

1. GENERAL

When reviewing research, the convened IRB is responsible for determining the approval status and appropriate approval period (up to one year) of a study under review and must notify the investigator and institutional officials of its decisions.

2. PURPOSE

This policy describes actions that the convened IRB may take during review of research and communication of these actions, as well as the process for review of investigator responses to IRB determinations.

3. DEFINITIONS





- a. Specified time period (such as annual, semi-annual, or quarterly review)
- b.



9.03 IRB members and the Institutional Official (IO) are notified of the IRB's actions and findings via summary documentation that is posted and can be printed from the secure IRB Members' folder on the T-drive.

10. APPLICABLE REGULATIONS/GUIDANCE

[45 CFR 46.111](#), OHRP "[Guidance on IRB Approval of Research with Conditions](#)" (11/10/10), OHRP "[Guidance on Written IRB Procedures](#)" (07/01/11)

APPROVED: \_\_\_\_\_ < signed > \_\_\_\_\_  
Dana G. Hoyt, President

DATE: \_\_\_\_\_ 6/17/15 \_\_\_\_\_

**CERTIFICATION STATEMENT**

This academic policy statement (APS) has been approved by the reviewer(s) listed below and