Purpose:
To develop a process for managing protocol deviations.

References:
- University of Arizona Human Subjects Protection Program, Policies and Procedures website (http://www.irb.arizona.edu/policies)
- All SOPs are applicable to this SOP.

Author(s):
Revised by SOPRC.

Target Audience:
This SOP applies to all clinical research personnel of the University of Arizona Cancer Center involved in screening and managing subjects enrolled in clinical trials.

Tools:
- Protocol Deviation (Waiver) Approval Form (Attachment 1)

Definition of Terms:
- Protocol Deviation: A condition during a study (e.g., a subject that does not meet the inclusion/exclusion criteria) which is not in compliance with the requirements of the protocol for which an amendment has not been granted.

Safety Issues:
If a need exits to eliminate an immediate hazard to a clinical study subject, a protocol deviation may be obtained.

Process Steps:
1) The PI identifies a need for a protocol deviation.
2) When requested by the PI, a member of the research team contacts the sponsor for approval of the protocol deviation. Immediate verbal approval must be documented by
the research team member and followed up with an approval written protocol deviation form. If the sponsor does not have a specific protocol deviation form, the requesting team member will use the UACC Protocol Deviation Approval Form (Attachment 1).

a) Complete the form with as much information as possible and have the principal investigator sign and date the form. A research team member will fax the form to the study sponsor, as applicable.

b) Once the signed and approved form is received, a note to file describing the deviation must be written and stored with the study records. File the original deviation approval form and note in the regulatory binder; place a copy in the subject’s research chart.

3) Deviation approvals are to be obtained prior to the deviation occurring.
4) Notification to IRB for safety-related protocol deviations must be submitted per the IRB policies and procedures.
5) All attempts should be made to follow the protocol. The PI may need to contact the study sponsor to discuss the need for a protocol amendment(s).
Attachment 1

Protocol Deviation (Waiver) Approval Form

Project #: ___________________________ Principal Investigator: ___________________________

Study sponsor: ___________________________ Subject ID: ___________________________

Date of verbal approval for protocol deviation: ___________________________

Given by: ___________________________

Deviation description:
________________________________________________________________________
________________________________________________________________________
________________________________________________________________________
________________________________________________________________________
________________________________________________________________________

Form completed by: ___________________________ Date: __________________________

Principal Investigator Signature: ___________________________ Date: __________________________

Study Sponsor Signature: ___________________________ Date: __________________________