

IRB Newsletter

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http://www.jefferson.edu/human_research/irb/
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NEW AND AMENDED POLICIES AND FORMS

Universal Consent form Template and Guidance Document: In the new consent form template (OHR-8 Universal), we have removed nearly all instructions and created a guidance document (OHR-8I) that provides instructions for completing the consent template. We have attempted to simplify and shorten the Universal Consent Template by asking that, when appropriate, preparers consolidate trial procedures and study article risks as much as possible. The OHR-8I guidelines, are in line with the recent consent form template guidelines set forth by the National Cancer Institute, and we urge you to inform your sponsors of this when creating your consent form. These guidelines also allow for a very brief synopsis of the study visits (like how many there will be and how often) and only the most serious of the potential risks of the study drug or device to be stated in the consent form, with the provision that study visit details and a complete listing of risks be included as an appendix to the consent form. Please see the OHR-8I Guidance for details regarding other aspects of the consent form template.

Remember, less is sometimes more. A shorter consent that is fully read and understood by a potential research participant is better than a longer, complicated, and incompletely reviewed document.

The OHR-8I is self-explanatory. Near the beginning of the OHR-8I, we quote an FDA Guidance document entitled "A Guide to Informed Consent - Information Sheet Guidance for Institutional Review Boards and Clinical Investigators" This Guideline explicitly states the following:

“Sample or draft consent documents may be developed by a sponsor or cooperative study group. However, the IRB of record is the final authority on the content of the consent documents that is presented to the prospective study subjects.”

This language can be helpful to you when interacting with the sponsor about use of Jefferson OHR-8 template language.

We have also eliminated at least some of the “you/your child” language throughout the consent form template.

The Surrogate Consent form (OHR-8B) is now designed to replace the last page (signature page) of the OHR-8. It should not be attached to the submission as a separate document. It should be included as an integral part of the consent form with the original submission or with an amendment as appropriate. Note that in some studies, patients and surrogate are consented. If that is the case, use the OHR-8B as an addendum as in the past.

Continuing Review and Amendments: The OHR-9 has been revised to include a question at the top of p.1 regarding whether the continuing review is being submitted simultaneously with an amendment. While the continuing review and the amendment are considered as separate transactions, please submit them together in paper. In the Portal, at the “Create an IRB Application” bullet, select the “Continuing Review/Amendment” transaction type from the drop down menu. This will allow you to upload the documents for the continuing review and the amendment together. (Note that OHR-12B & OHR-12C will continue to be handled by paper submission only, and therefore should not be bundled with continuing reviews.)

There is also a “Final Report/Amendment” option in the Portal.

Policy GA 120: Policy and Procedure for Reporting and Reviewing Unanticipated Problems Involving Risks to Subjects or Others: The following excerpts from the policy are meant to highlight important changes. Please also review the entire policy in order to be current with federal and local regulations.

Section 2, Definitions:

- Serious Adverse Event (SAE) is judged to be grade 3, 4 or 5. and is defined (21 CFR 314.80) as any serious adverse drug experience that results in any of the following:
 - Death
 - Life threatening adverse drug experience
 - Inpatient hospitalization or prolongation of existing hospitalization
 - A persistent or significant disability /incapacity
 - Congenital anomaly/birth defect

CFR 314.80 continues as follows:

“Important medical events that may not result in death, be life-threatening, or require hospitalization may be considered a serious adverse drug experience when, based upon appropriate medical judgment, they may jeopardize the patient or subject and may require medical or surgical intervention to prevent one of the outcomes listed in this definition. Examples of such medical events include allergic bronchospasm requiring intensive treatment in an emergency room or at home, blood dyscrasias or convulsions that do not result in inpatient hospitalization, or the development of drug dependency or drug abuse.”

An Emergency Department (ED) visit should be reported as an AE or SAE if the PI determines the ED visit was possibly, probably, or definitely related to the study article or a study procedure. All ED visits that last more than 24 hours should be considered hospital admissions and reported as SAEs whether or not related to study article or procedure.

Section 6, Reporting:

On-site SAEs (Grades 3-5) that are unexpected and deemed to be at least possibly or definitely related to the study article should be reported within two (2) working days of knowledge of the event, except that death should be reported within one (1) working day. Unrelated SAEs should be reported within 5 working days. SAEs occurring in drug studies must be reported whether or not considered drug-related and whether or not the event is listed in the Protocol, Investigator Brochure or consent form.

There is often medical judgment involved regarding whether an event represents a SAE. Severe anemia may not require reporting as a SAE in study subjects with diagnoses often associated with severe anemia. For example, severe anemia would not be reported in a subject with thalassemia, unless in the medical judgment of the PI or Co-I, the severe anemia represents a process separate from the disease. An example of the latter in the case of a subject with thalassemia may be severe anemia from a gastrointestinal hemorrhage with attribution to the study drug or concomitant medication.

The occurrence of events that are clearly part of a disease process should be noted in the protocol and, if possible, specific SAE reporting requirements established.

AEs and SAEs are reportable from the time the patient consents to 30 days after the last study intervention, or as specified in the protocol (usually based on drug half-life). SAEs that occur in device studies should be reported to the IRB if they are not identified in the device brochure, protocol, or consent form.

On-site AEs: Grade 1 AEs should not be reported to the IRB. Grade 2 AEs should NOT be reported at the time of continuing review or final report unless, in the opinion of the investigator, they represent events that exceed expected frequency or in some other way are judged to be unexpected and possibly associated with increased risk. If protocol or consent require changes, an amendment should be submitted with the continuing review. Grade 2 AEs that fit these criteria may also be submitted to the IRB as they occur. Grades 1 and 2 AEs should be kept in the study file if required by study sponsor.

Guidance G 619: Use of Radioactive Materials and Radiation Sources in Clinical Research: All human research studies involving use of radioactive materials or radiation-emitting devices require review and approvals by the Radiation Safety Committee (RSC) and the IRB. Typically, RSC review is done prior to or simultaneously with submission to the IRB. An RSC decision to approve the protocol is required before final approval is given by the IRB.

Researchers using radioactive drugs or radiation-emitting devices with human subjects should review this Guidance along with the OHR-32, "Human Subjects Research-Related Exposure to X-rays or Radioactive Materials" used for submitting the project to the Radiation Safety Committee.

The Guidance provides definitions, federal and local requirements for approval, and dosage limit guidelines.

The form OHR-32 asks for detailed information about the study.

Notification of Researchers and Study Personnel of Policy changes: When new policies are posted or existing policies are amended, investigators, key personnel and administrators will be notified via the appropriate list-serve.

The Electronic IRB Submission Process: As you should be aware by now, we have a bipartite electronic IRB submission process, whereby you create your study record and enter the transaction into JeffTrial and then upload the electronic documents to the Portal. We are now in the electronic era and there's no going back! However, sometimes going forward is not so easy either. Right now, we are in a temporary transitional stage as we move towards a totally paperless system. So, in addition to uploading documents to the Portal, we are requesting a nominal amount of paper copies, which by the way, are greatly reduced from our pre-electronic days (35 copies for full review of new submissions, continuing reviews, and amendments down to 6; 4 copies for expedited review down to 1.)

Why is this, you might ask? With some changes, we need to take smaller steps, and one of those is, for the moment, continuing to provide paper copies to the assigned reviewers on the IRB. Remember, we're not all former Atari champions! Once we all become used to the new electronic systems, we can begin to wean everyone off of receiving hard copy.

We also are aware that the introduction of the bipartite electronic submission process has created some confusion among the research community. Be assured that we are working on a cogent set of instructions that will walk you through both parts of the process. We plan to have this on the IRB website once the institution-wide web unification process is completed and we can again modify our website, sometime in April.

In the meantime, training documents pertaining to the use of JeffTrial are available under the JeffTrial link on the IRB homepage. Also, if you need to be registered as a JeffTrial user and you are involved in non-oncology research, please view the training video (also accessible under the JeffTrial link) and email kyle.conner@jefferson.edu once completed. (This training video replaces the in-person training sessions.) Oncology researchers should contact Sylvia O'Neill in the Kimmel Clinical Research Management Office for oncology-specific JeffTrial training.

Tips when using the Portal:

1. To use the portal, go to the DHSP (IRB) home page and click "Enter the Portal" in the navigation bar on the left. Use your campus key and password to log on.
2. At the "Create an IRB Application" option, select the type of application you are making from the drop-down menu. (If you are returning to an application that you were working on, click on the "Manage IRB Applications" option.)
3. Have your JeffTrial protocol # (from the Main>Details tab of your JeffTrial record), as you will need to enter this so that the Portal knows which study you are working with.
4. When possible, upload the IRB forms as word documents. This makes it easy for IRB members to submit suggested edits to the IRB secretary.
5. Documents with signatures should be uploaded as PDFs.

Emailing IRB approval materials: In our continuing efforts to make our services more user friendly, the Division of Human Subjects Protection will now be e-mailing ALL IRB approval letters and stamped documents to the contact person identified on the IRB transaction paperwork. (This is the person who previously would have been e-mailed to pick up the materials from our office.)

Materials for a given transaction will be e-mailed as **one PDF*** with the IRB approval letter appearing as the first document. (If you would like to have these documents saved as separate PDFs, you will need to print and scan them separately.) The emailed PDF will constitute an “original” copy for auditing purposes, and is scanned in color.

(*A joint amendment/continuing review submission is considered as two separate transactions, and so in this instance, you would be e-mailed 2 PDFs, 1 for each transaction.)

This change in operating procedure will take effect on **Monday, March 17** (St. Paddy’s Day!). As of this date, in-person pick up for these materials **will no longer be necessary**, and paper copies **will not be provided as a matter of course**. (Special situations will be addressed on a case by case basis.) However, approval materials issued prior to March 17 will be available in hard copy for pickup.

Going forward, please ensure that the appropriate person and email address is provided in the contact information section of the appropriate IRB form (OHR-1, OHR-4, OHR-15, etc.), so that this person receives the IRB approval and stamped materials promptly.

Please remember to pick up approval letters done prior to 3/17/2014 in the DHSP office.

Compliance Corner: A recurrent non-compliance issue (several times in the past three years by different investigators) is sending research data to collaborating entities or data analysis centers that is either not appropriately de-identified or includes information that is not approved by the IRB. These instances can result in serious HIPAA breaches, and be costly to TJU/TJUH to remedy. If you are sending images or other research related information to IRB-approved entities, please be sure that all identifying information is completely removed or obscured before sending. If PHI embedded in a report is not removable by existing technology, please be sure this is noted in the HIPAA section of the consent. If your protocol specifies sending research subject information from the TJUH clinical labs, JeffChart, Hospital or JUP records, please, when possible, use the OHR-30 form (on the DHSP website) and submit your completed request to TJUH Information Systems (Mary Ferro, at 3-6406 or Mary.Ferro@jeffersonhospital.org).

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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