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IRB Update

JULY 2011

THIS ISSUE

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July Edition Summary

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

There is no theme for the July edition of the IRB Newsletter, but we hope that you'll benefit from our compilation of explanations and reminders.

Also, the IRB usually issues revisions to forms annually on July 1, but this year the forms are still being reviewed by the IRB to include a change we think you'll be pleased to see. More to come…

Continuing Review – When is it REALLY Expedited?

Deb Clayton, MA, IRB Regulatory Affairs Monitor

In this position I learn something new every day. Recently I realized that Principal Investigators at National Jewish Health are not DIRECTLY notified when a study that had previously been reviewed by the full committee is changed to expedited review status.

It is important for researchers to know that the renewal period or the type of review cannot be determined by the investigator. The approval of the change requires the review and a determination of the full committee for changes to risk, review interval, and type of review (full committee versus expedited). Checking the box "Data Analysis Only" or indicating that the only activity left is long term follow up does not change the review process for that continuing review. But checking those boxes provides a signal to the Primary Reviewer (and full committee) that the study has changed since the last approval.

What I realized is that the PI is not formally notified that the study status, review interval, or change to the level of risk has been modified by the IRB. Starting immediately, on the approval letter that the PI receives to renew the study will include text in the box with the expiration date, any changes in risk or review made by the IRB about that study (when applicable). I wondered why we were sometimes receiving 20 copies of the continuing review submission for a study that was expedited. Now I get it…we weren't adequately informing the site of the determination of the IRB that effect how future reports should be submitted. I think this will help!

Continued on next page…

Continuing Review (Continued)

And what about all those trees (read: copies)? Since NJH does not yet have an electronic submission system, we will continue to require paper submissions to meet our review requirements as put forth in the regulations. There are some things you can do to reduce the amount of paper. Member copies can be double sided (only the Original and Primary reviewer copies need to be single sides). If you are in doubt about how many copies you need to submit, call the IRB and ask. I have thrown stacks of documents in the recycling when 20 were submitted and we only needed 2.

I hope this is helpful. Any suggestions concerning paper saving are welcome. Just remember that at this time we cannot accept reports via email.

Drop me an email or give me a call. I like hearing from you!

For more information, contact:
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Reminders for Submitting IGRs for Human Subjects Research

Emily Hoch, BA, Administrative Assistant
Wendy Charles, MS, CIP, CCRP, Director Research Regulatory Affairs

When Internal Grant Review forms (IGR) are submitted for IRB signatures on human subjects research, we offer the following guidance:

1. Please allow adequate time for our review. We request a 2-day turnaround time. Be aware that it takes an IRB reviewer approximately ½ hour to process the documentation, and reviewers may not be able to accommodate unexpected requests within a shorter time frame.
2. Provide contact information for the person submitting the IGR and the name of the contract person in Research Administration so we can direct questions to the right people.
3. Provide the due date so we can plan accordingly.
4. Provide supporting documentation, such as the grant proposal or progress report. We review this documentation against the IRB-approved protocol to ensure congruence.
5. If a human subjects protocol has not yet been submitted, please list 'pending' and we will sign off. No supporting documentation is required.
6. Please provide any other special instructions that may help us understand the circumstances of the submission.

We are happy to deliver signed documents back to you or to Research Administration—just let us know.

For more information, contact:
Emily Hoch
hoche@njhealth.org
303-398-1011

Reminders for IRB Submission Success

Michele Gaffigan, BA, IRB Coordinator

Conflict of Interest and Science Misconduct forms are required for each Investigator for each study. Please remember to have each Investigator (Principal and Co-investigators) fill out a COI form to submit with any initial submissions or personnel changes. The COI forms can be found on the Institutional Review Board website under Initial Submissions.

There are two CITI courses required for every researcher participating in human subjects research: Human Subjects Protection and the HIPS (HIPAA training) course. The HIPS course has only been required for a little over a year and does not expire. Occasionally there is some confusion due to the fact that the Human Subjects Protection course has a HIPAA module, however, this is not the "HIPAA training" that is being referred to.

Directions for the CITI course can be found on the Institutional Review Board website, or you can call me at x1477 or Emily Hoch at x 1011.

For more information, contact:
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303-398-1477

New COMIRB Liaison to NJH IRB

Wendy Charles

I'm pleased to announce that Ita Leitner is the new COMIRB liaison to the National Jewish Health IRB. She is available to help you accomplish a number of issues that arise when research is conducted simultaneously at UCD and NJH.

When National Jewish Health serves as the IRB of record, Ita will assist with the Facilitated Review process conducted by COMIRB.

Likewise, she is particularly helpful when COMIRB serves as the IRB of record for research that will have a portion performed at NJH. She can provide guidance on how to get NJH employees added to the COMIRB protocol and to ensure all documentation is in place before submitting for Facilitated Review to the NJH IRB.

Ita can be reached at:
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Free Books available in the IRB Office!

Wendy Charles

The IRB has an assortment of research resource books that we'd like to share with the National Jewish Health research community.

The titles are:
The CRC's Guide to Coordinating Clinical Research (2004)
Informed Consent: A Guide to the Risks and Benefits of Volunteering for Clinical Trials (2003)
Protecting Study Volunteers in Research: A Manual for Investigative Sites (1999)
A Guide to Patient Recruitment and Retention (2004)
Responsible Conduct of Research (2003)

There are only a limited number of copies available. Please come soon for best selection.

For more information, contact:
The IRB office
NationaljewishIRB@njhealth.org
303-398-1477

Get to Know the Research Regulatory Affairs Staff: Vacation Plans

Deb Clayton: July 8-18, Deb will be at the Jersey shore with her entire family to celebrate her Dad's 80th birthday.

Diana Pruitt: In May, Diana and her husband spent 6 "glorious" days cycling the coast of California. The trip was from Monterey to Santa Barbara. The rest of her summer will be spent cycling with friends and family throughout the beautiful state of Colorado.

Emily Hoch: Emily has been active taking several dance classes and spending free time with friends. She plans on mountain biking in the San Juan Mountains and will head up North to spend time with family and friends at their summer cabin on Leech Lake, MN.

Michele Gaffigan: After a very hectic beginning of summer, she hopes to spend the remainder of her summer relaxing and spending time with family. She will soon be going to her hometown in Michigan for a short visit, where she plans on spending as much time as possible enjoying the lake.

Sherri Gabbert: Sherri is looking forward to a 10-day trip to Scotland at the end of July, her first real vacation in many years. Though not currently fond of scotch whiskey or golf, she expects to become agreeably tolerant of both while motoring from St. Andrews to Loch Ness to Isle of Skye.

Wendy Charles: Wendy and her family will be traveling to San Francisco in mid-July. Her daughter will be attending a week-long (soccer) goal-keeping camp at a university in San Francisco, so the rest of the family will come along and tour the California coastline. With three kids in soccer, Wendy says that the rest of the summer involves nothing but soccer practice, camps, and tournaments.