INDIANA UNIVERSITY
PURDUE UNIVERSITY
INDIANAPOLIS

RESEARCH AND
SPONSORED PROGRAMS

To Whom It May Concern:

Effective January 17, 2006, the IUPUI IRBs instituted an electronic submission process whereby investigators were required to submit all documents to the IRB via the IRB website (http://www.iupui.edu/%7Eresgrad/spon/irb_submit.htm). This new process resulted in two important changes in IRB submissions: 1) all documents submitted to the IRB must be submitted electronically, and 2) principal investigator signatures on IRB documents were no longer required. Because of these changes, both investigators and sponsors have raised questions. This letter serves to provide further explanation regarding the new submission process.

Do all documents need to be submitted electronically? What if my sponsor won't provide me with an electronic version of the document?

Yes. This new process requires that the IRB receive all submission documents electronically. Please note that when this process was initiated, the Research Compliance Administration (RCA) office offered to accept hard copies of documents and to scan those documents such that they would be available electronically. We understood that not everyone had electronic copies of protocols, clinical investigator brochures, etc., or scanners in order to provide such electronic copies to the IRB. However, because the electronic process will continue, the RCA office can no longer accept paper documents effective May 1, 2006. We are encouraging people to work with their sponsors and departments to obtain electronic documents and/or a scanner.

How do I provide an original signature on the IRB submission documents?

With this new process, the IRB no longer requires original principal investigator (PI) signatures on the IRB documents. Because of the university's strict user and e-mail account authentication procedures, it was felt that adequate validation was provided to ensure that the documents were submitted directly from the principal investigator and/or on his/her behalf and that by doing so was sufficient proof that he/she was aware of his/her responsibilities as a PI. To demonstrate complete documentation within the IRB study files, RCA prints the e-mailed documents along with the e-mail in which the documents were submitted and stamps the IRB document with the date the submission was sent. We understand that some sponsors require the PI to provide an original signature on IRB documents. In these cases, we recommend the PI sign the IRB document, scan it, and submit it to the IRB electronically.

Why does the RCA office sometimes communicate revisions to me prior to the IRB meetings and other times do not?

Along with the electronic submission requirement, an electronic review and approval pilot program was also initiated with one of our IRBs (IRB-04). Submission to this IRB not only requires an electronic submission, but studies also receive an electronic review and approval. This means that all communication from the RCA office and IRB is done electronically. Studies submitted to IRB-04 receive a pre-review from a member of the RCA staff. Revisions and requested clarifications are "tracked" within the documents and the PI is given an opportunity to have these revisions and clarifications resolved prior to the IRB meeting. Communication of IRB deliberations is e-mailed and final approvals are ultimately sent via e-mail. The goal of this program is to provide a more efficient and timely review and approval for IRB submissions. We plan to implement this same electronic process with the other IRB committees in the near future.

For questions, comments, or concerns, please send an e-mail to resrisk@iupui.edu.

Sincerely,

Research Compliance Administration
Enclosures

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This e-mail communication was sent to all principal investigators and study contacts on December 22, 2005:

Dear IUPUI Research Community:

In the past year, RCA has been working diligently to develop an electronic research administration (ERA) system for the submission and management of protocols to be reviewed by the IUPUI/Clarian Institutional Review Boards (IRBs). Due to time limitations and budgetary constraints, the implementation of the ERA system has been delayed. The RCA office recognizes the value of moving to an electronic IRB system and was eagerly anticipating the release of the ERA system. However, until an ERA system can be implemented, an interim solution has been developed that will take an important step towards meeting the campus community's need for streamlined electronic IRB processes and RCA is excited to announce this new process.

Effective January 17, 2006, all items to be submitted to the IRB for review (including new studies, amendments, continuing reviews, general information, exempt/expedited applications, etc.) must be submitted electronically to the RCA office. To submit an item for IRB review, investigators and/or their staff will be required to submit that information via the IRB's website. (Refer to http://www.iupui.edu/~resgrad/spon/irb_submit.htm for soon-to-be-posted specific information about this procedure.) RCA staff will then process the item for review by making any paper copies of the documents that are necessary and routing the information to the IRB for review per usual practice.

In addition, RCA will be piloting a program with IRB-04 for its February meeting that will allow investigators an opportunity to address and resolve not only minor issues identified by the RCA staff in its pre-review of submissions before the meeting, but also to address potential scientific or study design concerns identified by an IRB member in a concurrent pre-review of those submissions. In other words, when a new full-board study has been received by the January 31, 2006 deadline for the February 2006 IRB-04 meeting, both RCA staff and an IRB member will conduct a pre-review of the study and promptly communicate with the investigator about those issues to allow for revisions and additional comment to be submitted before the IRB meeting. Moreover, responses generated from the IRB-04 review will be returned to the principal investigator electronically.

It is anticipated that by allowing for this intermediary communication process, some studies may be able to be granted "final approval" at the IRB meeting itself because the investigator has already addressed any minor issues previously identified and has had an opportunity to provide the IRB with additional information about or to resolve more substantive concerns. In this way, for at least some studies, it is expected that the IRB approval process timeline will be shortened and that the investigator will be able to initiate his/her new study more quickly.

Based upon this pilot program, RCA will be evaluating the new electronic process in an ongoing fashion to develop the best interim procedure that meets both the IRBs' and campus community's needs. RCA will endeavor to continue to provide good customer service and communication about this evolving electronic process, but we ask for your patience as we work through this process, as well. As always, RCA welcomes comments about your experiences with our office and the IRB.

Sincerely,
Research Compliance Administration, IUPUI

Also see the February edition of the R&SP Communicator at: http://www.iupui.edu/%7Erspcommu/2006/nl-february-06.htm.