**National Irish COVID-19 Biobank -Research Ethics Committee**

National Irish COVID-19 Biobank (NICB) Modification Application Form

Version 1

Please address the following points when submitting your application:

* Form expiry date 31 September 2024 (please [redownload](https://www.nrecoffice.ie/committees-nicb-rec-nicb-modifications/) form after this date)
* All main sections of this form are mandatory.
* Fill out this document in language comprehensible to a lay person.
* Provide section references and page numbers for all modifications to documentation.
* **Appendix 1** should be completed in full when an application to include retrospective bio-samples and data in the biobank is submitted for ethical assessment.
* **Appendix 2** should be completed in full when an application to include, in the biobank, participants with diminished capacity and/or participants who lack decision making capacity, is submitted for ethical assessment.
* **Appendix 3** provides a template table which should be copied into the cover letter included with this modification application.
* The inclusion of a cover letter with the submission of this form is a mandatory requirement. The cover letter should include a list of all documents included in the modification request, the document version numbers, the modifications, brief justifications and the action required (ethical review vs notification).
* All application documents should be numbered, and file names should include version number and/or date.
* Include clean and track changes versions of any relevant documentation, to highlight modifications.
* Quote the NICB-REC biobank reference (23-NICB-REC-001) in submission email subject line.

If you are uncertain whether the proposed change constitutes a substantial modification, please see [Guide to NICB Modifications - NREC (nrecoffice.ie)](https://www.nrecoffice.ie/committees-nicb-rec-nicb-modifications/)

**Note**: Scanned copies of this form will not be accepted. On completion, please convert this form to PDF format before submission.

# Table of Contents

[1 Biobank Information 3](#_Toc158217666)

[2 Nature of modification 4](#_Toc158217667)

[3 Site and/or Site Lead or Co-Director modification 5](#_Toc158217668)

[4 Details and justification for all other modification(s) 6](#_Toc158217672)

[5 Participants 6](#_Toc158217673)

[6 Declarations 7](#_Toc158217674)

[Appendix I – Retrospective biological samples and data 9](#_Toc158217675)

[1 Consent related to retrospectively collected samples and data 9](#_Toc158217676)

[1.1 Consent from retrospective participants across all sites 9](#_Toc158217677)

[1.2 Biobank sites providing retrospectively collected samples and data. 9](#_Toc158217678)

[1.3 Site specific retrospective bio-sample and data information 10](#_Toc158217679)

[Appendix 2 – Inclusion of participants with diminished capacity or who lack decision making capacity 21](#_Toc158217690)

[Appendix 3 – Cover letter table template 23](#_Toc158217691)

1. Biobank Information

Summary reference information of the biobank to date. This information is **pre-filled**. Any modifications to this summary information should be included in the relevant sections of this form.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Title | National Irish COVID-19 Biobank | | | |
| NICB-REC reference | 23-NICB-REC-001 | | | |
| Biobank Co-Directors | Name | Prof Paddy Mallon | | |
| Affiliation | University College Dublin | | |
| Name | Dr Colm Bergin | | |
| Affiliation | Trinity College Dublin | | |
| Lead contact | Name | Susanne Bracken | | |
| Email | brackesu@tcd | | |
| Biobank sites and site leads. | CR\* Site | Beaumont Hospital | Lead | Dr Eoghan de Barra |
| CR Site | Children’s Health Ireland | Lead | Dr Paddy Gavin |
| CR Site | Coombe Women’s University Hospital | Lead | Prof Michael O’Connell |
| CR Site | Cork University Hospital | Lead | Dr Corinna Sadlier |
| CR Site | Galway University Hospital | Lead | Dr Bairbre McNicholas |
| CR Site | Limerick University Hospital | Lead | Dr Patrick Stapleton |
| CR Site | Mater Misericordiae University Hospital | Lead | Dr Aoife Cotter |
| CR Site | National Maternity Hospital, Holles Street | Lead | Prof Donal Brennan |
| CR Site | St James’ Hospital | Lead | Prof Cliona Ní Cheallaigh |
| CR Site | St Vincent’s University Hospital | Lead | Prof Eoin Feeney |
| CR Site | Tallaght University Hospital | Lead | Prof Seamus Donnelly |
| CR Site | Sligo University Hospital | Lead | Dr Katherine Finan |
| CR Site | Wexford General Hospital | Lead | Dr Obada Yousif |
| US\* Site | University College Dublin | Lead | Prof Paddy Mallon |
| US Site | Trinity College Dublin | Lead | Dr Richard Flavin |
| US Site | Royal College of Surgeons in Ireland | Lead | Prof Gianpiero Cavalleri |
| US Site | University of Galway | Lead | Prof Aoife Lowery |
| US Site | University College Cork | Lead | Prof Louise Burke |
| U\* Site | University of Limerick | Lead | Dr Elizabeth Ryan |

\*Clinical recruitment (CR) sites, University storage (US) sites for bio-sample & data storage and University (U) site(s) not involved in recruitment or bio-sample & data storage.

1. Nature of modification

|  |  |
| --- | --- |
| Please indicate the nature of the proposed modification | |
| 1. Modification of biobank governance structures   *Please complete sections 4, 5 and 6 and attach a copy of updated documentation, along with original documentation version with tracked / highlighted changes.* | Yes  No |
| 1. Modification of biobank operations   *Please complete sections 4, 5 and 6 and attach a copy of updated documentation, along with original documentation version with tracked / highlighted changes.* | Yes  No |
| 1. Modification of the biobank protocol   *Please complete sections 4, 5 and 6 and attach a copy of updated documentation, along with original documentation version with tracked / highlighted changes.* | Yes  No |
| 1. Appointment/departure of a national Co-Director   *Please complete* sections *3.1, 5 and 6* | Yes  No |
| 1. Appointment/departure of a site lead   *Please complete sections 3.2, 5 and 6* | Yes  No |
| 1. Inclusion of a new biobank site   *Please complete sections 3.3, 5 and 6* | Yes  No |
| 1. Inclusion of an existing bio-sample and data repository/retrospective participant cohort   *For inclusion of retrospective participant cohorts please complete section 6 and Appendix 1* | Yes  No |
| 1. Inclusion of an additional prospective participant cohort   *Please complete sections 4, 5 and 6* | Yes  No |
| 1. If ‘Yes’ to (h) above, please indicate the prospective participant cohort   *For inclusion of participants with diminished capacity or who lack decision making capacity please complete section 6 and Appendix 2* | Participants with diminished capacity or who lack decision making capacity    Other prospective participant cohort(s) |
| 1. Modification of participant information leaflet/informed consent/assent form (PIL/ICF)   *Please complete sections 4, 5 and 6 and attach a copy of updated documentation, along with original documentation version with tracked / highlighted changes.* | Yes  No |
| 1. Modification of other approved documents   *Please complete sections 4, 5 and 6 and attach a copy of updated documentation, along with original documentation version with tracked / highlighted changes.* | Yes  No |
| 1. Modification not listed above   *Please complete sections 4, 5 and 6* | Yes  No |

1. Site and/or Site Lead or Co-Director modification

|  |  |  |
| --- | --- | --- |
| Sites, Site Leads and Co-Director modifications | | |
| * 1. Where a new Co-Director is appointed, please outline the suitability of the individual for the role in the text box below, and include a full CV with this modification. | | |
| Click to enter new Co-Director suitability for role. | | |
| * 1. Where a new Site Lead is appointed, please:   2. A – name the biobank site in the textbox below | | |
| Click to enter site. | | |
| * 1. B – name the new Site Lead and outline the suitability of the individual for the role, in the text box below. | | |
| Click to enter new Site Lead name and suitability for role. | | |
| * 1. Inclusion of a new site (complete all information) | | |
| Site name | Click here to enter site name. | |
| Site location | Click here to enter site address. | |
| Site Lead Name | Click here to enter name of Site Lead. | |
| Site Lead affiliation | Click here to enter Site Lead affiliation(s). | |
| Suitability of the individual for the role of site lead. | Click here to enter suitability of the named individual for Site Lead role. | |
| Please confirm a site suitability assessment has been carried out as per the NICB site assessment template. | | Confirmed |
| Please include a statement of site suitability in the text box below. | | |
| Click to include a statement of site suitability. | | |

1. Details and justification for all other modification(s)

This section should be completed for all modifications not captured in section 3.

|  |  |
| --- | --- |
| Details and justification for the modification(s) as indicated in Section 2 | Document reference -  section/page |
| Click to enter details and justification | Click to enter document reference |
| Click to enter details and justification | Click to enter document reference |
| Click to enter details and justification | Click to enter document reference |
| Click to enter details and justification | Click to enter document reference |
| Click to enter details and justification | Click to enter document reference |

1. Participants

|  |  |
| --- | --- |
| Impact of modification on participants | |
| Will existing participants need to be reconsented to participate in the biobank due to this modification? | Yes  No |
| If ‘Yes’, please outline the reconsent processes, in the text box below, and submit a copy of all updated documentation, along with original documentation versions with tracked changes. | |
| Click to enter text. | |
| A - If ‘No’ please confirm that the requested modification does not include changes for which an update to participant informed consent would be required. | Confirmed |
| B - If ‘No’ will participants receive further information because of this modification, without a requirement for re-consent? | Yes  No |
| If ‘Yes’ to ‘B’ above, please submit an edited PIL or supplementary information document as appropriate. | |

1. 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 modification receives a favourable opinion, I undertake to adhere to the approved modification 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** |  | |
| **Print name** | Click to enter name | |
| **Date** | Click to enter date | |
| **Signature – Biobank Co-Director** |  | |
| **Print name** | Click to enter name | |
| **Date** | Click to enter date | |
| 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** |  | |
| **Print name** | Click to enter name | |
| **Date** | Click to enter date | |
| **Signature – TCD DPO** |  | |
| **Print name** | Click to enter name | |
| **Date** | Click to enter date | |
| 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** |  | |
| **Print name** | Click to enter name | |
| **Date** | Click to enter date | |
| **Signature – TCD Authorised institutional signatory** |  | |
| **Print name** | Click to enter name | |
| **Date** | Click to enter date | |

Appendix I – Retrospective biological samples and data

This appendix is to be completed in full where a modification request is to include retrospective samples and data in the biobank.

Please note the following:

* The requirement for Informed Consent applies equally to both prospective and retrospective biobank participants.
* If the use of biological samples and associated data for health research has deviated from the scope of the original consent obtained from retrospective participants, re-consenting is likely to be required.
* Where consent for the processing of personal data associated with biological samples cannot be obtained, a consent declaration from the Health Research Consent Declaration Committee (HRCDC)[[1]](#footnote-2) is required.

1. Consent related to retrospectively collected samples and data
   1. Consent from retrospective participants (standardised across all sites)

|  |  |
| --- | --- |
| Standardised biobank reconsent strategy across sites | |
| Please provide detail of the reconsent process for retrospective participants below. | |
| Click to enter the NICB reconsent process for retrospective participants. | |
| Where retrospective participants are reconsented, will the current NICB-REC approved PIL/ICFs be used?  *If ‘No’ please submit reconsent PIL/ICFs with this modification request as well as any other relevant documentation.* | Yes  No |
| In the event retrospective samples and data are intended to be included in the biobank in the absence of informed consent please explain both the legal and ethical basis by which retrospective participant samples and data can be used for research in the text box below. | |
| Click to enter text or include N/A as appropriate. | |
| *Please include* ***site specific information*** *for each retrospective cohort, in section 1.3 below.* | |

* 1. Biobank sites providing retrospectively collected samples and data.

|  |
| --- |
| Please list all biobank sites providing retrospectively collected biosamples and associated data. |
| Click to enter biobank site |
| Click to enter biobank site |
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* 1. Site specific retrospective bio-sample and data information

For each biobank site listed in section 1.2 above, fill in a table below. Please address each biobank site separately.

* + 1. Click here to enter biobank site name.

|  |  |
| --- | --- |
| Retrospective cohort information at site | |
| 1. Is the scope of retrospective participant consent equivalent to the informed consent for participants prospectively recruited to the biobank? | Yes  No |
| * 1. If ‘**Yes**’ please provide further detail below | |
| Click to enter further detail | |
| * 1. If ‘**No**’ will retrospective participants be contacted and reconsented according to the process detailed in section 1.1 above? | Yes  No |
| * + 1. If ‘**No**’ will the biobank seek a consent declaration from the HRCDC for inclusion of the retrospective participant data, available at this site, in the biobank? | Yes  No |
| 1. Where no Consent Declaration will be sought from the HRCDC please provide further detail explaining how these data (and associated biosamples) can be used for research without informed consent. | |
| Click to enter further information | |
| 1. Please confirm that all retrospective bio-samples and data will be managed in accordance with the same governance, access and data protection standards applicable to the existing prospective/current participant cohort. | Yes  No |
| * + 1. If ‘No’ please explain below. | |
| Click here to enter further information | |
| 1. Please state the approximate number of retrospective participants to be included at this site. | |
| Click here to enter number of bio-samples and data | |
| 1. Please provide detail on the nature of the retrospective bio-samples and data at this site. For example:  * historical participants (eg those not involved in any current clinical trial or study) vs participants of ongoing research studies at the site location, * types of biosamples * scope of health data | |
| Click here to enter further information | |
| 1. Please include any relevant further information below. | |
| Click here to enter further information | |

* + 1. Click here to enter biobank site name.

|  |  |
| --- | --- |
| Retrospective cohort information at site | |
| 1. Is the scope of retrospective participant consent equivalent to the informed consent for participants prospectively recruited to the biobank? | Yes  No |
| * 1. If ‘**Yes**’ please provide further detail below | |
| Click to enter further detail | |
| * 1. If ‘**No**’ will retrospective participants be contacted and reconsented according to the process detailed in section 1.1 above? | Yes  No |
| * + 1. If ‘**No**’ will the biobank seek a consent declaration from the HRCDC for inclusion of the retrospective participant data, available at this site, in the biobank? | Yes  No |
| 1. Where no Consent Declaration will be sought from the HRCDC please provide further detail explaining how these data (and associated biosamples) can be used for research without informed consent. | |
| Click to enter further information | |
| 1. Please confirm that all retrospective bio-samples and data will be managed in accordance with the same governance, access and data protection standards applicable to the existing prospective/current participant cohort. | Yes  No |
| * + 1. If ‘No’ please explain below. | |
| Click here to enter further information | |
| 1. Please state the approximate number of retrospective participants to be included at this site. | |
| Click here to enter number of bio-samples and data | |
| 1. Please provide detail on the nature of the retrospective bio-samples and data at this site. For example:  * historical participants (eg those not involved in any current clinical trial or study) vs participants of ongoing research studies at the site location, * types of biosamples * scope of health data | |
| Click here to enter further information | |
| 1. Please include any relevant further information below. | |
| Click here to enter further information | |

* + 1. Click here to enter biobank site name.

|  |  |
| --- | --- |
| Retrospective cohort information at site | |
| 1. Is the scope of retrospective participant consent equivalent to the informed consent for participants prospectively recruited to the biobank? | Yes  No |
| * 1. If ‘**Yes**’ please provide further detail below | |
| Click to enter further detail | |
| * 1. If ‘**No**’ will retrospective participants be contacted and reconsented according to the process detailed in section 1.1 above? | Yes  No |
| * + 1. If ‘**No**’ will the biobank seek a consent declaration from the HRCDC for inclusion of the retrospective participant data, available at this site, in the biobank? | Yes  No |
| 1. Where no Consent Declaration will be sought from the HRCDC please provide further detail explaining how these data (and associated biosamples) can be used for research without informed consent. | |
| Click to enter further information | |
| 1. Please confirm that all retrospective bio-samples and data will be managed in accordance with the same governance, access and data protection standards applicable to the existing prospective/current participant cohort. | Yes  No |
| * + 1. If ‘No’ please explain below. | |
| Click here to enter further information | |
| 1. Please state the approximate number of retrospective participants to be included at this site. | |
| Click here to enter number of bio-samples and data | |
| 1. Please provide detail on the nature of the retrospective bio-samples and data at this site. For example:  * historical participants (eg those not involved in any current clinical trial or study) vs participants of ongoing research studies at the site location, * types of biosamples * scope of health data | |
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| 1. Please include any relevant further information below. | |
| Click here to enter further information | |

* + 1. Click here to enter biobank site name.

|  |  |
| --- | --- |
| Retrospective cohort information at site | |
| 1. Is the scope of retrospective participant consent equivalent to the informed consent for participants prospectively recruited to the biobank? | Yes  No |
| * 1. If ‘**Yes**’ please provide further detail below | |
| Click to enter further detail | |
| * 1. If ‘**No**’ will retrospective participants be contacted and reconsented according to the process detailed in section 1.1 above? | Yes  No |
| * + 1. If ‘**No**’ will the biobank seek a consent declaration from the HRCDC for inclusion of the retrospective participant data, available at this site, in the biobank? | Yes  No |
| 1. Where no Consent Declaration will be sought from the HRCDC please provide further detail explaining how these data (and associated biosamples) can be used for research without informed consent. | |
| Click to enter further information | |
| 1. Please confirm that all retrospective bio-samples and data will be managed in accordance with the same governance, access and data protection standards applicable to the existing prospective/current participant cohort. | Yes  No |
| * + 1. If ‘No’ please explain below. | |
| Click here to enter further information | |
| 1. Please state the approximate number of retrospective participants to be included at this site. | |
| Click here to enter number of bio-samples and data | |
| 1. Please provide detail on the nature of the retrospective bio-samples and data at this site. For example:  * historical participants (eg those not involved in any current clinical trial or study) vs participants of ongoing research studies at the site location, * types of biosamples * scope of health data | |
| Click here to enter further information | |
| 1. Please include any relevant further information below. | |
| Click here to enter further information | |

* + 1. Click here to enter biobank site name.

|  |  |
| --- | --- |
| Retrospective cohort information at site | |
| 1. Is the scope of retrospective participant consent equivalent to the informed consent for participants prospectively recruited to the biobank? | Yes  No |
| * 1. If ‘**Yes**’ please provide further detail below | |
| Click to enter further detail | |
| * 1. If ‘**No**’ will retrospective participants be contacted and reconsented according to the process detailed in section 1.1 above? | Yes  No |
| * + 1. If ‘**No**’ will the biobank seek a consent declaration from the HRCDC for inclusion of the retrospective participant data, available at this site, in the biobank? | Yes  No |
| 1. Where no Consent Declaration will be sought from the HRCDC please provide further detail explaining how these data (and associated biosamples) can be used for research without informed consent. | |
| Click to enter further information | |
| 1. Please confirm that all retrospective bio-samples and data will be managed in accordance with the same governance, access and data protection standards applicable to the existing prospective/current participant cohort. | Yes  No |
| * + 1. If ‘No’ please explain below. | |
| Click here to enter further information | |
| 1. Please state the approximate number of retrospective participants to be included at this site. | |
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| Click here to enter further information | |
| 1. Please include any relevant further information below. | |
| Click here to enter further information | |

* + 1. Click here to enter biobank site name.

|  |  |
| --- | --- |
| Retrospective cohort information at site | |
| 1. Is the scope of retrospective participant consent equivalent to the informed consent for participants prospectively recruited to the biobank? | Yes  No |
| * 1. If ‘**Yes**’ please provide further detail below | |
| Click to enter further detail | |
| * 1. If ‘**No**’ will retrospective participants be contacted and reconsented according to the process detailed in section 1.1 above? | Yes  No |
| * + 1. If ‘**No**’ will the biobank seek a consent declaration from the HRCDC for inclusion of the retrospective participant data, available at this site, in the biobank? | Yes  No |
| 1. Where no Consent Declaration will be sought from the HRCDC please provide further detail explaining how these data (and associated biosamples) can be used for research without informed consent. | |
| Click to enter further information | |
| 1. Please confirm that all retrospective bio-samples and data will be managed in accordance with the same governance, access and data protection standards applicable to the existing prospective/current participant cohort. | Yes  No |
| * + 1. If ‘No’ please explain below. | |
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| 1. Please state the approximate number of retrospective participants to be included at this site. | |
| Click here to enter number of bio-samples and data | |
| 1. Please provide detail on the nature of the retrospective bio-samples and data at this site. For example:  * historical participants (eg those not involved in any current clinical trial or study) vs participants of ongoing research studies at the site location, * types of biosamples * scope of health data | |
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| 1. Please include any relevant further information below. | |
| Click here to enter further information | |

* + 1. Click here to enter biobank site name.

|  |  |
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| Retrospective cohort information at site | |
| 1. Is the scope of retrospective participant consent equivalent to the informed consent for participants prospectively recruited to the biobank? | Yes  No |
| * 1. If ‘**Yes**’ please provide further detail below | |
| Click to enter further detail | |
| * 1. If ‘**No**’ will retrospective participants be contacted and reconsented according to the process detailed in section 1.1 above? | Yes  No |
| * + 1. If ‘**No**’ will the biobank seek a consent declaration from the HRCDC for inclusion of the retrospective participant data, available at this site, in the biobank? | Yes  No |
| 1. Where no Consent Declaration will be sought from the HRCDC please provide further detail explaining how these data (and associated biosamples) can be used for research without informed consent. | |
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| 1. Please confirm that all retrospective bio-samples and data will be managed in accordance with the same governance, access and data protection standards applicable to the existing prospective/current participant cohort. | Yes  No |
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| Click here to enter further information | |
| 1. Please include any relevant further information below. | |
| Click here to enter further information | |

* + 1. Click here to enter biobank site name.

|  |  |
| --- | --- |
| Retrospective cohort information at site | |
| 1. Is the scope of retrospective participant consent equivalent to the informed consent for participants prospectively recruited to the biobank? | Yes  No |
| * 1. If ‘**Yes**’ please provide further detail below | |
| Click to enter further detail | |
| * 1. If ‘**No**’ will retrospective participants be contacted and reconsented according to the process detailed in section 1.1 above? | Yes  No |
| * + 1. If ‘**No**’ will the biobank seek a consent declaration from the HRCDC for inclusion of the retrospective participant data, available at this site, in the biobank? | Yes  No |
| 1. Where no Consent Declaration will be sought from the HRCDC please provide further detail explaining how these data (and associated biosamples) can be used for research without informed consent. | |
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| 1. Please confirm that all retrospective bio-samples and data will be managed in accordance with the same governance, access and data protection standards applicable to the existing prospective/current participant cohort. | Yes  No |
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| Click here to enter further information | |
| 1. Please include any relevant further information below. | |
| Click here to enter further information | |

* + 1. Click here to enter biobank site name.

|  |  |
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| Retrospective cohort information at site | |
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| * 1. If ‘**Yes**’ please provide further detail below | |
| Click to enter further detail | |
| * 1. If ‘**No**’ will retrospective participants be contacted and reconsented according to the process detailed in section 1.1 above? | Yes  No |
| * + 1. If ‘**No**’ will the biobank seek a consent declaration from the HRCDC for inclusion of the retrospective participant data, available at this site, in the biobank? | Yes  No |
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| 1. Please provide detail on the nature of the retrospective bio-samples and data at this site. For example:  * historical participants (eg those not involved in any current clinical trial or study) vs participants of ongoing research studies at the site location, * types of biosamples * scope of health data | |
| Click here to enter further information | |
| 1. Please include any relevant further information below. | |
| Click here to enter further information | |

* + 1. Click here to enter biobank site name.

|  |  |
| --- | --- |
| Retrospective cohort information at site | |
| 1. Is the scope of retrospective participant consent equivalent to the informed consent for participants prospectively recruited to the biobank? | Yes  No |
| * 1. If ‘**Yes**’ please provide further detail below | |
| Click to enter further detail | |
| * 1. If ‘**No**’ will retrospective participants be contacted and reconsented according to the process detailed in section 1.1 above? | Yes  No |
| * + 1. If ‘**No**’ will the biobank seek a consent declaration from the HRCDC for inclusion of the retrospective participant data, available at this site, in the biobank? | Yes  No |
| 1. Where no Consent Declaration will be sought from the HRCDC please provide further detail explaining how these data (and associated biosamples) can be used for research without informed consent. | |
| Click to enter further information | |
| 1. Please confirm that all retrospective bio-samples and data will be managed in accordance with the same governance, access and data protection standards applicable to the existing prospective/current participant cohort. | Yes  No |
| * + 1. If ‘No’ please explain below. | |
| Click here to enter further information | |
| 1. Please state the approximate number of retrospective participants to be included at this site. | |
| Click here to enter number of bio-samples and data | |
| 1. Please provide detail on the nature of the retrospective bio-samples and data at this site. For example:  * historical participants (eg those not involved in any current clinical trial or study) vs participants of ongoing research studies at the site location, * types of biosamples * scope of health data | |
| Click here to enter further information | |
| 1. Please include any relevant further information below. | |
| Click here to enter further information | |

Please contact the National Office if further biobank site specific table repeats are required.

Appendix 2 – Inclusion of participants with diminished capacity or who lack decision making capacity

Explicit consent 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. However, it is recognised that, in limited situations, obtaining consent will not be possible and that the public interest of doing the research significantly outweighs the need for explicit consent. In these cases, a consent declaration from the HRCDC may be sought. For more information, visit – [www.hrcdc.ie](http://www.hrcdc.ie).

|  |
| --- |
| 1. Outline how the decision-making capacity of participant(s) is determined, and by whom. |
| Click to enter text |

|  |
| --- |
| 1. What arrangements have been made to support participants who may not adequately understand verbal or written information? |
| Click to enter text |

|  |
| --- |
| 1. For participants who regain decision-making capacity, what process will be in place to re-consent these individuals to continue their participation in the biobank? |
| Click to enter text |

|  |
| --- |
| 1. Will the biobank support research which has the potential to benefit participants who lack decision-making capacity? Please elaborate. |
| Click to enter text |

|  |
| --- |
| 1. Will participation in the biobank involve any foreseeable risk or burden for these participants or interfere in any way with their fundamental rights and freedoms. Please elaborate. |
| Click to enter text |

|  |
| --- |
| 1. 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 to enter text |

|  |
| --- |
| 1. Outline how the biobank’s approach to inclusion of participants with diminished or lacking decision-making capacity has taken into consideration the requirements of the Assisted Decision Making (Capacity) Act (ADMA) 2015, and as amended in 2022.   NOTE: Where research participants have formal decision supports (co-decision makers) in place as provided for in the ADMA, co-decision makers can provide lawful consent on behalf of an individual, in line with the participant’s will and preference.  Link: [Assisted Decision-Making (Capacity) Act 2015, Section 2 (irishstatutebook.ie)](https://www.irishstatutebook.ie/eli/2015/act/64/section/2/enacted/en/html#sec2)  Link: [Decision Support Service](https://www.decisionsupportservice.ie/?gclid=CjwKCAiAjfyqBhAsEiwA-UdzJMi5sYaxSz0KpzSlAJDF8rnE0hjyZZ6gPNyZys212bFrKj-gHE4XyhoCrxAQAvD_BwE) |
| Click to enter text |

Appendix 3 – Cover letter table template

Please include the following table template in the cover letter submitted with this application form (**the content in the table is for example only**). Please note all modified documents, the action required and justification for each modification:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Number | Document Name | Document version and date | Outline of modification(s) | Justification for modification(s) | Action |
| 1 | Cover letter | N/A | N/A | N/A | N/A |
| 2 | NICB-REC modification form | N/A | N/A | N/A | N/A |
| 3 | Main PIL/ICF-version date-clean/tracked | V3 17.01.24 | List of all modifications | Justification for each modification | For NICB-REC review |
| 4 | Paediatric Protocol-version date-clean/tracked | V2 16.01.24 | List of all modifications | Justification for each modification | For NICB-REC review |
| 5 | Main protocol-version date-clean/tracked | V2 15.01.24 | Correction of minor text errors | Posterity | For notification /non substantial modification |

1. [HRCDC | Guidance - HRCDC](https://hrcdc.ie/guidance/) [↑](#footnote-ref-2)