CONTINUING REVIEW or CLOSURE

Purdue University, Institutional Review Board, v20160525

INSTRUCTIONS

1. Amendments to the 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. **Attachments for studies still open to enrollment:** Attach the current consent form (clean copy) in pdf and all recruitment materials.
5. **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.

INVESTIGATOR INFORMATION

1. Principal Investigator contact information:

Name and Title	Department	Campus Address	Phone	Email	CITI Training Expiration Date

2. Co-Investigators and/or Key Personnel contact information:

Name and Title	Department/ Institution	Email	Directly Interacting with Subjects? Y/N	Accessing Identifiable Information? Y/N	CITI Training Expiration Date
			☐Yes ☐No	☐Yes ☐No	
			☐Yes ☐No	☐Yes ☐No	
			☐Yes ☐No	☐Yes ☐No	

3. Consultant(s) contact information:

Name and Title	Department/ Institution	Phone	Email	Directly Interacting with Subjects? Y/N	Accessing Identifiable Information? Y/N
				☐ Yes ☐ No	☐ Yes ☐ No
				☐ Yes ☐ No	☐ Yes ☐ No

CONFLICT OF INTEREST

4. Do the investigators or personnel have a significant financial interest in this study that has not previously been disclosed for this study?

☐ NO - If no, skip to question 6.
☐ YES - If yes, proceed to question 5.

5. Has a Significant Financial Interest Disclosure Form been filed?

☐ NO - If no, refer to Financial Conflict of Interest: Policy and Procedures.
☐ YES - If yes, proceed to question 6 below.

6. Do the investigators or personnel have any other known conflict of interest in this study for this study which have not been previously disclosed?

☐ NO
☐ YES - If yes, please explain the conflict:

STUDY INFORMATION

7. Study Title:

IRB Study number:

IRB Approval Expiration Date (see stamped consent form):

8. Funding Source: Has funding for this study changed since the last IRB review?

☐ NO

☐ YES

If yes, select all that apply:

- ☐ Federal Funding
  Identify the Sponsor and grant/award number:
- ☐ Other External Funding
  Identify the Sponsor and grant/award number:
- ☐ Departmental Funding
- ☐ Self-Funded

SECTION I: STUDY ACTIVITY SINCE EXPIRATION DATE

Has IRB approval expired on this study?
☐ NO, go to Section II
☐ YES, identify the study activities have been undertaken on the study since expiration of IRB approval?

Check all that apply. Dates are in the format of mm/yyyy.

☐ Subjects Recruited
Date range: _____ to _____
☐ Subjects Enrolled
Date range: _____ to _____
☐ Data collected about subjects (directly or indirectly)
Date range: _____ to _____
☐ Identifiable data about subjects used in data analysis
Date range: _____ to _____
☐ Identifiable data about subjects was secured and has not been accessed

Has the data been stored in a locked room?
☐ NO,

☐ YES, identify

Location of the Data: _____

Date: _____ to _____

Other: Please describe:

Date range: _____ to _____

I affirm that no activity was undertaken after expiration of IRB approval ☐ YES

☐ NO

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)**. To modify these documents, a separate Amendment must be uploaded.

☐ 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.
3. ☐ 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 the 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 the 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 **enrolled** (include those consented for screening), or whose records/samples have been accessed	
	Total number of subjects who **failed screening** (e.g. found ineligible to participate) after they were consented	
	Total number of subjects who **withdrew** from the study	
Since beginning of study	Total number of subjects **enrolled (include those consented for screening), or whose records/samples have been accessed**	
	Total number of subjects who **failed screening** (e.g. found ineligible to participate) after they were consented	
	Total number of subjects who **withdrew** from the study	
	Total number of subjects who have **completed** the study	
	Total number of subjects who have **yet to complete** 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 have 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				0
Not Hispanic or Latino				0
Unknown (Individuals Not Reporting Ethnicity)				0
Ethnic Category Total of All Subjects	0	0	0	0

Racial Categories				
American Indian/Alaska Native				0
Asian				0
Native Hawaiian or Other Pacific Islander				0
Black or African American				0
White				0
More Than One Race				0
Unknown or Not Reported				0
Racial Categories Total of All Subjects	0	0	0	0

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 convenience a **Tracking Log for Events Not Requiring Prompt Reporting to the IRB** is available on the Forms page of the HRPP website

3. Is there a data safety monitoring plan for this study? ☐ YES ☐ NO

Did this study have a data safety monitoring board?

☐ NO

☐ YES – Please upload the most recent monitoring report to COEUS 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 the investigator 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**.** Has the risk/benefit ratio of this study been altered since the inception of the study?

☐ NO

☐ YES – Please explain:

SECTION VI: REQUIRED ATTACHMENTS

Please check the appropriate boxes as they apply to the study. **Consent/Assent Documents and Recruitment Materials** (**Required** for studies in **Open to Enrollment** status):

	# Description
☐ Assent form; number of assents forms attached:	0
☐ Consent form; number of consents forms attached:	0
☐ Parent permission form; number of permission forms attached:	0
☐ Study information sheet; number of information sheets attached	0
☐ Recruitment materials (please list):	0

Submit clean (without the IRB stamp) copies with the submission in COEUS.

Other Study-Specific Documents

☐ HIPAA Authorization; (**Required** for **Open to Enrollment** studies if applicable)

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

Attach the following documents in COEUS, as applicable:

- ☐ Publications, per V.2.
- ☐ Audit reports, per V.3.
- ☐ Summaries, per Section IV.
- ☐ DSMB report, if the study includes a DSMB, submit 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 Request, I give my assurance that the information supplied in this form and attachments are complete and correct. I have read the **Researcher Responsibilities** and will conduct this research in accordance with these requirements. I will close this study with the IRB as soon as the study is complete. If I leave Purdue before the three-year record keeping requirement has passed, my regulatory file for this study will be left with a records custodian whose identity will be made known to the IRB.

Submit this form and attachments to the Human Research Protection Program office electronically via CoeusLite.