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| Project Final Report/Site Closure Report (HREC) | | | | | | | | | | | | | | | | |
| The **sponsor** is responsible for reporting to the reviewing Human Research Ethics Committee (HREC) regarding an approved research project. The sponsor must complete this report and submit to the HREC. The sponsor must provide a copy to the Coordinating Principal Investigator (CPI).  Submit this report to the reviewing HREC for either:  **Completion of the research project** (single-site or multi-site project)  **OR**  **Site closure** (selected site(s) closing in a multi-site project – submit a report for **each** site closure)  The site Principal Investigator (PI) should report to the site Research Governance Officer (RGO) as required. | | | | | | | | | | | | | | | | |
| Research Project | | | | | | | | | | | | | | | | |
| HREC reference number | | | | e.g. HREC/17/Abc/123 | | |  | | | HREC approval date | | | | Select date | | |
|  | | | | | | | | | | | | | | | | |
| Local reference number | | | | Enter text | | |  | | | Date of this report | | | | Select date | | |
|  | | | | | | | | | | | | | | | | |
| Project title | | | | Enter text | | | | | | | | | | | | |
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| Sponsor | | | | Enter text | | | |  | | | Sponsor telephone | | | | Enter text | |
|  | | | | | | | | | | | | | | | | |
| Sponsor contact (Aus) | | | | Enter text | | | |  | | | Sponsor email | | | | Enter text | |
|  | | | | | | | | | | | | | | | | |
| Coordinating Principal Investigator (CPI) for project | | | | | | | Enter text | | | | | | | | | |
|  | | | | | | | | | | | | | | | | |
| Study coordinator name | | | | Enter text | | | |  | | | Study coordinator email | | | | Enter text | |
| Report | | | | | | | | | | | | | | | | |
| Report type | | | | Select one | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | | |
| Reason | | | | Select one | | |  | | | | | | | | | |
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| If project/site was abandoned, were the participants informed? | | | | | | | | | | | | | | Select one | | |
|  | | | | | | | | | | | | | | | | |
| If project/site was abandoned, provide reasons | | | | | | | Enter text | | | | | | | | | |
|  | | | | | | | | | | | | | | | | |
| Lessons learned | | | | Enter text | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | | |
| Were participants recruited? | | | | | | | Select one | | | | | | | | | |
|  | | | | | | | | | | | | | | | | |
| If participants were *not* recruited, provide explanation (e.g. project is a registry) | | | | | | | Enter text | | | | | | | | | |
|  | | | | | | | | | | | | | | | | |
| Is the project a clinical trial? | | | | | | | Select one | | | | | | | | | |
| A. Clinical Trial | | | | | | | | | | | | | | | | |
| *For numbers of participants, provide the* ***cumulative total*** *since project/site commencement.* | | | | | | | | | | | | | | | | |
| Targeted participant enrolment number | | | | | | | Enter number | | | | | | | | | |
|  | | | | | | | | | | | | | | | | |
| Actual number of participants enrolled | | | | | | | Enter number | | | | | | | | | |
|  | | | | | | | | | | | | | | | | |
| Actual number of participants treated | | | | | | | Enter number | | | | | | | | | |
|  | | | | | | | | | | | | | | | | |
| Number of participants withdrawn | | | | | | | Enter number | | | | | | | | | |
| B. Health/Medical Research Project (e.g. clinical, health or social science research) | | | | | | | | | | | | | | | | |
| *For numbers of participants/records/samples, provide the* ***cumulative total*** *since project/site commencement.* | | | | | | | | | | | | | | | | |
|  | | Targeted number | | | Actual number | | | | | | | Number withdrawn | | | | |
| Participants | Enter number | | | Enter number | | | | | | | Enter number | | | | |
| Records | Enter number | | | Enter number | | | | | | |  | | | | |
| Samples | Enter number | | | Enter number | | | | | | |  | | | | |
| Project Final Report (completion of research project at all sites approved by the HREC) | | | | | | | | | | | | | | | | |
| Date of completion | | | | Select date | | |  | | |  | | | |  | |
|  | | | | | | | | | | | | | | | | |
| Date (or intended date) of database lock, if applicable | | | | | | | Select date | | | | | | | | | |
|  | | | | | | | | | | | | | | | | |
| Outcomes of project | | | | Enter text | | | | | | | | | | | | |
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| *Attach a list of publications, seminars, conferences etc. which feature findings from the research project (include those submitted for publication or future events).* | | | | | | | | | | | | | | | | |
| Is a list of publications etc. attached? | | | | | | | Select one | | | | | | | | | |
|  | | | | | | | | | | | | | | | | |
| If publication is not planned, provide brief explanation | | | | | | | Enter text | | | | | | | | | |
|  | | | | | | | | | | | | | | | | |
| Will participants be informed of research project results? | | | | | | | Select one | | | | | | | | | |
|  | | | | | | | | | | | | | | | | |
| If No, give explanation | | | Enter text | | | | | | | | | | | | | |
| Site Closure Report (one site closing in a multi-site project) | | | | | | | | | | | | | | | | |
| Site name (organisation) | | | | Enter text | | | |  | | | Principal Investigator (PI) | | | | Enter text | |
|  | | | | | | | | | | | | | | | | |
| State/Territory | | | | Enter text | | | |  | | | Date of site closure | | | | Select date | |
| Declaration | | | | | | | | | | | | | | | | |
| *To be completed by the Sponsor/CRO, or the Coordinating Principal Investigator (CPI) for a multi-site project, or the Principal Investigator (PI) for a single-site project.* | | | | | | | | | | | | | | | | |
| The information provided in this report is complete and correct. The project is being conducted in keeping with the conditions of approval of the reviewing HREC (and subject to any changes subsequently approved). The project is being conducted in accordance with the protocol. Any significant protocol deviation or violation has been reported to the reviewing HREC. The project is being conducted in compliance with the *National Statement on Ethical Conduct in Human Research* (NHMRC, 2007) and *Safety Monitoring and Reporting in Clinical Trials Involving Therapeutic Goods* (NHMRC, 2016), or as amended. | | | | | | | | | | | | | | | | |
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| Name | | | Enter text | | |  | | | Email | | | | Enter text | | | |
|  | | | | | | | | | | | | | | | | |
| Organisation | | | Enter text | | |  | | | Telephone | | | | Enter number | | | |

**Signature**

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**Date** Select date

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| *Office use only* | | | | |
| Research office acknowledgement – HREC | | | | |
| Name | Enter text |  | Position | Enter text |
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| Research office acknowledgement – RGO | | | | | | |
| Name | | Enter text |  | Position | | Enter text |
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**Signature**

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