Be sure to adjust the footer of the document with the appropriate contact details.

Insert date

Research Governance Officer

Level 7 Building 2

William McCormack Place

5b Sheridan Street, Cairns QLD 4870

Dear RGO,

**HREC Reference:** (*insert your relevant number*)

**SSA Reference:** (*insert your relevant number*)

**Principal Investigator:** (*insert Principal Investigator’s Name*)

Include a **brief** overview of the project here.

The site in the CHHHS is (insert site name).

The Sponsor for this Clinical Trial is (insert Sponsor name). *(Only applicable for Clinical Trials)*

The documents listed below, and this cover letter have been uploaded into ERM for the above referenced study for review and authorisation and provided in hard copy.

Please find enclosed: *(Please remove the documents that are not relevant to your project.)*

|  | **Document Name** | **Version** | **Date** |
| --- | --- | --- | --- |
|  | ERM SSA Form *(Mandatory)* | Sep ver 1 |  |
|  | HREA HREC/2021/QRBW/77577 *(Mandatory)* | Jun ver 2 |  |
|  | HREC Approval letter (original) *(Mandatory)* |  |  |
|  | Amendment HREC approval letter/s *(if relevant)** *Each amendment approval letter must be listed separately*
 |  |  |
|  | Protocol *(Mandatory)* | 4 |  |
|  | **Participant Information Sheet and consent Form (PISCF)***(Multi-site projects may require site specific PICFs)* |
|  | Phase 1b **Master** Participant Information Sheet and Consent form | 2.0 |  |
|  | Phase 2 **Master** Participant information Sheet and Consent form | 2.0 |  |
|  | Cairns Hospital Phase 1b PISCF - tracked | 1.0 |  |
|  | Cairns Hospital Phase 1b PISCF - clean | 1.0 |  |
|  | Cairns Hospital Phase 2 PISCF - tracked | 1.0 |  |
|  | Cairns Hospital Phase 2 PISCF - clean | 1.0 |  |
|  | **Participant Materials** *(you may have different study documents)* |
|  | Participant QR Code | 1.0 |  |
|  | Android Device Instructions for Patient Diary Access | 1.0 |  |
|  | Apple Device Instructions for Online Patient Diary Access | 1.0 |  |
|  | Patient Diary Android Screenshots | 1.0 |  |
|  | Patient Diary Apple Screenshots | 1.0 |  |
|  | Patient Diary Cycle 1-4 Version | 1.0 |  |
|  | Patient Diary Cycle 5 Onwards | 1.0 |  |
|  | **Contract, Indemnity, Insurance Documents**  |
|  | 1 x Clinical Trial Research Agreement (CTRA) / Collaborative Research Agreement (CRA) *(if an agreement/contract is relevant to your study you must list it and provide it)* | - |  |
|  | Certificate of Currency (Insurance) for period 01/11/2020 to 01/11/2021 | - |  |
|  | **Other Documents** |  |  |
|  | Clinical Trial Notification (CTN)  | - |  |
|  | GCP Certificate Dr. Brown | - |  |
|  | GCP Certificate Dr Smith | - |  |
|  | PHA approval letter |  |  |
|  | **Approvals and Letters of Support** |
|  | Head of Department signature page signed by the Business HoD *(Mandatory)* | - |  |
|  | Financial Controller Endorsement Memo *(Mandatory)* |  |  |
|  | Principal Investigator signature page signed by the PI *(Mandatory)* |  |  |

If you have any queries, please contact either Dr Smith or myself.

Yours faithfully,

Ms *Jane Doe*

Clinical Research Coordinator

On behalf of PI *Dr Smith, Cairns Hospital*

Include contact details.

***Please remove all template wording – eg. Red text or yellow/blue highlights***