**PIEC STUDY STATUS REPORT FORM**

For renewal of approval, please submit the completed form to PIEC at least one month or by the submission deadline for full board review before the expiry of the ethics approval period. Please complete all applicable sections.

| **1. PIEC Reference No:** | Text Field |
| --- | --- |

| **2. Protocol Title:** | Text Field |
| --- | --- |

| **3. Principal Investigator:** | Text Field |
| --- | --- |

| **4. Status of Study** |
| --- |
| * 1. **Not Yet Initiated** - No research-related activities have been performed since initial approval.   2. **Ongoing** - Research-related activities are still being performed.   3. **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   4. **Last Patient Last Visit Over, Data Analysis Ongoing** – Only for single-centre study. There will be no more contact with subjects or collection of individually identifiable data and the remaining research activities are limited to data analysis.   5. \***Completed** - No more research-related activities at site, including contact with subject, collection of individually identifiable data or data analysis. *\* For multi-centre study involving local and/or overseas sites, the study may be considered ‘completed’ when access to individually identifiable data is no longer required at sites under the oversight of PIEC.*   6. **Withdrawn** - The study is stopped before site initiation.   7. **Terminated** - The study is stopped after site initiation.   8. **Suspended** – The study is temporarily stopped. |
| **Please complete all sections below:**   * Study Status: * If the study is **Completed** , indicate the Completion date:  /  /  (DD / MMM / YYYY) * If the study is **Terminated/Withdrawn/ Suspended,** indicate the Termination/Withdrawal/Suspension date:  /  /  (DD / MMM / YYYY) and/or **Period of Suspension**, if available: Text Field * If the Study Status is ‘**Withdrawn**’**,** ‘**Terminated**’ **or** ‘**Not Yet Initiated**’, please give us the reasons for this:*- (Please attach letter from sponsor, if available)*   Text Field |
| **Summary of Study Progress:**  For ongoing projects: Please provide a summary of the study progress e.g. patients’ status, recruitment status, study plan in the next one year etc.  For terminated/suspended projects: Please provide a summary of what happens to subjects already enrolled in the study, how subjects are informed of the suspension or termination, plan of orderly termination of the study, or transfer of the study or study subjects, whichever applicable  Text Field |

| **5. Subject Recruitment Information:** |
| --- |
| **NOTE:**  *(****1) For multi-centre studies, please provide the information below for each study site under the purview of PIEC.***  ***(2) If your study involves only the use of human biological samples/records, please state the number collected for each study site.***   |  |  |  |  |  | | --- | --- | --- | --- | --- | | *Name of Study Site:* | Text Field | Text Field | Text Field | Text Field | | *Proposed Enrolment Target /*  *Number of samples/records required:* | Text Field | Text Field | Text Field | Text Field | | *Total No. of Subjects Screened:* | Text Field | Text Field | Text Field | Text Field | | *Total No. of Subjects Enrolled:* | Text Field | Text Field | Text Field | Text Field | | *Total No. of Subjects Who Have completed study / No. of samples tested /records reviewed:* | Text Field | Text Field | Text Field | Text Field | | *\*Total Number Of Subjects Withdrawn From Study:* | Text Field | Text Field | Text Field | Text Field |  |  |  |  |  |  | | --- | --- | --- | --- | --- | | *Name of Study Site:* | Text Field | Text Field | Text Field | Text Field | | *Proposed Recruitment Target /*  *Number of samples/records required:* | Text Field | Text Field | Text Field | Text Field | | *Total No. of Subjects Screened:* | Text Field | Text Field | Text Field | Text Field | | *Total No. of Subjects Enrolled:* | Text Field | Text Field | Text Field | Text Field | | *Total No. of Subjects Who Have completed study / No. of samples tested /records reviewed:* | Text Field | Text Field | Text Field | Text Field | | *\*Total Number Of Subjects Withdrawn From Study:* | Text Field | Text Field | Text Field | Text Field |  |  |  |  |  |  | | --- | --- | --- | --- | --- | | *Name of Study Site:* | Text Field | Text Field | Text Field | Text Field | | *Proposed Recruitment Target /*  *Number of samples/records required:* | Text Field | Text Field | Text Field | Text Field | | *Total No. of Subjects Screened:* | Text Field | Text Field | Text Field | Text Field | | *Total No. of Subjects Enrolled:* | Text Field | Text Field | Text Field | Text Field | | *Total No. of Subjects Who Have completed study / No. of samples tested /records reviewed:* | Text Field | Text Field | Text Field | Text Field | | *\*Total Number Of Subjects Withdrawn From Study:* | Text Field | Text Field | Text Field | Text Field |   *NOTE: Please print out additional page 2 if more tables are required.* |
| * Please state the reason(s) for **each subject’s** withdrawal from study.   Text Field   * If the number of subjects completed the study exceeds the proposed recruitment target approved by PIEC, please provide the reason(s):-   Text Field |

| **6. 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 subjects | Pregnant women, fetuses or neonates | |  | Cognitively Impaired Persons | Minors (Aged below 21 yrs.) | |  | Others, pls specify |  | |

| **7. Report On Research To Date:** |
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| **a. 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 |
| **b. Did you comply with the approved consent procedures and documentation?**  Yes  Not applicable as no consent is required for this study.  No – *If ‘No’, please explain the reasons for the deviation.*  Text Field |
| **c. Please list down all consent document(s) being currently used at the study site(s) if applicable, including version number and date.**  Text Field |
| **d. What measures are being taken to protect confidentiality of research data?** *(E.g. Where are the paper/electronic records stored? Are they are access-controlled? Has there been any breach of the confidentiality of the research data?)*  Text Field |
| **e. Are there any new proposed amendments to the current study?**  No  Yes – *If ‘Yes’, please submit the amended documents with the PIEC Amendment Cover Note.* |
| **f. 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 PIEC?**  No  Yes – *If ‘Yes’, please submit the reports using the Unanticipated Problems Involving Risks to Subjects or Others Reporting Form with this Study Status Report.* |
| **g. Are there any reports of study-wide adverse events, interim findings, data safety monitoring board (DSMB) review, recent literature, or any other information that evaluate the risk / benefit ratio of this study?**  No  Yes – *If ‘Yes’, please submit the reports along with this PIEC Study Status Report.* |
| **h. Considering the information listed above, has anything occurred since the last PIEC 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 these results?*  Text Field |
| **i. Is there any other relevant information** **or recent literature, especially information about the risks associated with the research?**  No  Yes – *If ‘Yes’, please provide details.*  Text Field |
| **j. 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. Completion of the study, in this instance, is when the last study site in a global study or the last study site in a local study is no longer involved in any research activities.**  Text Field |
| **k. 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 they are published (e.g. name of journal, book chapter, etc.):*  Text Field |
| **l. Have there been any complaints about the research?**  No  Yes – *If ‘Yes’, please provide details of the complaints.*  Text Field |
| **m. Have there been any change in the declaration of conflict of interest for all study team members and study staff since the initial approval of this research study?**  No  Yes – *If ‘Yes’, please provide details and submit an updated Conflict of Interest Declaration Form.*  Text Field |

| **8. 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 this report.**   |  |  |  | | --- | --- | --- | | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | *Principal Investigator’s Signature* | | *Date* | |  |  | | | *Full Name:* | Text Field | | | *Institution:* | Text Field | | | *Department:* | Text Field | | |