

**HUMAN SUBJECTS PROTECTION PROGRAM
CONTINUING REVIEW FORM**

NAME OF INVESTIGATOR/PROJECT APPROVAL NUMBER/TITLE OF PROPOSAL

Human subjects approval for this activity expires on the date indicated above. Depending upon the activity status of the project, attachments may be required. Refer to the IRB website (www.irb.arizona.edu) for detailed instructions and **to download the report template** (Continuing Review Report). **Note:** If renewal is not granted before the expiration date, all study activities must stop at that time. If study procedures/treatment must be continued for subject safety, contact the IRB office immediately.

Activity Status – check one box only

Category A: attach items 1-13 listed on reverse

- Enrollment of new subjects in progress
- Enrollment not initiated, but still planned
- Enrollment closed to new subjects but current subjects are still undergoing study procedure or being entered into extensions and/or sub-studies

Category B: attach items 1-12 listed on reverse

- Enrollment closed, follow-up only (**non-sensitive** data collection via telephone contact, questionnaire and/or record review)
- Local data analysis only: no subject contact/no additional data collection (annual review required)

Category C: attach items 1-8 listed on reverse

- Concluded: enrollment and all participation/follow-up/local data analysis completed

Category D: no attachments required; complete and submit this form only

- Study not begun: permanent withdrawal of study

Subject Numbers (local enrollment)

If more than one study population is involved, report enrollment under number 2 of checklist (see reverse)

- a) Number of new subjects enrolled (consented) since last reporting period _____
- b) Total number of subjects enrolled (consented) since start of project _____
- c) Number of males/number of females enrolled since start of project _____

Financial Interest Statements: see UA Individual COI & COC Policy at <http://www.vpr.arizona.edu/conflict-of-interest>

- a) Do ANY of the investigators or research personnel (or their relatives) serve as a speaker or consultant to the sponsor, the manufacturer, or the owner of the product or program being evaluated? **Yes** **No**
- b) Do ANY of the investigators or research personnel (or their relatives) have a proprietary interest, derive a direct or indirect benefit, hold equity or receive income annually from the sponsor, manufacturer, or owner of the product or program being evaluated? **Yes** **No**
- c) Do ANY of the investigators or research personnel (or their relatives) serve in an administrative or advisory capacity to the sponsor (e.g., Board of Directors with or without compensation)? **Yes** **No**

If **yes** to ANY of the above, **attach** copy of UA Conflict of Interest and Commitment Disclosure Form.

I certify that this research will be conducted in accordance with the currently approved protocol/amendments and that no changes to procedures or study documents will be made without the knowledge/approval of the IRB.

Signature of Principal Investigator
(required for all projects)

Date

Signature of Departmental Review Chair
(not required for Category C or Category D) Date

FOR HSPP OFFICE USE ONLY

Required Attachments

Go to the "Forms Online"- "Continuing Review" section of our website (www.irb.arizona.edu) for detailed guidelines and to **download** the Periodic Review Report Template.

Complete and submit this form with required attachments:

Category A: attach items 1-13

Category B: attach items 1-12

Category C: attach items 1-8

Category D: no attachments required;
complete and submit this form only

Check enclosed items below:

Submit report containing the following information:

- _____ 1. If new subjects were enrolled OR previously enrolled subjects were re-consented, **list** and **submit** a copy of all versions of consent documents and/or disclaimer forms **used** during this reporting period.
(subject's/parental consent forms, HIPAA authorization forms, minor's assent form, disclaimer forms, oral consenting scripts, etc.)
- _____ 2. A **summary** of progress *since initial project approval* (if no enrollment since original approval, explain)
- _____ 3. A **summary** of changes made *since last project approval* (state IRB approval date or "pending approval")
- _____ 4. A **summary** of any adverse events/unanticipated problems involving risk to local subjects/study personnel *since last project approval* (for each, include date reported to IRB)
- _____ 5. If new information has become known *since last project approval* that could affect the risk/benefit ratio or influence willingness of subjects to continue in the study :
-**state** date submitted to IRB **or** attach new information and explain why it was not submitted previously
-**describe** actions taken, or to be taken, to inform subjects and/or minimize risk
- _____ 6. A **list** of subjects who withdrew or were removed from research participation *since last project approval*. Include subject ID (not name), date of and reason for withdrawal or removal (if known).
- _____ 7. A **summary** of any complaints about the research or its conduct *since last project approval*.
- _____ 8. - For **all projects**: A **list** of relevant progress reports (narrative section only) submitted to or received from sponsor, interim findings, and other relevant information (especially information about risks associated with the research) submitted to the IRB *since last project approval*.
- For **all projects**: Please list and submit a copy of any of the above items *not yet* on file with the IRB.
- For **Biomedical** projects: In addition to the above items, **list** data safety monitoring board (DSMB) reports and multi-center trial reports, submitted to the IRB *since last project approval*.
- _____ 9. An **abstract** summarizing study purpose, procedures, and subject population currently included under this project approval.
- _____ 10. If project is funded or funding is being sought, provide list of all sponsors (current or pending) and indicate status of each. **Reminder**: All protocols, grant proposals and/or revised documents must be submitted for IRB review and approval prior to implementation.
- _____ 11. Submit a copy of each consent document/authorization form/disclaimer form needed in new approval period (*without IRB stamp*). *Re-approved consent documents, with current IRB approval stamp, will be returned for duplication and use in enrolling (consenting) subjects.*
- _____ 12. Current Verification of Human Subjects Training Form (VOTF)
List all current study personnel. If personnel changes occurred since previous VOTF version, specify individuals removed or added under this section.
Note: Use current downloadable version of VOTF available at www.irb.arizona.edu/hstraining.html.
- _____ 13. A **summary** of investigator's review of relevant recent literature including impact on risks, benefits, and procedures (attach references and/or reprints, if necessary)

Please return Periodic Review Form and attachments to:

University of Arizona
Human Subjects Protection Program
1235 N. Mountain Avenue
PO BOX 245137
Tucson, Arizona 85724-5137

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