee considered that the information on how the public health impact of the biobank will be measured is unclear. Further information clarifying the metrics which will be monitored, and the associated key performance indicators (KPIs) was required. The Committee suggested that the performance of the NICB, once fully operational, should be benchmarked against National biobanks in other countries.
- The Committee considered that commercialisation should be recognised as an integral part of the research process. The importance of commercialisation in facilitating the development and use of new medicines which benefit patients and impact public health should be transparent and communicated to participants and potential participants. The website may provide a suitable medium for this information.

- The Committee agreed that it is necessary for PPI member(s) to be included on the Access Committee as a quorum fulfilment requirement for each meeting.
- The Committee considered that the NICB-REC should have sight of the Public feed-back and complaints process once it had been developed.
- The Committee considered the information provided around sustainability and cost recovery plan to be vague. Further information was required to clarify what the cost of access will be and whether different applicant types (commercial entities vs academic entities) will have different cost structures.

4. Documents submitted for ethical review

a. Template access agreement

- The Committee noted that the NICB sample and data access policy states no transfer to the researcher will commence until local REC approval is confirmed. The Committee suggested this statement should also be included in the access agreement.
- The Committee noted that the access agreement would require additional clauses governing the i) use of samples and date for genomic research, ii) access to samples and data of minors, iii) transfer of samples and data outside of the EEA and iv) research undertaken by commercial entities.
- The Committee agreed that until these additional governance safeguards for these specific uses are available for ethical assessment, ethics approval for access will be limited to standard access applications, and the NICB should not distribute samples and data for the aforementioned purposes.
- The Committee agreed that a modification application should be submitted at a future date for ethics assessment regarding the provision of samples and data for uses i) – iv) noted above.
- In the context of transparency as an ethical principle, the Committee had the following queries regarding the generation, safeguarding and future use of participant genomic data:
    - Where bio-samples are accessed for whole genome sequencing, the future use of this data by the researcher should be transparent within the access agreement. While it is understood that genome sequence data will be returned to the biobank the following is not clear and should be clarified by special clauses within the access agreement:
        - Will the researcher own the genome sequence data generated as part of the research project?
        - Will the researcher be required to share genomic data generated as part of the project on open repositories for the public good? Eg: the EU Genome archive.
        - Will the researcher be required to destroy genomic data generated as part of the project?
        - Will a genetic discrimination/stigma check be undertaken as part of an access assessment for genomic research. The Committee recommended that

appropriate expertise is included on the access committee to perform genetic risk evaluations.

- Regarding the transfer of samples and data outside of the EEA, the Committee commented as follows:
  - For each access application from outside the EEA, the legal basis for transfer of biosamples and data outside the EEA is required prior to access assessment. The Committee considered that this information should be requested in the access application form
  - The legal basis for transfer should be included in the special terms of the access agreement.
- The Committee noted the terms and conditions in the access agreement for the return and reuse of raw data from third party research studies. The Committee agreed that raw data should be returned to the biobank as outlined in the agreement, for future research use, for the public good. However, the Committee commented that the access agreement contains potentially prohibitive terms related to NICB future use of research findings for which the researchers hold the Intellectual Property (IP) rights to. Prohibitive terms may unnecessarily deter potential applicants and limit use of the biobank. The Committee recommended that the NICB review these terms and conditions in consultation with the Technology Transfer Offices, or equivalent at each of the host institutions to ensure all terms are appropriate and in line with the National IP policy as applicable
- Biological sample return: The Committee acknowledged that the volume of biological sample accessed by the researcher will be justified and proportionate to the specific requirements of the research project, with minimal waste. However, it was recommended that in the event biological samples are distributed and are unused or not fully used (for example where a project does not progress) that the biosamples are returned to the biobank rather than destroyed. It was recommended that the integrity of the biosamples and return of the biosamples should be assured through the addition of clauses for this eventuality, in the access agreement.
- The Committee noted that section 9.3 which outlines researcher correspondence with a participant allows the researcher to communicate with a participant once the content of the communication is approved by the NICB. The Committee recommended that this clause is strengthened to ensure third parties should not correspond with participants when contacted. The Committee recommended that an NICB standard response should be issued to and used by researchers in this instance, which advises the participant to contact the biobank directly.
- The Committee noted that the access agreement made no reference to the Irish Health Research Regulations in relation to data protection legislation which governs the use of personal health data of Irish citizens for research. The Committee recommended that relevant information should be included in the access agreement.
- As the NICB is not a legal entity it was unclear to the Committee which host organisation would be the authorised signatory of the legal access agreement(s) between the researcher applicant(s) and the NICB. This was considered to be a governance item outside the scope of the NICB-REC ethics assessment.

- Standard terms and annexes: Annex 3 is listed as annex 4 and annex 4 is listed as annex 3. The Committee recommended that these references are corrected.

b. Sustainability and cost recovery plan

- The Committee noted that the cost recovery plan includes no actual costs. The difference between costs from industry vs academia was not included. The Committee considered that actual costs should be included in the plan and resubmitted to the NICB-REC.
- The sustainability and cost recovery plan references different costs for new acquisition cohort vs pre-existing cohort. The Committee noted that while access to pre-existing cohorts is referenced in the plan, the biobank does not currently have ethical approval to include or distribute retrospectively collected participant bio-samples and data. Pre-existing cohorts can be included in the biobank and distributed to researchers only after the NICB has submitted an application for such to the NICB-REC and ethical approval has been granted.
- The Committee encouraged a differentiated pricing structure for academia according to where an institution is based (Low to middle income country (LMIC) v High income country (HIC))

c. Access committee Terms of Reference (ToR)

- The Committee noted that no information has been provided regarding the duration of an access committee member term. This information should be clarified and included in the ToR.
- Quorum details for meetings have not been provided. This information should be clarified and included in the ToR.
- The PPI membership requirement is stated as up to two. The minimum PPI membership number and the PPI member requirement for quorum should be included in the ToR.
- The criteria for assessment of an access request should be clarified and included in the ToR.
- The Committee noted the timeline for researcher access assessments is provided as 14 days which may be restrictive. The Committee suggested the inclusion of the term *'generally'* 14 days.
- The Committee queried whether the access committee will have any secondary functions and if so these should be outlined in the ToR.
- The Committee recommended that processes for access committee member appointment, training and replacement should be clarified and included in the ToR.

d. NICB sample and data access policy

- The Committee considered that there are some language inconsistencies within the document as follows:
  - Page 1, Section entitled 'Benefits' does not include any text related to benefits.
  - Page 1, Section entitled 'Principals':
    - The Committee suggested that access and prioritisation would not be considered 'principles'.

        - The Committee considered that the text under ‘Equity’ is aligned with equitable access rather than the more general term ‘equity’.

- Page 5, Diagram ‘steps to access’.
  - The Committee considered that this diagram may be improved by including decision points throughout the access process to clarify where and why an application may be progressed or not.
- Appendix one: Access application
  - Overall, the Committee discussed that the access application form requests the appropriate amount of information to enable a robust review for the purposes of access, while not overburdening the applicants.
  - The Committee discussed that the actual amount of funding available for a research project would need to be requested to enable an assessment of sufficient provisions for the proposed research.
  - The Committee discussed that access applications from outside the EEA would require additional information including the legal basis for participant sample and data transfer outside of the EEA.

e. Conflict of interest policy

- The Committee discussed that member conflict of interest should be assessed prior to appointment to the access committee. This would not negate the need to appropriately manage conflicts of interest with any application assessed by the access committee at each meeting.

f. Recognition policy

- This document was considered to be appropriate for its purposes.

Opinion

A favourable ethics opinion with associated conditions (See Appendix I) was agreed by NICB-REC member consensus.

Meeting close

The Chairperson thanked the members and closed the meeting.

Appendix I – Single national ethics opinion of NICB-REC

Opinion

The NICB-REC ethics opinion on Part 4 of the NICB 'Researcher Access, commercialisation and downstream impact' application is as follows: **Favourable with conditions**

Summary of conditions

- The NICB must not distribute participant bio-samples and data, for i) use of samples and date for genomic research, ii) access to samples and data of minors, iii) transfer of samples and data outside of the EEA and iv) research undertaken by commercial entities., until the additional clauses in the access agreement, related to these items, have been assessed by the NICB-REC by way of a modification application.
- The NICB must remove involvement of the National Office or the NICB-REC from the access application process.
- The NICB must provide further information regarding:
  - the formal criteria which will be used to assess applications for access to the biobank.
  - the specific expertise the Access Committee members have, which will enable an appropriately informed assessment of access applications.
  - the member quorum for Access Committee decision making.
  - the number of PPI members required to fulfil a decision-making quorum at Access Committee meetings.
  - The actual costs within the cost recovery plan.
  - The NICB metrics which will be monitored, and the associated key performance indicators (KPIs).

Summary of recommendations

- Information is included in the Access Committee terms of reference document as follows:
  - Required skillset for the access committee membership
  - Information on quorum for decision making
  - Stated minimum PPI member number for the committee and for quorum.
  - Any secondary functions of the Access Committee.
  - Processes for member appointment, training and replacement
- The NICB Access Committee should include appropriate expertise to determine whether applications fall within the research scope of the biobank.
- Appropriate expertise is included on the Access Committee to ensure genetic risk evaluations can be carried out appropriately when research projects are undertaking genetic or genomic analysis.
- Availability of a flow chart to clarify for researchers the access process steps, decision points and timelines.

- Availability of an infographic which provides a clear visualisation of data protection requirements would be useful for applicants, particularly those outside the EEA.
- A differentiated pricing structure for academia according to where institution is based (Low to middle income country (LMIC) v High income country (HIC)).
- FAIR data principles are appropriately referenced in the access agreement template, the sample and data access policy and the NICB access application form.
- An NICB standard response is issued by the NICB to researchers, for use when they are contacted by a participant, which advises the participant to contact the biobank directly.
- The biobank review terms and conditions, related to biobank use and distribution of returned research results and findings, in consultation with the technology transfer offices at each of the host institutions.
- Relevant information related to the Irish Health Research Regulations is included in the access agreement.
- Biosamples are returned to the biobank rather than destroyed in the event they remain unused or not fully used for the research project (for example where a project does not progress).
- Language inconsistencies within the sample and data access policy should be amended for clarity
- The amount of funding available to carry out the research is requested in the access application form to enable an assessment of appropriate resources.
- A survey for biobank participants to gather general feedback.
- A survey for researchers accessing the biobank to inform the accessibility of the process itself once it has been established.
- The performance of the NICB, once fully operational, is benchmarked against National biobanks in other countries.
- From a PPI perspective the Committee recommends a public social media video focussing on biobanking in general would raise public awareness and potentially contribute to increased participant understanding of what a biobank is and how it works to support health research.
- The NICB-REC should have sight of the public feed-back and complaints process once it had been developed.
- The importance of commercialisation in facilitating the development and introduction of new medicines which benefit public health should be transparent and communicated to participants and potential participants. The website may provide a suitable medium for this information.
- Conflict of interest for all Access Committee members should be assessed prior to appointment to the Access Committee.