

December 2009 HSPO Update

Required Use of On-line IRB eSubmission Tool, effective January 2010

Effective January 1, 2010, new research proposals submitted to the IRB must be made using the on-line submissions process via the IRB eSubmission tool in PRAMS, the IRB's electronic Protocol Review and Approval Management System. The on-line tool enables the IRB to conduct electronic reviews and allows researchers to track their submissions and view their research documentation in the IRB's database. A link and instructions to use the IRB eSubmission tool are provided on the [Investigator Resources](#) page of the IRB web site, under 'Making an IRB Submission'.

Individuals already in the process of filling out an IRB application using the old style IRB forms must complete and submit these forms to the IRB by December 31, 2009, or enter the information into an application within the IRB eSubmission tool. Effective January 1, 2010 applications using the old forms-based process will no longer be accepted.

The PRAMS IRB eSubmission system includes on-line applications to submit the following:

- **Initial applications for a new research study** (*including requests for an IRB Determination or Exemption, Expedited, Facilitated or Full review, and Humanitarian Use Device requests*)
- **Modification/Amendment of currently approved study** (*study initially submitted via eSubmission*)
- *Next roll out: An online Continuation Review process will be implemented early in 2010*

For *eSubmission studies*, the following issues should continue to be submitted via the IRB Drop Box process until an electronic submission process is developed: Continuation Review, Problem Reports, Protocol Exception Requests, Protocol Deviations, and Emergency Use Requests.

For *ongoing studies not in eSubmission*, a process will be developed for researchers to use the eSubmission tool, but meanwhile all issues for these studies should be submitted via the IRB Drop Box.

Again, researchers and coordinators are reminded that anyone with a pending application started, who wishes to use the old IRB forms, must complete and submit it by the **December 31, 2009 deadline.**

PRAMS IRB eSubmission Workshops

Weekly workshops are conducted to show faculty and staff how to use the IRB eSubmission tool and how to view/track their own research in the PRAMS system. Remaining dates this month include December 16, 22 and 30. For more dates and details see Educational Resources on the [IRB web site](#).

Questions may be directed to the staff of the HSPO at 531-5687 or e-mailed to hspo@hmc.psu.edu.