Clinical Research Standard Operating Procedure

SOP 102-ADM  Review and Approval Process of University of Arizona Cancer Center (UACC) Clinical Research Standard Operating Procedures

Approval signature: [Signature]
Michael Bookman, M.D., Director of CRSS

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Revision dates: 4/8/03, 2/19/04, 1/25/05, 10/22/08, 12/13/2011

Purpose:
To ensure approval and periodic review of all University of Arizona Cancer Center (UACC) Clinical Research standard operating procedures (SOP) in accordance with Good Clinical Practice and federal, state and international regulations.

References:
- SOP 101-ADM, How to write and format an UACC clinical research SOP.
- All SOPs are applicable to this SOP.

Author(s):
Revised by SOPRC.

Target Audience and/or Responsibilities:
SOPRC: Responsible for interacting and communicating with SOP initiators, and SOP committee reviewers for appropriateness and completion of SOP documentation.

Director of CRSS: Final review and signature approval for SOP.

Tools:
- SOP development checklist, SOP 101-ADM
Definition of Terms:
- **SOP**: Detailed, written instructions to achieve uniformity of the performance of a specific function.
- **SOPRC**: Standard Operating Procedure Review Committee.

Safety Issues:
The availability of SOPs in a standard format enhances the safe delivery of clinical research practice and ensures compliance with appropriate guidelines.

Process Steps:
1) SOPRC coordinator receives draft SOP from SOP initiator.
2) SOPRC coordinator uses SOP Development Checklist (SOP 101-ADM) to verify SOP submission documents for completeness, pre-review process.
3) If package is complete, coordinator contacts SOP initiator with tentative review date. Go to step #7.
4) If the SOP draft is incomplete, the SOP initiator is notified to revise SOP and resubmit to SOPRC.
5) If the SOP draft is complete but questions or concerns remain, return draft to the SOP initiator for comments and resubmission to the SOPRC for pre-review.
6) If it is determined by the SOPRC that the SOP is not required or necessary, return to SOP initiator with a written explanation.
7) 
   a. SOPRC coordinator prepares package for full committee review and includes all the required documentation as defined in SOP 101-ADM.
   b. SOPRC coordinator distributes package (electronically when possible) to committee members for review prior to the next meeting.
   c. SOPRC coordinator prepares agenda for regularly scheduled SOPRC meeting and distributes SOP package for full committee review 5-7 days before the meeting. Full committee review of the SOP may include review and input, as appropriate, from individuals unaffiliated with the SOPRC.
8) SOPRC meets and reviews submitted SOP(s):
   a. The committee approves the SOP: assigns a SOP reference number and revision period.
   b. If the SOP needs further revisions or is rejected. It is returned to the SOPRC designee (SOPRC Coordinator) who will notify the SOP initiator in writing, of the SOPRC decision.
9) Once approved by the SOPRC, the SOP is given to the Director of Clinical Research Shared Service for signature.
10) The SOP becomes effective after 30 days of the approval signature, unless otherwise specified.
11) SOP training is provided and documented by the SOP initiator(s) and/or department head/supervisor. Training records and SOP documents are maintained by the SOP coordinator.

12) The approved SOP is posted in a PDF format on the University of Arizona Cancer Center intranet.