

# Submission of Amendment

## Amendment

### Amendment

Dependents: 8

A1. *Only substantial amendments, as defined in section 11 of the [Standard Operating Procedures for HDECs](#), need to be submitted to HDECs.*

Is your amendment **solely** related to the following (select any that apply):

- Minor or administrative changes to protocol or associated documents e.g. protocol clarification letters that do not impact participants.
- Updated version of an investigator's brochure (where the study involves a new medicine / device) that has not resulted in changes to the PISCF.
- Updated versions of participant ID / alert cards; participant instructions for sample collection or medicine / device use
- Minor administrative changes to PISCFs and associated documents, e.g. change in Sponsor or contact details, correction of errors in approved documents.
- Translated documents (including documents translated from US English to New Zealand English), or translation certificates.
- Changes to the research team or addition of new site, other than the appointment of a new CI
- Changes in funding arrangements, except where these may alter the ability of participants to access publicly funded compensation in the event of injury
- Changes in arrangements for recording or analysing study data.
- Extension of the study beyond the expected end date given in the application form, except where this is related to other changes that are substantial.
- None of the above.

**Your amendment is not substantial and does not require HDEC review. Please upload any documents here. Notification of receipt only will be provided by the HDEC Secretariat.**

[Depends on A1. Only substantial amendments, as defined in section 11 of the Standard Operating Procedures for HDECs, need to be submitted to HDECs.](#)

Your amendment is not substantial and does not require HDEC review. Please upload any documents here. Notification of receipt only will be provided by the HDEC Secretariat.

Upload Document

Add Another

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A2. Please describe the amendment you wish to make to your study, and how each document meets the HDEC SOP criteria for a substantial amendment.

**Documents that do not meet the criteria for being significantly amended should not be uploaded with the application.**

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A3. Please explain why this amendment is being made.

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A4. Please indicate whether the amendment:

- concerns urgent safety measures that have already been implemented
- notifies the HDEC/SCOTT of a temporary halt of your study
- requests that your study re-commence following a temporary halt or suspension of approval
- none of the above

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A5. Please briefly explain the effect that you consider that this amendment may have on the following ethical aspects of your study.

Benefits:

Risks:

Respect for persons and populations:

Fairness:

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A6. Please explain your answer above.

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A7 Please provide the current number of New Zealand participants (i.e. those currently in screening or enrolled on the study) affected by this amendment.

A8. Please upload all relevant supporting documents, and submit the form.

***For all updated documents please include a 'clean' and 'tracked changes' version.***

Depends on A1. Only substantial amendments, as defined in section 11 of the Standard Operating Procedures for HDECs, need to be submitted to HDECs.

A8. Please upload all relevant supporting documents, and submit the form.

***For all updated documents please include a 'clean' and 'tracked changes' version.***

N.B. Please only upload documents relevant to the substantial amendment.

Upload Document

Add Another