|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Progress Report – Project Form (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 reviewing HREC. The sponsor must provide a copy to the Coordinating Principal Investigator (CPI).  **This *Progress Report – Project Form* must include information from all sites approved by the HREC receiving this report.** | | | | | | | | | | | | |
| 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 | | | | | | | | | |
|  | | | | | | | | | | | | |
| 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 period start date | | | Select date | |  | | Report period end date | | | Select date | | |
|  | | | | | | | | | | | | |
| Sites included in report | | | Enter text | | | | | | | | | |
|  | | | | | | | | | | | | |
| Summary of progress | | | Enter text | | | | | | | | | |
|  | | | | | | | | | | | | |
| Is an amendment request being submitted with this report? | | | | | | | | | | | Select one | |
|  | | | | | | | | | | | | |
| Did the reviewing HREC waive the informed consent requirement? | | | | | | | | | | Select one | | |
|  | | | | | | | | | | |  | |
| Are participants being recruited for the project? | | | | | | | | | | | Select one | |
|  | | | | | | | | | | | | |
| If participants are *not* being recruited, provide explanation (e.g. project is a registry) | | | | | | | | | | Enter text | | |
|  | | | | | | | | | | | | |
| Is the project a clinical trial? | | | | | Select one | | | | | | | |
| A. Clinical Trial | | | | | | | | | | | | |
| *For questions below regarding numbers of participants, provide the* ***cumulative total*** *since project commencement.* | | | | | | | | | | | | |
| Date of first site initiation visit (project commencement) at a site approved by the HREC | | | | | | | | | | Select date | | |
|  | | | | | | | | | | | | |
| Date first participant randomised/recruited at a site approved by the HREC | | | | | | | | | | Select date | | |
|  | | | | | | | | | | | | |
| Targeted participant enrolment number (total for all sites approved by the HREC) | | | | | | | | | | | Enter number | |
|  | | | | | | | | | | | | |
| Actual number of participants enrolled (total at all sites approved by the HREC) | | | | | | | | | | | Enter number | |
|  | | | | | | | | | | | | |
| Actual number of participants treated (total at all sites approved by the HREC) | | | | | | | | | | | Enter number | |
|  | | | | | | | | | | | | |
| Number of participants withdrawn (total at all sites approved by the HREC) | | | | | | | | | | | Enter number | |
|  | | | | | | | | | | | | |
| Reason(s) for participant withdrawal | | | | | | Enter text | | | | | | |
|  | | | | | | | | | | | | |
| Number of participants that have completed the core research project (total at all sites approved by the HREC) | | | | | | | | | | | Enter number | |
|  | | | | | | | | | | | | |
| Is recruitment on target (overall, for all sites approved by the HREC)? | | | | | | | | | | Select one | | |
|  | | | | | | | | | | | | |
| If recruitment is *not* on target, provide key reason(s) | | | | | Enter text | | | | | | | |
| B. Health/Medical Research Project (e.g. clinical, health or social science research) | | | | | | | | | | | | |
| Date project commenced at a site approved by the HREC | | | | | | | | | | Select date | | |
|  | | | | | | | | | | | | |
| Date first participant was consented at a site approved by the HREC (if applicable) | | | | | | | | | | Select date | | |
|  | | | | | | | | | | | | |
| *For numbers of participants/records/samples, provide the* ***cumulative total*** *since project commencement.* | | | | | | | | | | | | |
|  | **Targeted number**(total for all sites approved by the HREC) | | Actual number(total for all sites approved by the HREC) | | | | | **Number withdrawn**(total for all sites approved by the HREC) | | | Number completed the research project(total for all sites approved by the HREC) |
| Participants | Enter number | | Enter number | | | | | Enter number | | | Enter number |
| Records | Enter number | | Enter number | | | | |  | | |  |
| Samples | Enter number | | Enter number | | | | |  | | |  |
|  | | | | | | | | | | | | |
| Reason(s) for participant withdrawal (if applicable) | | | | | Enter text | | | | | | | |
|  | | | | | | | | | | | | |
| Is recruitment on target (overall, for all sites approved by the HREC)? | | | | | | | | | | Select one | | |
|  | | | | | | | | | | | | |
| If recruitment is *not* on target, provide key reason(s) | | | | | Enter text | | | | | | | |
| Audit | | | | | | | | | | | | |
| Has the research project been subject to audit by a Regulator or organisation/ body (at a site approved by the HREC) in the past 12 months or since the previous report? | | | | | | | | | | | Select one | |
|  | | | | | | | | | | |  | |
| Date of audit | | | Select date | |  | | Auditing organisation | | | Enter text | | |
| 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. | | | | | | | | | | | | |
|  | | | | | | | | | | | | |
| Name | | | Enter text | | |  | | Email | | | Enter text | |
|  | | | | | | | | | | | | |
| Organisation | | | Enter text | | |  | | Telephone | | | Enter number | |

**Signature**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |

**Date** Select date

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| *Office use only* | | | | |
| Research office acknowledgement – HREC | | | | |
| Name | Enter text |  | Position | Enter text |
|  | | | | |
| Comment | Enter text | | | |
|  | | | | |

**Signature**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |

**Date** Select date

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  |  | |  |  |  | |
| Research office acknowledgement – RGO | | | | | | |
| Name | | Enter text |  | Position | | Enter text |
|  | | | | | | |
| Comment | | Enter text | | | | |
|  | | | | | | |

**Signature**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |

**Date** Select date

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |