

PRINCIPAL INVESTIGATOR RESPONSIBILITIES INFORMATION SHEET

Congratulations! Your project has been approved or re-approved. To promote the *Responsible Conduct of Research*, the following information is provided for your reference and to retain with your study documents or in your site binder. Below are some of the important elements for conducting your study with regards to the Human Subjects Protection Program (HSPP). For a more thorough understanding of your responsibilities and the most current forms, visit the HSPP web site at <http://www.irb.arizona.edu>.

Topics: "Changes to the Project," "Unanticipated Problem or Adverse Event Reporting," "Renewal, Withdrawal or Conclusion of the Project"

CHANGES TO THE PROJECT (AMENDMENTS)

The IRB Must Approve All Modifications to the Research Activities and Applications Prior to Implementation unless it is to eliminate apparent immediate hazards to the participant.

- Changes include: protocol amendments, local procedural changes, personnel changes, recruitment material, form additions/changes (consents, questionnaires), enrollment status change, etc.
- Use the Request for Amendment Form. No additional cover letter is necessary.
- Brief Description of the Amendment – List:
 - Substantial changes (e.g. procedures, subject selection, risk/benefit ratio, local study conduct, sponsor change, local personnel change, sub-studies, questionnaires/surveys, etc.)
 - Non-substantial changes (editorial changes [correcting page numbering, grammar], administrative changes [updating sponsor contact info], and clarifications [re-wording of sections with no change in the procedure].)
- Rationale for the Amendment – Discuss the rationale for changes, how local procedures are impacted, change to the risk/benefit ratio, how local subjects are affected. If no change, state why.
- Do not cut and paste the sponsor's list of changes into the Request for Amendment Form.
- Highlight all changes to revised forms. If yellow is not used, include a clean copy of consenting instruments for approval stamp.

Form must be signed by a UA PI or a Co-PI or materials will be returned.

UNANTICIPATED PROBLEM OR SERIOUS ADVERSE EVENT REPORTING

- Unanticipated Problems Involving Risks to Subjects or Others (which may include accidental or inappropriate disclosure of confidential information, serious adverse events, complaints relating to the study from any source, protocol deviations/violations, use of unapproved study materials/methods, etc.) need to be reported to the Human Subjects Protection Program office (see reporting requirements in our Policies and Procedures found at www.irb.arizona.edu under Sections II.C, II.C.1, II.E, II.E.1, II.F, II.F.1, III.I, and III.I.1).
- Use the Study Related Problems Form. No additional cover letter is necessary.
- Brief Description of the reportable item:
 - Provide date of report (if different from "Date of Request" at top of form), any relevant identification numbers or dates on reports received from sponsor or other non-local entity (if applicable), and description of reportable item.
- Causality Assessment:
 - Related, probably related, or possibly related (greater possibility that it is related than not related)
 - For non-local events, causality assessments by the reporting investigator, the sponsoring agency and the UA investigator may differ and may all be listed in the space provided on the form (identify source of each assessment).
- UA PI's assessment of local impact (including whether any study documents need revision):
 - If no changes to the consenting instruments are being made, state reason (e.g., only new subjects would be impacted and study is closed to enrollment, risk is already in currently approved form, risk only impacts subjects actively receiving study drug and no local subjects are being actively treated).

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RENEWAL, WITHDRAWAL, OR CONCLUSION OF THE STUDY

Please Note!! It is the responsibility of the Principal Investigator to provide the HSPP office with timely materials for *renewal, withdrawal or conclusion* of a project. A reminder of when your project is due for review may be sent to you, however it is only a reminder. Please take responsibility for submitting review materials 30 - 45 days prior to the current project approval expiration date. Failure to provide renewal documents will result in **administrative closure** of your project. If your study is being *withdrawn* or *concluded*, the required documentation may be submitted whenever all study activities have stopped or been completed (even if well before the current expiration date).

- Review the Guidelines for Continuing Review (detailed explanation of forms, activity status categories and attachment requirements) found on the HSPP website, www.irb.arizona.edu, under the Forms Online, Continuing Review menu items
- For renewal of project approval, submit the following 30 - 45 days before expiration of your current project approval.
 - Current version of the Continuing Review Form (received by mail or printed from IRB website) - requires reporting of current activity status, enrollment numbers, financial interest
 - Current version of the Continuing Review Report (download from our website) - depending on study status, may require reporting of progress to date, changes that have been made during reporting period, unanticipated problems or serious adverse events submitted during report period, abstract of current study purpose/procedures/population, summary of review of relevant literature published during report period
- For *withdrawal* of project, submit the following (only if no enrollment OR activities involving receipt/use of tissue or data collected from human subjects has occurred or will occur)
 - Current version of the Continuing Review Form
- For *conclusion* of project, submit the following if all study activities (including data analysis and response to sponsor queries) have been completed.
 - Current version of the Continuing Review Form interest
 - Current version of the Continuing Review Report (and any indicated attachments)

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