



## IRB Review Communications Policy

**Date:** September 9, 2016 (*Reissue of notice originally dated August 18, 2015*)

**From:** Kathleen A. Hay, Ph.D., C.I.P, Director  
Human Subjects Protection Office

**Subject:** IRB review communications to investigators

It is the policy of the Penn State College of Medicine Institutional Review Board (IRB) that IRB findings and actions are reported to investigators in writing using memos generated from the Centralized Application Tracking System (CATS IRB). These system-generated memos, which are from the IRB staff member assigned to the submission, notify the investigator of the IRB's decision to approve or disapprove the proposed research study, of modifications required to secure IRB approval of the research study, and of the review outcome for other issues submitted to the IRB. Since the CATS IRB system, which was implemented in December 2013, requires an electronic identity authentication process, these memos do not include a physical or electronic signature.

The assigned IRB staff member generates correspondence to notify the investigator of IRB decisions made at convened committee meetings, or of non-committee decisions made during expedited review conducted by the IRB chair or experienced IRB reviewers designated by the chair in accord with federal regulations (45 CFR 46.110b and 21 CFR 46.110b). Institutional policy HRP-030 outlines the process for the chair to designate experienced IRB members to conduct review. The institutional official is responsible for designating the IRB chair, the director of the Human Subjects Protection Office and IRB members, as registered in the institution's federalwide assurance and IRB registration renewals.

Please contact the Human Subjects Protection Office at (717) 531-5687 should you need any further information. Thank you very much.

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