**CENTRAL ADELAIDE LOCAL HEALTH NETWORK**

Royal Adelaide Hospital Research Ethics Committee

Human Research Ethics Committee (TQEH/LMH/MH)

*The Queen Elizabeth Hospital / Lyell McEwin Hospital / Modbury Hospital*

**REQUEST FOR REVIEW OF UPDATED DOCUMENTATION**

**STUDY MONITORING REPORTING**

This form is to be used with the submission of all information which requires Ethics Committee review.

This includes the following. Please select type of document/s submitting.

[ ]  Amendments to Protocols and/or Information Sheets [ ]  Protocol Deviations

[ ]  Amendments to Investigator Brochures [ ]  SAE Notifications

[ ]  Safety reports such as SUSARS, DSUR, SAE, DSMB reports, Dear Investigator letters.

|  |  |
| --- | --- |
| **Date:** |       |
| **CALHN Reference Number:** |  |
| **HREC Reference Number:** | HREC/     /     /      |
| **Title of Research** |  |
| **PRINCIPAL INVESTIGATOR** | Name: |       |
| Email: |       |
| Phone: |       |
| Department: |       |
| Organisation: |       |
| **STUDY COORDINATOR:** | Name: |       |
| Email: |       |
| Phone: |       |
| **Study Status***Please tick all that apply* | [ ]  Not yet recruiting [ ]  Subjects on active treatment[ ]  Recruiting [ ]  Subjects on the same drug in other studies[ ]  Subjects in follow-up [ ]  No active subjects |
| **Do you believe these changes raise ethical concerns?** | No [ ] Yes [ ]  | If *Yes*, please provide details      |
| **Documents for review***Please list the name, version number and date of all documents you would like reviewed* |       |
| **Does the Patient Information Sheet or Consent Form need to be changed?** | Yes [ ]   No [ ]  | Please attach a tracked changed version |

|  |  |
| --- | --- |
| **Principal Investigator or Delegate** | *I confirm the above information is correct* |
| **Name** |       |
| **Signature** |  | **Date** |       |

**Attach this form with your submission, and e-mail to:** Health.CALHNResearchEthics@sa.gov.au

If you have any questions please contact the CALHN Research Office on **08 8222 4139** (RAH) or **08 82226841** (TQEH)

or e-mail: Health.CALHNResearchEthics@sa.gov.au

**NOTIFICATION OF A PROTOCOL DEVIATION / VIOLATION**

|  |  |
| --- | --- |
| **Date of deviation** |       |
| **Deviation Type**  | **[ ]**  Eligibility criteria breach**[ ]**  Protocol required procedure not performed**[ ]** Protocol procedure performed outside the protocol required time**[ ]**  Incorrect therapy given to participant(s)**[ ]**  Medication error**[ ]**  Other:  |
| **Deviation Details***Brief explanation and risk assessment* |       |
| **What actions have been taken as a result of this event?** | **[ ]**  Participant(s) to be withdrawn **[ ]**  Participant(s) will remain on the study but data analysis will be modified **[ ]**  Change to the protocol (*If Yes, please submit amended protocol)***[ ]**  Change to the Participant Information and Consent Form/s(*If Yes, please submit amended PIS)***[ ]**  Previously Enrolled Participants are to be notified (*If Yes, please submit notification documentation)***[ ]**  The study is to be suspended**[ ]**  The study is to be stopped **[ ]**  No action**[ ]**  Other:  |
| **Has this type of deviation been reported previously?** |       |
| **Other Comments** |       |

**NOTIFICATION OF A SAE [ ]  Related to Study [ ] Unrelated [ ]  Probably [ ]  Possibly**

|  |  |
| --- | --- |
| **Participant ID(s)** |       |
| **Date of Event** |       |
| **Event Details**  |       |
| **Event Management** |       |
| **Event Outcome** |       |
| **What background rate of this event would you expect in normal practice?** | Click to select |
| **Has this type of SAE been reported previously, during this trial?** |       |
| **Does study documentation require amendment as a result of this SAE?***If Yes, please submit amended documentation* |       |
| **Other Comments** |       |

**INVOICE DETAILS: Who and where Invoice to be billed.**

|  |  |
| --- | --- |
| **Company/Sponsor Name** |       |
| **Special Invoice Codes as Required by Sponsor***(e.g Purchase Order #)* |       |
| **Company Address** |       |
| **Email Address** |       |
| **Contact Name** |       | **Contact No.** |       |
| **Position** |       |

**AMENDMENT REVIEW FEES**

The following HREC amendment review fee will be charged for all Sponsor initiated amendments:

* **$300 ex GST** **– Administrative Amendments**

 Administrative Amendments are those that do not impact or alter the risk level of the project, and which can be reviewed and assessed easily, e.g. updated contact details on a participant information sheet.

* **$600 ex GST** **– Amendments**

Amendments include Protocol Amendments, Investigator Brochure revisions, and other amendments which are more complex in nature or which may alter the risk level of the project.

* **Safety Reports are not charged.**