IRB Newsletter

Beneficence • Respect for Persons • Justice

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http://www.jefferson.edu/human_research/irb/
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New and Revised Policies: Please note that DHSP Policies GA-118 and G-602 have been updated and new versions are now posted in the DHSP Policy and Procedure Manual. G-118, "Policy on Protocol Inclusion/Exclusion Waivers," now specifies that requests for waivers regarding an Investigator Initiated-Treatment Trial (IITT) should be made with the OHR-31 (new form on our website) with the justification and risk assessment completed in sufficient detail to allow an informed decision by the IRB reviewer. Waiver requests for sponsored studies should also include the document from the sponsor approving the waiver.

DHSP Policy G-602 now specifies that an Emergency Department visit in which a research subject stays for more than 24 hours should be reported as an SAE (related or not to the study article). In addition, deaths that occur 30 days after study treatment has ended do not require individual reporting unless it is believed that the death is study-related. Deaths of subjects occurring 30 days after treatment has ended or who are on long-term follow-up, should be reported in aggregate at the time of continuing review in OHR-9, Section A, #15 and Section C, #2.

IRB Turn-around Time: While the primary objective of the IRB is to protect research participants from harm, we also strive to provide excellent service to the Jefferson community. One aspect that is always on the minds of investigators and study coordinators is IRB turn-around time. We are currently doing an extensive internal audit that will provide information about turn-around times, and we will make the results of that audit available in a forthcoming IRB Newsletter. Meanwhile, there are ways that you as investigators and research coordinators can help the IRB improve turn-around time. Some suggestions follow:

- Insure that your CITI training is up-to-date.
- Insure that your COI disclosures are current.

- Carefully follow directions on the OHR-2, answer the questions, and ensure lay language.
- Have the PI or co-investigators actually read and edit the OHR-2 and consent form (spell check is NOT ENOUGH).
- Use Jefferson template language in all consent forms. If sponsor accepts it, turnaround time is shortened. If our language is not acceptable, involve the Director or Associate Director of DHSP as soon as possible in negotiations with the sponsor. Including us on the e-mail correspondence is often very helpful as we can weigh in on the language.
- Make certain that copies of submissions include all necessary pages – we receive several submissions every year with pages missing. These submissions must be NOT APPROVED because they are incomplete.
- Submit to IRB and ORA (for contract and budget negotiations) simultaneously.*

*It is recognized that some investigators do not want to do IRB paperwork until after contract negotiations are completed. However, waiting can cause unacceptable delays especially in studies with a competitive enrollment strategy. According to the ORA, it is unusual for a Confidential Disclosure Agreement (CDA) to be signed and not have a contract negotiated. About 75-80% of signed CDAs result in a formal agreement.

Clinical Research Coordinator Course: We will be offering the Clinical Research Coordinator Course every 4 months. Please contact Kathleen Avender (3-9820) in advance if you have personnel in your department who would like to attend or should be attending this course.

Helpful Hints: ALWAYS USE CURRENT FORMS FROM THE DHSP WEBSITE FOR YOUR SUBMISSIONS!! Forms change, often in important ways. An example is the new NIH rules on COI disclosure limits. We have recently had several submissions for which forms dating back to 2007 were used and that's just not acceptable!

Compliance Corner: There are three mechanisms by which the IRB deals with issues of compliance; 1) A formal investigation process as defined in TJU Policy #110.15, "Institutional Review Board Review of Noncompliance Issues," 2) A meeting with the investigator to discuss a corrective action plan (CAP) for compliance findings that do not rise to the level of noncompliance as defined in 110.15, and 3) A written CAP submitted to the IRB for review by the Director, Associate Director, or any of the IRB chairs or vice chairs.

TJU Policy 110.15 deals with serious or continuing noncompliance. The policy defines noncompliance as a violation of any federal, state or local regulation or any university or IRB policy that governs human research. "Serious" noncompliance is noncompliance that may affect subject safety, increase risks to subjects, affect the integrity of data, violate the rights and welfare of subjects, or affect a subject's willingness to participate in a research study. "Continuing" noncompliance means a pattern of noncompliance that indicates a lack of understanding about the regulations or ethical requirements that may affect the rights and welfare of participants. Pattern and frequency of noncompliance are assessed by the number of incidents occurring during the course of a protocol, and whether the same noncompliant action was repeated or many different noncompliance events occurred.

Since Patrick Herbison joined the DHSP staff as Quality Improvement Coordinator last July, he has completed 29 QI audits. Only 4 audits have resulted in meetings with the investigator to discuss corrective action plans and just one required a formal non-compliance investigation as required by TJU Policy 110.15.

The following are the most common audit findings:

- Not maintaining organized files and IRB correspondence.
- Consent form documentation issues (missing printed name, signature, date, subject initial/date on each page).
- Most current, IRB approved consent form not used to consent subject.
- Not documenting that eligibility criteria were met.
- SAEs/UAPs not reported in required timeframes.
- PHI not stored in a secure manner.

Since the last Newsletter there have been two noncompliance events judged to be serious and that were investigated according to TJU Policy 110.15.

- A study in which signed consent forms were destroyed (Note: it is a good idea to file consent forms in perpetuity or at least until 3 years after close of study.
- A study with multiple protocol violations, some of which could have posed increased risk to participants, a PI allegedly (?) ignoring requests for dose reduction (allowed by protocol) by a subject, and a physician writing study orders who was not listed as a Co-I on the study.

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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