1. This form should be used as a guide for the information required in the annual report
2. The form is not intended to be a replacement for the annual report form provided by the reviewing HREC, however it outlines the information required by the NALHN RGO at the point of annual review. If the HREC form does not ask these questions, they should be summarised in the ‘project report’ section.
3. Annual reviews with little detail will be returned and this information will be requested.

|  |  |
| --- | --- |
| SSA Number |  |
| HREC number |  |
| Project Title |  |

**Essential Documents**

|  |  |  |  |
| --- | --- | --- | --- |
| **Current Documents** | **Version** | **Date** | **n/a** |
| Investigator Brochure |  |  |  |
| Protocol |  |  |  |
| PISCF (Master Main) |  |  |  |
| PISCF (Site Version) |  |  |  |

Insert lines for additional PISCF (eg pregnant partner) if required.

**Recruitment - Clinical Trials only**

|  |  |
| --- | --- |
| Target recruitment number in NALHN |  |
| Total number recruited since approval |  |
| Total number withdrawn |  |

**Auditing**

Has the research project been subject to an audit at the site in the past 12 month ? Yes  No

*If yes, please attach a copy of the audit report (if not previously submitted to RGO)*

**Insurance**

This section is required to be completed for a commercially sponsored research project or a project conducted by a collaborative group; it is not required for an investigator initiated research project

Is the insurance certificate current? Yes  No  N/A

\***If not previously submitted to RGO, please submit**\*

**Research Personnel**

List all current members of the research team **at this site**:

|  |  |
| --- | --- |
| Name | Role in the project |
|  |  |
|  |  |

Insert additional lines if required

**Confidentiality and storage of data/samples**

|  |
| --- |
| Please state what measures are taken to ensure the security of the data/samples collected during the project |
|  |

List of people who have access to data/data storage

|  |  |  |  |
| --- | --- | --- | --- |
| Name | Role | Access to data storage | Access to Data |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

Insert rows as needed

**Publications and presentations**

Publications in peer reviewed journals (please attach list)

Presentations (please attach list)

**Site Budget**

Please attach a copy of correspondence with your Divisional Business Consultant/Cost Centre Manager, confirming that the ongoing budget management is satisfactory.