## CONTINUING REVIEW or CLOSURE

## for Expired Studies

Purdue University, Institutional Review Board, v20160208

|  |
| --- |
| **INSTRUCTIONS** |

1. Amendments to your study must be submitted separately from the request for Continuing Review. The only amendments permitted using this form are those minor changes requested by the IRB.
2. Additional pages may be added as necessary. Please indicate in the appropriate sections/questions on this form when attachments have been provided.
3. **CITI Education for studies NOT closing**: All Principal Investigators, Co-Investigators and Key Personnel CITI certifications must be current. Studies cannot be approved until all of the aforementioned investigators have their current CITI certifications for Human Subjects Research.
4. **For studies conducted with collaborative institutions**, provide a copy of the collaborative institution’s current IRB approval, or indicate that IRB oversight has been deferred to Purdue University. See Section VI Required Attachments.

|  |
| --- |
| **STUDY INFORMATION** |

|  |  |  |  |
| --- | --- | --- | --- |
| IRB Study Number: |  |  |  |
| Study Title: |  |
| Principal Investigator: |  |  |  |
| Key Personnel: |  |
| Study Expiration Date |  |  |  |
|  |
| **Complete the following information:** |
| PI Email: |  | PI Phone: |  |

 Department:

 Purdue Address:

|  |
| --- |
| **SECTION I: STUDY ACTIVITY SINCE EXPIRATION DATE** |

What activity has been undertaken on your study since expiration of IRB approval? Check all that apply.

[ ]  Subjects Recruited

 Date range: \_\_\_\_\_\_\_\_\_\_\_\_\_

[ ]  Subjects Enrolled

 Date range: \_\_\_\_\_\_\_\_\_\_\_\_\_

[ ]  Data collected about subjects (directly or indirectly)

 Date range: \_\_\_\_\_\_\_\_\_\_\_\_\_

[ ]  Identifiable data about subjects used in data analysis

 Date range: \_\_\_\_\_\_\_\_\_\_\_\_\_

[ ]  Identifiable data about subjects was secured and has not been accessed

 Location of the Data:

 Date: \_\_\_\_\_\_\_\_\_\_\_\_\_

[ ]  Other: Please describe:

 Date range: \_\_\_\_\_\_\_\_\_\_\_\_\_

**SECTION II: STUDY STATUS GOING FORWARD, AFTER IRB REVIEW**

**(Check one and follow the related instructions)**

[ ]  **Open to Enrollment** – Check one of the following and **Attach copies of last IRB approved consent document(s) and recruitment material(s)**. Note that if you wish to update these documents, an Amendment must be filed.

[ ]  Enrollment of new subjects or review of records/specimens continues. **Skip to Section III**.

**OR**

[ ]  No subjects have been enrolled to date. **Please explain below** why no subjects have been enrolled**, then skip to Section IV.**

[ ]   **Closed to Enrollment** – Check which of the following conditions apply, **then skip** to **Section III**

[ ]  No new subjects are being enrolled but they are still receiving research-related intervention or interaction.

**OR**

[ ]  No new subjects are being enrolled. Subjects they have completed research-related interventions; but long-term follow-up procedures continue. Long-term follow-up includes:

* Research interactions that involve no more than minimal risk to subjects, or
* Collection of follow-up data from procedures or intervention that would be done as part of routine clinical care. Research interventions which would not be performed for clinical purposes are considered research-related interventions and are not considered follow-up.

[ ]  **Data Analysis Only –** If the following conditions are met, **skip to Section III.**

* Subjects have completed research-related intervention or interaction and long-term follow-up has been completed, **AND**
* Remaining research activities are limited to only data analysis that may require access to identifiable records and/or specimens whether identified directly or via code with existing code key.

[ ]   **Study Closed** – Check all that apply, **then go to Section III:**

1. [ ]  No further interventions/interactions with subjects, no follow-ups, nor access to personally identifiable information for research purposes are occurring.
2. [ ]  All data analysis involving the research site(s) under this study is complete. **OR**

[ ]  Data have been de-identified. No direct identifiers or code key(s) (if data are coded) exist that would allow for the potential identification of subjects.

1. [ ]  Grant funds associated with the study are no longer being accessed. **OR**

[ ]  An associated grant remains active, the human subject research activities have ended and a Memorandum of Understanding with the Office of Research Administration has been executed. **Any questions related to grant funds should be directed to** **vprregulatory@purdue.edu****.**

|  |
| --- |
| **SECTION III: SUBJECT SUMMARY** |

[ ]  Check here if your study utilizes accessing existing records about or specimens from people. Provide the number of records/specimens that have been reviewed or collected in the Subject Summary Table.

[ ]  Check here if the IRB has approved a waiver of consent for your study. When this form asks for the number of subjects, document the number of individuals enrolled or the number of records that have been reviewed in the Subject Summary Table.

2. **Subject Summary Table**

|  |  |
| --- | --- |
| **Subject Summary Table** | **On-Site\*** |
| **Since last IRB review** | Total number of subjects **CONSENTED (include those consented for screening)** |  |
|  | Total number of subjects who **FAILED SCREENING** (e.g. found ineligible to participate)after they were consented |  |
|  | Total number of subjects who have **WITHDRAWN** from the study |  |
| **Since beginning of study** | Total number of subjects **CONSENTED (include those consented for screening)** |  |
|  | Total number of subjects who **FAILED SCREENING** (e.g. found ineligible to participate) after they were consented |  |
|  | Total number of subjects who have **WITHDRAWN** from the study |  |
|  | Total number of subjects who have **COMPLETED** the study |  |
|  | Total number of subjects who have **YET TO** **COMPLETED** the study |  |

\* On-Site refers to the study site(s) for which the study was approved by the Purdue IRB. For multi-site trials, do not include subject summary information for study sites over which the Purdue PI did not have oversight.

2. **Withdrawal**. If any subjects withdrawn from the study since the last IRB review, state the reason(s) for subject withdrawal(s):

3. **Ethnic/Racial Reporting Required for Federally-Sponsored and VA Studies**

|  |  |  |
| --- | --- | --- |
| **Ethnic Category** | **Sex/Gender** | **Total** |
| **Females** | **Males** | **Unknown or Not Reported** |  |
| Hispanic or Latino |       |       |       |  |
| Not Hispanic or Latino |       |       |       |  |
| Unknown (Individuals Not Reporting Ethnicity) |       |       |       |  |
| **Ethnic Category Total of All Subjects** |  |  |  |  |
|  |
| **Racial Categories** |
| American Indian/Alaska Native |       |       |       |  |
| Asian |       |       |       |  |
| Native Hawaiian or Other Pacific Islander |       |       |       |  |
| Black or African American |       |       |       |  |
| White |       |       |       |  |
| More Than One Race |       |       |       |  |
| Unknown or Not Reported |       |       |       |  |
| **Racial Categories Total of All Subjects** |  |  |  |  |

|  |
| --- |
| SECTION IV: STUDY EVENTS |

1. Since the last IRB approval, did any unanticipated problems involving risks to subjects or others, adverse events, protocol deviations, subject complaints or noncompliance occur that required prompted reporting to the IRB?

[ ]  NO

[ ]  YES – Provide a summary of these events either in the space provided or as an attachment, and the date(s) these events were reported to the IRB.

2. Since the last IRB approval, did any protocol-related adverse events, protocol deviations or subject complaints occur that did not require prompt reporting to the IRB?

[ ]  NO

[ ]  YES – Provide a summary of these events either in the space provided or as an attachment. For your convenience a **Tracking Log for Events Not Requiring Prompt Reporting to the IRB** is available on the Forms page of our website

3.Is there a data safety monitoring plan for this study?

[ ]  Did this study have a data safety monitoring board?

[ ]  NO

[ ]  YES – Please provide the most recent monitoring report if it has not already been provided to the IRB.

4**.** Have changes to risks to subjects presented by this study been identified (whether by type, frequency, duration and/or severity) since the last IRB approval?

[ ]  NO

[ ]  YES – Please explain:

|  |
| --- |
| **SECTION V: SUMMARY** |

1. **Study Progress:** Describe the progress of the research, including any preliminary observations and information about study results or trends:

2**. Literature Summary:** Summarize the recent literature that has been published or presented by you or others relevant to this study since the last IRB approval. Include in the summary if there has been a demonstrated significant impact on the well-being of subjects?

3**.** Have there been any external reviews of this study (ie, by a study sponsor, federal agency, regulatory body, or other IRB) since the last IRB review?

[ ]  NO

[ ]  YES – Please identify when the review was conducted, by whom, and a summary of any findings. Attach the report(s) if available.

4**.** Do you believe that the risk/benefit ratio of this study has altered since the inception of the study, based on your experience with the study, the information provided on this form and any attachments?

[ ]  NO

[ ]  YES – Please explain:

|  |
| --- |
| **SECTION VI: REQUIRED ATTACHMENTS** |

Submissions that do not include the required attachments applicable to your study will be returned to investigators without review. Please check the appropriate boxes as they apply to your study.

Consent/Assent Documents and Recruitment Materials (Required for studies in Open to Enrollment status): Submit clean (without the IRB stamp) copies with your submission.

[ ]  Assent; Number Attached:

**[ ]**  Subject Informed Consent; Number Attached:

**[ ]** Parent Permission/Consent; Number Attached:

**[ ]** Study Information Sheet; Number Attached:

**[ ]** Recruitment materials (please list):

**Other Study-Specific Documents**

**[ ]**  HIPAA Authorization; Number Attached:      ; (**Required** for **Open to Enrollment** studies)

**[ ]** IRB Approvals from other institutions, if Purdue has not deferred IRB review (please list):

**Include the following documents**, as applicable:

[ ]  Publications, per V.2.

[ ]  Audit reports, per V.3.

[ ]  Summaries, per Section IV.

[ ]  DSMB report, if the study includes a DSMB and you are submitting the most recent DSMB report per IV.3.

[ ]  Interim findings, per V.1.

[ ]  Multi-center trial reports, if there are any available.

|  |
| --- |
| **PRINCIPAL INVESTIGATOR’S ASSURANCE** |

By submitting this form, the principal investigator assures that all information provided is accurate. S/he assures that procedures performed under this project will be conducted in accordance with the HRPP’s [***Researcher Responsibilities***](http://www.purdue.edu/research/vpr/rschadmin/rschoversight/humans/approval.php).

Principal Investigators Signature: \_\_     \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_     \_\_\_\_\_\_\_

Submit this signed form and attachments to the Human Research Protection Program office either via hardcopy or electronically. **Forms received without signatures will be returned without being processed.** A signed form and attachments can be submitted electronically as an email attachment to irb@purdue.edu. If a signed form is submitted electronically, a paper copy need not be submitted.

Campus Address: U.S Mail Address:

Human Research Protection Program Human Research Protection Program YONG 10th Floor, Rm. 1032 Purdue University

765-494-5942 YONG, Rm. 1032

irb@purdue.edu 155 Grant Street

Office Hours: M-F 8-11 am 1-5 pm West Lafayette, IN 47906-2114

**QUESTIONS?** Call our office at 765-494-5942 or attend walk-in hours.

WALK-IN HOURS – Come speak to a Protocol Analyst

Monday 9:30 am - 11:30 am
Tuesday 2:00 pm - 4:00 pm
Thursday 9:30 am - 11:30 am