

* Log into HDEC online forms <https://nz.ethicsform.org/Signin.aspx>
* The first screen will show a list of your HDEC projects. Click on the title of the project you are submitting a report for.
* The next screen is the project navigation dashboard. Click on the “Post-approval” tab in the horizontal menu.
* On the next screen (the post-approval dashboard) there is a button “Create a new Post-approval Form”. Click on this.
* Look to the left of the screen under the heading Post-approval Forms. A new form will have now been created and an icon will appear. It will have a five digit number. If this is your first Post-approval Form for the study it will be the only form under the heading. If it’s one of several, the one you just created will be at the bottom. Click on the form title/number to highlight it.
* The title/number will now be highlighted in red. This means the form can now be completed or edited. To start working on the form look to the table in the centre of the screen. You can either click the PAF filter or click on “*here”* in the instruction line “Click *here* to begin completing/reviewing the form (etc)”.
* You will now be taken to the actual form. On the first page you asked to select the type of Post-approval Form you want to submit. The questions on the subsequent pages will change according to which type of form you select. Use the green directional arrows at the top and bottom of the screen to move from page to page.
* Don’t forget to use the “Save” button to save your work.
* HDEC progress reports are very detailed. A list of the current questions can be found in the following pages of these instructions.

**Submitting an HDEC progress report (or other HDEC Post-approval Form)**

**Welcome  *Haere Mai*  |  Respect  *Manaaki* |  Together  *Tūhono* |  Aim High  *Angamua***



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* When you’re finished completing the form, save it, then click the Navigate icon located on the top and bottom of the screen.
* You will now be returned to the Post-approval form dashboard. The icon for the specific form you have been working on should still be highlighted red. This means the system knows you are still working towards submitting this form.
* If you have made any minor amendments to the study in the previous year you should now upload any latest versions of study documents using the “Documents” tab in the main table. Use the Navigate button to return to the Post-approval Form dashboard when finished.
* You are now ready to submit your form. Click the “e-Submission” tab on the main table.
* The e-Submission screen now opens and the first button is a “Check for completeness”.\* Click this button. If all questions in the form are complete the screen will now confirm this.
* When your form is confirmed as complete click the next button “Proceed to submission history”. A line of text will appear under the submission panel below. Scroll down the screen. A “Submit” button will now be available under the panel. Click the button to complete the process. Within a few seconds the submission panel will confirm that the form has been submitted. Well done!

\*Note: If you have omitted to complete any part of the form you will be unable to submit. The screen will tell you which questions you need to go back and answer. Click the “Navigate” tab of the main table and reopen the form for editing. Remember to save changes. When finished use Navigate to go back to the dashboard and return to e-Submission.

**Post-approval Form Filter**

**Current HDEC Progress Report Questions (February 2019)**

**Filter.** Which of the following post-approval items would you like to submit?

* an amendment
* a progress report
* a protocol deviation or violation
* a report of a serious adverse event (to SCOTT only)
* notification of conclusion of the study
* a final report

**Progress Report**

**P1.** What is the current status of your study?

If your study is the New Zealand arm of an international study, please answer the questions below for the New

Zealand arm only.

* This study has been abandoned prior to commencement
* This study is yet to commence
* This study has commenced and is continuing
* This study has concluded

**P4.** On what date did this study commence?

**P5.** On what date do you expect this study to conclude?

**Administrative Section**

**P6.** Are there any new study sites (localities) since the last annual progress report, or if this is the first report, since

approval?

* Yes
* No

**P7.** Has there been any change to the Sponsor since the last annual progress report, or if this is the first, since approval? If the study is not sponsored please select ‘not sponsored study’.

* Yes
* No
* Not sponsored study

**P8. Clinical Trials Registration**: Does this study require registration on a clinical trial registry?

* Yes
* No
* Not Applicable

**P9. Funding** Status/Changes: Select the appropriate box that best describes the funding status of this study.

* Not funded
* Pending
* Awarded
* Funding has ended
* New funding source

**P10.** Please explain your answer to P9.

[< 600 characters]

**P11.** Since your approval, or the last progress report, has the study been audited or reviewed by a third party? For example by the sponsor, a funding agency or an external provider.

* Yes
* No

**P12.** Does the study have data safety monitoring arrangements? For example an individual monitor or a data safety

monitoring committee.

* Yes
* No

**Commercial Studies and Claims**

**P13.** Is this study a commercially sponsored intervention study?

* Yes
* No

**P14.** Has the conduct of this study over the past year complied with all relevant ethical standards?

* Yes
* No

**P15.** Please briefly explain your answer in P14.

[< 600 characters]

**Non-substantial Changes Update**

**P16. FOR HDEC** - Please briefly describe any minor (non-substantial) amendments **and** protocol deviations or violations that have been made or occurred to this study since the previous progress report (or, if this is the first progress report, since the study commenced).

Please upload any new versions of documents that contain non-substantial amendments. This includes minor changes to advertising, PIS/CF etc. **Note** you do not need to submit all localised versions of the PIS/CF.

**FOR SCOTT** - Please briefly describe any minor (non-substantial) amendments that have been made to this study since the previous progress report (or, if this is the first progress report, since the study commenced).

[< 1200 characters]

**Recruitment Update**

**P17.** Please indicate how many participants have been recruited to this study in New Zealand, and whether recruitment is on target.

*If your study involves human tissue and/or health information rather than human participants, please enter “0” and “on*

*target”.*

* behind target
* on target
* ahead of target

**P18.** Please list recruitment by site:

[< 600 characters]

**P19.** Have any participants voluntarily withdrawn from this study?

* Yes
* No

**P20.** Have any participants been withdrawn by the Investigator?

* Yes
* No

**Maori Consultation Update**

**P21.** Has Maori consultation occurred since or before initial HDEC approval?

* Yes
* No

**Summary of report**

**P22.** The progress report should provide the HDEC with a description of the progress of the study over the past approval period, and the study’s current status. Please provide a summary for the reviewing HDEC outlining:

* Progress towards achieving research objectives;
* Barriers to meeting research objectives, and strategies to overcome barriers;
* Your analysis of the study’s adverse events and unanticipated problems and any effect on the research;
* Any scientific developments affecting the equipoise, safety, efficacy or other fundamental aspect of the study;
* Your opinion as to whether the risk/benefit ratio for the study remains reasonable;
* For community based studies, have any findings have been shared with the local community?
* Any other relevant comments.

[< 1200 characters]

**P23.** *An annual safety report must be attached if your study involves a new medicine. Please upload an annual safety report in the “Documents” tab, if required.*