

## Human Subjects Protection Office (HSPO)

[www.hmc.psu.edu/irb](http://www.hmc.psu.edu/irb) Ph. 717-531-5687

### April 2009 HSPO Update

#### Updated IRB SOPs

The overall IRB Standard Operating Procedures were reviewed and revised recently to make minor editorial corrections and incorporate changes needed to correspond to updated practice. Links are provided on the IRB web site to [IRB Policies and Procedures](#), including the following updated SOPs:

- IRB Standard Operating Manual
- SOP Handling Allegations of Non Compliance
- SOP IRB Review of Protocol Exceptions
- SOP Recruitment of Research Participants
- SOP Reporting and Review of Unanticipated Problems
- SOP Research in Emergency Situations

The only procedure that changed significantly is the SOP Reporting and Review of Unanticipated Problems. Updates were made to clarify the definitions for unanticipated problems, the process for IRB review and handling of reported problems, and the following reporting requirements which affect investigators:

- Reporting is required for suspensions for any reason other than planned suspensions for interim analyses, including sponsor-imposed suspension for risk.
- Incarceration of a study volunteer is no longer reported as an unanticipated problem, but instead is submitted as a modification request.

The process for reporting unanticipated problems, and explanations about what is new, will be outlined in a workshop on April 22, 2009. For registration details see the [IRB Workshop flyer](#).

#### IRB Submission Forms Updated

The IRB submission forms have been updated to include brief instructions on how to submit the materials to the IRB Drop Box located on the HSPO server. Effective January 1, 2009 all submissions to the IRB must be made as electronic files to the *IRB Drop Box*, rather than in paper format. Detailed steps are provided in the [IRB Drop Box Instructions](#), which were recently updated to include steps to access the drop box from outside the institution.

#### IRB Signature Pages

The IRB forms were also updated to move the Assurance Statements pages that principal investigators and key personnel sign into a separate document. Links to the applicable Assurance Statement signature pages are provided on the IRB web site, under Investigator Resources, [Application Process & Form](#), for the following forms:

- Exemption Determination
- Application Form for Human Research
- Humanitarian Device Exemption form

When submitting a modification to add a new investigator, you only need to submit the signed assurance statement applicable to the individual (i.e., new principal investigator or key personnel statement).

**Please contact the HSPO at (717) 531-5687 if you have any questions about this update.**