

# IRB Newsletter

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[http://www.jefferson.edu/university/human\\_research.html](http://www.jefferson.edu/university/human_research.html)

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## Final Common Rule published

The U.S. Department of Health and Human Services published [online](#) the final update to the regulations around human research. These are called the “Common Rule” since they apply across 16 federal departments and were last modified in 2009. However, this is the most extensive revision to the Common Rule since its inception in 1991. FDA regulations regarding clinical trials will be updated in the near future that will take into account these new regulations. Overall, we are quite pleased with how the final regulations look. These regulations move toward the goal of reducing oversight and regulatory requirements on minimal risk research. A number of the draft proposals we and others had concerns about have been dropped or modified. Here are a few highlights of most interest to the Jefferson community:

- **Biospecimens and stored identifiable data:** Researchers will have the option of relying on broad consent obtained for future research as an alternative to seeking IRB approval to waive the consent requirement. There will be no change to the current policy which does not require consent for studies involving non-identified stored data or biospecimens.
- **Reducing need for annual reviews:** For minimal risk studies or studies in long term survivor follow up, there may not be a need for yearly IRB review.
- **New categories of exempt studies:** This is expected to reduce administrative burden around minimal risk studies.
- **Public posting of consents of federally funded clinical trials**
- **Goal of simplifying consent:** There is general consensus that consents currently are too long and are created as legal documents. Many specifics on what this will look like are lacking, but example will be the requirement for a short summary at the front of each consent.
- **Greater use of single IRBs for multiple-site studies**

These do not go into effect until January 18, 2018. We will be spending the next few months examining details of the entire document, discussing approaches with colleagues at other institutions and thought leaders, and examining our current policies. Our plan is to transmit clearly any changes in our procedures that impact the Jefferson research community.

### **Avoiding non-approval**

New protocols, amendments and continuing reviews which come to the full board can be voted on in two ways: 1) approve with prescriptive changes or 2) not approve. Submissions on the agenda are sometimes tabled if there are missing forms or inadequate information is provided by the investigator. The dual mandate of protecting human subjects and facilitating research requires a clear and complete submission to allow reviewers to assess a protocol.

The most common reasons for non-approval of continuing review include:

- Omission of critical information and leaving questions unanswered.
- Lack of internal consistency of reports. For example, the numbers in the demographic table in the OHR-9 need to add up correctly.
- Failure to explain an enrollment rate below initially proposed.
- Hurried preparation and lack of proofreading.
- Failure to report the disposition of subjects for deaths, withdraws, completions.
- Failure to provide monitoring or DSMB reports.

To ensure that your submission is reviewed in a timely manner, please take these steps above and make sure that your submission is clear, consistent and complete.

### **“One IRB” Initiative**

As Jefferson moves forward with the process of integration with the new members of our Jefferson family –Abington and Aria, and soon, Philadelphia University and Kennedy—OHR has been busy forging new relationships with our IRB colleagues at these institutions and discussing the most efficient routes for integration of IRB operations. Our goal is to eliminate duplication of effort and allow for one IRB to cover research conducted anywhere in the Jefferson Health entity.

At this point, we are happy to announce that we can offer the “One IRB” option to any research conducted at Jefferson, Methodist, Abington, Aria, and in the Jefferson Cancer Network.

- For research to be conducted at Jefferson and/or Methodist, submit to the Jefferson IRB.
- For research to be conducted at Aria, submit to the Jefferson IRB.
- For research to be conducted at Abington, submit to the Abington IRB. The Abington IRB contact is Aisha Parker, [aisha.parker@jefferson.edu](mailto:aisha.parker@jefferson.edu), 215-481-7467. To subsequently add any Jefferson sites to the study, you would submit an amendment to Abington IRB.
- For research to be conducted at both Jefferson and Abington, contact the Jefferson Clinical Research Institute (JCRI). The JCRI works closely with the IRB to support research studies across the Jefferson Enterprise. These studies will be submitted to the Jefferson IRB.

JCRI is particularly interested in facilitating trials that can be conducted at more than one site but can be managed as a single site point of contact for sponsors. Investigator-initiated studies should be developed and operationalized on a case by case basis with JCRI guidance. Assistance with managing central IRB submissions is also available. Finally, budget and contract negotiations, account establishment and post award management will be handled within the JCRI Business Operations.

For more information contact:

**Clinical Operations**

Suzanne Adams 215-955-8848

Thomas Salerno 215-503-8954

**Business Operations**

Laura Vinci 215-503-4883

Ronald Polizzi 215-503-2127

We also offer use of the following commercial IRBs for phase 1, 2, 3 and 4, commercially funded, multi-center research studies:

- Western IRB (WIRB)
- Copernicus IRB\*
- New England IRB\*
- Midlands IRB\*
- Aspire IRB\*
- Quorum Review IRB
- Schulman Associates IRB
- Any other commercial IRB that has AAHRPP accreditation

(\*These IRBs are in the Western-Copernicus Group (WCG) network. Submission to these IRBs should be made through WIRB. Please contact OHR for more information.)

For information on how to request use of a commercial IRB, please refer to:

[http://www.jefferson.edu/university/human\\_research/using-a-central-irb.html](http://www.jefferson.edu/university/human_research/using-a-central-irb.html)

Most cooperative group oncology studies are reviewed by the NCI Central IRB (CIRB). Please contact Josh Schoppe for more information about the CIRB process, 215-955-0448,

[Joshua.Schoppe@jefferson.edu](mailto:Joshua.Schoppe@jefferson.edu)

Following the final mergers with Philadelphia University and Kennedy, we will be working on bringing their IRBs into the One IRB initiative, and will provide further information at that time.

**Compliance Corner - Consent Signatories**

After the informed consent discussion with the subject, who signs the consent form when the subject is physically unable to? Who signs the consent forms when you are using the short form process? And who signs when both the subject and the investigator speak Albanian? The Office of Human Research (OHR) receives great questions like these about the signatory requirements for all types of consenting scenarios. Guidance is now available on the OHR website to help you determine who needs to sign the consent forms in the most commonly encountered situations. The document is called the [Consent Signatories Guidance](#) and is located on the OHR website in the [IRB Reference Documents](#) section. To double-check the signatory requirements for any consent scenario you encounter, please use this guidance as a reference. If you need additional clarification, or have comments or suggestions for the guidance document, please contact [patrick.herbison@jefferson.edu](mailto:patrick.herbison@jefferson.edu) . Please note that you do not need a password to open these links, just click cancel/ok if necessary.

This and past issues of the IRB Newsletter can be accessed from the OHR web page.  
The link is in the [IRB Reference Documents Box](#).

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