Instructions for completing the National Human Research Ethics Progress/Final Report Form	
Introduction	This is the National Human Research Ethics Progress/Final Report Form. It is a requirement of ethics approval to for researchers to provide updates, usually annually to the HREC. *National Statement 5.4.8* This form is used for submitting annual progress reports and the final report to: • The relevant ethics review body (incl. HREC, Sub-Committee, Executive Committees or by delegation to the Executive Officer) • The Research Governance Sites.
Support and Resources	Throughout the document, you will find embedded guidance to help you complete each section of the form. 🔴 **Immediate attention/action:** form cannot be submitted until the information is confirmed/actioned 🟡 **For attention:** responding to this question will affect branching and question visibility please ensure you are correctly responding Further guidance from the following support materials: • Written (links will be added in the future) • Video (links will be added in the future) Contact the Research Office managing your study for clarification.
Submission Process	On submission of the report, it will be received by the managing research office and scheduled for review by the relevant ethics review body. If further information is required before the review body Note/Approve the report, you will receive a communication through the system. Once the relevant review body has reviewed and the report is acknowledged the report will be provided to each Research Governance Office that has an active site listed in the system. They will review the report with specific focus on the site-specific information provided and will acknowledge the report.

National Human Ethics Progress/Final Report Form

(Reporting Period)

Project Details

Information in this section is pre-filled by data that exists in the system. If there are any errors here, please <follow this process tbd>

Project Title	Pre-filled by system
Short Title or Acronym	Pre-filled by system
NOSS Reference	Pre-filled by system
HREC Approval date	Pre-filled by system
HREC Expiry date	Pre-filled by system
HREC Name	Pre-filled by system
Study Type	Pre-filled by system
Study Sponsor	Pre-filled by system
Coordinating Principal Investigator Name	Pre-filled by system

- Where the Coordinating Principal Investigator is incorrectly listed <by this process tbd> BEFORE this report is submitted.
- Where the Study Type is showing incorrectly you will need to have this corrected <by this process tbd> prior to submitting the form as this will affect questions that appear in this form.

Current Study Progress

Information provided in this section of the form allows the HREC (or relevant review body) to understand what stage the overall study is at. Please select the closest that describes the current stage of the overall study.

- Selecting a status from this section indicates you are submitting a Progress Report

☐ **Not Yet Commenced -** No Clinical activities involving participants (including participant recruitment) have commenced.	Please explain the reason for the study not commencing
☐ **In Progress/Active -** Clinical or study activities have commenced	Please provide expected completion date.
☐ **Recruitment Ended (for a study with participant - recruitment)** When the last participant has met the last study analysis endpoint. • When reached at a single site study, this is likely the time point when data analysis can begin. • When reached at the last site in a multi-site study, this is likely the time point when data analysis can begin. • Participants may still be undergoing follow-up visits. **Data Collection Completed (for a study with no participant recruitment)**	Please provide expected completion date.
☐ **Temporary Halt/Suspended** A stoppage of the study (by the Sponsor, HREC or Coordinating Principal Investigator) to protect participant	Please provide further details

safety or avoid potential harm to participants. For health and medical research this could include other reasons.	
Selecting a status from this section indicates you are submitting a Final Report	
☐ **Abandoned** The application has been approved/authorised, but it has been determined that the project will never commence.	Please provide further details
☐ **Terminated** After study start but before study close, discontinuation of a research project by the investigator or sponsor, wherein activity will not resume. Possible reasons include: Ethical, safety, financial or other grounds. Will never progress to "Closed".	Please provide further details
☐ **Closed** The study has finished; participants are no longer being treated or examined. No additional amendments can be submitted.	Please provide further details

HREC Approved Sites

Information in this section is pre-filled by data that exists in the system. If there are any errors here (e.g missing sites), please contact the managing research office to have this corrected before the annual report is submitted.

Where the Principal Investigator is incorrectly listed a Change of Principal Investigator form should be submitted BEFORE this report is submitted.

Site Identifier	Site Name	Site Status	Principal Investigator	Date Site Authorised	Date Site Closed/Terminated/ Abandoned
Pre-filled by system	Pre-filled by system	Pre-filled by system	Pre-filled by system	Pre-filled by system	Pre-filled by system
Pre-filled by system	Pre-filled by system	Pre-filled by system	Pre-filled by system	Pre-filled by system	Pre-filled by system
Pre-filled by system	Pre-filled by system	Pre-filled by system	Pre-filled by system	Pre-filled by system	Pre-filled by system

HREC Approved Sites – External to the National One Stop Shop

Use this section for any sites that have been approved under this HREC approval that are not being managed in this system. Information in this section should be manually completed.

Principal Investigator's listed here should be the currently approved Principal Investigator for the Site. Where is it identified that the current Principal Investigator is different to the approved PI <follow this process tbd>

Site Name	Site Status	Principal Investigator	Date Site Authorised	Date Site Closed/Terminated/ Abandoned

Project Progress Summary

This section shows when one of the **Progress Report** statuses are selected above.
(Not Yet Commenced, In Progress/Active, Recruitment Ended/Data Collection Completed, Temporary Halt/Suspended)

Information provided in this section of the form allows the HREC (or relevant reviewing body) to understand what has happened in the last 12 months what is anticipated to happen in the next 12 months and a confirmation that the study documents being used have been review by the relevant reviewing body.	
Is this study proceeding as expected?	☐ Yes ☐ No - if no please provide details including plans to bring study back on track
Please provide a short statement regarding the general progress of the project over the reporting period, for annual reports this should.	
What actions are planned in the next 12 months?	
Please confirm the Protocol currently in use.	<document name> <document version><document date>
Please list each of the current Participant Information Sheets in use for this study.	<document name> <document version><document date>

OR

Project Final Summary

This section shows when one of the Final Report statuses are selected above.
(Abandoned, Terminated or Closed)
If you are not submitting the **final report** please change the study status above.

Information provided in this section of the form allows the HREC (or relevant review body) to understand what has happened in the last 12 months and what the **final outcome** of the research was.	
Please provide a short statement regarding the general progress of the project over the reporting period	
Briefly summarise the study outcomes	
List all publications to date, and those submitted for publication, which contain findings from the research project	
List all Conferences, seminars etc. at which findings from the research project have been presented	
These questions will appear when "Terminated" was selected as the study status	
What was the justification for early termination	
What are the potential implications for: 1. Research participants 2. The integrity of the study data as a result of terminating the study early	

Reporting and Monitoring **Clinical Trial**

Information provided in this section of the form allows the HREC (or relevant reviewing body) to ensure it meets its obligations under the National Statement 5.4 (Monitoring approved research)

This section may show/hide questions based off the study type noted above. This is to ensure researchers are only asked questions that are specific to their scenario. If the study type is incorrect contact the managing research office.

Will you be submitting the annual safety report with the progress report?	☐ Yes - Please detail a clear summary of the evolving safety profile of the trial. ☐ No

Guidance text provided when yes has been selected above.

- *a brief description and analysis of new and relevant findings*
- *a brief discussion of the implications of the safety data to the trial's risk-benefit ratio*
- *a description of any measures taken or proposed to minimise risks*
- *for Investigational Medical Products (IMPs) not on the Australian Register of Therapeutic Goods, a brief analysis of the safety profile of the IMP and its implications for participants taking into account all available safety data and the results of relevant clinical or non-clinical studies*

The Executive Summary of safety information produced for international regulators, such as a Development Safety Update Report (DSUR), may serve as the annual safety report sent to HRECs and can be uploaded in the Document upload section.

In the last 12 months has the project had an audit that has not already been reported to the HREC (or relevant reviewing body)?	☐ Yes - Please upload a copy of the audit report in the Document Upload section. ☐ No

In the last 12 months have there been any safety events that have implications to the continuing of this project HREC (or relevant reviewing body)? Examples include:
• Suspected unexpected Serious Adverse event (is this via the annual safety report?)
• Significant Safety Issues
  ○ Urgent Safety Measures
  ○ Temporary Halt of a trial for safety reasons
  ○ Notification of an amendment
  ○ Early Termination of a trial for safety reasons
• Serious Breach of GCP or the protocol
• Complaints about the conduct of Research or potential breaches of the Australian Code
	☐ Yes – if yes have they all been reported to the HREC (or relevant reviewing body)?
	☐ No – if no please ensure any outstanding safety events are reported to the HREC (or relevant reviewing body) prior to submitting this form

It is the is CPI's responsibility to ensure that all safety events that have implications to the continuing safety of this project are submitted for review by the HREC (or relevant reviewing body).
Please urgently submit the relevant Safety Reporting form BEFORE this report is submitted.

Are there any other issues that you wish to report?	

OR

Reporting and Monitoring **Non-Clinical Trial**	
Information provided in this section of the form allows the HREC (or relevant review bodies) to meet its obligations under the National Statement 5.4 This section may show/hide questions based off the study type noted above. This is to ensure researchers are only asked questions that are specific to their scenario. If the study type is incorrect please contact the reviewing	
In the last 12 months have there been any safety events that have implications to the continuing of this project? Examples include: • Deviations from the Protocol • Complaints about the conduct of Research or potential breaches of the Australian Code	☐ Yes - if yes: any safety events that have not yet been reported to the HREC should follow <this process tbd>. ☐ No
Are there any other issues that you wish to report?	

Compliance, Confidentiality and Storage	
Information provided in this section of the form allows the HREC (or relevant reviewing body) to meet parts of their monitoring requirements.	
Has the project been conducted in accordance with the NHMRC National Statement on Ethical Conduct in Human Research (revised)	☐ Yes ☐ No - please explain why
Has the study been conducted in accordance with the approved protocol and any study amendments?	☐ Yes ☐ No – please provide further details
Please expand on the measures that are taken to ensure the security of the data/samples collected during the project; Guidance: Identify the location of investigator site files (e.g. locked cabinet, compactus, electronic, etc.). Who has access to these records? Has this changed during the course of the study at this site? Describe any changes. Outline what standards, guidelines and legislation apply to the research and the storage and access to this project's records/data. Are participant records are stored separately? Provide information on the location and access to participant information.	

Recruitment and/or Data Collection	
The information in this section of the form relates to the overall study. Selecting the method for data collection will show/hide questions to ensure the researcher is only asked questions specific to their study. Select access to participants OR access to data (which ever best describes your study) Linked datasets can be selected in addition to the above options or as its own category	
Please select the method for how data is collected for this study:	☐ Access to Participants – Patients/Staff OR ☐ Access to Data or Tissue Samples only (medical records, biobanks, local datasets, clinical quality registries) AND ☐ Linked Datasets

When Access to Participant is selected this section appears

Access to Participant or Staff - Recruitment and Data Collection	
Information provided in this section of the form allows the HREC (or relevant reviewing body) to understand how the collection of data is progressing.	
Planned Recruitment for study	☐ There is a number or range – please add ☐ There is no specific number or range e.g. competitive recruitment
Actual Recruitment at time of completing report.	
Is recruitment on target?	☐ Yes ☐ No - Please explain why recruitment is behind schedule. Indicate any steps taken/to be taken to boost study recruitment
Number of withdrawals at time of completing report	
Is the rate of withdrawal for this study consistent with the expected rate?	☐ Yes ☐ No - Please explain why withdrawal is not consistent with expected rate.
Is the rate of loss to follow-up for this study consistent with the anticipated rate?	☐ Yes ☐ No - Please explain why loss to follow up is not consistent with anticipated rate.
Number of Aboriginal and Torres Strait Islander participants enrolled?	

When Access to Data or Tissue Samples only is selected this section appears

Access to Data or Tissue Samples only (medical records, biobanks, local datasets, registries)	
Information provided in this section of the form allows the HREC (or relevant reviewing body) to understand how the collection of data is progressing.	
Please select the method of data collection:	☐ Medical Records (Public Health Service) ☐ Medical Records (Other) ☐ Biological/Tissue Samples/Biobanks ☐ Local/Statewide/National Datasets ☐ Data collected for Registries
Medical Records (section appears when selected above)	
Information provided in this section of the form allows the HREC (or relevant reviewing body) to understand how the collection of data is progressing.	
Number of records accessed	
Is data collection on track?	☐ Yes ☐ No - Please explain why collection is behind schedule. Indicate any steps taken/to be taken to boost collection.
Any other comments	
Tissue Samples (eg biobank) (section appears when selected above)	
Information provided in this section of the form allows the HREC to Information provided in this section of the form allows the HREC (or relevant reviewing body) to understand how the collection of data is progressing.	
Is the planned rate of data/sample collection on target overall to ensure this study will meet its endpoint?	☐ Yes ☐ No - Please explain why collection is behind schedule. Indicate any steps taken/to be taken to boost collection
Are you using retrospective samples under a previous HREC study.	☐ Yes – if yes provide HREC approval ☐ No
Are the samples stored correctly and is compliance maintained as per the approved protocol?	☐ Yes ☐ No
Existing Datasets (section appears when selected above)	
Information provided in this section of the form allows the HREC to Information provided in this section of the form allows the HREC (or relevant reviewing body) to understand how the collection of data is progressing.	
A question about data custodian approval.	☐ Yes ☐ No - Please explain ....
Has there been any changes to where / how data is retrieved / submitted?	☐ Yes - Please explain .... ☐ No
Has data management deviated from the HREC-approved data management plan/protocol?	☐ Yes - Please explain .... ☐ No
Is your data management plan still up to date?	☐ Yes ☐ No - Please explain ....

Data collected for Clinical Quality Registries (section appears when selected above)	
Information provided in this section of the form allows the HREC (or relevant reviewing body) to Information provided in this section of the form allows the HREC to understand how the collection of data is progressing.	
Consent	
Numbers	
How has the data been used	

Linked Data (section appears when selected above)	
Data custodian approvals obtained	☐ Yes ☐ No
Had linked data been delivered by Data Linkage Unit(s)	☐ Yes ☐ No
Have there been changes to the research team accessing the linked data?	☐ Yes - If yes, have these changes been notified to the HREC approving the Data Linkage? ☐ No
Have you received the linked data?	☐ Yes - date received ☐ No
Any variations to data requested	☐ Yes Please explain .... ☐ No

Document Upload	
By uploading documents in the following format, you will have clear easy to find documents Only document directly related to this report should be uploaded here. Any documents required for amendments or safety reporting will need to be submitted with the correct form.	
Document Type	**Document Title/Description**
Certificate of Currency (appears when Commercially Sponsored Clinical Trial)	
By uploading the certificate of currency here the system will manage the distribution of the document to all authorised sited in the system.	
Upload the current certificate of currency	

Declaration & Submission
The CPI holds overall responsibility for the information provided in this report form regardless of who submits the form.
(Progress Report) By submitting this report, I confirm the following: • I am the CPI of this project (or have delegated authority to submit)

- This project is being/has been conducted as originally approved by the relevant ethics committee (and subject to any changes subsequently approved as amendments)
- This project continues to be conducted in compliance with the NHMRC national Statement on Ethical Conduct in Human Research
- All amendments have been submitted for HREC and/or RGO review prior to implementation
- All relevant safety reports have been submitted for HREC and/or RGO review
- All serious breaches of good clinical practice or protocol have been reported to the HREC and/or RGO review.
- This report accurately reflects the progress of the project.

(Final report) By submitting this report, I confirm the following:

- I am the CPI of this project (or have delegated authority to submit)
- This project was conducted as originally approved by the relevant ethics committee (and subject to any changes subsequently approved as amendments)
- There is no further ongoing study activity occurring and any future requests will be via a new application.

Name of Person Submitting	
Role of Person Submitting the form	
Date	

Site Name (this section repeats per site listed above)	
Site authorisation date	Pre-filled
Site Recruitment and/or Data	
Section Guidance: The information in this section of the form relates to the activity at the site named above only. The response provided to the question "*Please select the method for how data is collected for this study*" in the earlier section of this form will determine the questions that appear in this section. Information provided in this section of the form allows the Authorising Institution to monitor research activity, continuously improve the quality and compliance of research and satisfy state and national reporting requirements.	

Investigators at (Name) It is the Principal Investigators responsibility to report any changes to Associate Investigators, External Investigators and XX to the Site RGO. If the list of names provided here is different to <assumed section in system that will list site investigators>, please follow <this process tbd>.	
Please list the current investigators completing study activity at this site.	

When Access to Participants is selected above this section appears

Site (Name) Access to Participants or Staff - Recruitment or Data Collection	
Planned number of participants for this study at this site	(if this already exists in another part of the system it should prefill)
Actual recruitment at site at time of completing report.	(if this already exists in another part of the system it should prefill)
Is Recruitment on target at this site?	☐ Yes ☐ No - Please explain why recruitment is behind schedule. Indicate any steps taken/to be taken to boost study recruitment
The next questions will only appear if study type = Clinical Trial	
Date first participant recruited to the study at this site.	(if this already exists in another part of the system it should prefill)
How many participants are currently enrolled and ongoing/actively being treated at this site?	
How many participants have withdrawn from this study at this site?	
Is the rate of withdrawal for this study consistent with the anticipated rate?	☐ Yes ☐ No - Please explain why withdrawal is not consistent with anticipated rate.
How many participants are currently in follow up at this site?	
Is the rate of loss to follow-up for this study consistent with the anticipated rate?	☐ Yes ☐ No - Please explain why loss to follow up is not consistent with anticipated rate.

Is this site part of a decentralised trial /tele-trial?	☐ Yes - Please list the Primary Site, please list the Satellite site/s ☐ No
Total revenue to date	NAS collection requirement
Total expenditure to date	NAS collection requirement

When Access to Data or Tissue Samples only is selected this section appears

Site (Name) Access to Data or Tissue Samples Only (medical records, biobanks, local datasets, clinical quality registries)	
Is the planned rate of data/sample collection on target overall to ensure this study will meet its endpoint?	☐ Yes ☐ No - Please explain why collection is behind schedule. Indicate any steps taken/to be taken to boost collection
General comment on site	