IRB Newsletter

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Thomas Jefferson University
Division of Human Subjects Protection
1015 Chestnut St., Suite 1100
Philadelphia, PA 19107

http://www.jefferson.edu/human_research/irb/
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OHR Leadership: Many of you know that Bruce Smith will be retiring as of July 1, 2015 and that Dr. Walter Kraft will become Director of the OHR dividing his time equally between meeting OHR responsibilities and his other activities that include clinical research, practice, and teaching. Both Kyle Conner and Patrick Herbison will be taking on added responsibilities in order to keep the office running smoothly.

From Dr. Smith,: "I can't express how much I have appreciated working with the OHR staff, the many dedicated IRB members, and Jefferson employees at every level who have shown such tremendous support for our Human Research Protection Program. The dedication of every Jeffersonian involved in the protection of the rights and welfare of research subjects and the cooperation of investigators, coordinators and key personnel with meeting the (sometimes) onerous requirements of federal and local regulations has made my job a pleasure and contributed greatly to making Jefferson's HRPP one of the most highly regarded programs in the country. Dr. Walter Kraft will become Director of OHR as of July 1, 2015. I am confident that under his leadership Jefferson's HRPP will continue to improve and excel."

Dr. Smith will be continuing on in a limited role after July 1 in assisting with preparation of the re-accreditation application for AAHRPP (Association for the Accreditation of Human Research Protection Programs)

Vice Chair of Board 153: Dr. Kraft is stepping-down as Vice Chair of the Weinstein Board as of May 1, 2015. We are very pleased to announce that he will be replaced by Craig Hooper, PhD. Craig is Professor in the Department of Cancer Biology, an accomplished scientist, and a long-term member of the IRB. He is well-versed in human subjects protection regulations and we are very pleased that he has accepted this position.

OHR Move: By the time you read this newsletter, the OHR will be re-located to Jefferson Alumni Hall, Mezzanine, (West) Suite M-34, formerly the home of Office of Technology Transfer. The move occurred with a minimum in disruption in service due in large measure to the hard work and diligence of the OHR staff, Tina Tsaganos from Jefferson Facilities Design and Construction and Phil Berg in the Office of the Vice President for Research, Facilities and Finance Planning.

Forms and Policies: Subject initials and date on every page of consent forms is no longer required. If sponsor requires, please make sure you add it to the footer before submitting for initial review.

Essential Documentation Binder: As a reminder, a model study binder has been developed that will help you organize the essential documentation for your next human research study. The binder contains sections for each type of documentation that you are required to maintain for each study. It also contains examples of forms that should be maintained for each study (e.g. screening and enrollment log, delegation of responsibility log). By using this binder, you can help ensure that you will maintain all the essential documentation needed for your studies. The binder may not be helpful for sponsored studies where binders and forms are already provided, but it may be helpful for departmentally funded studies where a study binder is not made available. If you are interested, and will be running a departmentally funded study in the future, please contact Patrick Herbison (patrick.herbison@jefferson.edu) to arrange a meeting to have the binder delivered along with brief instructions for its use. Again, a special thanks to Beth Duddy, RN, BSN and Pranoti Pradhan for helping with the development of this valuable resource.

Compliance Corner: Since the last Newsletter, we have had two non-compliance issues. One concerned conduct of research without an IRB-approved consent form. A clinical consent was used and there was confusion regarding the use of blood specimens sent for analysis in a CLIA-certified laboratory and the use of these specimens for research. All issues were resolved with the PI and a corrective action is in place. No subject came to harm in any way. The lesson to be gained is to insure you keep clinical and research efforts separate and well documented and never perform research without IRB approval. If you are not sure, call the DHSP to discuss!

One other non-compliance hearing was convened related to theft of de-identified subject data from a locked vehicle. Again no subject was harmed and the de-identification of information was appropriate. If you must take research-related material off campus ensure it is safely stowed in the trunk of your vehicle or keep it on your person.

This and past issues of the IRB Newsletter can be accessed from the DHSP web page. The link is in the IRB Reference Documents Box.

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Editors: J. Bruce Smith, MD, CIP, Walter Kraft, MD, and Kyle Conner, MA, CIP
Assistant Editor: Kathleen Avender