

**Project Progress Report**

This **Annual** or **Final** Progress Report Form is to contain information related to **Eastern Health only.**

The site Principal Investigator **(PI)** should report to the **Eastern He**a**lth** site Research Governance Officer **(RGO)** according to **Eastern Health** site policy.

Please forward completed report to **ethics@easternhealth.org.au** as a PDF document.

**Please make sure all relevant fields are completed to avoid delays in response.**

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| **Report Type** | Choose an item. | **EH Local Reference** |  Click here to enter text.  |
| **Date of Report** | Click here to enter a date. | **HREC Reference No.** |  Click here to enter text.  |
| **Study Title** |
| Click here to enter text. |
| **Principal Investigator Name** | Click here to enter text. |
| **Study Coordinator Name** | Click here to enter text. |

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| **Reporting Period** | **From** | Click here to enter a date. | To | Click here to enter a date. |

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| **Are participants still being recruited** | Choose an item. |

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| **Project Type →** | Choose an item. |
| **Recruitment** |  |
| **First EH Site Initiation Visit Date** | Click here to enter a date. |
| **Project Commencement Date at EH** | Click here to enter a date. |
| **First Participant Randomised/Recruited/Consented at EH** | Click here to enter a date. |
| **Targeted Participant Enrolment Number at EH Sites Only.***Site by Site, within EH, can be entered in Summary if required* |  Click here to enter text. |
| **Actual Participant Enrolment Number at EH Sites Only***Site by Site, within EH, can be entered in Summary if required* |  Click here to enter text. |
| **Number of Participants Withdrawn at EH Sites Only***Site by Site, within EH, can be entered in Summary if required* |  Click here to enter text. |
| **Reason for Withdrawals** | Click here to enter text. |
| **Is Recruitment on Target** | Choose an item. |
| **Summary of Study Progress** |
| Click here to enter text. |

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|  **During this Reporting Period at Eastern Health** |  |
| **Have there been any amendments to this project**  | Choose an item. |
| **Have they all been reported to the EH Office of Research and Ethics Office** | Choose an item. |
| **Have there been any adverse events**  | Choose an item. |
| **Have they been reported EH Office of Research and Ethics Office** | Choose an item. |
| **Have there been any Protocol Breaches/Deviations or Violations** | Choose an item. |
| **Have these been reported to the EH Office of Research and Ethics Office** | Choose an item. |
| **Have there been any Changes in Personnel** | Choose an item. |
| **Have they been reported to the EH Office of Research and Ethics Office** | Choose an item. |
| **Has a current insurance certificate been submitted**  | Choose an item. |

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| **Has the study been subject to an audit by a Regulator or organisation/body at the site in the last 12 months** | Choose an item. |
| **Date of Audit** | Click here to enter a date. |
| **Auditing Organisation Name** |  Click here to enter text.  |
| **If Audited were any adverse findings made** | Choose an item. |
| **Findings** | Click here to enter text. |

**Declaration:** 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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| **Principal/Associate Investigator Name** |  Click here to enter text.  |
| **Signature\*** |  |
| **Email Address** |  Click here to enter text.  |
| **Telephone** | Click here to enter text. |

**\*Accepted Signatures for this report are:**

1. **A copy of this form, signed in wet ink, scanned and forwarded to our office electronically.**
2. **Unsigned, completed form, forwarded to our office electronically via PI/AI email address.**
3. **Unsigned, completed form forwarded to our office electronically but has cc’d the PI or AI.**
4. **Signature MUST NOT be a Copy and Paste only – Forms will be returned.**

***These options are to indicate and verify the PI/AI’s knowledge/completion of this report.***

**Note: Non-reporting can lead to a suspension and possible withdrawal of ethical approval of a study, including other investigator/sponsor related studies.**

**Reporting is a Condition of Ongoing Approval**