SOP 119-ADM Long-Term Follow-up of Clinical Research Subjects

Approval signature: _____
Robert Livingston, M.D., Director of CRSS

Approval date: 1.14.09

Approval date: 2/9/04
Revision dates: 1/18/05, 12/17/08
Next review date: 12/2011

Purpose:
This standard operating procedure (SOP) describes the steps for long-term follow-up of clinical research subjects. The IRB continuing review process states "studies for which enrollment, subject participation, subject follow-up, and local data analysis have been completed must be officially concluded. When data analysis will be performed by the sponsor, a study may be concluded locally only after all data have been submitted to the sponsor, queries have been answered, and final monitoring or close-out visit has been conducted".

References:
- 21 CFR 312.60 General responsibilities of investigators.
- 21 CRF 312.62 Investigator record keeping and record retention.
- ICH section, 4.9 Records and reports.
- University of Arizona Continuing Review Form Guidelines http://www.irb.arizona.edu
- All SOPs are applicable to this SOP.

Authors:
Reviewed by SOPRC.

Target Audience or Responsibilities:
This SOP applies to all Arizona Cancer Center clinical research personnel involved in conducting research trials.

Tools:
- Research protocol
- University of Arizona Continuing Review Form Guidelines http://www.irb.arizona.edu
- Sample of contact references.
- All SOPs are applicable to this SOP.

Definition of Terms:
- **Documentation:** All records, in any form (including, but not limited to, written, electronic, magnetic, and optical records, and scans, X-rays, and electrocardiograms) that describe or record the methods, conduct, and/or results of a trial, the factors affecting a trial, and the actions taken.

- **OnCore:** Database used to store protocol and patient data at the Arizona Cancer Center.
- **Protocol**: A document that describes the objective(s), design, methodology, statistical considerations, and organization of a trial. The protocol usually also gives the background and rationale for the trial, but these could be provided in other protocol referenced documents.

Safety Issues:
The availability of SOPs in a standard format enhances the safe delivery of clinical research practice and ensures compliance with the research protocol as well as with appropriate FDA regulations and GCP and ICH guidelines.

Process Steps:
1) Complete all follow-up requirements (visits, contacts and/or procedures) per research protocol.
2) Schedule follow-up requirements, if applicable.
3) Document scheduling, if applicable.
4) Document all subject follow-up visits, contacts and/or procedures. Subject contact may be completed by phone, letter or e-mail per the research protocol requirements. Make three attempts to obtain current status. If status cannot be obtained after at least three attempts, the subject can be considered lost to follow-up.
5) Update OnCore in the subject console with off-treatment date, off-study date, last date of contact and date of death, if applicable.

Sample of Contact References for Long-Term Follow-Up Completion

- Call the patient.
- Check on-line with the Social Security Death Index, available at http://ssdi.genealogy.rootsweb.com/
- Call the patient's primary care physician for a date of last contact.
- Send a letter to the patient's last known address.
- If there's no response to the first letter, send a certified letter to the patient.
- Contact the next of kin, or other contact person designated in the patient's record.