HRCDC
Health Research Consent Declaration Committee

HRCDC Guidance notes
-
Seeking an amendment to a consent declaration

Index

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Owner: Secretariat, HRCDC

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1. General

- These guidance notes have been prepared to assist the data controller organisation(s) with making an application to the Health Research Consent Declaration Committee (HRCDC) seeking **an amendment** to a **consent declaration**.
- The guidance notes set out **examples scenarios** that may require an amendment to a consent declaration.
- It is up to the data controller(s) of the research study to **determine** whether an **amendment is required.**
- It is advised to be **open and informative** and provide **robust answers**. This will avoid the Secretariat and/or HRCDC requesting further information and resulting in a delayed decision.
- Please ensure all questions are **fully considered and adequately addressed** to ensure completeness and quality and facilitate the HRCDC making an informed decision.
- The data controller **must engage** with their **Data Protection Officer** (DPO) prior to completing and submitting the application.
- The Applicant(s) **should consult** with the **Secretariat** in advance of any submission as necessary, for any queries regarding the amendment application process.

2. Example amendments to a consent declaration

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

** Please note that where an amendment request form is submitted for consideration, the HRCDC reserves the right to request that the Applicant/data controller submit a new application for consideration if this is considered appropriate in the context of the proposed changes to be made to the study.*

- 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 data sources, processing of sensitive personal data not previously referenced (e.g., genomic data), new clinical site for data collection, transfer of data to new/different organisations, expansion or change in the volume and/or type of personal data to be processed etc.),
- a change in the purpose of the research, and therefore the purpose of the data processing, beyond that outlined in the original application that was considered by the HRCDC and the consent declaration made (e.g., expanded, or additional disease areas, interventions, participant cohorts etc. not detailed in the original application),
- an amendment/change has been submitted to the Research Ethics Committee, that affects the data processing and the scope of the consent declaration,
- the jurisdiction of data processing has changed (e.g., data is being processed outside of the EEA or will be processed in another EEA state not previously covered under the consent declaration),

- a change to the assent protocol and/or deferred consent protocol is made and has required amendments to the requisite ethics approval,

- request to amend a 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

3. Unnecessary amendment requests

The following general examples reflect the type of changes to a research study that should not require an amendment request to the consent declaration:

- minor changes to the research study protocol or other study documentation (e.g. correcting errors, updating contact points, minor clarifications),
- minor, immaterial updates to documentations previously submitted to the HRCDC,
- changes to the Applicant's/Principal Investigator's research team,
- changes to the research team at a trial site,
- changes in funding arrangements.

4. Submitting an amendment

- Amendment requests should be submitted using the amendment request application form, available on the HRCDC website and emailed to secretariat@hrcdc.ie.
- The Secretariat shall generally validate the amendment request application form 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.
- The amendment request shall be referred to the HRCDC for consideration at the next available meeting, which the Applicant(s) shall be informed of.
- Amendment requests will be processed and considered in line with Secretariat and HRCDC procedures that pertain to amendment requests *[link to these procedures to be provided].*

5. Applicant(s)

- Applications requesting an amendment to a consent declaration should be submitted by the data controller(s) of the research study. It is the responsibility of the data controller/Applicant to submit the amendment request in a timely manner.
- Where a new joint data controller is joining the research study, this new controller must also be a co-applicant.
- All joint data controller(s), including the new data controller(s), must sign the amendment form.
- **Until the relevant changes have been approved by the HRCDC, they are not covered by the consent declaration**.

6. Requirements

- All **proposed changes** to any aspect of the **consent declaration** should be clearly laid out in the amendment request application form.

- All relevant sections of the amendment request form should be fully completed by the Applicant/Data Controller. It is the responsibility of the Applicant/Data Controller to ensure that all the proposed changes to the study that affect the consent declaration and data processing activities are clearly laid out in the amendment request application form.
- The **justification** for the changes must be clearly set out.
- Evidence of **research ethics** approval, or ethics amendment approvals (or provisional approval) for the proposed changes must be submitted. The amendment request cannot be considered by the HRCDC without such confirmation.
- All proposed changes to the data processing activities that are covered by the consent declaration **should be reflected in the Data Protection Impact Assessment (DPIA).** Relevant supporting documents that have been changed (e.g., updated DPIA, updated study information leaflets and assent/consent forms etc) should accompany the HRCDC amendment request form.
- Seeking consultation with and feedback from the **Data Protection Officer**, or equivalent, from each data controller is required with regards the amendment request.
- The **public interest case** for the amendment request maybe required, depending on the nature of 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 conditions to the amendment as suitable safeguards