To

The Member Secretary

GCU - Institutional Ethics Committee

Garden City University, Bangalore-49

Dear Sir/Madam,

**Subject: Submission of Detailed interim / status report for funded/Sponsored Projects**

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| **SL. No** | **Details** |  |
| **1** | **Details of Research Team** |  |
| 1.1 | GCU IEC Study Ref. No |  |
| 1.2 | Name of the Researcher/Principal Investigator: |  |
| 1.3 | University Registration Number/Employee ID:  Designation & Department: |  |
| 1.4 | Mobile No & email ID: |  |
| **2** | **Registration** |  |
| 2.1 | Is the study a ‘clinical trial’? | Yes / No |
| 2.2 | Is the study registered on a publically accessible database? | Yes / No |
| 2.3 | If yes, please provide the name of the database and the registration number | Database:  Registration number: |
| 2.4 | If no:  What is the reason for non-registration?  What are your intentions for registration? |  |
| **3** | **Details of study** |  |
| 3.1 | Full title of study: |  |
| 3.2 | Date of favorable ethical opinion: |  |
| 3.3. | GCU IEC approval validity expiring on |  |
| 3.4 | Details of the extensions taken |  |
| 3.5 | Sponsor: |  |
| 3.6 | Registration No. For e.g.: CTRI Number: |  |
| **4** | **Commencement and termination dates** |  |
| 4.1 | Has the study started? | Yes / No |
| 4.2 | If yes, what was the actual start date? |  |
| 4.3 | If no, what are the reasons for the study not commencing?  What is the expected start date? |  |
| 4.4 | Is the study over? | Yes / No |
| 4.5 | If no, what is the expected completion date? |  |
| 4.6 | If you do not expect the study to be completed, give reason(s) |  |
| **5** | **Recruitment of participants/animals** |  |
| 5.1 | Number of participants /animals recruited: | Proposed in original application:  Actual number recruited to date: |
| 5.2 | Number of participants /animals completing trial: | Actual number completed to date: |
| 5.3 | Number of withdrawals from trial to date due to: | Total study withdrawals: |
| 5.3.1 | Withdrawal of consent |  |
| 5.3.2 | Loss to follow-up |  |
| 5.3.3 | Death (where not the primary outcome) |  |
| 5.4 | Have there been any serious difficulties in recruiting participants? | Yes / No |
| 5.5 | If yes, give details: |  |
| **6** | **Safety** |  |
| 6.1 | Have there been any serious adverse events (SAEs) in this study? | Yes / No |
| 6.2 | Have these SAEs been notified to the Committee?  If no, please submit details with this report and give reasons for late notification*.* | Yes / No /Not applicable |
| **7** | **Serious breaches of the protocol/Good clinical practice** |  |
| 7.1 | Have any serious breaches of the protocol or GCP occurred in relation to this trial during the year? | Yes / No |
| 7.2 | If yes, please give the date of each notification to the GCU IEC.  Please provide the GCU IEC with a copy of each notification for information (unless previously notified). |  |
| 8 | **Other issues** |  |
| 8.1 | Are there any other developments in the trial that you wish to report to the Committee? | Yes / No |
| 8.2 | Are there any ethical issues on which further advice is required? | Yes / No |
| 8.3 | Are there any ethical issues on which further advice is required? | Yes / No |

**Declaration**

Signature of Researcher/Principal Investigator:

Date of submission:

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| --- |
| **Discussion following GCU IEC review:**  Motion : [ ] Approved  [ ] Further clarification required  Clarifications :  **Reviewer’s Signature : \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  **Name of the Reviewer : \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** |