Oklahoma State University Institutional Review Board Standard Operating Procedures		
Protocol Completion/Closure	SOP #	RR 407
	Effective Date	1/1/2012
	Revision Date	12/17/2015
	Revision #	1
	Approval: IRB	02/10/2016

1. POLICY

The completion or termination of a protocol is a change in activity and must be reported to the IRB by investigators.

Specific Procedures

1.1 Determining When a Protocol Can Be Closed

1.1.1 When individually identifiable follow-up data are no longer being collected on subjects enrolled and when data analysis of <u>identifiable</u> data is complete, the protocol will be closed.

2.1 Protocol Closure

2.1.1 The IRB Coordinator will use the University Research Compliance (URC) tracking system to identify all protocols expiring approximately 60 days prior to the first day of the month in which the protocol's current approval will expire. An email will be sent to the investigators of these protocols requesting an email response to close the protocol or submission of a continuation/renewal form requesting extension of approval. A second notice will be sent to all investigators who have not responded 30 days prior to the first day of the month in which a protocol's current approval will expire. If a continuation/renewal form is not submitted or email notice that the protocol should be closed is not received before the approval expiration date, the protocol will be administratively closed. A final notice letter will be sent to investigators notifying them that the protocol has been closed and no human subjects research may continue without re-application.

2.1.2 Upon completion of all interactions with human subjects and de-identification of any identifiable data, investigators may request closure of a protocol via written notice to the IRB. The request will be evaluated to verify that closure does not pose any risk to participants.

2.1.3 The administrative steps for closing a protocol are as follows:
Locate the protocol in the URC tracking system and select closed from the pull down menu.
Remove the protocol file from the IRB active files and note the date of closure on the file folder.
File the closed protocol in the IRB archive files.

2.4 Notification of the IRB
Closure of protocols is documented monthly by the IRB Coordinator and is made available to all members *via* the IRB web distribution site and presented to the Board at the next convened meeting.

2. SCOPE

These policies and procedures apply to all requests for continuation/renewal of approved protocols submitted to the IRB.

3. RESPONSIBILITY

The IRB Staff is responsible for ensuring that all protocol completion documentation is received, reviewed, presented to the IRB, and filed appropriately.

4. APPLICABLE REGULATIONS AND GUIDELINES

45 CFR 46.103, 46.109

5. REFERENCES TO OTHER APPLICABLE SOPS

RR 406

6. IMPLEMENTATION OF PROCEDURES

Who	Task	Tool
IRB Coordinator	Use URC tracking system to identify expiring protocols. Prepare and send 30 and 60 day notice letters and final notice letters.	
IRB Coordinator	Close protocols in URC tracking system. Pull protocol files for closure, date files and file closed protocols in IRB archive files.	
IRB Manager	Review protocol closure requests to verify requirements are met.	