

STANDARD OPERATING PROCEDURES

| Index | Page |
|--|-------------|
| 1. Introduction | 2 |
| 2. Application Submission | 2 |
| 3. Application Requirements | 3 |
| 4. HRCDC Meeting Procedures | 5 |
| 5. HRCDC Consideration Process | 6 |
| 6. HRCDC Decisions | 9 |
| 7. Resubmitting Applications | 11 |
| 8. Declaration Amendment | 11 |
| 9. Secretariat Responsibilities | 12 |
| 10. HRCDC Publications & Reports | 13 |
| 11. Report of Breaches | 14 |
| 12. Declaration Terminated | 14 |
| 13. Document Storage & Retention | 14 |
| 14. Secretariat Contact | 15 |
| | |
| Appendix I Applicant Pre-submission checklist | 16 |
| Appendix II Secretariat Triage Criteria | 18 |
| Appendix III Conflict of Interest Policy | 20 |

These SOPs shall be kept under review and shall be amended if and as required.

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Approver: Chairperson

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1. Introduction Contents

- 1.1 This document sets out standard operating procedures (SOPs) under which the Health Research Consent Declaration Committee (HRCDC) and the Secretariat supporting the HRCDC will act.
- 1.2 The HRCDC is an independent statutory body established under Statutory Instrument (S.I. No. 314 of 2018 and as amended under S.I.No. 188 of 2019) - **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 Regulations. The HRCDC is accountable to the Minister for Health.
- 1.3 The Health Research Regulations 2018 ('Regulations') provide the HRCDC with the power to make a declaration in certain circumstances that the explicit consent of a data subject is not required for the processing of the data subject's personal data for the purposes of health research.
- 1.4 The Secretariat to the HRCDC is provided by and located at the Health Research Board (HRB). The Secretariat's role is set out in the Schedule to the Regulations and is to administratively support the HRCDC in all aspects of its work. All correspondence and enquiries to the HRCDC should come through the Secretariat.
- 1.5 The Secretariat is accountable to the HRCDC and Health Research Board.
- 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 means the Regulation as numbered in the Health Research Regulations, 2018.

Principles of the HRCDC and Secretariat

- 1.7 When carrying out their respective functions the HRCDC and the Secretariat will, at all times, act with good governance, integrity and administrative behaviour 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;
 - (i) focusing on consensus;
 - (ii) confidentiality for restricted information;
 - (iii) open mindedness and fairness;
 - (iv) compliance with relevant legislative requirements.

Purpose of HRCDC SOPs

- 1.8 These SOPs set out:
 - (i) the procedures to be followed by both HRCDC and the Secretariat in carrying out their respective functions. They can be used as a guide to the expectations of the HRCDC and the Secretariat;
 - (ii) guiding procedures to Applicants regarding the submission and consideration process of applications for a consent declaration.

2. Application Submission

- 2.1 A data controller/researcher/organisation (the 'Applicant') intending to submit an application seeking a consent declaration from the HRCDC should initially seek advice from their organisation's Data Protection Officer (they may also seek guidance from the HRCDC Secretariat) prior to completing an application to assist the Applicant in determining:
 - (i) whether a consent declaration is required from the HRCDC; and
 - (ii) the type of application required;

- a. where a new research project has commenced on or after August 8th, 2018 and there is no explicit consent (Regulation 5); or
 - b. where a current research project is underway since before August 8th, 2018, and the existing consent is compliant under the previous EU Directive 95/46/EC and Data Protection Acts, 1998 & 2003 (Regulation 6(4)(b)); or
 - c. where a current research project is underway since before August 8th, 2018 and no consent was sought (Regulation 6(4)(a)).
- 2.2 Applicants intending to submit an application seeking a consent declaration from the HRCDC, should consult the HRCDC's consent declaration decision tree which assists in choosing the correct application process. The decision tree also outlines important preliminary steps that must be completed prior to the submission of an application to the HRCDC, via the Secretariat.

Pre-submission advice

- 2.3 The Secretariat may provide guidance with respect to correctly completing the HRCDC application forms and with clarifying the pre-conditional steps that must be undertaken by applicants prior to the submission of an application.
- 2.4 The Secretariat cannot offer advice as to whether the data processing in question is GDPR compliant or not. Questions regarding GDPR compliance should be directed to the Applicant's Data Protection Officer, or by seeking legal advice.
- 2.5 The Secretariat cannot offer advice as to whether the research in question may be of sufficient public interest that it might outweigh the fundamental rights and freedoms of the data subject. This is the exclusive remit of the HRCDC itself.
- 2.6 All queries to the Secretariat must be submitted in writing to: secretariat@hrcdc.ie. Further information can be found at: www.hrcdc.ie
- 2.7 Where possible, answers to commonly asked queries will be provided via a dedicated online [FAQ webpage](#) which will be updated regularly.
- 2.8 If necessary, and where appropriate, advice to Applicants may be provided in writing (by email), by phone or in person, depending on the nature of advice required.
- 2.9 In exceptional circumstances, and with the prior agreement of the HRCDC Chairperson, it may be appropriate to provide more detailed pre-submission advice. For example, where data processing raises challenging, or new, issues around data protection and explicit consent arise. In such instances, it may be agreed that a detailed briefing paper and a subsequent meeting with the Applicant may be the most appropriate method to provide pre-submission advice.
- 2.10 Any pre-submission advice provided by the Secretariat and/or HRCDC to an Applicant will be recorded in writing by the Secretariat.
- 2.11 Any pre-submission advice provided by the Secretariat and/or HRCDC to an Applicant which has been recorded by the Secretariat, will be appended to the application documentation to be considered by the HRCDC.

3. Application Requirements

General

- 3.1 Applications may be submitted by:
- (i) a researcher or organisation seeking to access (and subsequently process) personal information that they themselves do not currently hold, for the purpose of health research; or

- (ii) a data controller (i.e. the person or organisation who controls the personal information - e.g. medical practitioner, health professional, hospital, higher education institute etc.) who is seeking permission to further process personal information that they are holding for the purpose of health research.
- 3.2 Only one application should be submitted in respect of any data processing activity. However, there may be exceptions where complex data flows within a single data processing activity may require more than one application for the sake of clarity.
- 3.3 The application content should be clear and comprehensive, *i.e.* it should not use overly technical language or acronyms, and all data flows must be clearly and adequately explained.
- 3.4 All applications must be made using the appropriate consent declaration application form. Applications can be downloaded at: www.hrcdc.ie.
- 3.5 Applications must be submitted electronically to secretariat@hrcdc.ie. The Applicant will be notified as to when they can expect their application to be considered.
- 3.6 Applications shall be considered on a first come basis and at the next available meeting slot of the HRCDC. If the next meeting is fully booked, the Applicant will be notified, and the application will be considered at the next available meeting if possible.
- 3.7 To assist Applicants with preparing their submission, an Applicant pre-submission checklist form is available at www.hrcdc.ie and as set out in Appendix I. This checklist sets out the documentation and information required to ensure a valid application. NOTE: the pre-submission checklist for Applicants reflects the criteria used by the Secretariat to assess the validity of an application.

Validation of applications

- 3.8 Applications must be signed, and accompanied by relevant supporting documentation, in either Word or PDF format, and should be in black and white only. Application forms should not include embedded documents.
- 3.9 On receipt of an application the Secretariat will allocate a reference identification number to the application will determine whether the application submitted is valid or invalid and will notify the Applicant accordingly.
- 3.10 The Secretariat will carry out an application validation assessment on submitted applications, taking into consideration the validation assessment criteria set out Appendix II. Such assessment will generally be within 10 working days of the receipt of the application but may take longer depending on the volume of applications received and the resources available.
- 3.11 The validation assessment criteria, as set out in Appendix II, reflect the requirements set out in the Health Research Regulations 2018 and must be met before the application can be confirmed as valid for submission to the HRCDC for consideration.
- 3.12 Following the validation assessment, the Secretariat will email the Applicant to confirm whether the application is valid, or whether further information is required.
- 3.13 If further information is requested by the Secretariat the validation of the application will remain on hold pending satisfactory responses. Delays in responding with further information may subsequently delay the application being put forward to the HRCDC for consideration.
- 3.14 Following the receipt of responses to a request for further information and/or the submission of an amended application, the Secretariat may follow up with further queries and/or clarification, which will be raised at their discretion either by telephone or email.
- 3.15 The Secretariat will notify the Applicant of the reasons an application is considered not to be valid.

- 3.16 Applicants shall be notified as to when they may expect their application to be considered by the HRCDC.
- 3.17 An Applicant may re-submit an application that was previously deemed invalid at any time, with any additional information that may have been originally requested. The Secretariat will assess the application in accordance with this Section 3.

4. HRCDC Meeting Procedures

General policy

- 4.1 All valid applications 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.

Meeting schedules

- 4.2 HRCDC will hold at minimum 6 meetings in each year for the purposes of consideration of applications. The HRCDC will consider a maximum of 6 applications per meeting, depending on the complexity of the individual applications.
- 4.3 Notice of a meeting and the agenda will be sent out by the Secretariat to each member of the HRCDC at least 10 working days in advance of the meeting.
- 4.4 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.
- 4.6 A schedule of meetings for each calendar year will be published by the Secretariat on the HRCDC website for information.

Meeting agenda

- 4.7 The Secretariat will prepare the agenda for the meeting in consultation with the Chairperson or the Vice Chairperson as appropriate. The agenda will include the following standard items:
- The date, time and venue of the meeting,
 - Disclosures of interest, if any,
 - Minutes of the previous HRCDC meeting,
 - Matters and action points arising at previous meeting(s),
 - New applications to be considered at the meeting,
 - Returning applications requiring amendments for further consideration at the meeting,
 - Provisionally approved applications that were required to provide further information to the HRCDC,
 - Annual reviews of existing consent declarations,
 - Report of declaration breaches,
 - Activities report.
- 4.8 The agenda may include other items as they may arise such as:
- Matters relating to the establishment or membership of HRCDC,
 - Matters relating to HRCDC procedures,
 - Issues relating to the continuous improvement programme 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.

Quorum requirements and meeting attendance

- 4.9 The quorum for a meeting of the HRCDC is 7 members, a least one of whom must be the Chairperson or Deputy-Chairperson, and at least one of whom is a data subject representative. The Secretariat shall keep a record of attendance.

- 4.10 If the Chairperson is unavailable for a meeting then the Deputy-Chairperson or alternate Deputy-Chairperson will act as Chairperson, or if all Chair/Deputy –Chair person’s will be absent, the Chairperson will ask one other HRCDC member to act as Chairperson or, if necessary, the HRCDC members present will agree on a member to act as Chairperson for that meeting. The Chair may ask the Deputy-Chairperson to chair at least one meeting with the Chairperson in attendance.
- 4.11 HRCDC members must attend in person. However, in exceptional circumstances HRCDC members may partake by teleconference or videoconference with the agreement of the Chairperson.
- 4.12 The following should not be counted for the purpose of the quorum:
- The Secretariat
 - Observers
 - Expert advisors
 - Members who are yet to arrive at the meeting, or who have left early
 - Members who submit written comments but do not attend either in person or by teleconference or videoconference
- 4.13 Where the Secretariat is concerned that a scheduled meeting may not be attended by a quorum of HRCDC members due to foreseen absences it shall, in consultation with the Chairperson, consider the following options;
- Postponing and re-arranging the meeting
 - Cancelling the meeting
 - Continuing with a meeting with HRCDC members who can attend and develop advice to be considered at a quorate meeting by teleconference at a later date.
- 4.14 Any business of the HRCDC that does not require a consent declaration decision (e.g. training/education) may proceed without a quorum at the discretion of the Chairperson.

Activities Report

- 4.15 Members shall be informed of activities undertaken by HRCDC members or the Secretariat outside HRCDC meetings, including at least the following:
- Any advice given, or actions taken, by the Secretariat. This advice will be provided on the relevant template with the next meeting minutes.
 - Any activities undertaken by the Secretariat or individual HRCDC members on behalf of HRCDC.
 - Any other issues that the Secretariat and/or Chairperson consider to be of interest or relevance to the HRCDC business.
- 4.16 The Secretariat will prepare the report for distribution to the HRCDC with the applications for each meeting.
- 4.17 Once the report has been finalised, any further business that takes place prior to the meeting may be deferred to the report for the following meeting. Where exceptionally the Chairperson or Secretariat considers it essential that a matter is reported to the HRCDC as soon as possible, a further written report may be prepared, or verbal report made to the meeting.
- 4.18 The activities report, and any attachments are mainly for the information of HRCDC members and should not normally require detailed discussion. HRCDC members may discuss any comments about the actions taken on their behalf.

5. HRCDC Consideration Process

Distribution of applications

- 5.1 The Secretariat will distribute a copy of the valid applications to the HRCDC attending the meeting no later than 10 working days prior to the meeting. Applications may be distributed nearer to the date of the meeting in exceptional circumstances with the agreement of the Chairperson.
- 5.2 The Secretariat will provide a summary of the application and comments on the validation criteria met by that application, and any other comments as deemed relevant for the HRCDC in carrying out its consideration on the application.
- 5.3 HRCDC members will consider the application in full. They 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.

Written comments from members

- 5.4 In exceptional circumstances, a HRCDC member who is unavailable to attend a meeting may submit comments in writing on any agenda item. These should normally be received by the Secretariat at least 3 working days prior to the meeting so that copies may be made available in advance to members. Where later comments are received, they may be tabled at the meeting at the discretion of the Chairperson. The minutes should record that written comments were submitted from the HRCDC member concerned. The written comments shall be included within minutes, but specific comments will not be attributable to individual members.

Conflict of interest

- 5.5 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.
- 5.6 In the case of a conflict of interest, the HRCDC member shall adhere to the conflict of interest policy as set out in Appendix III, and must complete a conflict of interest disclosure form, describing the nature of the conflict.
- 5.7 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.
- 5.8 It is the responsibility of each HRCDC member to highlight any potential conflicts of interest to the Chairperson or Deputy-Chairperson.
- 5.9 HRCDC members shall leave the meeting for the discussion of any application where a conflict may arise.

Confidentiality of proceedings

- 5.10 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.
- 5.11 The terms and conditions of appointment for all HRCDC members and Secretariat include requirements to keep the business of HRCDC confidential.

Observers

- 5.12 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.
- 5.13 External observers should have no vested interest in, or scientific or management responsibility for, any applications being considered at the meeting.
- 5.14 External observers may also include representatives of appointing authorities, auditors and Department of Health staff.
- 5.15 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

- 5.16 HRCDC may seek the advice of an expert advisor on any aspects of an application that are relevant to the formation of a final declaration 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.
- 5.17 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.
- 5.18 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.
- 5.19 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.

HRCDC Conduct of considerations

- 5.20 The Chairperson of the meeting is responsible for the conduct of the business and for ensuring that the HRCDC reaches clearly agreed decisions on the advice to be given on all matters.
- 5.21 The HRCDC shall determine its decision on any application by consensus wherever possible.

- 5.22 Where a consensus is not achievable, 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.

6. HRCDC Decisions

Possible HRCDC decisions

- 6.1 The HRCDC decisions shall fall under the following categories after consideration of an application at meeting;
- (i) An application meets the requirements the Health Research Regulations and a declaration is made;
 - (ii) An application meets the requirements of the Health Research Regulations and a conditional declaration is made;
 - (iii) An application meets requirements of the Health Research Regulations but further information is required prior to making a declaration
 - (iv) An application does not meet the requirements of the Health Research Regulations and further information is required from the Applicant prior to making a declaration
 - (v) An application does not meet the requirements of Health Research Regulations and a declaration is not made
 - (vi) A declaration is considered not to be required.

Decision letters

- 6.2 The declaration decision letters will be prepared by Secretariat and will generally issue to the Applicant within 10 working days of the HRCDC meeting.
- 6.3 All letters shall be in the name of the HRCDC whose delegated authority will publish the declaration decisions on the HRCDC website.
- 6.4 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;
 - A list of all documents considered at the meeting, giving reference numbers or dates;
 - A named contact point (The Secretariat) for receipt of queries from the Applicant.
- 6.5 The decision letter shall set out the main points of the application considered by the HRCDC when making a declaration and will not attribute particular comments or questions to individual HRCDC members.
- 6.6 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 conditions specified as part of the decision.

Declaration is made (Regulation 9)

- 6.7 The HRCDC may make a declaration without conditions with respect to an application.
- 6.8 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 shall lapse if no such confirmation is received by the HRCDC within that time frame.

Declaration is refused (Regulation 8(4)(c))

6.9 Where the HRCDC refuses to make a declaration with respect to an application, the Applicant may appeal the decision in accordance with Section 6.25 – 6.28.

Request for further Information (Regulation 8(2))

6.10 The HRCDC may consider it appropriate to request further information from the Applicant before making a final declaration. Applicant must provide additional information within 15 working days of the request for further information, or the application will be refused. The Secretariat may extend this period at the request of the Applicant where there are reasonable grounds for requiring more time to respond.

6.11 Where the HRCDC requests further information, it shall additionally decide the procedures for considering that information and making a final declaration.

6.12 HRCDC may decide that the further information should be considered at a future meeting of the HRCDC.

6.13 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.

6.14 If a declaration is made, Section 6.8 shall apply

6.15 If a declaration is revoked by the HRCDC, the Applicant may appeal the decision in accordance with Section 6.25 – 6.28.

Conditional declaration (Regulation 8(4)(b))

6.16 The HRCDC may make a declaration with conditions attached that must be met by the Applicant. These shall be clearly set out in the decision letter. The HRCDC may apply a timeline by which the conditions must be met.

6.17 The Applicant should notify the Secretariat in writing once the conditions have been met and provide copies of final documentation where appropriate. The Secretariat will then write to confirm that a declaration has been made by the HRCDC.

6.18 If a declaration is made, Section 6.8 shall apply.

6.19 Where the HRCDC attaches conditions to a declaration the Applicant may appeal the decision in accordance with Section 6.25 – 6.28.

Revoking a declaration (Regulation 10)

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

6.21 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.

6.22 The HRCDC shall make its final decision upon receipt of the Applicant's written representation.

6.23 If a declaration is made then Section 6.8 shall apply.

6.24 If a declaration is revoked by the HRCDC, the Applicant may appeal the decision in accordance with Section 6.25-6.28

Appealing a decision (Regulation 11)

6.25 Where the HRCDC:

- (i) attaches a condition(s) to the declaration;
- (ii) refuses to make a declaration;
- (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.

- 6.26 The Appellant shall request the Minister to establish an independent appeals panel to further consider the Applicant's appeal.
- 6.27 The appeals panel shall be established by the Minister within 40 working days upon receipt of the notice of appeal from the Applicant, where the appeal shall be considered as soon as practicably possible.
- 6.28 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, after which the appeals panel shall stand dissolved.

7. Resubmitting Applications

- 7.1 An Applicant may not submit a new application relating to the same proposal where the HRCDC considered the application and did not make a declaration and where the appeals process was not followed.
- 7.2 If significant and material changes have been made to a proposal following from the previous application, then a new application form must be submitted, where a new reference number shall be assigned. The Applicant must reference the previous application.
- 7.3 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.

8. Declaration Amendment

Determining the requirement for an amendment

- 8.1 The examples set out below reflect the type of changes to data processing which may affect an existing declaration made by the HRCDC;
- Change of data controller or data processor with no change in purposes, data sources, data items or data flows,
 - Extension of end date,
 - Change in identifiable data items requested,
 - Change in purpose of application,
 - Change in data flows, for example where an additional organisation requires access to identifiable data,
 - Changes are made to the extent of data requested, e.g. additional datasets or extension of time covered
- 8.2 The Applicant should contact the Secretariat to discuss the amendment and required action in advance of any submission.

Submitting an amendment

- 8.3 Amendment requests should be submitted on the amendment to declaration request form, available on the HRCDC website and emailed to the HRCDC contact email.
- 8.4 The points below must be addressed in order for the Secretariat to confirm a valid amendment request:
- Amendment request form has been completed and signed.
 - The change to the application is clearly detailed - changes are most likely to be in relation to data flows, data items, data sources, purposes of the application, data controller or data processor.
 - The justification for the change is clearly detailed.

- Any supporting documents that have been substantially changed should be submitted
- 8.5 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.
- 8.6 The amendment request shall be referred to the HRCDC for consider at the next available meeting for consider and shall be considered in accordance with the procedures set out in Section 8.

9. Secretariat Responsibilities

- 9.1 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 for resubmission and summary of complex requests to ensure that HRCDC time is best directed.
 - Triage 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.
 - Recording apologies for absence prior to the meeting.
 - Ensuring the meeting will be quorate.
 - Recording attendance by HRCDC members, experts and observers for the discussion of each application.
 - 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 consider and approval at the following meeting.
 - Facilitating training on behalf of the HRCDC members and Secretariat.

Minutes

- 9.2 The minutes of the HRCDC meeting should be prepared by the Secretariat within 15 working days of the meeting.
- 9.3 The minutes should contain a record of the following, whether in the main text of the minutes or in attachments:
 - The attending members, absent members, Applicants, expert advisors and observers present for the discussion.
 - Any interests disclosed, the detail of the interest and the decision of the Chairperson on the participation of the HRCDC member concerned.
 - A non-confidential summary of the application purpose, why a declaration is being sought, what data items are required and the applying organisation
 - A summary of the application points considered
 - The decision of the HRCDC on the application and the rationale for the decision, including:
 - (i) in the case where a declaration is made, any conditions recommended to the Applicant must be met in the timelines requested by the HRCDC and prior to the start of the research project;
 - (ii) in the case where a declaration is not made, a clear rationale shall be outlined, including issues noted by the HRCDC and any further information required and action points;
 - (iii) the outcome of any vote taken;
 - (iv) 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;

- (v) 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;
- (vi) details of advice provided by the expert advisor, along with their role and organisation;
- (vii) education items will be recorded in the minutes as an education item with the presenter's names, organisation, title of presentation and educational objectives.

- Breach of declarations/conditions of declarations
- Review and approval of minutes to the previously held meeting
- Activities report
- Any Other Business

- 9.4 Some issues documented 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.
- 9.5 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.
- 9.6 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. The final version shall be signed and dated by the Chairperson or Deputy-Chairperson as appropriate.
- 9.7 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.
- 9.8 The minutes of HRCDC meetings are to be published on the HRCDC website and freely available to Applicants or any other interested party. Copies of minutes should be retained by the Secretariat. Sensitive or confidential information will be redacted prior to publication.

10. HRCDC Publications & Reports

HRCDC publications

- 10.1 A register 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.
- 10.2 The HRCDC shall provide the Minister with an annual report by March 31st, which shall detail the HRCDC activities carried out in the immediately the preceding year.

Applicant annual review

- 10.3 An annual review is required to be submitted by the Applicant each year on the anniversary of date the consent declaration was made. It is the Applicant's responsibility to ensure that this is submitted.
- 10.4 The annual review should be provided on the annual review form which is available on the HRCDC website. This should be completed and submitted by the applicant to secretariat@hrcdc.ie
- 10.5 Following submission of the annual review, the Secretariat will consider and may request any further information from the Applicant that is required. The following issues may result in the report being submitted to the HRCDC for consideration:

- (i) Where conditions of the declaration do not appear to have been met. The Applicant should provide an explanation in relation to the issues faced in meeting the requirements;
 - (ii) Where there are changes to the exit strategy specified within the application such that an extension to the declaration is required;
 - (iii) Where a new exit strategy is available, but the applicant has not engaged with this or has provided reasons why the exit strategy cannot be adopted which requires an assessment by the HRCDC;
 - (iv) Where security breaches have been reported;
 - (v) Where the Applicant has been asked to report to the HRCDC on certain issues at annual review stage;
 - (vi) HRCDC requested to consider the annual review submission at the time of the original application or at the last annual review stage;
 - (vii) Where the Applicant has not provided a clear public benefit in the activity continuing;
- 10.6 The HRCDC may recommend an outcome which may impact the consent declaration made or may amend the recommended conditions attached to the declaration.
- 10.7 Where any changes are specified, including changes to exit strategy or time extensions, the Applicant may be advised to submit an amendment request as soon as possible in accordance with Section 8.
- 10.8 The Applicant shall receive an outcome letter no later than 30 working days after an annual review is received. If an annual review is referred to a HRCDC meeting, the Applicant shall be notified. Any queries raised by the HRCDC shall generally be communicated to the Applicant within 10 days of the HRCDC meeting.

11. Report of Breaches

- 11.1 Any breach of conditions attached to a consent declaration made should be reported to the Secretariat within 10 working days, along with remedial actions taken or to be taken. This is a standard condition of the consent declaration made.
- 11.2 The report of any breach should include:
- (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
- 11.3 The Secretariat shall submit the report to the HRCDC at the next meeting and may request further clarification at this stage.

12. Declaration terminated

- 12.1 An Applicant no longer requiring a declaration as they will no longer be processing personal data without consent, should inform the Secretariat in writing as soon as possible. The Applicant should complete the Termination of Declaration form available on the HRCDC website (www.hrcdc.ie)
- 12.2 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.
- 12.3 The application will remain on the declaration register on the HRCDC website. A register of applications designated expired will be maintained by Secretariat so that these can be removed in a timely manner.

13. Document Storage & Retention

- 13.1 Unsuccessful applications shall be retained for 2 years from the date of submission.
- 13.2 Successful applications shall be retained for 5 years after the termination or expiration of a declaration. Electronic documents only shall be retained where possible.

- 13.3 Signed final copies of the minutes of full HRCDC meetings and business should be retained for at least 30 years. Where electronic versions are available, paper copies shall be destroyed.
- 13.4 Electronic records of decisions made by the HRCDC shall be kept indefinitely.
- 13.5 Any remaining historic paper files will be retained until these are scanned.
- 13.6 Where applications recorded are destroyed in accordance with this Section, they should be shredded and disposed of as confidential waste.

14. HRCDC Secretariat Contact

Email: secretariat@hrcdc.ie

Website: www.hrcdc.ie

T: Programme Manager: +353 (1) 234 5179

T: Project Officer: +353 (1) 234 5257

T: Administrative Assistant +353 (1) 234 5197

APPENDIX I – APPLICANT PRE-SUBMISSION CHECKLIST

APPLICANT PRE-SUBMISSION CHECKLIST & GUIDANCE NOTES

The following pre-submission checklist has been developed by the Secretariat to assist the Applicant with the application process when seeking a declaration from the HRCDC.

The checklist below reflects the information required by the HRCDC to enable them to make a fully informed decision with respect to the declaration being sought by the Applicant. This checklist further reflects the requirements set out in the Health Research Regulations, 2018.

It is essential the Applicant consults with their Data Protection Officer prior to submitting.

APPLICATIONS BEING SUBMITTED TO SEEK A CONSENT DECLARATION

- Application Form 1: **'New research' project**: Commencing on/after Aug 8th, 2018. The project is outside the scope of the existing consent (Regulation 5)
- Application Form 2: **'Current research' project**: Commenced before Aug 8th, 2018, where the existing consent was compliant under previous data protection law (Regulation 6(4)(b))
- Application Form 3: **'Current research' project**: Commenced before Aug 8th, 2018, where no consent was ever sought (Regulation 6(4)(a))

PART A: APPLICANT DETAILS

- The Data Controller(s) and Joint-Controller is specified
- Data Processor(s) are specified
- Funders/Sponsors are specified
- Ethics Approval has been granted - **copy provided**
- Jurisdiction of processing is addressed

PART B: NATURE OF HEALTH RESEARCH AND PERSONAL DATA INVOLVED

- Describe in detail the extent and type of personal data being processed.
- The duration of the data processing/use of data, with start and end points
- Evidence that data use is restricted to those processing the data for research
- Evidence of data minimisation - consider why the extent of data is required and can this be minimised, yet still enable the Applicant to address the re
- Evidence that anonymization¹ of data is not possible
- Evidence that data processing will not damage/distress the data subject
- Evidence of public/patient/focus group engagement regarding the research objectives
- Outline of exit strategy where no declaration shall be requirement
- Rationale for non-consent **[AF1 & AF3]**

PART C: LEGAL BASIS FOR THE PROCESSING OF PERSONAL DATA

- Applicant meets one of the legal basis under Article 6²
- Applicant meets one of the conditions under Article 9(2)³

PART D: **[AF1 & AF3]** THE PUBLIC INTEREST CASE

¹ Recital 26 GDPR states that 'anonymous information, namely information which does not relate to an identified or identifiable natural person or to personal data rendered anonymous in such a manner that the data subject is not or no longer identifiable'

² Legal basis for processing

³ Exemptions to processing of special categories of personal data

- Statement that the Public Interest outweighs the requirement for explicit consent

PART D: [AF2] EVIDENCE THAT CONSENT WAS OBTAINED, AND EFFORTS MADE TO RE CONSENT

- Evidence of previous Consent documentation - **Copy provided**
- Patient Information leaflet - **Copy provided**
- Evidence that re-consenting was attempted/considered and not feasible

PART E: INFORMATION REQUIREMENTS, DATA SECURITY ARRANGEMENTS AND TRAINING

- A Data Protection Impact Assessment (DPIA) has been completed - **Copy provided**
- The Data Controller's DPO(s) has been consulted - **Feedback provided**
- Evidence of transparency arrangements
- Evidence of controls in place to limit and log access to data
- Evidence of data subject engagement
- Data protection law training has been completed by the health researchers

PART: F SIGNATURES - DATA CONTROLLER(S)

- Signature of Applicant
- Signature of Co-Applicant

OTHER: MAYBE REQUESTED BY SECRETARIAT

- Evidence of Patient Information Leaflet - **Copy provided**
- Contractual arrangements between data controllers/processors - **Copy provided**
- Secretariat/HRCDC Pre-submission advice - **Appended**

APPENDIX II - VALIDATION ASSESSMENT CRITERIA

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

TO BE APPENDED TO APPLICATION FOR HRCDC REVIEW

| | |
|-------------------------|--|
| Application Ref: | |
| Applicant: | |
| Title: | |
| Objective: | |

DECLARATION for:

- Application Form 1. **'New research' project:** Commencing on/after Aug 8th, 2018. The project is outside the scope of the existing consent (Regulation 5)
- Application Form 2. **'Current research' project:** Commenced before Aug 8th, 2018, where the existing consent was compliant under previous data protection law (Regulation 6(4)(b))
- Application Form 3. **'Current research' project:** Commenced before Aug 8th, 2018, where no consent was ever sought (Regulation 6(4)(a))

- VALID**
- NOT VALID**

DATE VALIDATED/NOT VALIDATED:

Points to note for ease of reference when reviewing the application:

- PART A:
- PART B:
- PART C:
- PART D:
- PART E:
- PART F:

PART A: APPLICANT DETAILS

- The Data Controller(s) and Joint-Controller is specified
- Data Processor(s) are specified
- Funders/Sponsors are specified
- Ethics Approval has been granted - **copy provided**
- Jurisdiction of processing addressed

PART B: NATURE OF HEALTH RESEARCH AND PERSONAL DATA INVOLVED

- Nature and Use of data being processed
- The duration of the data processing/use of data, with start and end points

- Evidence that the data use is restricted to those processing the data for research
- Evidence of data minimisation
- Evidence that anonymization of data is not possible
- Evidence that data processing will not damage/distress the data subject
- Evidence of public/patient engagement regarding the research objectives
- Exit strategy where no declaration shall be requirement
- Rationale for non-consent **[AF1 & AF3]**

PART C: LEGAL BASIS FOR THE PROCESSING OF PERSONAL DATA

- Applicant meets one of the legal basis under Article 6
- Applicant meets one of the conditions under Article 9(2)

PART D: **[AF1 & AF3] THE PUBLIC INTEREST CASE**

- Statement that the Public Interest outweighs the requirement for explicit consent

PART D: **[AF2] EVIDENCE THAT CONSENT WAS OBTAINED, AND EFFORTS MADE TO RE CONSENT**

- Evidence of previous Consent documentation - **copy provided**
- Patient Information leaflet - **copy provided**
- Evidence that re-consenting was attempted/considered and not feasible

PART E: INFORMATION REQUIREMENTS, DATA SECURITY ARRANGEMENTS AND TRAINING

- A Data Protection Impact Assessment (DPIA) has been completed - **copy provided**
- The Data Controller's DPO(s) has been consulted - **feedback provided**
- Evidence of transparency arrangements
- Evidence of controls in place to limit and log access to data
- Evidence of data subject engagement - **feedback provided**
- Data protection law training has been completed by the health researchers

PART: F SIGNATURES - DATA CONTROLLER(S)

- Signature of Applicant
- Signature of Co-Applicant

OTHER: MAYBE REQUESTED BY SECRETARIAT

- Evidence of Patient Information Leaflet - **copy provided**
- Contractual arrangements between data controllers/processors - **copy provided**
- Pre-submission advice - **appended**

APPENDIX III – Disclosure CONFLICT OF INTEREST POLICY

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

General

The HRCDC is an independent committee appointed by the Minister for Health under the Health Research Regulations 2018 (formally titled Data Protection Act 2018 (Section 36(2)) (Health Research) Regulations 2018.

Section 5(3) of the Health Research Regulations 2018, provides for the mechanism of 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 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 members who has a material interest, such as pecuniary or other beneficial or competing interests in any matter that arises shall;

- (i) disclose to the HRCDC the nature of his or her interest in advance of any 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.

The HRCDC member shall formally disclose and record any interest by completing the 'conflict of interest' form as set out in Appendix I.

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;
- (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 project, 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) 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 so remote or insignificant that it cannot reasonably be regarded as likely to influence a person 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. Particulars are to be recorded in the minutes of the meeting of the HRCDC. All interests disclosed shall be recorded 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.

APPENDIX - I

DISCLOSURE OF INTEREST FORM

Title of Application:

Application Reference ID:

Disclosure of Interest:

Please outline the type of 'material interest' in the subject matter of the Application, which may be considered as a real, potential or apparent interest:

I, the undersigned, do hereby declare that I have reviewed the HRCDC Standard Operating Procedures, in particular Section 5.5 – 5.9 ‘Conflict of Interest’.

I hereby declare that the disclosed information herein is correct and that no other situation of real, potential or apparent conflict of interest is known to me at this time.

Print Name:
Signed:
Date:

By signing this disclosure of interest form I consent to the HRCDC holding and processing my data for the purpose of managing conflicts of interests. I understand that this disclosure form may be released under a Freedom of Information (2014) request. I am aware that failure to make a full disclosure may result in withdrawal of my membership.

HRCDC role: *Please tick the relevant box below*

- Chairperson
- Deputy Chairperson
- Ordinary Member
- Secretariat