Oklahoma State University Institutional Review Board Standard Operating Procedures		
Protocol Modification	SOP #	RR 405
	Effective Date	1/1/2012
	Revision Date	12/17/2015
	Revision #	1
	Approval: IRB	02/10/2016

1. POLICY

Any 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.

Specific Procedures

1.1 Submission of Protocol Changes

1.1.1 Investigators must submit requests for changes to their approved protocol to the IRB using the Approved Protocol Modification Request form. Examples of changes that require IRB review include, but are not limited to, changes in:

- Project Title
- Principal Investigators and Co-Investigators
- Sponsor
- Subject Population
- Recruitment Procedures
- Research Site(s)
- Research Procedures
- Consent/Assent/Parental Permission Forms

If an investigator makes changes to the protocol without prior IRB approval to eliminate apparent hazards to the subjects, the investigator must immediately report the changes to the IRB for review.

1.1.2 The Investigator submits one (1) completed Approved Protocol Modification Request form and any revised documents to the Office of University Research Compliance (URC).

1.1.3 Upon receipt of the form and ancillary materials, the request is entered into the IRB electronic tracking system by the IRB Coordinator.

1.2 Review of Approved Protocol Modification Request

1.2.1 Determination of minor or substantive change
The modification request is reviewed by the IRB Manager or IRB Chair to determine if the proposed change(s) to the protocol is minor or substantive. A minor change meets the criteria for minimal risk and makes no substantial alteration in the level of risk to subjects. A substantive change would involve actions that would increase the risk level of the research to greater than minimal risk.

1.2.2 Review of minor changes
Minor changes to approved protocols are reviewed using the following expedited review procedure (as allowed by the federal regulations, 45 CFR 46.110). The IRB Chair designates the IRB Manager, who is a primary member of the IRB, to review and approve minor revisions. This expedited review process allows minor changes to be reviewed within the IRB office. In the absence of the IRB Manager, the IRB Chair may designate another experienced IRB member to

conduct the review. If additional expertise is needed to review the proposed changes, additional reviewers will be assigned in accordance with pre-review procedures in SOP RR 403. The expedited reviewer exercises all the authority of the IRB except the reviewer cannot disapprove the research.

1.2.3 Review of substantive changes
When a proposed change is determined to be substantive, it must be reviewed by a quorum of the IRB at a convened meeting. The request is placed on the agenda of the next scheduled meeting and the investigator is notified of the date and time of the meeting.

The Approved Modification Request form and any attachments are prepared for distribution to Board members for review, as stipulated in SOP RR 404.

A primary reviewer is assigned by the IRB Manager to lead discussion of the modification request. If the protocol was initially reviewed at the full board level, the primary reviewer will be the same as that for the initial full board review if possible.

1.2.4 Review Outcomes
For expedited review, the review outcomes and notifications are the same as outlined in SOP RR 403. For full board review, the review outcomes and notifications are the same as outlined in SOP RR 404.

Approval of a modification request does not alter the end date of the approval period of the protocol. It remains the same as that assigned at the initial or continuation review.

If the modification request is part of a continuation review, the correspondence from the IRB incorporates written notification of IRB approval or disapproval of the modification request into the IRB continuation approval/disapproval letter.

2. SCOPE

These policies and procedures apply to all requests for modifications to approved protocols submitted to the IRB.

3. RESPONSIBILITY

Investigators are responsible for submitting a complete, signed Approved Protocol Modification Request form, any modified documents, and for responding to any revisions requested by IRB reviewers in a timely manner.

The IRB Coordinator is responsible for receiving the modification request, tracking the request and documenting revisions in the IRB electronic tracking system. In addition, the IRB Coordinator is responsible for sending any revisions requested by the IRB to the investigator, reviewing revision responses, and generating modification approval/disapproval letters.

The IRB Manager or the IRB Chair is responsible for reviewing modification requests to determine if proposed changes are minor or substantive.

The IRB Manager and/or any other IRB member(s) designated by the IRB Chair is responsible for reviewing minor changes.

IRB members are responsible for reviewing substantive changes.

4. APPLICABLE REGULATIONS AND GUIDELINES

45 CFR 46.103, 46.109, 46.115

5. REFERENCES TO OTHER APPLICABLE SOPS

RR 402
RR 403
RR 404

6. ATTACHMENTS

7. IMPLEMENTATION OF PROCEDURES

Who	Task	Tool
IRB Coordinator	Receive submissions, review for sufficient information, complete IRB electronic tracking system entry.	
IRB Manager	Review request to determine if proposed changes are minor or substantive.	
IRB Manager	Determine if additional expertise is needed for review of minor changes. Assign reviewers, if needed.	
IRB Manager	Review and approve minor changes as appropriate.	
IRB Manager	Assign primary reviewer for review of substantive changes.	
IRB Members	Review substantive changes at convened meeting.	
IRB Coordinator	Generate correspondence notifying investigator of modification request approval status (approved, pending revision, approved with conditions, or disapproved) and document in IRB electronic tracking system. If protocol was placed in pending or approved with conditions status, upon approval of revisions, or receipt of requested documentation and/or information, update approval status in IRB electronic tracking system and generate correspondence notifying investigator.	