HRCDC
Health Research Consent Declaration Committee

# HRCDC Guidance notes
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# Seeking an amendment to a consent declaration

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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 or queries.

## 2. Example amendments to a consent declaration

The following general examples reflect the type of changes to data processing activities which may affect an existing scope of the consent declaration made by the HRCDC:

- change of data controller,
- inclusion of a new data controller in the research study and is deemed a 'joint-controller',
- inclusion of a new data processor in the research study,
- an extension to the duration of the consent declaration is required,
- a substantial change to the extent of, or nature of personal data being processed,
- a substantial change in the data processing activities that are undertaken for the purpose of the study (e.g. the addition of a new clinical site for data collection, the transfer of data to/from different organisations etc)
- additional processing of sensitive personal data not covered under the consent declaration (eg whole genome sequencing)
- a change in the purpose of the research study, and therefore the purpose of the data processing, that is beyond the scope of the consent declaration made,
- the jurisdiction of data processing has changed (eg data is being processed outside of the EEA or will be processed in another EEA state not previously covered under the consent declaration),
- the source of the personal data being processed has changed,
- a change to the assent protocol and/or deferred consent protocol is made and has required amendments to the requisite ethics approval,
- an amendment to a condition attached to the consent declaration is proposed,
- an amendment to the research ethics committee approval has been requested that affects the data processing covered under 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.
- If an amendment request is approved by the HRCDC, all specific and standard conditions attached to the live consent declaration apply to the amendment and must be met, unless such conditions have already been met.

## 5. Applicant(s)

- Applications requesting an amendment to a consent declaration should be submitted by the data controller(s) of the research study.
- 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 new data controllers, must sign the amendment form.

## 6. Requirements

- All **proposed changes** to any aspect of the **consent declaration** should be 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 must be submitted.
- 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).
- 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.
- Any **supporting documents** that have been substantially changed should be submitted (eg assent/deferred consent documentation).