HREC/RGO Annual Progress Report/Final Report

This report should be submitted to the approving HREC and site RGO's on an annual basis (minimum) and at the completion of the project.
(National Statement Section 5.5.5 refer to https://www.nhmrc.gov.au/book/chapter-5-5-monitoring-approved-research)

Insert your institutional logo here

Form developed by Health Translation Queensland Human Research Ethics and Governance Working Group

SECTION 1: PROJECT DATA

HREC REF. NO: HREC / / / **Approving HREC Name:**

PROJECT TITLE:

REPORTING PERIOD: (12 month period covered by this report) to

COORDINATING PRINCIPAL INVESTIGATOR (CPI):

SPONSOR OF THE STUDY (if applicable):

CONTACT PERSON

SITES APPROVED (only complete if changed since last report):

Name of Site & SSA Ref #	Name of Local Site PI	Commencement date at Site	Recruitment # to date at Site	Local Site PICF version number and date

SECTION 2: STUDY STATUS

In progress at all sites listed above: Yes No (if no, please identify sites that are not active):

In progress at some sites: Yes No (please identify sites in progress):

In progress, but closed to recruitment: Yes No

Discontinued/Abandoned: **Not yet commenced:** **On hold:**

If study has been discontinued/abandoned; not yet commenced or on hold, please provide an explanation:

Completed at all sites (this is a Final Report – please attach list of results/publications):

HREC Expiry date for study:

Is an extension to HREC approval required? Yes No

(If yes, please submit an application to the HREC to extend the study, providing appropriate justification for the extension)

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SECTION 3: HREC APPROVED DOCUMENTATION

Provide version number and dates of the below Master HREC Approved Documents currently in use (only complete if changed since last report).

Protocol	**Version Number:**		**Date:**	
Master PICF (if applicable)	**Version Number:**		**Date:**	
Questionnaire (if applicable)	**Version Number:**		**Date:**	
OTHER (please specify)		**Version Number:**		**Date:**
OTHER (please specify)		**Version Number:**		**Date:**
OTHER (please specify)		**Version Number:**		**Date:**

SECTION 4: CHANGES TO THE APPROVED STUDY

Have there been any amendments to the approved study (including changes to the research team) since the original submission or last progress report?

- ☐ Yes → If Yes, please submit an Amendment to the HREC and appropriate RGO
- ☐ No → If No, go to Section 5

If yes, provide list of any approved amendments

SECTION 5: MANAGEMENT OF RISKS

Have there been any complaints regarding the conduct of the study since approval of the study or last progress report?

- ☐ Yes → If Yes, please provide further details as an attachment
- ☐ No

SECTION 6: CLINICAL INTERVENTION (Including clinical trials)

Have any issues in regards to safety occurred since the submission of the last progress report?

- ☐ Yes → If Yes, please provide further details as an attachment
- ☐ No

Have all urgent safety measures including amendments, temporary halt or early termination of the study for safety reasons been submitted to the HREC and authorising RGO?

- ☐ Yes
- ☐ No → If No, please provide further details as an attachment
- ☐ NA

Have all serious Adverse Events been reported to the study sponsor within 24 hours of becoming aware of the event?

- ☐ Yes
- ☐ No → If No, please provide further details as an attachment
- ☐ NA

Have all significant safety issues and suspected unexpected serious adverse reaction (SUSARS) arising from a site been reported to the relevant local institutional RGO within 72 hours of becoming aware of the event?

- ☐ Yes
- ☐ No → If No, please provide further details as an attachment
- ☐ NA

Is a Data Safety Monitoring Committee (DSMC) or independent safety monitoring required for this study?

- ☐ Yes → If yes, please provide further details of last meeting and any recommendations for submission to HREC/RGO
- ☐ No

SECTION 7: OTHER CONSIDERATIONS

Are there sufficient funds to complete the study in the manner as approved by the HREC and authorised by the relevant RGO.

☐ Yes
☐ No → If No, please provide further details

Have any concerns arisen from the study that you wish to draw to the HREC and RGO attention? For example, barriers and obstacles encountered in the research project, difficulties with recruitment/data collection

☐ Yes → If yes, please provide further details and any recommendations for submission to HREC/RGO
☐ No

SECTION 8: PROGRESS TO DATE

Please provide a brief statement on progress so far including:

- **Summary of findings to date**
- **Details of any publications accepted or in press**
- **Details of any presentations given**

For Final Report: description on how the results have been disseminated back to the appropriate parties as per approved protocol

DECLARATION BY COORDINATING PRINCIPAL INVESTIGATOR:

I certify that the above project was carried out/ is being carried out in accordance with the approved protocol submitted to and approved by the HREC

NAME	SIGNATURE	DATE