## **Annual reporting requirements**

Each year a project status report must be submitted for all projects that are ongoing or have been completed in the reporting period. The continuation of approval for ongoing projects is subject to the receipt and acceptance of the annual report by the Human Research Ethics Committee (HREC).

Details collected in the annual report assist the HREC to monitor research activity and provide evidence of compliance with the National Statement on Ethical Conduct in Human Research (2007) and Australian Code for Responsible Conduct of Research 2007.

It is the responsibility of the Principal Investigator to ensure that all information submitted to the HREC is a true and correct record of activity for the reporting period.

All researchers must be aware of and adhere to the National Statement on Ethical Conduct in Human Research (2007), and Australian Code for Responsible Conduct of Research 2007 and relevant National Health and Medical Research Council Guidelines, which are being continuously updated. Please refer to the [Human Research Ethics website](https://www.adelaide.edu.au/research-services/oreci/human/applications/) for further information at <https://www.adelaide.edu.au/research-services/oreci/human/>.

## **Extension of ethics approval**

If you wish to extend the existing ethics approval for another three year period, prior to expiry, submit the annual report in conjunction with a new ethics application using the current template. In the ethics application, focus on the research activities yet to be undertaken or that are ongoing.

For projects involving higher degree students, current ethics approval needs to be maintained for the duration of candidature up until submission of their thesis/PhD. An extension of approval should be obtained when the research cannot be completed in the existing ethics approval period. For students in the writing up stage of their higher degree and no further interactions with participants or data collection activities are planned, please submit **only** the completed Annual Report on Project Status to hrec\_report@adelaide.edu.au who will advise if a new ethics application is also required.

##  **Notes for completing the report**

This report is to be completed annually on the anniversary of the date of ethics approval. An annual report is required for all projects, even if the project has not commenced or no work was undertaken. Completion of this report is also required at the conclusion of the project.

Additional rows can be added to the tables if there is insufficient room.

Failure to submit an annual report may lead to withdrawal of ethics approval of the project.

How to submit:

1. Check that you have answered all relevant questions.

2. ‘Save’ as one PDF document including

3. Email the PDF report to hrec\_report@adelaide.edu.au (hrec\_report@adelaide.edu.au).

**Please refer to the Annual reporting requirements and Notes for completing the report information to guide the completion of this report.**

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| **1 PROJECT DETAIL** |
| Project title:  |       |
| HREC Approval Number: |       | Approval Expiry date: | Enter a date |

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| **2 REPORTING PERIOD**  |
| This report is for the reporting period from: | Enter a date | to: | Enter a date |

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| **3 INVESTIGATORS AND OTHER APPROVALS** |
| *It is the responsibility of the Principal Investigator named below to ensure that all information submitted to the HREC is a true and correct record of activity for the reporting period.* |
| Principal Investigator Name: |       | School: |       |
| **Provide details of co-investigators and others involved in the project**  |
| Name:  |       | University ID: |       | Institution: |       |
| Name:  |       | University ID: |       | Institution: |       |
| Name:  |       | University ID: |       | Institution: |       |
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| Name:  |       | University ID: |       | Institution: |       |
| **Provide details of other HREC approvals obtained for this project**   |
| Committee name: |       | Approval number: |       |
| Committee name: |       | Approval number: |       |
| Committee name: |       | Approval number: |       |
| Committee name: |       | Approval number: |       |

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| **4 PROJECT STATUS** |
| **IN PROGRESS**  | [ ]  Work is in progress i.e. data is still being collected, or data collection is completed but analyses are continuing as per the existing ethics approval.  | Anticipated date of completion: Enter a date |
| **EXTENSION REQUIRED**  | [ ]  The project is continuing and an extension of ethics approval is required [ ]  The project is for a student’s higher degree and data collection is completed More information about the process for gaining an extension of ethics approval is available at: <https://www.adelaide.edu.au/research-services/oreci/human/applications/extension/>  |
| **NOT YET COMMENCED** | [ ]  Project not commenced in reporting period  | Anticipated date of commencement: Enter a date |
| **INACTIVE** | [ ]  No activity in the reporting period (approval remains current) | Anticipated date of re-commencement: Enter a date |
| **NEVER COMMENCED** | [ ]  Work never commenced and approval no longer required  |
| **ABANDONED** | [ ]  Work commenced and was abandoned and approval no longer required | Date work was abandoned: Enter a date |
| **COMPLETED** | [ ]  Work as approved was completed during the reporting period  | Date of completion: Enter a date |

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| **5 PARTICIPANTS**  |
| How many participants are/have been involved in the project? If the number of participants differs from the approved protocol, please explain. |       |
| How many participants have withdrawn from the project to date? |       |
| If known, briefly list the reasons for participants withdrawing. |       |

| **6 RESEARCH RECORDS AND MATERIALS** |
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| How are research records and materials being securely stored? |       |
| Where are they stored? |       |
| Who has access to them? |       |
| If project is completed, how long will they be retained? |       |
| If project is abandoned, what has happened to the records and materials that were collected? |       |

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| **7 VARIATIONS TO THE APPROVED PROTOCOL***The HREC granted ethics approval for your project on the basis of a protocol submitted. A condition of approval requires any proposed variations to the protocol being approved by the HREC prior to implementation.* |
| Have there been any variations to the protocol in the reporting period which have not been submitted to the HREC? Variations include changes to: | **YES**  | **NO** | If you answered **YES** to any of these options, please provide details of the variations and the reasons why approval has not been sought from the HREC.  |
| * Investigators
 |[ ] [ ]        |
| * Study design and research plan
 |[ ] [ ]        |
| * Participants/records/materials/samples
 |[ ] [ ]        |
| * Method of recruitment
 |[ ] [ ]        |
| * Information and consent documents
 |[ ] [ ]        |
| * Other
 |[ ] [ ]        |

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| **8 REPORT OF ACTIVITY** |
| Provide a concise summary in plain language of the current status, progress and outcomes of the research for the reporting period. Include details of any data collection undertaken, difficulties encountered, and results/interpretations of any analyses conducted during the reporting period.  |       |
| Provide details of any publications or presentations of outcomes of research undertaken during the reporting period.  |       |
| If you agreed to give feedback or findings to participants, provide details what has been provided during the reporting period or when this will occur.  |       |
| What mechanisms have you used to monitor the conduct and progress of the research project? |       |
| Report on compliance with conditions of approval prescribed by the HREC. |       |
| If the project is ongoing, briefly outline the actions planned for the next year?  |       |

| **9 ADVERSE EVENTS AND OTHER INCIDENTS AND COMPLAINTS** |
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| In the reporting period, have there been any adverse events, other unforeseen incidents or unexpected outcomes in your project? (*e.g. side effects of drugs or procedures, participant distress, breaches of participant privacy, failure to obtain other necessary approvals)* | **YES** [ ]   **NO** [ ]   |
| If **YES,** please provide a brief summary of the issues and outcomes.  |       |
| Were all events or incidents reported to the HREC? | **YES** [ ]   **NO** [ ]  **NA** [ ]  |
| If the event or incident was not reported to the HREC, attach a report detailing the event. |       |
| How many participants were involved? |       |
| Please describe any complaints received in relation to the project.  |       |
| What action/s has been taken in response to any complaint? |       |

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| **10 COMMENTS FOR THE HREC** |
| Is there anything else you want to report to the HREC? |       |

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| **REPORT COMPLETED BY:** |       |
| **DATE REPORT COMPLETED:** | Enter a date. |

To submit the report:

1. **Save** the entire document (including any supplementary information you are attaching) as one **PDF document**.
2. **Email** the PDF document to: hrec\_report@adelaide.edu.au (hrec\_report@adelaide.edu.au)