

Submission of Final Report

Main requirements for final report

FR1. Did the study end more than one year ago?

- Yes
- No

FR1.1. Please explain why the final report is being submitted more than one year after the study conclusion.

FR2. Please summarise in plain English the main objectives / aims of the study.

FR3. Numbers of participants

Note the field will accept text if a comment is required.

Number of New Zealand participants enrolled

Number of New Zealand participants who completed the study

Participants enrolled worldwide (if applicable)

Participants completed worldwide

FR4. Please summarise the key results (primary endpoints and any other significant results) of your study.

Dependents: 1

FR5. Did the study reach its objectives / aims?

- Yes
- No

[Depends on FR5. Did the study reach its objectives / aims?](#)

FR5.1. Please explain why the primary aims of the study were not met.

Safety Outcomes

FR6. Please summarise any significant safety issues in your study, including the number of participants who withdrew/were withdrawn from your study for safety reasons.

FR6.1. Please include a summary of all deaths and serious or significant unexpected adverse events in New Zealand participants, including your assessment of whether these were related to the study or not.

FR7. Other ethical issues

Dependents: 1

FR7. Did any significant ethical issues arise in the study that have **not** previously been reported to HDEC?

- Yes
- No

[Depends on FR7. Other ethical issues](#)

FR7.1. Please summarise the issue(s), including steps taken to address the issue(s)

Ethnicity Data

FR8. Please provide ethnicity data for participants enrolled in the study in New Zealand. State the number of participants identifying as:

New Zealand European

Māori

Samoan

Cook Island Māori

Tongan

Niuean

Chinese

Indian

Other (e.g. Dutch, Japanese, Tokoloan)

All research in New Zealand should collect good quality ethnicity data. If ethnicity data was not collected for participants, provide a justification for this.

Communication of Study Results

Dependents: 1

FR9. Have the study results been published, including websites, journal papers, other reports or articles, or conference presentations?

- Yes
- No

[Depends on FR9. Communication of study results](#)

FR9.2. Please explain why the results have not been published.

FR9.1. Research papers / reports may be uploaded here.

FR9.1. Research papers / reports may be uploaded here.

[Upload Document](#)

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Study results

Dependents: 3

FR10. Will New Zealand participants be informed of study results?

- Yes
- No

[Depends on FR10. Will New Zealand participants be informed of study results?](#)

FR10.1. Please detail how New Zealand participants will be informed of the results of this study.

If participants will be informed via a website please insert the link.

[Depends on FR10. Will New Zealand participants be informed of study results?](#)

If participants will be informed in writing please attach the letter template here.

Upload Document

Depends on FR10. Will New Zealand participants be informed of study results?

FR10.2. Participants have a right to be informed of the results of research they are enrolled in. Provide a justification for not informing participants of study results.

Supporting Documents

Any supporting documents with the final report may be uploaded here.

Upload Document

Add Another