PennState

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To: Leslie J. Parent, Vice Dean for Research and Graduate Studies, Institutional Official
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From: James A. Taylor, III, Director of Office for Research Information Systems

Date: November 3, 2016

Subject: IRB Statement of 21 CFR Part 11 Compliance

Researchers at The Pennsylvania State University are required to use an electronic system (CATS IRB) to submit applications for the use of human participants in research. CATS IRB is also used by Penn State's Institutional Review Boards and compliance offices to conduct and record the review and approval process of that research. This statement serves to document Penn State's compliance with 21 CFR Part 11 (Electronic Records: Electronic Signatures) for research subject to FDA regulation.

CATS IRB, a closed system, conforms to Part 11 as follows:

- Development practices and appropriate controls – All changes to CATS IRB follow best practice software development practices to ensure that the changes are appropriate, reliable and correct, which require the persons doing the work have adequate training and experience and which employ appropriate and strict change control procedures.
- Generating copies - CATS IRB allows for a copy of the study and related documents to be printed. A related history log of changes is available in the system and can be separately printed or displayed. The availability of this information is the same when a study is in retention.
- Authorized access – CATS IRB is limited to use by authorized individuals within the institution. Authority checks are made to ensure that only authorized individuals can use and take assigned action the system.
- Auditability – CATS IRB tracks all changes made by individuals in the system with author information and date/time stamps as well as a description of what action was taken. Detailed change summaries exist to account for what changes were made per action.
- Responsibility of those providing electronic signature – Policies exist that define responsibilities of those providing electronic signatures and which deter signature falsification.
- Electronic signature management - Electronic signatures are unique (included are a unique identification code and password which are checked periodically) and are linked to their respective electronic records. Identities of individuals are verified upon assignment of electronic signatures. Electronic signatures have the same legally binding equivalent of traditional handwritten signatures. Letter sent to FDA time-stamped 11-03-16