ACMS-IRB Study Status Report Form

|  |  |
| --- | --- |
| 1. **ACMS-IRB Reference No:**
 |  |
| 1. **Protocol Title:**
 | Text Field |
| 1. **Principal Investigator:**
 | Text Field |
| 1. **Status of Study**
 |
| * Study Status:Choose from list
* If the study is COMPLETED, please ensure that ALL of the following criteria are fulfilled, by checking the boxes.

[ ] The research is permanently closed to the enrollment of new participants[ ] All participants have completed all research-related interventions[ ] Collection and analysis of individually identifiable data has been completed* Completion date:\_\_­\_/\_\_\_/\_\_\_\_ (DD/MMM/YYYY)
* If the Study Status is ‘**Withdrawn**’, ‘**Terminated**’ or ‘**Not Yet Initiated’**, please give us the reasons for this: *(Please attach a separate page if there is insufficient space.)*

Text Field |
| 1. **Subject Recruitment Information:**
 |
| **NOTE:**1. *For multi-site studies, please provide the information below for each study site*
2. *If your study involves only the use of human biological samples/records, please state the number collected for each study site*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Name of Institution: |  |  |  |  |  |
| Proposed recruitment Target: |  |  |  |  |  |
| Total No. of Subjects Screened: |  |  |  |  |  |
| Total No. of Subjects Enrolled: |  |  |  |  |  |
| Total No. of Subjects Who Have Completed Study: |  |  |  |  |  |
| \*Total Number of Subjects Withdrawn From Study: |  |  |  |  |  |

* Please state the reason(s) for each subject’s withdrawal from study. Please attached a separate page if there is insufficient space:

Text Field |

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| * **Subject Enrolment by Gender**

*Please give us a break down of the total enrolled subjects as follows:*

|  |  |  |  |
| --- | --- | --- | --- |
| *The total No. of Subjects enrolled who are:* | No. of Male Adults | No. of Female Adults | Children (Persons less than 21 yrs) |
|  |  |  |

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| 1. **Description of Subjects Enrolled**
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| * Did you enrol any of these categories of participants in this study?

[ ] No [ ] Yes—If ‘Yes’, please tick all applicable boxes below: [ ] Non-English speaking subject [ ] Pregnant women, foetuses or neonates [ ] Cognitively Impaired Persons [ ]  Prisoners* How did you conduct the consent process with these categories of participants?

Text Field |
| 1. **Report On Research To Date:**
 |
| 1. Did you encounter any problems relating to ethical issues?

[ ] No[ ] Yes—*If ‘Yes’, what were the problems and what did you do about them?*Text Field |
| 1. Did you comply with the approved consent procedures and documentation?

[ ] Yes[ ] No-*If ‘No’, please explain the reasons for the deviation*Text Field |
| 1. Please state the document version number and/or version date of the consent document being currently used at the study site(S) if applicable.

Text Field |
| 1. What measures are being taken to protect confidentiality of research data? (Eg: Where are the paper/electronic records stored? Are they access-controlled? Has there been any breach of the confidentiality of the research data?)

Text Field |
| 1. Are there any new proposed amendments to the current study?

[ ] No[ ] Yes—*If ‘Yes’, please submit the amended documents with the an Amendment Cover Note* |
| 1. Are there any unanticipated events involving risks to subjects or others (including serious adverse events) at your trial sites, which have yet to be reported to the ACMS IRB?

[ ] No[ ] Yes- *If ‘Yes’, please submit the reports with this Study Status Report* |
| 1. Are there any evaluation reports of study-wide adverse events, interim findings, recent literature, or any other information that may affect the risk/benefit ration of this study?

[ ] No[ ] Yes-*If ‘Yes’, please submit the reports with this Study Status Report* |
| 1. Considering the information listed above, has anything occurred since the last ACMS IRB review which may have altered the risk/benefit relationship?

[ ] No[ ] Yes-*If ‘Yes’, please provide a current assessment of the risk/benefit relationship of the research based on results, internal and external adverse events and other factors. Also, in your opinion, should any changes in the consent form be made based on those results?**Text Field* |
| 1. Is there any other relevant information, especially information about risks associated with the research?

[ ] No[ ] Yes-*If ‘Yes’, please provide details*Text Field |
| 1. Please provide a summary of your research findings (e.g. interim analyses/multi-centre trial reports etc.) If your study is completed, please submit final analyses and conclusions when they are ready, but not more than 3 months after completion.

Text Field |
| 1. Have you published your research findings?

[ ] No[ ] Yes-*If ‘Yes’, please provide details (e.g report, dissertation, thesis, journal article, book, etc). Include details such as where published (e.g. name of journal, book chapter, etc):*Text Field |
| 1. Have there been any complaints about the research?

[ ] No[ ] Yes-*If ‘Yes’, please provide details of the complaints.*Text Field |
| 1. For completed/terminated studies, will the leftover samples or data be destroyed at the completion of the study, or will they be stored for future use?

[ ] Yes, the samples or data will be destroyed[ ] No, the samples or data will NOT be destroyed1. Where will the samples or data be stored?

Text Field1. For how long will these samples or data be stored?

Text Field1. What will these samples or data be used for?

Text Field |
| 1. **Declaration of Principal Investigator:**
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| I confirm that the information submitted in the above study status report is true and accurate at the date of submission of the report.\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_­­­­­­­­­­­­­­­­­­\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*Principal Investigator’s Signature Date*Full Name: Text FieldInstitution: Text Field |

This Page is for information only and need not be submitted

**Guidance on using the ACMS IRB Project Status Report Form**

***Important***

*While the ACMS IRB will make every effort to remind Principal Investigators, it is their responsibility to submit the Status report in a timely manner. Please note that if the Study’s ACMS IRB Ethics approval expires, prospective research data cannot be collected, and no procedures that are being performed for the purposes of the study may be conducted until the Status report is reviewed and approved.*

The ACMS IRB Study Status Report Form is used for:

* Renewal of Approval (report to be submitted to ACMS IRB at least 4-6 weeks prior to expiry date)
* Study Completion (report to be submitted to ACMS IRB within 4-6 weeks of completion)
* Study Termination (report to be submitted to ACMS IRB within 4-6 weeks of completion)

Form Completion Guidelines

1. ACMS IRB Reference No-Please state the ACMS IRB reference number as stated in the approval letter.
2. Protocol Title-Please state the protocol title
3. Principal Investigator-Please state the name of the Principal Investigator
4. Study Status
5. **Not Yet Initiated**-No research-related activities have been performed since first approval. Please provide reasons.
6. **Ongoing**-Research-related activities are still being performed.
7. **Enrolment Closed, Subject Follow Up Only**-The Study is permanently closed to new participants, AND all participants have completed research-related interventions, AND the research remains active only for long-term follow up
8. **Last Patient Last Visit Over, Data Analysis Ongoing**-There will be no more contact with subjects and the remaining research activities are limited to data analysis
9. **Completed**-there will be no more research activities, including contact with subjects or any data analysis. Please indicate the study completion date.
10. **Withdrawn**-The study is stopped before ACMS IRB Approval.
11. **Terminated**-The study is stopped after ACMS IRB Approval.