HRCDC
Health Research Consent
Declaration Committee

HRCDC STANDARD OPERATING PROCEDURES

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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] 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

Introduction

3.1. An applicant, as defined under Regulation 8(1) is a data controller seeking a consent declaration.

3.2. A data controller (the 'Applicant'), should, prior to submission, seek advice from their organisation's Data Protection Officer (DPO).

Pre-submission

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

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

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

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

3.7. Relevant pre-submission clarification provided by the Secretariat 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.

3.8. The Secretariat or the HRCDC cannot 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.

3.9. The Secretariat or HRCDC cannot 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.

3.10. 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.

3.11. Further information and guidance can be found at: www.hrcdc.ie.

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

3.12. Applications may be submitted by a data controller organisation (or organisation and/or individual authorised to act on its behalf) seeking to process 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.

3.13. 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.

3.14. 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.

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

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

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

3.18. The application form specifies the information required to be submitted with the application. Once all of the required information is received by the secretariat the applicant will receive a formal acknowledgement of receipt, including a unique reference identification (ID).

3.19. All HRCDC meeting dates and submission deadline dates are published on the HRCDC website. 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.

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.

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[5], 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.

[5] 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.

4.3. The Secretariat will complete a pre-review and validation assessment on the submitted application, using an assessment sheet. The criteria set out in the assessment sheet reflect the requirements to be met under the Regulations.

4.4. For applications seeking an amendment to a consent declaration, confirmation that requisite research ethics committee approval is in place[6], and any changes/updates to the data protection impact assessment and DPO feedback must be provided from the data controller, when seeking an amendment to a consent declaration.

4.5. 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. If further information is not provided within a reasonable period of time, the application may be deemed withdrawn from the application process.

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

4.7. 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

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.

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.

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

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 and 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 (e.g. 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 HRCDC members present at a non-quorate meeting develop advice under Section 5.13(ii) then this advice may be considered at a quorate meeting of the HRCDC at a later date.

5.15. 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 for the HRCDC, to assist with its review of the application. 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.

Decision-making process

6.3. 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.

6.4. 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.

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

6.6. Where a consensus is not achievable at a meeting, 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. Where the vote is tied, the Chairperson may give a casting vote.

Conflict of Interest

6.7. 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.

6.8. In the case of a potential conflict of interest, the HRCDC member shall adhere to the conflict-of-interest policy. 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.

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

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

Confidentiality of proceedings

6.11. HRCDC members do not sit on the HRCDC in any representative capacity.

6.12. All appointed HRCDC members and Secretariat are required to keep the business of the HRCDC confidential. HRCDC meetings are held in private and are not open to the public.

Observers

6.13. 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. They will not take part in the meeting.

6.14. External observers should have no vested interest in, or scientific or management responsibility for, any applications being considered at the meeting, that they are present for.

Expert advisors

6.15. 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.

6.16. 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.

6.17. 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 final 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 written advice received should then be considered promptly in accordance with procedures agreed at the meeting.

6.18. Expert advisors are required to treat in full confidence all information provided about the application and to return or delete 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.

Decisions 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. 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.

7.4. 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' or 'notes'.

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

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

7.6. 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)(c))

7.7. Where the HRCDC refuses to make a declaration with respect to an application, the Applicant may appeal the decision.

Request for further Information (Regulation 8(2)

7.8. 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.

7.9. 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.

7.10. 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.

7.11. The HRCDC, where it is of the view that it will benefit the committee discussions, may invite the applicant to join the HRCDC meeting to address the queries raised in the 'request for further information'. The sole purpose of the applicant attendance is to answer these queries, as communicated by the Secretariat. Other topics in relation to the application will not be discussed. This option is entirely voluntary, and the applicant may decide to decline the invitation.

7.12. If a declaration is made, Section 7.6 shall apply.

7.13. If a declaration is not made by the HRCDC, the Applicant may appeal the decision.

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 additional 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, by the requested deadline, once the specific conditions have been met 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 7.6 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 7.7.

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 7.7.

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.

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[7] 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 9.17-9.21)

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

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

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

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 process and/or deferred consent process 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. 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.

Considering an amendment

9.10. The HRCDC chairperson / deputy chairperson may review and make a decision on low-risk, administrative or technical amendments to consent declarations.

9.11. Examples of amendments that could potentially be considered 'administrative/technical amendments' are as follows:

- Extending the duration of the consent declaration
- Adding a new study site (e.g., hospital) and where there are no other study changes and the same consent documents are used at this new site
- Change/clarification to the data controllership.
- Changes / clarification to data processors involved in the study.
- Changes clarifications to third parties involved in the study.

9.12. If satisfied with the technical nature of the amendment The Chair will then complete a review of the amendment by documentation and provide feedback to the secretariat. The Chair can potentially:

- Approve the amendment.
- Request further information.

- Refer the amendment to the full HRCDC, for consideration and decision.

9.13. The applicant will be informed in writing the outcome of the review by the chair / deputy chair in exactly the same manner as an amendment considered by the HRCDC.

9.14. The HRCDC will be informed of any approvals by the Chair at the next available HRCDC meeting, see also section 11.3.

9.15. All other amendment requests 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.

9.16. 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

9.17. 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.

9.18. 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.

9.19. 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.

9.20. 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.

9.21. 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 four to six weeks 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, and 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:

- Pre-review and validation assessment of applications to ensure validity for HRCDC consideration.
- Preparing and distributing the agenda and applications for the HRCDC,
- 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,
- 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, 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,
- A summary of any amendments considered by the Chair / Deputy Chair since the previous meeting and details of any decision made.
- 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 publicly available. Electronic Copies of minutes are retained by the Secretariat.

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. Where the Chairperson or Secretariat considers it necessary for a matter to reported to the HRCDC as soon as possible, a written report may be prepared, or otherwise communicated by email correspondence.

11.12. 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 may affect 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 and it is deemed to be significant, 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 each year which shall detail the HRCDC activities carried out in the preceding year.

15. Document Storage and 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.

15.3. Approved copies of the minutes of HRCDC meetings should be retained for at least 30 years.

15.4. Electronic records of decisions made by the HRCDC shall be kept for 30 years.

HRCDC
Health Research Consent
Declaration Committee

16. HRCDC Secretariat Contact

Email: secretariat@hrcdc.ie
Website: www.hrcdc.ie

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[8].

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

[8] 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.

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.

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.