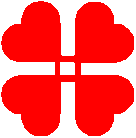
****

**Philippine Heart Center**

**Institutional Ethics Review Board**

8/F Medical Arts Building

East Avenue, Quezon City, 1100 Philippines

Tel./Fax no. 89252401 loc.3899; email add: irbphc@gmail.com

**CONTINUING REVIEW FORM**

DIRECTIONS FOR SUBMITTING A CONTINUING REVIEW FORM

* This form must be submitted four weeks before the expiration date
* Request for continuation of a current approved research protocol will be reviewed at a regularly convened meeting of the IRB committee that issued the original approval unless the criteria for expedited review are met.
* Continuation forms will not be accepted for studies 60 days past the expiration date of a study; a new submission is required. Studies that are expired are lapsed in IRB approval and this is non-compliance
* Please ensure that the PI and all key personnel have completed the GCP within the last 3 years.
* Once you receive approval to conduct research, it is the PI’s responsibility to gain approval to continue the research at the interval set by the IRB for your study as well as to close the study by submitting a closure form at the end of the study
* Please call us if you have any questions along the way: 9252401 loc.3899

**WHAT TO SUBMIT**

All required documents must be submitted four weeks prior to the expiration date

* + Submit one copy single-sided of the Continuation Form with original signature
  + Two clean unstamped copies, single sided, of the informed consent/assent/information sheet currently in use (if applicable)
  + 1 copy of the completed and signed original [**Investigator’s Progress Report**](http://www.uab.edu/irb/forms/ipr.doc).
  + 1 copy of the most recently approved **Consent/Assent Form.** If the study is closed to enrollment, do not send a consent form. If using an addendum consent form for currently enrolled participants, send 1 copy for review.
  + 1 copy of the revised consent/assent form, if applicable, with changes highlighted. Please use underlining or shading to highlight changes.
  + 1 copy of all [**approved amendments/revisions**](http://www.uab.edu/irb/forms/project-revision-amendment.doc) since their last renewal. copy of each previously submitted **Investigator’s Progress Report**
  + 1 copy of any progress report/s submitted to the sponsoring/funding agency since last renewal, if applicable.

ACTION REQUESTED:

* Renew - New participant accrual to continue
* Renew - Enrolled participant follow up only
* Terminate - Protocol discontinued

**PRINCIPAL INVESTIGATOR (PI)**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Name of PI |  | | | |
| PI’s Signature |  | Specialization |  | |
| Mobile no. |  | Email add. |  | |
| Has any potential and/or financial conflict of interest arisen since the last IERB review ?  If yes, a “Financial Conflict of Interest Detailed Disclosure Form” must be submitted to the IERB annually or when a change occurs. | | | | * Yes * No |

**STUDY INFORMATION**

|  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| IERB No. |  | | | | Protocol No. | |  | | CTRD No. | |  |
| Sponsor/CRO | |  | | | | | | | | | |
| Protocol Title | |  | | | | | | | | | |
| 1. Original Approval Date | | |  | | | | | Expiration Date | |  | |
| 1. **Date of Submission** | | | |  | | | | | | | |
| 1. Is the submission date after or on the expiration date? | | | | | | * Yes If **yes**, please answer below * No | | | | | |
| If **yes**, your study has a lapse in IERB approval. Please indicate whether or not any research activities have taken place during the lapse in IERB approval. | | | | | | * Yes, I did conduct research activities during the lapse in approval * No research activities occurred during the lapse | | | | | |
| ***Note:*** *If your protocol does not receive approval prior to the expiration date, non participants can be enrolled, no data can be collected or used for research if collected during the period of lapse approval.*  *Repeat lapses of IERB approval is deemed non-compliance.* | | | | | | | | | | | |

**C. STATUS OF PROJECT**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  |  |  |  |
| Any amendment since the last review? (Describe briefly.) | |  | No |  | Yes |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |  |  |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  |  |  |  |
| Any change in participant population, recruitment or selection criteria since the last review? (Explain the changes.) | |  | No |  | Yes |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |  |  |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  |  |  |  |
| Any change in the Informed Consent process or documentation since the last review? (Please explain.) | |  | No |  | Yes |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |  |  |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  |  |  |  |
| Is there any new information in recent literature or similar research that may change the risk/ benefit ratio for participants in this study? (Discuss and attach a narrative.) | |  | No |  | Yes |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |  |  |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  |  |  |  |
| Any complaints about the research from subjects enrolled at the local site since the last IERB review | |  | No |  | Yes |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |  |  |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  |  |  |  |
| Any unexpected complication or side effect noted since the last review? (Discuss and attach a narrative.) | |  | No |  | Yes |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |  |  |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  |  |  |  |
| Were these protocol deviation/ violation reports? Summarize, to include the nature and frequency of deviation/violation. What corrective actions were taken? | |  | No |  | Yes |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |  |  |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  |  |  |  |
| Did any participant withdraw from this study since the last approval? (Reasons for withdrawal) | |  | No |  | Yes |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |  |  |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  |  |  |  |
| Any new investigator that has been added to or removed from the research team since the last review? (Please identify them and submit the CVs of new investigators.) | |  | No |  | Yes |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |  |  |

|  |  |  |  |
| --- | --- | --- | --- |
|  |  |  |  |
| Summary of protocol participants: | | |  |
|  |  |  |  |
|  |  | Accrual ceiling set by IERB |  |
|  |  |  |  |
|  |  | New participants accrued since last review |  |
|  |  |  |  |
|  |  | Total participants accrued since protocol began |  |
|  |  |  |  |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  |  |  | |  |
|  | Accrual Exclusions: | | |  |
|  |  |  | |  |
|  |  | None | |  |
|  |  |  | |  |
|  |  | Male | |  |
|  |  |  | |  |
|  |  | Female | |  |
|  |  |  | |  |
|  |  | Others (Specify) |  |  |
|  |  |  | |  |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  |  |  |  |
| Are there any new collaborating sites that have been added or deleted since the last review? Please identify the sites and note the addition or deletion. | |  | No |  | Yes |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |  |  |

|  |  |  |  |
| --- | --- | --- | --- |
|  |  |  |  |
| Impaired Participants: | | |  |
|  |  |  |  |
|  |  | None |  |
|  |  |  |  |
|  |  | Physically |  |
|  |  |  |  |
|  |  | Cognitively |  |
|  |  |  |  |
|  |  | Both |  |
|  |  |  |  |

|  |  |  |  |
| --- | --- | --- | --- |
|  |  |  |  |
|  | Action Requested: | |  |
|  |  |  |  |
|  |  | Renew - New participant accrual to continue |  |
|  |  |  |  |
|  |  | Renew - Enrolled participant follow up only |  |
|  |  |  |  |
|  |  | Terminate - Protocol discontinued |  |
|  |  |  |  |

*To be filled up by IERB*

|  |  |  |  |
| --- | --- | --- | --- |
|  |  |  |  |
| Date received: |  |  | Received by: |
|  |  |  |  |
|  |  |  | *Signature over Printed Name* |
|  |  |  |  |

Is the risk-benefits ratio still favorable? Yes or No. Explain.\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  |  |  |  |
| Recommended Action: | | |  | Type of review: | |  |
|  |  |  |  |  |  |  |
|  |  | Approve |  |  | Expedited review |  |
|  |  |  |  |  |  |  |
|  |  | Request an amendment to the  protocol or the consent form.  (State the required amendment below) |  |  | Full board review |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  |  | Request further information. |  | Date of meeting: | |  |
|  |  |  |  |  |  |  |
|  |  | Suspend or terminate the study |  |  | |  |
|  |  |  |  |  |  |  |
|  |  | Others: |  |  |  |  |
|  |  | Comments: | | | |  |
|  |  |  |  |  |  |  |

Recommendation:

|  |  |
| --- | --- |
|  |  |
| Changes to the protocol : | |
|
|  |  |

|  |  |
| --- | --- |
|  |  |
| Changes to the informed consent form : | |
|
|  |  |

|  |  |
| --- | --- |
| IERB Final Decision: |  |

|  |  |  |
| --- | --- | --- |
| Primary Reviewer : |  | Approved by : IERB Chairman |
| *Signature over Printed Name / Date* |  | *Signature over Printed Name / Date* |

|  |  |
| --- | --- |
| Date IERB Approval Expires (One year from approval date): |  |