**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](mailto: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](mailto: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.**