HRCDC
Health Research Consent
Declaration Committee

HRCDC STANDARD OPERATING PROCEDURES

Index

Version: 2
Date updated: 25th January 2023

HRCDC
Health Research Consent
Declaration Committee

HRCDC Standard Operating Procedures

1. Purpose and scope

1.1. This document sets out standard operating procedures ('SOPs') of the Health Research Consent Declaration Committee ('HRCDC') and the HRCDC Secretariat ('Secretariat') that supports the mandate of the HRCDC.

1.2. The HRCDC is an independent statutory body established under Statutory Instrument (S.I. No. 314 of 2018[1] and as amended under S.I. No. 188 of 2019[2] and S.I. 18 of 2021[3]) - the Health Research Regulations 2018, (formally titled Data Protection Act 2018 (Section 36(2)) (Health Research) Regulations 2018). Members of the HRCDC are appointed by the Minister for Health under the provisions of the Health Research Regulations 2018 (the 'Regulations').

1.3. The HRCDC is accountable to the Minister for Health and is responsible for fulfilling its mandate as set out in the Regulations. In accordance with Regulation 8 of the Schedule to the Regulations, the HRCDC has the autonomy to determine its own procedures and does so while ensuring proper and effective operational oversight and accountabilities.

1.4. The Health Research Regulations 2018 ('Regulations') provide for the HRCDC to make a statutory consent declaration for the processing of personal data for health research, in certain circumstances where it is not feasible to obtain explicit consent from the research participants. The consent declaration can only be made where the public interest in the health research significantly outweighs the public interest in requiring explicit consent and where all suitable and specific data protection safeguarding measures as required under the Regulations, are implemented.

1.5. The Secretariat to the HRCDC is provided by and located at the Health Research Board[4] (HRB). The Secretariat's role is to support the HRCDC in all aspects of its work. All correspondence and enquiries to the HRCDC should come through the Secretariat.

1.6. Unless otherwise stated, a reference to a numbered section is a reference to the section numbered in these SOPs. Any reference to a Regulation or Schedule means the Regulation or Schedule as numbered in the Health Research Regulations, 2018.

1.7. These SOPs set out:

(i) the guiding procedures to be followed by both the HRCDC and the Secretariat in carrying out its respective duties.

(ii) information regarding the submission and decision-making process for Applicants seeking a consent declaration or an amendment to a consent declaration.

(iii) information for other relevant stakeholders on the guiding procedures of the HRCDC and the Secretariat.

[1] http://www.irishstatutebook.ie/eli/2018/si/314/made/en/pdf
[2] http://www.irishstatutebook.ie/eli/2019/si/188/made/en/pdf
[3] http://www.irishstatutebook.ie/eli/2021/si/18/made/en/pdf
[4] https://www.hrb.ie/

2. Conduct of the HRCDC and Secretariat

2.1. When carrying out its respective functions the HRCDC and the Secretariat will, at all times, act with good governance, integrity and in the public interest, having due regard to the provisions of the Regulations. The HRCDC and Secretariat shall have regard to the principles of:

(i) collegiality and collaboration,

(ii) confidentiality of confidential information,

(iii) open mindedness and fairness,

(iv) transparency in all its business,

(v) compliance with relevant legislative requirements.

3. Application submission

General

3.1. An applicant, as defined under Regulation 8(1) is a data controller seeking a consent declaration. The application or amendment request may be made by an authorised individual(s)[5] on behalf of the data controller organisation(s).

3.2. A data controller (the 'Applicant') intending to submit an application seeking a consent declaration from the HRCDC, or an amendment to a consent declaration (See Section 9 on Amendments), should, prior to submission, seek advice from their organisation's Data Protection Officer (DPO).

3.3. Depending on the nature of the research study, Applicants should also seek guidance from the research ethics committee(s) (REC). Applicants may also seek guidance from the Secretariat regarding the consent declaration application process and requirements.

3.4. Applicants may also consult the HRCDC's consent declaration 'decision flow chart[6], as a general guide to assist with determining if a consent declaration is required for a research study.

Pre-submission advice

3.5. The Secretariat, on behalf of the HRCDC, has responsibility for liaising with applicants regarding the consent declaration process.

3.6. The Secretariat can provide guidance to Applicants with respect to the consent declaration application process and any subsequent application seeking an amendment to a consent declaration.

3.7. All queries should be directed to the Secretariat by email: secretariat@hrcdc.ie.

3.8. Advice to Applicants may be provided in writing (by email), by phone or in person, whichever is deemed appropriate

3.9. Relevant pre-submission advice provided by the Secretariat and/or HRCDC to an Applicant may be recorded in writing by the Secretariat and may be provided with the application documentation to be considered by the HRCDC, as necessary.

3.10. In specific circumstances where more complex data processing and data protection queries are raised by the Applicant, or queries relating to other research matters, the Secretariat may

[5] E.g., Principal Investigator, authorised member of research study team, sponsor, authorised contract research organisation etc.

[6] https://hrcdc.ie/wp-content/uploads/2020/06/Decision-Tree-23.06.2020-v3.pdf

advise the Applicant to seek wider counsel from authorities such the Department of health and/or Data Protection Commission, and/or research ethics committee (REC) and in consultation with their DPO.

3.11. Neither the Secretariat nor the HRCDC can provide advice on data protection matters, or other matters relating to health research. All queries regarding data protection legislation, the Regulations and compliance, and health research matters must be directed to the Applicant's DPO or equivalent authority within the data controller organisation or other relevant body or individual.

3.12. Neither the Secretariat nor HRCDC can determine for a data controller whether a consent declaration is required for a health research study. It is up to each data controller(s) to make this determination.

3.13. The Secretariat cannot offer advice as to whether the research in question may be of sufficient public interest such that a consent declaration maybe granted. This is the exclusively determined by the HRCDC.

3.14. Further information and guidance can be found at: www.hrcdc.ie. Specific guidance notes regarding the consent declaration application form can be found here[7].

Submitting an application

(The following outlines the procedures for submitting an application seeking a consent declaration, or an application seeking an amendment to consent declaration)

3.15. Applications may be submitted by a data controller organisation (or organisation and/or individual authorised to act on its behalf) seeking to process[8] personal data (which includes pseudonymised data) for health research, where it is considered that explicit consent for such processing cannot be feasibly obtained from the research participant.

3.16. As a general rule, one application (i.e., new consent declaration application or amendment request for an existing consent declaration) should be submitted in respect of a health research study. Under specific circumstances and subject to Secretariat guidance, the HRCDC may consider, only where appropriate to do so, one application that relates to more than one research study. There may also be exceptions where more than one application is required (e.g., for reasons of clarity where there are complex data flows). This will be determined on a case-by-case basis subject to the nature and context of the research studies and the detail provided by the applicant.

3.17. The Applicant is responsible for ensuring that the information detailed in the application is clear, consistent and comprehensive, *i.e.,* it should not use overly technical language or undefined acronyms, information should be consistent throughout all the documentation, all data flows must be clearly and adequately described etc.

3.18. All applications must be made using the appropriate application form. Application forms and associated guidance notes can be downloaded at: https://hrcdc.ie/apply/.

3.19. Applications must be signed by an authorised representative on behalf of the data controller(s) and accompanied by the relevant documentation. All documentation must be submitted in either Word or converted to PDF format. Application forms should not include

[7] https://hrcdc.ie/apply/#b-3

[8] **Processing includes activities such as** accessing, collecting, recording, storing, adapting, anonymisation, analysis, linking, combining, sharing, transfers, archiving and destruction (Ref Art 4(2)/GDPR)

embedded documents. Working hyperlinks to webpages can be provided as sources of supplementary information, where appropriate.

3.20. Application forms must be submitted electronically to secretariat@hrcdc.ie. Scanned application forms will not be accepted.

3.21. The Applicant will receive a formal acknowledge of receipt from the Secretariat, including a unique alpha-numeric reference identification (ID).

3.22. All HRCDC meeting dates and submission deadline dates are published on the HRCDC website. For valid applications submitted by the noted deadline, the Secretariat will endeavour to complete the pre-review and validation assessment process and prepare the application for the next HRCDC meeting. However, The Secretariat cannot guarantee that Applications submitted by the submission deadline will be considered at the next HRCDC meeting; this is subject to the number of applications received and the capacity of the Secretariat and HRCDC.

3.23. Applications shall be considered at the next available meeting of the HRCDC, on a first come basis and subject to the completeness of the application. The Applicant will be notified by the Secretariat when the application will be considered by the HRCDC. In exceptional circumstances, applications may be considered by written procedure (see Appendix 1).

4. Pre-review and validation process

4.1. The Secretariat will conduct a pre-review and validation assessment of the application for (i) administrative completeness and (ii) to ensure that the necessary information has been provided to enable the HRCDC to consider the application. This process aims to ensure that requisite supplementary documents are provided and to identify any missing or inconsistent information where further details or clarifications are required from the Applicant. Where any material omissions are noted (e.g., missing REC approval, supporting documentation etc.), the Secretariat will aim to notify the applicant as soon as practicable after the submission date.

4.2. The Secretariat will not complete the pre-review and validation process of the application where the research study seeking a consent declaration does not have the requisite research ethics committee approval or provisional approval[9], and/or where a data protection impact assessment has not been carried out, as required under Regulation 5, or where other documentation or material required have not been submitted.

4.3. The Secretariat will complete a pre-review and validation assessment on the submitted application, using the assessment sheet set out in Appendix 2. The criteria set out in the assessment sheet reflect the requirements to be met under the Regulations. The pre-review and validation assessment will help enable the Secretariat to determine if an application can be deemed valid for HRCDC consideration.

4.4. The Secretariat will aim to complete the pre-review and validation process generally within 10 working days of the receipt of the application; however, this may take longer depending on the volume of applications received and the capacity of the Secretariat.

4.5. For applications seeking an amendment to a consent declaration, a full assessment is not repeated by the Secretariat. The amendment application will be assessed for administrative completeness, to ensure all requisite supplementary documents are provided and that the information provided is clear and consistent. Confirmation that requisite research ethics

[9] With regards new consent declaration applications, confirmation of approval from the Chairperson of the REC only is not sufficient; the study must obtain REC approval from the full research ethics committee.

committee approval is in place[10], and any changes/updates to the data protection impact assessment and DPO feedback must be provided when seeking an amendment to a consent declaration.

4.6. Following the assessment of an application, the Secretariat will liaise with the Applicant to confirm whether the application is valid for HRCDC consideration, or whether further information is required.

4.7. Where further information is requested by the Secretariat the application will not proceed for HRCDC consideration until the Applicant provides the necessary information requested. Delays in the provision of such information may subsequently delay the application being put forward to the HRCDC for consideration.

4.8. Following the receipt of further information, the Secretariat may follow up with further queries or seek clarification from the Applicant, if necessary.

4.9. Generally, where the Applicant is requested to provide further information and clarification arising from the Secretariat's pre-review and validation process, it should be provided by way of written reply (i.e., email or letter correspondence). In certain circumstances, the Applicant may be required to revise and re-submit the application from that was submitted. The Secretariat will re-assess the revised, re-submitted application in accordance with Section 4.

4.10. Where further information is requested by the Secretariat but where the Applicant, after a reasonable period, does not respond to the Secretariat's queries or otherwise does not satisfactorily engage with the Secretariat or the HRCDC in the process, their application may be removed from the application process and deemed withdrawn.

5. HRCDC Meeting Procedures

General policy

5.1. Completed, valid applications (i.e., new consent declaration application form or amendment request form) will be considered at a meeting of the HRCDC held in accordance with the provisions of the Schedule to the Regulations and in line with these SOPs. In exceptional circumstances, applications may be considered by written procedure (see Appendix 1 on Written Procedure).

Meeting schedules

5.2. The HRCDC will hold at minimum 6 meetings in each year for the purposes of consideration of applications. The number of applications considered per meeting will be subject to the complexity of the individual applications and the time available.

5.3. Notice of a meeting and the meeting agenda will be communicated by the Secretariat to each member of the HRCDC at least 7 working days in advance of the meeting.

5.4. A meeting may also be held:
(i) If at least 40% of the HRCDC members request one to be held;
(ii) If requested by the Minister for Health.

[10] For amendment requests, approval from the Chairperson of the REC may be acceptable subject to the nature of the amendment request.

5.5. A schedule of HRCDC meetings, including application submission deadlines, will be published by the Secretariat on the HRCDC website for the ensuing year. Any additional meetings subsequently scheduled will be published once confirmed.

5.6. If there are insufficient applications for consideration at the next scheduled HRCDC meeting, or other business for consideration, the Chairperson may, at their discretion, cancel the meeting.

Meeting agenda

5.7. The Secretariat will prepare the agenda for the meeting in consultation with the Chairperson or the Deputy Chairperson as appropriate. The agenda may include the following standard items, as applicable:

- The date, time and venue of the meeting,
- Disclosures of interest, if any,
- Minutes of the previous HRCDC meeting,
- Matters arising at previous meeting(s),
- Amendment applications,
- New applications seeking a consent declaration,
- Returning applications where further information was requested by the HRCDC at a previous meeting,
- Annual reviews of existing consent declarations,
- Events and Secretariat activities report,
- Any other business.

5.8. The agenda may include other items as they may arise such as:

- Matters relating to a consent declaration that has previously been made,
- Matters relating to the establishment or membership of HRCDC,
- Matters relating to HRCDC procedures,
- Matters relating to the continuous improvement of the HRCDC,
- Educational training topics to be delivered as required for the HRCDC,
- Any other relevant items of business for consideration by the HRCDC.

5.9. The quorum for formal decisions regarding business matters of the HRCDC is 7 members, at least one of whom must be the Chairperson or Deputy Chairperson, and at least one of whom is a public, patient and carer representative. The Secretariat shall keep a record of attendance.

5.10. The HRCDC may convene with less than 7 members as is required for non-business matters (eg training/events), but may not make formal decisions on consent declaration applications or amendment applications, or any other formal business matters that requires a quorum.

5.11. Committee meetings may be conducted virtually or in person. Members will attend virtual meetings using the video conferencing and electronic tools provided, with the support of the Secretariat. On occasion and with advanced notice, face-to-face meetings will be arranged.

5.12. The following should not be counted for the purpose of the quorum:

- The Secretariat
- Observers
- Expert advisors
- Members who are not in attendance for formal decision-making regarding HRCDC business.

5.13. Where the Secretariat is concerned that a scheduled meeting may not be quorate within the meaning of Section 5.9 of these SOPs, due to foreseen or unforeseen absences, it shall in consultation with the Chairperson, consider the following options:
(i) Postpone and rearrange the meeting or
(ii) Continue the meeting and develop advice.

5.14. Where the Secretariat is concerned that part of a scheduled meeting may not be quorate within the meaning of section 5.9 of these SOPs, due to foreseen or unforeseen absences or due to conflicts of interest on an agenda item, it shall, in consultation with the Chairperson, consider the following options:
(i) Not consider the item and defer it to a future quorate meeting,
(ii) Continue with the agenda item and develop advice.

5.15. Where the HRCDC members present at a non-quorate meeting develop advice under Section 5.13(ii) or 5.14(ii), then this advice may be considered at a quorate meeting of the HRCDC at a later date. Alternatively, at the discretion of the Chairperson, the agenda item and the corresponding advice developed may be considered in line with Section 5.16.

5.16. In exceptional circumstances and at the discretion of the HRCDC Chairperson, the HRCDC may make formal business decisions by written procedure subject to the written procedure process provided in Appendix 1.

6. HRCDC decision-making process

Circulation of applications and agenda items

6.1. The Secretariat will circulate a copy of the valid applications to the HRCDC no less than 7 working days prior to the meeting. Applications and other agenda items may be circulated nearer to the date of the meeting in exceptional circumstances with the agreement of the Chairperson.

6.2. The Secretariat will provide a summary of each application, observational comments on the assessment sheet and any other comments as deemed relevant for the HRCDC to assist with its decision (Appendix 2). For applications seeking an amendment to a consent declaration, the Secretariat will also circulate a copy of the minutes and the decision letter that pertains to the original consent declaration, and any previous amendments where applicable.

6.3. In advance of the meeting, HRCDC members will review the application and accompanying documentation.

Decision-making process

6.4. The Chairperson of the meeting is responsible for the conduct of the business and for ensuring that the HRCDC reaches clearly agreed decisions based on the information provided by the applicant.

6.5. At the meeting, the Chairperson will ensure that all HRCDC members present will have opportunities to express their views on the application, based on the information provided. Members are expected to offer their own summary of any issues raised by the application and to raise pertinent issues and questions on the application during the meeting for wider discussion purposes.

6.6. The HRCDC shall determine its decision on any application at a meeting by consensus wherever possible.

6.7. Where a consensus is not achievable at a meeting, exceptionally a formal vote should be taken by a counting of hands. The advice of the HRCDC should be determined by a simple majority of those HRCDC members present and entitled to vote. A record should be kept of numbers of votes. Where the vote is tied, the Chairperson may give a casting vote.

Conflict of interest

6.8. Members of the HRCDC are not participating on the HRCDC as a representative of their profession, organisation or employer, but for their personal expertise and knowledge. Given the expert membership and the national role of the HRCDC it is probable that, from time to time, individual members may have interests, or perceived interests, in the outcome of HRCDC business.

6.9. In the case of a potential conflict of interest, the HRCDC member shall adhere to the conflict of interest policy as set out in Appendix 3. Where there may be a potential conflict of interest, the member shall disclose and describe the nature of the potential conflict to the Secretariat and HRCDC for discussion.

6.10. Upon receipt of applications for consideration, HRCDC members should immediately disclose any perceived or material interests that they have in relation to the purpose, role or remit of the HRCDC. The purpose of this disclosure is to ensure that the functions of HRCDC can be exercised openly and free of bias that could affect the independence of the group and to mitigate any actual conflict, or perception of conflict, and to ensure public and stakeholder confidence that an impartial and independent decision regarding any application is made.

6.11. It is the responsibility of each HRCDC member to highlight any potential conflicts of interest to the Chairperson or Deputy-Chairperson.

6.12. HRCDC members shall leave the meeting for the discussion of any application where a conflict may arise.

Confidentiality of proceedings

6.13. HRCDC members do not sit on the HRCDC in any representative capacity and need to be able to openly and freely discuss any application submitted to them. For this reason, HRCDC meetings are held in private, and members are encouraged to raise any matters of concern. All discussions are confidential.

6.14. All appointed HRCDC members and Secretariat are required to keep the business of the HRCDC confidential.

Observers

6.15. External observers may be invited to attend meetings, with the prior agreement of the Chairperson, and will be arranged by the Secretariat. External observers must sign a confidentiality agreement.

6.16. External observers should have no vested interest in, or scientific or management responsibility for, any applications being considered at the meeting.

6.17. External observers may include representatives of appointing authorities, auditors and Department of Health staff.

6.18. Observers will not normally take any part in the HRCDCs deliberations on particular applications. Exceptionally, they may be invited by the Chairperson to answer specific

questions if they possess expertise that it is thought could usefully inform the deliberations. In this case, the fact of any contribution will be recorded in the minutes.

Expert advisors

6.19. In exceptional circumstances, the HRCDC may seek the advice of an expert advisor on any aspects of an application that are relevant to the formation of a final decision, and which lie beyond the expertise of the members or on which HRCDC is unable to agree. Expert advisors may include specialists in legal or technical aspects, specific diseases or methodologies, or may be representatives of communities, patients or special interest groups.

6.20. Expert advisors are not members of HRCDC and should not be involved in the business of HRCDC or any declaration decisions, other than that related to the application on which their advice is sought to assist in the determination process.

6.21. The advice of an expert advisor will be sought using one of the following procedures:

(i) The Secretariat or Chairperson may write to the expert advisor seeking written advice prior to the meeting. A copy of the advice sought and received should be made available to HRCDC members prior to the meeting or tabled at the meeting. The substance of the advice should be recorded in the minutes.

(ii) The expert advisor may be invited to attend the meeting in person for discussion of the application concerned. The attendance of the expert advisor and the substance of his/her advice at the meeting should be recorded in the minutes. The expert advisor will not have a part in the consideration of the application, or the decision taken by HRCDC.

(iii) The HRCDC may decide at the meeting to recommend a declaration for the application under consideration, pending written advice from an expert advisor. The Secretariat or the Chairperson should normally write to the expert advisor within 5 days of the meeting. The written advice received should then be considered promptly in accordance with procedures agreed at the meeting.

6.22. Expert advisors are required to treat in full confidence all information provided about the application and to return or destroy any application documentation. When an expert advisor is approached to provide specialist advice, the advice given should be recorded in the minutes as given by an expert advisor and will specify their role and organisation. The Secretariat should also record what the Committee decided to do when taking the advice into consideration.

7. HRCDC Decisions

Possible HRCDC decisions

7.1. The HRCDC decisions shall fall under the following categories after consideration of an application:

(i) An application meets the requirements the Health Research Regulations and a declaration is made. The declaration made shall include standard conditions that apply to all consent declarations, and it may include other further specific conditions and recommendations attached.

(ii) Further information is required from the Applicant prior to making a declaration.

(iii) An application does not meet the requirements of Health Research Regulations and a declaration is not made.

Decision letters

7.2. The declaration decision letters will be prepared by the Secretariat and will generally issue to the Applicant within 10 working days of the HRCDC meeting.

7.3. All letters shall be in the name of the HRCDC whose delegated authority will publish the declaration decisions on the HRCDC website.

7.4. The following information may be included in the letter or in enclosures:

- The decision by the HRCDC,
- A summary of the main points considered by the HRCDC,
- Any specific conditions in place and confirmation of whether conditions must be met prior to final approval,
- Standard conditions regarding making a declaration,
- Any recommendations attached to the consent declaration,
- Start and end date of the declaration,
- Right to appeal and the timeframe for accepting or appealing the decision,
- A named contact point (The Secretariat) for receipt of queries from the Applicant.

7.5. The HRCDC may also give advice or make suggestions that are not binding on the Applicant and not material to the declaration made. These shall be clearly distinguished from any standard and specific conditions specified as part of the decision under the heading 'Recommendations'.

Declaration is made (Regulation 8(4)(a))

7.6. The HRCDC may make a declaration with respect to an application, noting the standard conditions that shall apply to all consent declarations made.

7.7. The Applicant shall confirm in writing to the HRCDC his or her acceptance of the declaration within 30 working days of the date of the notification of the declaration. The declaration may lapse if no such confirmation is received by the HRCDC within that time frame. Any queries, requests for clarification or responses that the Applicant may have regarding the HRCDC's decision before accepting the declaration, should be raised within these 30 working days.

Declaration is refused (Regulation 8(4)©)

7.8. Where the HRCDC refuses to make a declaration with respect to an application, the Applicant may appeal the decision in accordance with Section 7.22 – 7.25.

Request for further Information (Regulation 8(2))

7.9. The HRCDC may consider it appropriate to request further information from the Applicant before making a final declaration. The Applicant should respond within 15 working days, or the application may be refused. This period may be extended at the request of the Applicant where there are reasonable grounds for requiring more time to respond.

7.10. Where the HRCDC requests further information, it shall additionally decide the procedures for considering that information and making a final declaration. The HRCDC may decide that the further information should be considered at a future meeting of the HRCDC.

7.11. Where an Applicant's response is incomplete or does not appear to fully address the matters raised, then the HRCDC is entitled to insist on a complete response prior to the next meeting where a final decision shall be made, or the application may be refused.

7.12. If a declaration is made, Section 7.7 shall apply.

7.13. If a declaration is not made by the HRCDC, the Applicant may appeal the decision in accordance with Section 7.22 – 7.25.

Declaration with specific conditions (Regulation 8(4)(b))

7.14. The HRCDC may make a declaration with specific conditions attached that must be met by the Applicant. These specific conditions shall be clearly set out in the decision letter and are separate to the standard conditions that shall apply to all consent declarations made. The HRCDC may apply a timeline or deadline by which the specific conditions must be met or whereby a response or update must be provided. The HRCDC may also attach specific conditions that must be met prior to the consent declaration coming into effect.

7.15. The Applicant should notify the Secretariat in writing once the specific conditions have been met, or where relevant, by the requested deadline, and provide copies of the relevant final support documentation where appropriate. The Applicant is required to provide an update on the progress and implementation of the attached specific conditions as part of the Annual Review.

7.16. If a declaration with specific conditions is made, Section 7.7 shall apply. In addition, the Applicant must confirm that they understand and accept the specific conditions attached within the 30 working days.

7.17. Where the HRCDC attaches specific conditions to a declaration the Applicant may appeal the decision in accordance with Section 7.22 – 7.25.

Revoking a declaration (Regulation 10)

7.18. The HRCDC may revoke a declaration if conditions imposed are not met. The Applicant shall be informed of the HRCDC's intention to revoke a consent declaration and reasons for the proposed revocation.

7.19. The Applicant may make a written representation to the HRCDC within 10 days of notice of revocation, to outline why the declaration should not be revoked.

7.20. The HRCDC shall make its final decision whether or not to revoke the declaration upon receipt of the Applicant's written representation. The HRCDC will give notice in writing notifying the person of its decision and the reasons for making the decision.

7.21. If a declaration is revoked by the HRCDC, the Applicant may appeal the decision in accordance with Section 7.22 – 7.25.

Appealing a decision (Regulation 11)

7.22. Where the HRCDC:

(i) attaches a condition(s) to the declaration or,
(ii) refuses to make a declaration or,
(iii) revokes a declaration,

the Applicant or the 'Appellant' may, within 30 working days upon receipt of the decision, give written notice to the Minister and the HRCDC of his or her intention to appeal the decision made by the HRCDC.

7.23. The Appellant shall request the Minister to establish an independent appeals panel to further consider the Applicant's appeal.

7.24. The appeals panel shall be established by the Minister within 60 working days upon receipt of the notice of appeal from the Applicant, where the appeal shall be considered as soon as practicably possible and in line with Regulation 11.

7.25. The decision by the appeals panel to:
(i) confirm the HRCDC's decision and not make a declaration or
(ii) allow the appeal and make a declaration or
(iii) vary the HRCDC decision,
shall be notified to the Appellant by the Secretariat. The Appeal panel shall stand dissolved 30 working days after notification of its decision.

8. Resubmitting Applications

8.1. An Applicant may not submit a new application relating to the same, unchanged research proposal where the HRCDC considered the application and did not make a declaration, and where the appeals process was not followed.

8.2. A new application form for the research proposal may be submitted if significant and material changes have been made to the proposal, from the previous application where a consent declaration was not made. A new reference number shall be assigned. The Applicant must reference the previous application in the materially different, submitted application

8.3. If more than one 'resubmission' is made, the Secretariat or HRCDC members may determine that it is necessary to have a discussion with the Applicant to clarify the points raised and may request a representation and/or meeting with the Applicant.

9. Applying for an amendment to a consent declaration

General

9.1. Where a consent declaration has been made to a health research study, it is acknowledged that changes to the study may occur which, depending on their nature, may affect the consent declaration that is in place. In such a scenario the Applicant/Data Controller of the study should submit a consent declaration amendment request form to the HRCDC for consideration.

9.2. The Applicant should contact the Secretariat in advance of any submission seeking an amendment to discuss the amendment and any required action. Applicants should further consult with the amendment guidance notes[11] and DPO as necessary.

9.3. All applications seeking an amendment to a consent declaration are validated and pre-reviewed and put forward for HRCDC consideration by the Secretariat, as per Section 4.

9.4. Where an amendment request form is submitted for consideration, the HRCDC further reserves the right to request that the Applicant/data controller submit a full new consent declaration application (not an amendment request form) for consideration if this is considered appropriate in the context of the proposed changes to be made to the study (see Section 9.14 – 9.18)

9.5. Until the relevant changes have been approved, they are not covered by the consent declaration.

[11] https://hrcdc.ie/apply/#b-3

Determining the requirement for an amendment

9.6. An amendment is generally considered to be a relevant change to the research that would impact the consent declaration that has been made. The following general example scenarios reflect the type of changes which may affect the existing scope of the consent declaration made by the HRCDC and when an amendment request form may need to be submitted for consideration.

- change in the data controllership of the research study (e.g., removal of a data controller, the inclusion of a new data controller deemed a 'joint controller'),
- inclusion of a new data processor in the research study,
- relevant change in the data processing activities to be undertaken that is not covered under the existing consent declaration (e.g., change in/new data sources, processing of sensitive personal data not previously referenced (e.g., genomic data), new clinical site for data collection, transfer of data to new/different organisations, expansion or change in the volume and/or type of personal data to be processed etc.),
- a change in the purpose of the research, and therefore the purpose of the data processing, beyond that outlined in the original application that was considered by the HRCDC and the consent declaration made (e.g., expanded, or additional disease areas, interventions, participant cohorts etc. not detailed in the original application),
- an amendment/change has been submitted to the Research Ethics Committee, that affects the data processing and the scope of the consent declaration,
- the jurisdiction of data processing has changed (e.g., data is being processed outside of the EEA or will be processed in another EEA state not previously covered under the consent declaration),
- a change to the assent protocol and/or deferred consent protocol is made,
- request to amend a specific condition that has been attached to the consent declaration or to extend the duration of the consent declaration is required,
- any other relevant changes to the study which will impact the data processing activities and scope of the consent declaration.

9.7. It is the responsibility of the Applicant/Data Controller to determine if an amendment to the consent declaration is required and to complete and submit the amendment request form in a timely manner.

Submitting an amendment

9.8. Amendment requests should be submitted using the HRCDC amendment request application form, available on the HRCDC website by the data controller(s) of the research study. Once completed, it should be emailed in PDF or MS Word format to secretariat@hrcdc.ie; scanned versions of the amendment request form should not be submitted.

9.9. The points below must be addressed prior to submitting an amendment request application:

- confirmation that research ethics approval (or provisional approval) is in place for the changes to the study that is the subject of the amendment request must be provided by the Applicant[12]. The amendment request cannot be considered by the HRCDC without such confirmation,

[12] Research ethics committee approval and/or a consent declaration may be time limited. Accordingly, where a consent declaration may be about to expire and an amendment to extend the duration of a consent declaration is sought, researchers are reminded that live research ethics committee approval and a live consent declaration are required to continue to undertake the health research and to process personal data without consent.

- all relevant sections of the amendment request form should be fully completed by the Applicant/Data Controller(s),
- the Amendment request form should be signed by the relevant Applicant/data controller(s). Where there are joint controllers or changes in controllership (including removal or addition of a data controller or transfer of controllership) all joint data controller(s) (original and new) must sign the amendment form and the joint controllers must also be a co-applicant,
- Relevant supporting documents that have been changed or updated (e.g., updated DPIA, updated study information leaflets and assent/consent forms etc) should accompany the HRCDC amendment request form.

9.10. It is the responsibility of the Applicant/Data Controller to ensure that all the proposed changes to the study that affect the consent declaration are clearly laid out in the amendment request application form.

9.11. The Secretariat shall generally validate the application within 10 working days of receipt of an amendment request but may take longer depending on the volume of applications received and the resources available.

Considering an amendment

9.12. The amendment request shall be referred to the HRCDC for consideration at the next available meeting and shall be considered in accordance with the procedures set out in Sections 4, 5 & 6. In brief this includes:

- submitted amendment requests will be pre-reviewed and validated by the Secretariat and further information and clarification may be requested. Where the amendment request form is incomplete, it may be returned so that it can be correctly and comprehensively completed by the Applicant,
- when deemed valid and ready, the amendment request will be considered at the next available HRCDC meeting,
- in exceptional circumstances amendments may be considered by written procedure. Considering applications by written procedure is at the complete discretion of the HRCDC and will depend on the nature of the amendment that is requested. Further information on the written procedure process is provided in Appendix 1,
- the quorum for considering amendment requests is 7 members.

9.13. The HRCDC may approve the amendment with or without specific conditions, request further information from the Applicant or not approve the amendment. Where an amendment is approved all standard conditions attached to the live consent declaration apply to the amendment and must be met. In addition, where applicable, specific conditions previously attached to the consent declaration also continue to apply. The HRCDC may also attach further specific conditions to the amendment as suitable safeguards.

Requesting a full new consent declaration application

9.14. The HRCDC reserves the right to request the Applicant/data controller to submit a full new consent declaration application for consideration if this is considered appropriate in the context of the proposed changes to be made to the study. Applicants will be informed of this on the HRCDC website, the amendment request form, and the accompanying Applicant guidance notes.

9.15. It will be at the discretion of the HRCDC whether the changes to the study can be considered as an amendment request or should be considered as a full new application.

9.16. Whether a full new application is required will be determined as follows:

- As part of the amendment request form, the Applicant/Data Controller will be requested to explain and justify why the proposed changes that affect the declaration should be considered as an amendment and are proportionate and remain within the scope/purpose of the study for which the consent declaration was initially made.
- The Secretariat will undertake a pre-review and validation assessment of the submitted amendment form and it will be tabled for the HRCDC's consideration at a meeting, when ready.
- At the meeting the HRCDC shall discuss and consider the amendment request form.
  - Where the proposed changes are deemed reasonable and proportionate to consider as an amendment, it will be considered as an amendment request by the HRCDC,
  - where the proposed changes are deemed to be too extensive and disproportionate, the HRCDC can request that a full new HRCDC application from is submitted for consideration. Where a new application is required, this will be communicated to the Applicant.

9.17. Where a full new application is requested and subsequently submitted, it will be provided with a new HRCDC Ref ID and processed as a new Application.

9.18. If a consent declaration is made for the full new submitted application form, the previous consent declaration will continue to remain in place (i.e., the new declaration will not replace the previous declaration). Correspondingly, the Applicant/data controller of the study may be required to submit two separate Annual Reviews the HRCDC (i.e., one pertaining to the original declaration and one for new declaration).

10. Applicant Annual Review

10.1. Regulation 13 provides that the HRCDC may review the operation of declarations made by it or by an appeal panel and may, for the purpose of that review, seek information from a person to whom a declaration was granted in relation to any aspect connected with the operation of that declaration.

10.2. An annual review is required to be submitted by the Applicant each year on the anniversary of date the consent declaration was made.

10.3. The Secretariat shall issue an annual review template for completion one month prior to the anniversary of the consent declaration. This should be completed and submitted by the applicant to secretariat@hrcdc.ie**.** It is the responsibility of the Applicant to fully complete the Annual Review form in a timely manner.

10.4. If the annual review is not submitted, the Secretariat shall issue reminders to the Applicant. Where there are extensive delays or a lack of engagement on the Annual Review, the matter may be raised with the Chairperson of the HRCDC and subsequently may be further raised with the HRCDC.

10.5. Failure to submit an Annual Review to the HRCDC, may lead to a revocation of the consent declaration.

10.6. Following submission of the Annual Review, the Secretariat will consider it. Where it is considered that the Annual Review is satisfactorily completed based on the information provided, including satisfactory responses to the attached specific conditions, the Secretariat

will inform the Applicant and provide an update on the status of the attached specific conditions.

10.7. As a general rule, attached specific conditions may be deemed 'met' or 'underway' and will remain valid for the duration of the consent declaration, subject to the nature of the condition and the response from the Applicant. The Applicant will also be required to continue to report on the progress made with regards the attached specific conditions at the next Annual Review, including providing an update on conditions that are deemed underway. In some scenarios the Applicant maybe requested to provide further information or an update on the attached conditions prior to next Annual Review.

10.8. Where the Annual Review is submitted but not fully completed, the Secretariat may request further information from the Applicant that is required. Where deemed necessary, the Applicant may also be required to amend and resubmit the Annual Review.

10.9. Where the Secretariat identifies potential issues or concerns arising from the Annual Report then these will be raised and discussed with the HRCDC Chairperson. Following discussion with the Chairperson, a reply to the Annual Review will be issued by the Secretariat or it may be deemed necessary to table the matter at the next available HRCDC meeting. An outcome may be decided which may impact the consent declaration made and/or the conditions or recommendations attached. This includes, among other outcomes, revoking the consent declaration.

10.10. Where the information in the Annual Review specifies any changes to the research that may affect the consent declaration, the Applicant may be advised to submit an amendment request as soon as possible in accordance with Section 9.

10.11. Generally, and subject to the capacity of the Secretariat, the Applicant shall receive an outcome letter on their Annual Review within 30 working days after an annual review is received; this timeline will likely be extended where an annual review is referred to the Chairperson or to a HRCDC meeting. Any queries raised by the HRCDC shall generally be communicated to the Applicant within 10 days of the HRCDC meeting.

11. Secretariat Responsibilities

General

11.1. The secretariat to a HRCDC meeting will be the Secretariat. The responsibilities of the Secretariat in relation to HRCDC meetings include:

- Preparing and distributing the agenda and applications for the HRCDC,
- Provision of summary of applications and summary of complex requests to ensure that HRCDC time is best directed,
- Pre-review and validation assessment of applications to ensure validity for HRCDC consideration; raising and pre-empting issues etc,
- Inviting, where appropriate, others to attend and making the necessary arrangements,
- Preparing the venue/videoconference facilities,
- Recording apologies for absence prior to the meeting,
- Ensuring the meeting will be quorate,
- Recording attendance by HRCDC members, experts and observers,
- Advising the meeting as necessary on compliance with SOPs,
- Advising members as necessary on additional points gained through the Secretariat assessment or providing clarification where relevant,

- Recording votes where a vote is taken on a decision,
- Preparing the minutes of the meeting for consideration and approval at the following meeting,
- Facilitating training on behalf of the HRCDC members and Secretariat,

Minutes

11.2. The minutes of the HRCDC meeting should be prepared by the Secretariat within 15 working days of the meeting.

11.3. The minutes should contain a record of the following:

- The attending members, absent members, Applicants, expert advisors and observers present,
- Any declaration of potential interests and the decision of the Chairperson on the participation of the HRCDC member concerned,
- Review and approval of minutes to the previously held meeting,
- Matters arising from previous minutes, if applicable,
- Information and/or discussions on matters relating to existing consent declarations and previous applications, if applicable (e.g., relevant updates on responses to specific conditions attached to existing declarations; declarations/conditions of declarations not being met; breaches, outcome of applications considered by written procedure etc),
- A non-confidential summary of the application(s) considered at the meeting and why a declaration is being sought, and the applying organisation/data controller,
- A summary of the application points considered and of the HRCDC's discussion,
- The decision of the HRCDC on the application considered at the meeting and the rationale for the decision, including:
  - (i) in the case where a declaration is made, any specific conditions and recommendations attached to the consent declaration and any applicable timelines,
  - (ii) in the case where the decision is deferred pending further information, the further information that is required,
  - (iii) in the case where a declaration is not made, a clear rationale shall be outlined for not making the declaration, including the issues noted by the HRCDC,
  - (iv) the outcome of any vote taken, if applicable,
  - (v) where requested by a HRCDC member, and on agreement with the Chairperson, recognition of formal dissent from the decision of the HRCDC by a named HRCDC member, with reasons,
  - (vi) any additional points raised that are not suitable for inclusion in the decision letter e.g. where the HRCDC request a specific action arising but not directly linked to an application,
  - (vii) details of advice provided by the expert advisor, along with their role and organisation,
  - (viii) education items will be recorded in the minutes as an education item with the presenter's names, organisation and topic of presentation,
- A summary of any application that was considered by written procedure since the previous HRCDC meeting and the corresponding decision of the HRCDC,
- Annual Reviews,
- Activities report and events of interest,
- Any Other Business

11.4. Some issues may be solely for information of HRCDC members e.g. where the information is confidential, sensitive, or not otherwise in the public domain and publishing would prejudice the effective operation of the HRCDC, or that of the entity providing information to the HRCDC.

11.5. The minutes shall be presented as the outcome of collective discussion. Unless an individual HRCDC member requests that a formal dissent is recorded, the minutes shall not attribute particular statements to individual HRCDC members attending the meeting or providing written comments.

11.6. The minutes shall be distributed to all HRCDC members with the agenda for the following meeting of the HRCDC for formal ratification as a true record. Any necessary revisions shall be incorporated in the final version of the minutes.

11.7. Where revisions are made to the minutes, the Chairperson shall consider the need to write to Applicants correcting any inaccuracies or clarifying points made in the letter sent after the meeting. However, no substantially new request for information may be made at this point unless there are exceptional circumstances.

11.8. Once approved by the HRCDC, the minutes of the meeting are to be published on the HRCDC website and made freely available to Applicants or any other interested party as soon as practicable. Copies of minutes should be retained by the Secretariat. The Secretariat will endeavour to ensure that sensitive or confidential information is not published within the minutes.

11.9. Where the HRCDC decides to request further information on an application, and its final decision is therefore deferred until receipt and consideration of such information, the section of the minutes of the discussion for that application will be published once the HRCDC have completed their deliberations on that application.

Activities report and other matters.

11.10 Members shall be informed of activities undertaken by the Secretariat outside HRCDC meetings, such as for example the following:

- Any activities undertaken by the Secretariat or individual HRCDC members on behalf of HRCDC,
- Any other matters that the Secretariat and/or Chairperson consider to be of interest or relevance to the HRCDC business,
- Any events attended by the Secretariat and/or HRCDC members.

11.11 The Secretariat will prepare the report for circulation to the HRCDC with the applications for each meeting.

11.12 Once the report has been finalised, any further activities that take place prior to the meeting may be deferred to the report for the following meeting. Where the Chairperson or Secretariat considers it necessary for a matter to reported to the HRCDC as soon as possible, a further written report may be prepared, or otherwise communicated by email correspondence.

11.13. The activities report, and any attachments are generally for the information purposes and should not normally require detailed discussion by the HRCDC.

11.14. The Secretariat will also inform the HRCDC of any advice received and/or discussions held outside of HRCDC meetings that pertain to or is of general relevance to the business of the HRCDC.

12. Report of Breaches

12.1. Where a relevant breach occurs that affects the integrity of the Declaration and the protection of data subjects, it must be reported by the Applicant as soon as practicable once identified, along with remedial actions taken or to be taken. This is a standard condition of the consent declaration made. Breaches should also be reported as part of the Annual Review.

12.2. When reporting a breach, the following information should be provided:
(i) the nature of the breach and how it occurred,
(ii) the action taken to rectify and mitigate the breach, including details of national guidance followed,
(iii) who was informed about the breach,
(iv) what actions have been taken to ensure that the breach does not occur again.

12.3. Where a breach is reported, the Secretariat shall inform the Chairperson of the HRCDC, and if deemed appropriate it may be reported to the HRCDC at the next meeting. The Secretariat, Chairperson and/or HRCDC may request further clarification from the Applicant. Based on the information provided and the nature of the breach, a response will be issued to the Applicant. An outcome may be decided which may impact the consent declaration made.

13. Declaration terminated

13.1. An Applicant no longer requiring a declaration should inform the Secretariat in writing as soon as possible.

13.2. Once received the Secretariat shall consider the information provided, update the declaration register and write to the Applicant to confirm that the declaration is terminated.

13.3. The application will remain on the declaration register on the HRCDC website.

14. HRCDC Publications & Reports

14.1. A register/log of all decisions made by the HRCDC, including declarations made and subsequent amendments to declarations made, and appeals, in relation to each application will be maintained by the Secretariat and published on the HRCDC website.

14.2. The HRCDC shall provide the Minister with an annual report by March 31st, which shall detail the HRCDC activities carried out in the preceding year.

15. Document Storage & Retention

15.1. Unsuccessful applications shall be retained for 5 years from the date of the HRCDC's decision.

15.2. Successful applications shall be retained for 5 years after the termination or expiration of a declaration. Electronic documents only shall be retained where possible.

15.3. Signed final copies of the minutes of full HRCDC meetings and business should be retained for at least 30 years, but will likely be retained indefinitely. Where electronic versions are available, paper copies shall be destroyed.

15.4. Electronic records of decisions made by the HRCDC shall be kept indefinitely (i.e., decision register).

15.5. Any remaining historic paper files will be retained until these are scanned.

15.6 Where applications recorded are destroyed in accordance with this Section, they should be shredded and disposed of as confidential waste.

16. HRCDC Secretariat Contact

Email: secretariat@hrcdc.ie
Website: www.hrcdc.ie
T: Programme Officer: +353 (1) 234 5257
T: Administrative Assistant +353 (1) 234 5197

APPENDIX I – Written Procedure Process

The vast majority of HRCDC business, including applications submitted to the HRCDC, will be considered at a meeting of the HRCDC. However, in exceptional circumstances, the HRCDC may decide on a business matter or an application (either new consent declaration application or amendment request application) by written procedure.

The following describes the process and timeframe for application review and consideration by written procedure; applications considered by written procedure will continue to have due regard to the overall Standard Operating Procedures of the HRCDC contained in this document[13].

i. As per Section 4 of the SOPs, the Secretariat will undertake its validation and pre-review process.

ii. Where it is deemed potentially appropriate to consider the application by written procedure, the Chairperson will be consulted. The decision on whether an application can be considered by written procedure is at the complete discretion of the Chairperson of the HRCDC and is determined on a case-by-case basis, considering the complexity, nature, urgency of the application, and the length of time until the next available HRCDC meeting, among other factors.

iii. Where the Chairperson is of the view that the application can be considered by written procedure, in Lew of Section 6.1. the Secretariat will aim to notify the HRCDC members of this as soon as practicable and provide no less than 2 working days' notice prior to circulating the application for consideration.

iv. The Secretariat will prepare and circulate the application pack, the validation assessment sheet and will also provide the HRCDC with a written procedure feedback form.

v. When considering applications by written procedure, the HRCDC member shall adhere to the conflict-of-interest policy as set out in Appendix III and as per Sections 6.8-6.12 of the SOPs. Where there may be a potential conflict of interest, the member shall disclose and describe the nature of the potential conflict to the Secretariat, and this will be discussed with the Chairperson.

vi. Using the feedback form, each individual HRCDC member will be requested to note whether they are of view that a consent declaration should or should not be made or if further information is required, in addition to providing their overall feedback on the Application, including any potential specific conditions, recommendations or the further information that is required.

vii. Once circulated, the HRCDC will be provided with at least 5 working days to review the application and submit their decision and feedback in writing to the Secretariat. If requested by a member of the HRCDC, and with the approval of the Chairperson, this timeframe can be extended to no more than 10 working days.

viii. In exceptional circumstances where the application is particularly time-sensitive, the HRCDC may be requested to consider the application and submit their decision and feedback within a shorter timeframe.

[13] Where other non-application business matters are considered by written procedure, the principles of the above procedure will apply (e.g., timelines, Conflict of interest etc.), while some specific procedures may be adapted (e.g., use of feedback form), where appropriate.

ix. As per Section 5.9, the quorum for a decision by written procedure is 7, at least one of whom must be the Chairperson or Deputy-Chairperson, and at least one of whom is a public, patient and carer representative. The Secretariat shall keep a record of those who have replied by written procedure. If a quorum is not reached within the set timeline, the application will be formally considered at the next available HRCDC meeting.

x. Once received, the Secretariat will keep a record of each HRCDC member's written procedure responses and collate and review the findings within 5 working days, to determine whether there is a clear consensus amongst the members.

xi. The Secretariat will consult with the Chairperson of the HRCDC on the findings from the written procedure.

xii. Where the result of the written procedure is a clear decision to make a consent declaration with or without specific conditions (Regulations 8(4)(a) and 8(4)(b)) the Secretariat, in consultation with the Chairperson, shall draft a provisional decision letter based on the feedback provided by the HRCDC members. This provisional decision letter will then be circulated to the HRCDC for formal approval.

xiii. Subject to the feedback and approval of the HRCDC, the decision letter will be finalised and the forwarded to the Applicant.

xiv. Where the result of the written procedure is that further information is requested (Regulation 8(2)) or where the Declaration is refused (Regulation 8(4)(c)) or there is otherwise no clear consensus, the Application will be tabled at the next HRCDC meeting and a formal decision made at this point. The Applicant will be informed if the application is to be tabled at the next meeting.

xv. If further information is requested as a result of the written procedure responses, in some scenarios it may be considered possible to request such information in advance of the HRCDC meeting. The Secretariat will consult with the Chairperson to determine whether this is practicable or whether the request for further information should be formally developed at the next available HRCDC meeting.

xvi. The application considered by written procedure will be noted and minuted at the next HRCDC meeting.

HRCDC
Health Research Consent
Declaration Committee

APPENDIX 2 – Pre-review and validation assessment sheet

Secretariat triage list to ensure **validity** of Applications

-

Application Ref:	Next number sequence on worksheet
Application Title:	Title of research on application
Applicant Organisation (Data Controller(s)):	Part A: Applicant Details 1
Lead Applicant:	Part A – Applicant Details 2
Research Objective:	Lay Summary of Research
Reason for seeking a Declaration:	Part B, Section 5 & Part C, Section 1 [• *FOR CSO APPLICATIONS DELETE AS REQUIRED* The Applicant is seeking to access and obtained pseudonymised data (research microdata files) from the COVID-19 Data Research Hub, hosted by the Central Statistics Office. As the data being accessed is pseudonymised data and that it is not feasible to seek consent from individuals whose data is held by the CSO within the COVID-19 data hub, a consent declaration is required.]
Duration of Declaration	Part B, Section 1& 11– Nature of health research and personal data being used [• *FOR CSO APPLICATIONS DELETE/AMEND AS REQUIRED* The consent declaration is requested for one year in line with the duration of the Officer of Statistics appointment made to the Applicant]
REC Approval Date	Found on the attached Rec Approval letter
RDGB Approval status	[•Research Data Governance Board approval/conditional approval has been granted for eligibility and recommendation to access COVID19 Data Research Hub] *OR* [•The Applicant has received confirmation from the Research Data Governance Board (RDGB) Secretariat, that a validated RDGB application has been scheduled for RDGB review] *[DELETE THIS ENTIRE SECTION, OR CHOOSE OPTION ABOVE AS APPROPRIATE]*

☐ Application Form 1. **'New research'** project: Commencing on/after Aug 8th, 2018. - USE THIS OPTION FOR NEW APPLICATION

☐ Application Form 2. **'Current research'** project: Commenced before Aug 8th, 2018, where the existing consent was initially considered compliant under previous data protection law (Regulation 6(4)(b)), but following the Amendments (2021) and after consideration by the Applicant, the consent was not fully compliant.

Points to note for ease of review of applications: THIS SECTION IS USED FOR NOTES OF THE SECRETARIAT FOR THE HRCDC.

HRCDC
Health Research Consent Declaration Committee

PART A: **where is this information found**

PART B:

PART C:

PART D:

PART E:

PART F:

The following observations have been made by the Secretariat regarding potential conditions/recommendations as enhanced safeguards, if a consent declaration was favorable:

APPLICANT DETAILS

☐The Data Controller(s) and Joint-Controller is specified[14] Part A: Applicant Details 1

☐Data Processor(s) are specified[15] (including the Irish research sites i.e., hospital sites etc.)Part A: Applicant Details 6

☐Specify arrangements/contract/agreements in place with controller(s)/Processors Part A: Applicant details 7

☐Funders/Sponsors are specified[16] Part A Applicant Details 8

☐Research units have been identified

☐Any person (other than a joint data controller or data processor) with whom it is intended to share any of the personal data obtained or further processed (including where it has been pseudonymised or anonymised)[17] Part A Applicant Details 9

☐Jurisdiction of processing addressed Part A Applicant Details 10

☐Ethics Approval has been granted[18]

☐Research Data Governance Board approval status completed/copy of outcome letter has been provided. Delete if not a CSO application

NATURE OF HEALTH RESEARCH & PERSONAL DATA

☐Nature and Use of data being processed Part B, 2

☐The duration of the data processing/use of data, with start and end points Part B, 1

☐Appendix I is completed; Design & Methodology Found at bottom of application (Part B, 3)

☐Evidence that the data use is restricted to those processing the data for research Part B, 4i)

☐Evidence that anonymization of data is not possible[19] Part B, 6

☐Evidence that data processing will not damage/distress the data subject[20] Part B, 7

☐Evidence of data minimisation[21] Part B, 8

[14] Regulation 5(4)(b)
[15] Regulation 3(1)(b)(iv)
[16] Regulation 3(1)(b)(v)
[17] Regulation 3(1)(b)(vi)
[18] Regulation 5(4)(c)(vii)
[19] Regulation 5(4)(c)(i)
[20] Regulation 5(4)(c)(ii)
[21] Regulation 3(1)(c)(iii) and Regulation 5(4)(c)(iii)

☐There will be no disclosure of personal data unless required by law or subject has given his or her explicit consent to the disclosure[22] Part B, 9
☐Reference any data linkages[23] Part B, 10
☐Exit strategy where no declaration shall be required Part B, 11

CONSENT

☐Rationale for non-consent[24] **Part C, 1**
☐Evidence of public/patient engagement or consultations (the research objectives/ feasibility of obtaining consent)[25] Part C, 3
☐This section is adequately addressed if participants lack decision-making capacity Part C, 4

THE PUBLIC INTEREST CASE

☐Statement that the Public Interest outweighs the requirement for explicit consent[26] Part D

LEGAL BASIS FOR THE PROCESSING OF PERSONAL DATA

☐Applicant meets one of the legal basis under Article 6[27] Part E
☐Applicant meets one of the conditions under Article 9(2)[28] Part E

INFORMATION REQUIREMENTS, DATA SECURITY ARRANGEMENTS & TRAINING

☐Evidence of transparency arrangements[29] Part F, 1
☐Evidence of controls in place to limit and log access to the data[30] Part F, 2ii
☐Measures to protect the security of the personal data concerned[31] Part F, 2iii
☐Arrangements to anonymise, archive or destroy personal data[32] Part F, 2iv
☐Other technical and organisational measures designed to ensure that processing is carried out in accordance with the Data Protection Regulation[33] Part F, 2v
☐Data protection law training has been completed by the health researchers[34] Part F, 3
☐A Data Protection Impact Assessment (DPIA) has been completed[35]
☐The Data Controller's DPO(s) has been consulted[36]

SIGNATURES - DATA CONTROLLER(S)

☐Signature of Applicant (Data Controller Part A, 1)
☐Signature of Co-Applicant

OTHER: AS REQUESTED BY SECRETARIAT

☐Evidence of Patient Information Leaflet/Consent Forms

[22] Regulation 5(4)(c)(iv)
[23] Regulation 5(4)(d)
[24] Regulation 5(4)(e)
[25] Regulation 5(4)(d)
[26] Regulation 5(4)(e)
[27] Regulation 5(4)(a)(i)
[28] Regulation 5(4)(a)(ii)
[29] Regulation 3(1)(d)
[30] Regulation 3(1)(c)(iv) and Regulation 3(1)(c)(v)
[31] Regulation 3(1)(c)(vi)
[32] Regulation 3(1)(c)(vii)
[33] Regulation 3(1)(c)(viii)
[34] Regulation 3(1)(b)(vii)
[35] Regulation 5(4)(d)
[36] Regulation 5(4)(c)(vi)

☐Data Protection Policies & transparency notices or equivalent
☐Contractual arrangements between data controllers/
☐Pre-submission advice

HRCDC
Health Research Consent Declaration Committee

APPENDIX 3 – Conflict of interest policy

DISCLOSURE AND CONFLICT OF INTEREST POLICY

-

Health Research Consent Declaration Committee (HRCDC) members and HRCDC Secretariat

Title:	**Disclosure and Conflict of Interest Policy**
Document Type:	Policy
Reference/version no:	3.0
Status:	Final
Last Updated:	November 2021
Background:	Policy for HRCDC and Secretariat regarding the management of an interest that may arise during the course of business.

HRCDC
Health Research Consent
Declaration Committee

General

The HRCDC is an independent committee appointed by the Minister for Health under the Health Research Regulations 2018 (S.I.314[37] and as amended under S.I. 188[38] of 2019 and S.I. 18 of 2021[39])

Section 5(3) of the Health Research Regulations 2018, sets out a mechanism for the HRCDC to disclose any material interest in any matter as it pertains to the decision-making function of the HRCDC.

HRCDC members are participating on the committee to bring their personal expertise and knowledge to bear when reviewing applications. Given the expertise of the HRCDC, it is probable that, from time to time, individual members will have interests, and perceived interests, in the outcome of the HRCDC business. The purpose of this document is to mitigate any conflict, or perception of conflict, and to ensure public and stakeholder confidence that an impartial and independent review is provided when reviewing applications.

Procedure

1. Schedule 5(3) of the Health Research Regulations 2018, state that the HRCDC member who has a material interest, such as pecuniary or other beneficial or competing interests in any matter that arises during the course of HRCDC business shall:

(i) disclose to the HRCDC the nature of his or her interest in advance of any matter under consideration; and
(ii) refrain from influencing or seeking to influence a decision in relation to the matter; and
(iii) take no part in any deliberation or decision in relation to the matter; and
(iv) withdraw physically from the meeting for so long as the matter is being discussed or considered by the HRCDC and not to vote or otherwise act as a HRCDC member, in relation to the matter.

2. Where a material interest is disclosed pursuant to Section 1, the following shall apply:

(i) the disclosure shall be recorded in the minutes of the meeting concerned; and
(ii) the disclosure shall be for as long as the matter of the disclosure is being discussed; and,
(iii) the member of the HRCDC by whom the disclosure is made, shall not be counted in the quorum for the meeting.

3. Any failure to comply with the conditions set out in Section 1 by the member of the HRCDC having disclosed a material interest, shall then result in the Chairperson determining the final decision in relation to the matter being discussed. Should the Chairperson disclose a material interest, then the other members of the HRCDC shall appoint another member to determine the final decision in relation to the matter being discussed.

4. Any failure to comply with the conditions set out in Section 1 by the member of the HRCDC who have disclosed a material interest, may be removed by the Minister of Health and disqualified from being a member of the HRCDC.

5. A conflict of interest for a HRCDC member shall be deemed to exist in any of the following *example* circumstances:

(i) where they are the Applicant seeking a declaration from the HRCDC,

[37] http://www.irishstatutebook.ie/eli/2018/si/314/made/en/pdf
[38] http://www.irishstatutebook.ie/eli/2019/si/188/made/en/pdf
[39] http://www.irishstatutebook.ie/eli/2021/si/18/made/en/pdf

(ii) where they are a named or un-named collaborator or co-sponsor with the Applicant seeking a declaration from the HRCDC,
(iii) where they have, or have had, a personal relationship, or is in some way related to the Applicant, co-Applicant on a personal level,
(iv) where they stand to benefit directly should the HRCDC decide to provide a consent declaration,
(v) where they have an interest in a competing research study, technology or process, or an interest in or association with, work for or support by a commercial entity or organisation having a direct competitive interest,
(vi) where they have been involved in the ethics approval decision-making process, or equivalent, for the research study under consideration,
(vii) Any other reason considered relevant by the HRCDC.

6. A HRCDC member will not be regarded as having a material interest in a matter if the interest is such that it would not reasonably be regarded as likely to influence another HRCDC member in considering, discussing or in voting on, any question relating to the matter.

7. If a member of the HRCDC is in doubt as to whether a material interest exists, he/she should consult with the Chairperson or Deputy-Chairperson, as appropriate. The particulars of any interest disclosed shall be recorded in the minutes of the meeting of the HRCDC, by the Secretariat.

8. These principles shall also apply to the Secretariat administering the applications if such material interest arises during the course of their operations.

9. It is the responsibility of HRCDC and Secretariat and any person acting on its behalf to be aware of the rules in relation to disclosure and conflict of interest and to abide by them.
