

PROTOCOL CHANGES

SOP #:	404	VERSION #:	1	EFFECTIVE DATE:	11/1/14	SUPERSEDES DOCUMENT:	/ /
THIS POLICY PERTAINS TO:			ALL RESEARCH SUBMITTED TO THE IRB				
RESPONSIBILITY FOR EXECUTING POLICY:		IRB CHAIRPERSON, IRB VICE CHAIRPERSON, IRB COORDINATOR, INVESTIGATORS, IRB MEMBERS					
LAST REVIEWED ON:		/ /		RESULTS:	REVISED		
APPROVAL AUTHORITY:		Associate Vice President for Research and Economic Development					
APPROVED BY:					DATE:		10/23/14

1. POLICY

Changes in approved research, during the period for which approval has already been given, may not be initiated without prior IRB review and approval, except where necessary to eliminate apparent immediate hazards to human subjects. In such cases, the Investigator must inform the IRB of the implemented change within 72 hours.

2. SPECIFIC POLICIES

2.1 Protocol Changes

2.1.1 Information Needed For Review of Protocol Changes

Investigators must submit requests for changes to the IRB on the Protocol Change Form. Each Protocol Change/Amendment will include:

- Description of the change;
- Reason for the change;
- Whether or not changes affect the consent document;
- The impact the change will have on the study and/or the participants;
- All appropriate documents;
 - Revised informed consent (if applicable);
 - Revised Key Personnel Listing (if applicable);
 - Sponsor correspondence concerning the amendment (if applicable);
 - Highlighted amended protocol (if appropriate).

2.1.2 Determinations and Full Board Review

Upon receipt of the protocol change, the IRB Secretary with the assistance of the IRB Coordinator will determine if the revision meets the criteria for minimal risk. If the change represents more than a minimal risk to subjects, it must be reviewed and approved by the IRB at a convened meeting.

For a protocol change to be considered to involve greater than minimal risk, the proposed change would increase risk or discomfort or decrease the benefit. The IRB must review and approve the proposed change a convened meeting before the change can be implemented unless the change is

necessary to eliminate an immediate hazard to the research participants. In the case of a change implemented to eliminate an immediate hazard to participants, the IRB will review the change to determine that is consistent with the ensuring the participant's continued welfare.

The review of protocol changes will be done using the primary reviewer system. If possible, the prior primary reviewer of the initial IRB submission will be assigned as the reviewer. All other members will receive all of the materials.

If the protocol change might affect the willingness of a participant to continue in the study, or if it changes the risk benefit for the participants already enrolled, the Investigator will be directed to notify the participants. Depending on the seriousness, the Investigator may be directed to contact the participants by letter, re-consent at next opportunity, or phone participants to schedule a visit for immediate re-consent.

2.1.3 Expedited Review

If the protocol change is a minor change involving no more than minimal risk to the subject, it will be reviewed by the Expedited review process and will be reported to the IRB on the next month's proposal list. The documentation of review will be made on a report of action form.

2.1.4 Changes to Exempt Proposals

During the approval period, the Investigator must inform the IRB of any changes in the study scope or design prior to implementation of the changes to insure that the study continues to meet the exempt criteria.

2.1.5 Notification of Investigator

All approvals for requested revisions will be reported to the Investigator.

3. RESPONSIBILITY

The IRB Secretary and IRB Coordinator are responsible for the first review of the protocol change and either assigning it for expedited review or assigning a Primary Reviewer to review the proposed changes at a Full Board meeting.

Primary Reviewers are responsible for the review of the protocol change.

IRB Members are responsible for the review of minor protocol changes to exempt and expedited research.

The IRB Secretary is responsible the documentation of receipt of the protocol change and correspondence pertaining to the protocol change.

4. APPLICABLE REGULATIONS AND GUIDELINES

21 CFR 812.64

21 CFR 56.108, 56.109, 56.113

45 CFR 46.103, 46.109, 46.115

FDA Information Sheets, 1998

5. ATTACHMENTS

Protocol Change Form

6. PROCEDURES EMPLOYED TO IMPLEMENT THIS POLICY

Who	Task
<i>IRB Secretary</i>	<p>Upon receipt of a protocol change, date-stamp the current date on the form.</p> <p>Input the information about the protocol change onto the IRB database.</p> <p>Attach all information related to the protocol change to the study file.</p> <p>In consultation with the IRB Coordinator, determine which can be reviewed via expedited review, and which must be placed on the agenda for the next meeting.</p> <p>Assign Primary Reviewer as necessary.</p>
<i>IRB Members</i>	Review protocol change.
<i>Primary Reviewers</i>	Review protocol change at convened IRB meeting.
<i>IRB Secretary</i>	Complete processing of protocol change.