Revised 13 Oct 2017

**CONTINUING REVIEW**

# **Purdue University, Institutional Review Board**

Federal regulations require many research studies approved by the IRB to be reviewed subsequently. Your study approval letter from IRB will indicate when your study approval expires. Should you wish to continue your research beyond that date, you will need to complete this form, along with a Cover Page for IRB Submission, which can be found at [www.irb.purdue.edu](http://www.irb.purdue.edu) (under “Application Forms”; Note that with continuing reviews, you only need to complete the first two items on that Cover Page, along with the PI’s signature).

**SECTION I: STUDY INFORMATION**

1. Project Title:

2. Principal Investigator:

 (Name, Title, Department, E-mail, Phone)

3. IRB Study Number:

4. Current Approval Expiration Date:

5. Has IRB approval already expired on this study? [ ]  YES [ ]  NO

 If YES, please identify study activities have been undertaken since expiration of IRB approval,

 checking all that apply:

 [ ]  Subjects have been recruited since expiration

 [ ]  Subjects have been enrolled since expiration

 [ ]  Data have been collected about subjects (directly or indirectly) since expiration

 [ ]  Identifiable data about subjects have been used in data analysis since expiration

 [ ]  Other activities (Please describe):

6. Has funding for this study changed since the last IRB review? [ ]  YES [ ]  NO

 If YES, please check all that apply:

[ ]  It is now federally funded (Identify the Sponsor and grant/award number:      )

[ ]  It now has other external funding (Identify the Sponsor and grant/award number:      )

[ ]  It is now funded by Purdue (department, college, center, etc.)

[ ]  I now fund it myself

7. Do any of investigators or personnel have a significant financial interest in this study that has not

 previously been disclosed? [ ]  YES [ ]  NO

8. If YES to Q7: Have you disclosed your financial interest to Purdue? [ ]  YES [ ]  NO

9. If NO to Q8: Disclosure by going to the online Purdue Disclosure Database, at <https://webapps.ecn.purdue.edu/VPR/PDD/>. Login using your career account and click on the “My Disclosures” tab, then follow directions. Click the box at right to indicate you have done so: [ ]

10. Do the investigators or personnel have any other known conflict of interest for this study which have

 not been previously disclosed? [ ]  YES [ ]  NO

 If YES, please explain the conflict:

**Check only one of the three status options below and follow the instructions:**

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

[ ]  **Open to Enrollment** – Check which of the following two conditions apply:

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

[ ]  No participants have been enrolled to date. **Skip to Section IV**

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

 [ ]  No new participants are being enrolled but they are still receiving research-related

intervention or interaction.

[ ]  No new participants are being enrolled. Participants 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 both of the following conditions are met, **skip to Section III.**

* Participants have completed research-related intervention or interaction and 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 identified directly or via code with existing code key.

**SECTION III: STUDY PARTICIPANT SUMMARY**

[ ]  Check here if the study involved existing records about or specimens from people. Provide the number of records/specimens reviewed or collected in the Participant Summary Table below.

[ ]  Check here if the IRB has approved a waiver of consent for the study.

|  |  |
| --- | --- |
| **Participant Summary Table** | **On-Site\*** |
| **Since** **last IRB review** | Total number of participants **enrolled** (include those consented for screening), or whose records/samples have been accessed: |  |
|  | Total number of participants who **failed screening** (i.e., found ineligible to participate)after they were consented: |  |
|  | Total number of participants who **withdrew\*\*** from the study: |  |
| **Since beginning of study** | Total number of participants **enrolled (include those consented for screening), or whose records/samples have been accessed:** |  |
|  | Total number of participants who **failed screening G** (i.e., found ineligible to participate) after they were consented: |  |
|  | Total number of participants who **withdrew\*\*** from the study: |  |
|  | Total number of participants who have **completed** the study: |  |
|  | Total number of participants who have **yet to complete** the study: |  **\*\*\*** |

\* **On-Site** refers to the study site for which the study was approved by the Purdue IRB. If multi-site, only include participant summary information for site(s) over which the Purdue PI had oversight.

\*\* If any participants **withdrew** from the study since the last IRB review, please state the reason(s) for withdrawal(s) if known:

\*\*\* Note that for federally-funded studies, the sponsors will request a breakdown of participants by sex/gender, ethnicity, and racial category. You would, therefore, be wise to have that information ready for reports to funders.

**SECTION IV: STUDY EVENTS**

11. 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? [ ]  YES [ ]  NO

If YES, please 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:

12. 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? [ ]  YES [ ]  NO

 If YES, please provide a summary of these events either in the space provided or as an attachment:

13. Is there a data safety monitoring plan for this study? [ ]  YES [ ]  NO

14. Did this study have a data safety monitoring board? [ ]  YES [ ]  NO

 If YES, please provide the most recent monitoring report if it has not already been provided to the IRB.

15**.** 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? [ ]  YES [ ]  NO

 If YES, please explain:

16**.** Have there been any external reviews of this study (i.e., by a study sponsor, federal agency, regulatory body, or other IRB) since the last IRB review? [ ]  YES [ ]  NO

If YES, please identify when the review was conducted, by whom, and a summary of any findings:

**SECTION V: RECENT FINDINGS RELEVANT TO THIS STUDY**

17.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:

18**.** Has the risk/benefit ratio of this study been altered since the inception of the study? [ ]  YES [ ]  NO

 If YES, please explain:

**SECTION VI: DOCUMENTS TO UPLOAD FOR CONTINUING REVIEW EVENTS**

Please check the appropriate boxes below as they apply to this study and (1) upload the checked files (2) along with this form, with (3) the Cover Page for IRB Submission (which can be found at [www.irb.purdue.edu](http://www.irb.purdue.edu) (under “Application Forms”):

Consent/Assent and Recruitment Documents (for studies checked as “Open to Enrollment”):

[ ]  Assent form; number of assents forms attached:

**[ ]**  Consent form; number of consents forms attached:

**[ ]** Parent permission form; number of permission forms attached:

**[ ]** Study information sheet; number of information sheets attached:

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

**Other Study-Specific Documents (for studies checked as “Open to Enrollment”, if applicable):**

**[ ]**  HIPAA Authorization

**[ ]** IRB approval(s)from other institution(s), if Purdue has not deferred IRB review [please list

name(s) of other institution(s)]:

[ ]  For studies conducted with collaborating institutions, provide a copy of the collaborative

 institution’s current IRB approval, or indicate that IRB oversight has been deferred to Purdue.

 [ ]  DSMB report, if the study includes a DSMB, submit the most recent DSMB report

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