Clinical Research Shared Service Standard Operating Procedure

SOP 113-ADM  Completion and Routing of University of Arizona Cancer Center Periodic Review Forms

Approval signature: [Signature]

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Purpose:
The Department of Health and Human Services (DHHS) and the Food and Drug Administration (FDA) regulations require re-evaluation of research at intervals that are appropriate to the degree of risk. The Institutional Review Board (IRB) is responsible for continuing review of human subject's research projects to ensure that the rights and welfare of human subjects are protected. This standard operating procedure (SOP) describes the process followed at the University of Arizona Cancer Center (UACC) to complete and route Periodic Review Forms.

References:
- 56.109 (f) Code of Federal Regulations & ICH Guidelines
- 56.113 Code of Federal Regulations & ICH Guidelines
- University of Arizona Human Subjects Training (CITI) http://www.citiprogram.org
- University of Arizona Continuing Review Process guidelines http://www.irb.arizona.edu
- All SOPs are applicable to this SOP.

Authors:
Revised by SOPRC.

Target Audience or Responsibilities:
This SOP applies to the members of the Clinical Research Shared Service (CRSS), any members of the clinical research team and any members of the Investigators administration staff involved in completing or routing a Periodic Review Form.

Tools:
- Continuing (Periodic) Review Form http://orcr.vpr.arizona.edu/irb/forms
- Social Security website (www.rootsweb.com)
- University of Arizona Continuing Review Process guidelines http://www.irb.arizona.edu,
- OnCore Accrual Data

Definition of Terms:
• **Adverse Event (AE):** Any untoward medical occurrence in a patient or clinical investigation subject administered a pharmaceutical product and which does not necessarily have a causal relationship with this treatment. An adverse event (AE) can therefore be any unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of a medicinal (investigational) product, whether or not related to the medicinal (investigational) product. Any adverse change from baseline (pretreatment) intercurrent illness which occurs during the course of a clinical study after consent has been signed, whether considered related to treatment or not.

• **Anticipated (Expected) Adverse Events:** There is a reasonable possibility that the event/experience may have been caused by the investigational product (s). Adverse events outlined in the protocol, Investigator’s Brochure and Informed Consent Form as known side effects that are expected.

• **Clinical Research Coordinator (CRC)**
• **Clinical Research Shared Service (CRSS)**
• **Clinical Trials Office (CTO)**
• **Continuing (Periodic) Review Form (CRF/PRF):** A form supplied in a specific format by the Institutional Review Board (IRB) to use as a tool for continuing review of human research projects. At the discretion of the IRB, approval of the PRF will extend the clinical research trial for a designated period of time. This form consists of study specific questions, a conflict of interest statement and a summary of study activities to date.

• **Enrolled:** All subjects who sign an informed consent form are considered enrolled.

• **Institutional Review Board (IRB) or Western Institutional Review Board (WIRB):** An independent body constituted of medical, scientific, and non-scientific members, whose responsibility is to ensure the protection of the rights, safety and well-being of human subjects involved in a trial by, among other things, reviewing, approving, and providing continuing review of trial protocol and amendments and of the methods and material to be used in obtaining and documenting informed consent of the trial subjects.

• **OnCore:** Database used to store protocol and patient data at the University of Arizona Cancer Center.

• **Project Approval Form (PAF):** Signed by the Principal Investigator which assures to the IRB that all other investigators (collaborating investigators, involved statisticians, consults, or advisors) are fully aware of, and concur with, the project submission and that all Human Subjects training verification information provided is accurate. This form must also be signed by the Head of Department, Dean of the College or a comparable authority.

• **PI:** Principal Investigator.

• **Serious Adverse Event (SAE) or Serious Adverse Drug Reactions (Serious ADR):** Any event or experience that is a significant hazard, contraindication, side effect, or precaution experienced by a study subject once they have signed an informed consent form.

An SAE is any untoward medical occurrence at any dose of drug (investigational or not) and is considered a serious adverse event when it:
• results in death or is life threatening (immediate risk of death);
• results in patient hospitalization or prolongation of existing hospitalization;
• results in persistent or significant disability/incapacity;
• is a congenital anomaly/birth defect;
• important medical events that may not result in death, be immediately life threatening, or require hospitalization, may be considered an SAE when, based upon appropriate medical judgment, they may jeopardize the patient and may require intervention to prevent one of the outcomes listed in this definition.

• **Unanticipated Adverse Events (Unexpected Adverse Drug Reaction):** Any adverse experience, the specificity or severity of which is not consistent with the current Investigator Brochure, or if an Investigator Brochure is not required, that is not consistent with the specificity or severity in the risk information described in the general investigational plan or elsewhere in the current application, as amended.

• **Verification of Human Subject Training Form (VOTF):** Validation that all research personnel involved in any Clinical Trial Protocol has successfully taken and passed a written examination based on Protecting Study Volunteers in Research: A Manual for Investigative Sites designed to protect human subjects in research with dignity and trust.

**Safety Issues:**

Evaluation of current data to ensure that the rights and welfare of human subjects are protected, that risks remain minimized and potential benefit identified.

**Process Steps:**

1) The IRB sends the CRF/PRF to the PI/IRB Coordinator approximately 30 days in advance of the due date.

2) Preparation: The IRB Coordinator (or PI) prepares all the required CRF/PRF study documentation.
   - Send the CRC a CRF/PRF Review Completion Form: The CRC/Research Nurse to verify patient enrollment/accrual status.
   - The CRC:
     - reviews source documents for subject updates;
     - verifies which consents were used during the reporting period.

When this information is completed, it is returned to the IRB Coordinator (or PI).

3) Completion of the CRF/PRF (sample Attachment 1 and detailed in the University of Arizona Continuing Review Process guidelines found at www.irb.arizona.edu).
   - Reviews the study documents and actions for the past year.
   - Verifies the current contact list in OnCore for participating investigators and study personnel and updates the VoTF as needed.
   - Reviews and/or revises the consents as needed.
   - The PI reviews the CRF/PRF report and, if required, the PI provides a literature research for the study.
4) The PI returns the signed CRF/PRF and required attachments to the IRB Coordinator (or CTO personnel) who enters status into OnCore.
5) The IRB Coordinator (or CTO personnel) obtains a signature from the Department Review Chair and submits the entire package to the IRB for approval. When the CRF/PRF documentation is completed by the IRB Coordinator (or PI), and all signature/s obtained, the completed CRF/PRF and all documents are entered into OnCore by the IRB Coordinator (or CTO personnel).
6) The IRB Coordinator (or CTO personnel) distributes, on receipt, the approval document and forms to study and clinic personnel as appropriate as well as attaching the approved document/s in OnCore.