

# IRB Update

OCTOBER 2011

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## Training Opportunities Offered by the NJH IRB

Deb Clayton, MA, IRB Regulatory Affairs Monitor

New to Human Subjects' Research? New to Human Subjects' Research at National Jewish Health? Need a Refresher?

Human subjects research guidance and regulations are an ever-changing landscape. The National Jewish Health IRB is expected to be aware of the changes and make sure they are captured in the studies we oversee. It's hard to keep up with all of the changes sometimes. And those forms! Applications, change updates, continuing review reports, waivers, HIPAA authorizations...where to begin?

We understand that applying and reporting are only part of the many tasks facing researchers and the research staff. We fully realize that it is a complex process to navigate, sometimes even to the seasoned veteran. To those new to research it can be downright daunting.

The NJH IRB staff has prepared more than a dozen modules specific to applying, amending and reporting for human subjects' research studies. The modules cover everything from preparing the initial submission to literature searches and how to use the library at no charge. We are also preparing a high-level overview module: a one to two hour overview of the entire submission, renewal and completion process. That training module will be available for small group training in early November.

We will also be presenting the overview module 4 times per year, institution-wide, beginning in January 2012.

There are several ways that you can tap into these training opportunities. IRB staff can bring training to your unit and present it in a group setting. This can be topical or, once available, will include the overview module. We also offer one hour one-on-one training, by appointment. You can schedule this on-site training by calling Deb Clayton at ext. 1393 or emailing [claytond@njhealth.org](mailto:claytond@njhealth.org). Training can be schedule Tuesday-Thursday (with the exception of IRB meeting dates) between 10:00 am – noon and 1:30-3:30 pm. One-on-one appointments are scheduled on a first come, first served basis. The institution-wide training opportunities will be announced once the schedule is finalized.

## CONTACT US

National Jewish Health  
Institutional Review Board  
1400 Jackson Street  
Room M211  
Denver, CO 80206-2761

Phone: 303.398.1477  
Fax: 303.270.2292

[nationaljewishIRB@njhealth.org](mailto:nationaljewishIRB@njhealth.org)

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## Training Opportunities (continued from first page)

A list of available training modules will be available on the NJH IRB website in the coming days. Keep checking back as we add topics and establish firm dates and locations for IRB training. We are committed to making your human subjects research experience at National Jewish Health as pain-free as possible.

For more information, contact:

Deb Clayton  
claytond@njhealth.org  
303-398-1393



## Letter of Assurance Available

Wendy Charles, MS, CIP, CCRP, Director, Research Regulatory Affairs

Commercial sponsors have occasionally requested information about the National Jewish Health IRB membership and organization.

To better assist researchers with sponsor requests for this information, I wrote a memo that describes our Federalwide Assurance, IRB Registration, methods of managing IRB member conflict of interest, and the degree to which the IRB adheres to the International Conference on Harmonization (ICH) Guidelines.

The memo is available on the IRB website Home page:

<http://www.nationaljewish.org/research/support/compliance/irb/> or by clicking this link:  
<http://www.nationaljewish.org/pdf/IRB%20Letter%20of%20Assurance.pdf>.

(Be advised that the memo will be updated again prior to the renewal of our Federalwide Assurance, March 10, 2012.)

For more information, contact:

Wendy Charles  
charlesw@njhealth.org  
303-398-1855



## Documents Stamped at Initial Review

Wendy Charles

In the past, when new studies received initial approval, the IRB had only provided copies of the documents that were approved or required a formal acknowledgement. The IRB has since realized that researchers could benefit from receiving recognition of all documents that were submitted.

The IRB now stamps and returns copies of all submitted documents, including conflict of interest declarations. We hope this effort assists researchers with document management and

improves communication about what had been received / approved.

Please let us know if you believe a document has been omitted or has not been stamped.

For more information, contact:

Wendy Charles  
charlesw@njhealth.org  
303-398-1855

## Proposed Changes to the Common Rule

Wendy Charles. Portions edited from the HHS news release, July 22, 2011

The U.S. Department of Health and Human Services announced that the federal government is considering ways of enhancing the human subjects research protection regulations often referred to as the Common Rule.

The current regulations governing human subjects research were developed years ago when research was predominantly conducted at universities, colleges, and medical institutions, and each study generally took place at only a single site. Expansion into many new scientific disciplines and venues and an increase in multi-site studies have highlighted ambiguities in the current rules.

The proposed changes are an effort to update the regulatory framework to keep up with the needs of researchers and research subjects.

The government is seeking the public's input on the proposed changes, found in an Advance Notice of Proposed Rulemaking (ANPRM):

<http://www.gpo.gov/fdsys/pkg/FR-2011-07-26/html/2011-18792.htm>.

Changes to regulations occur in phases involving extensive deliberation and public comment. The proposed modifications to the Common Rule are only in the first phase of comment. When HHS has made refinements based on feedback, the proposal will be subject to a second period of public comment.

The ANPRM comment period closes Wednesday, October 26, 2011.



## Please remember...

Wendy Charles

### Photocopies

The purpose of requiring at least one complete photocopy of submitted materials is to ensure that IRB staff have a copy to stamp and return to the researcher.

While the IRB encourages researchers to provide double-sided copies, the IRB has noted that some researchers make a double-sided photocopy of an entire stack of documents at once. When doing so, portions of documents are often photocopied on to the back sides of other documents. The IRB is then unable to use these photocopies for stamping.

When making double-sided photocopies, researchers are asked to photocopy only one document at a time so that all documents remain discrete for stamping.

### CITI Training

October 1, 2011 marked the three year anniversary of National Jewish Health's affiliation with the CITI program for online human subjects protection training.

Because human subjects protection education expires after three years, many researchers will soon be required to renew their human subjects protection education.

A study cannot be approved/renewed if current (within three years) human subjects protection education is not on file for all members of the research team.

For more information, contact:  
The IRB Office  
[nationaljewishirb@njhealth.org](mailto:nationaljewishirb@njhealth.org)  
303-398-1477