

JULY/AUGUST 2010

THIS ISSUE

IRB Introduces Newsletter	1
Institutional HIPAA Training Requirement	1
IRB Forms Were Revised	2
Informed Consent Templates are Back	3
Continuing Review News	3
On the Compliance Radar	4
Please Remember	4

IRB Introduces Newsletter

The National Jewish Health IRB is pleased to introduce a newsletter to serve as an additional communication tool. We will use this newsletter to inform investigators and research staff about changes and updates on human subject research regulations, NJH policy, IRB guidance, or updates to forms.

The IRB newsletter will be published every other month. Archived copies will be available on the IRB website.

Institutional HIPAA Training Requirement

Steve Leibold, NJH Privacy Officer

Although the Health Insurance Portability and Accountability Act (HIPAA) has been effective since 2003, we are still experiencing a number of unauthorized disclosures of protected health information (PHI) while conducting research. National Jewish Health does require a basic HIPAA course in NetLearning but it does not adequately explain the precautions researchers must take when accessing, using, or disclosing PHI.

Consistent with the University of Colorado, Denver, National Jewish Health now requires all research investigators, study staff, IRB staff, and IRB Committee Members to complete research-specific HIPAA training. This training requirement took effect July 1, 2010 for all initial review, continuing review, and personnel changes submitted or approved after that date.

We have reciprocity with COMIRB for the CITI HIPAA course, so if you have taken HIPAA training through COMIRB, you will not be required to take this course again.

We believe the additional education will lessen the likelihood of future PHI disclosures and protect both you and NJH.

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Institutional HIPAA Training Requirement (Cont)

Protection of individuals' protected health information and fully informing them of what their PHI is being used for is not only the ethical thing to do, it's the law!

Please review the *HIPAA Educational Requirements for Research Personnel* policy at: <http://spyderweb.njrc.org:88/documents/index.php?docid=1911&mode=view>.

The instructions for accessing the NJH CITI HIPAA course are provided on the IRB website.

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IRB Forms Were Revised

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

On July 1, 2010, the IRB revised all submission forms.

Description of Changes

The majority of changes clarify existing questions, but some forms have new elements. The changes are summarized below:

New Protocol Application and Application for Research on Data and/or Specimens:

- The submission checklist is now the first page of the application form.
- There are clearer questions about inclusion/exclusion, pregnancy and follow-up, and the informed consent process.
- There are more questions about access to medical records and guidance about waivers of informed consent and authorization.

Exempt Application:

- The Exempt application form now appears very similar to the Application for Research on Data and/or Specimens. There are more questions about the conduct of research and access to subjects.
- The application form now includes several follow-up questions to help investigators verify that a particular Exempt category is appropriate.
- As always, studies requesting Exempt Category 4 should complete the Application for Research on Data and/or Specimens.

Amendment Forms:

- Amendment forms request billing information. The IRB bills for review of amendments as described in the IRB Fee Schedule. (There is no charge for processing personnel changes or amendments for exempt studies.)

New Form: NJH Clinical Trials Listing:

- This form promotes inclusion of the study onto the NJH clinical trials listing website. NJH's goal is to eventually post all studies on the website.
- Investigators are no longer allowed to post their own listings on the NJH website. The IRB must review and approve listings. The form provides instructions for submitting listings to the webmaster.
- Requests for Listing may be reviewed at initial review or as an advertising amendment.

How to access forms

Forms are available on the IRB website. We encourage researchers to download forms from the IRB website each time a form is needed to make sure they are using the most current version.

When to start using the revised forms

If a researcher has already started to fill in an obsolete form, we will accept the old forms for a few weeks. However, we ask researchers to start using the new forms as soon as possible and to make the transition to the new forms by **September 1, 2010** for all submissions.

Informed Consent Templates are Back

Wendy Charles

The NJH IRB developed consent form templates to help investigators communicate study details more effectively to subjects. Based on feedback from investigators, we are pleased to offer more options.

Combined consent and authorization forms

Consistent with COMIRB, National Jewish Health is offering investigators the option to include HIPAA Authorization language into the consent form. When using this option, a separate authorization form is not needed.

We are also offering a consent form template that does not include authorization language. Investigators would then need to use a separate HIPAA authorization form.

More guidance

The consent and consent/authorization templates provide more instructions on how to customize the forms for their particular studies. Please start using the new templates.

More flexibility

Templates are a guide but they need not be followed verbatim. Investigators should modify consent form language to ensure that study descriptions remain accurate for their studies. The only sections that cannot be modified are the research injury language, HIPAA authorization, and signature section.

To review the informed consent templates, visit the IRB website, *Informed Consent* section.



Continuing Review News

Deb Clayton, M.A. IRB Monitor.

Welcome to my column. I am Deb Clayton, the Regulatory Affairs Monitor for the NJH IRB. My primary responsibility is review of on-going human subjects research, focused specifically on Continuing Review and also most changes and updates submitted for IRB review.

I am also responsible for coordinating the NJH IRB education series that formally begins in September 2010 and is held monthly for 12 months.

The IRB recently revised many of our forms and reports. You will notice when using the new continuing review report forms that we have made some changes. They represent our efforts to provide more direction for the user. The changes in the forms are both in response to your questions and to clarify what the IRB is looking for in the updated sections. Our IRB staff is certain that when we repeatedly stipulate the same thing it is probably because the question was unclear or the

guidance was insufficient. I always welcome feedback from users to provide more comprehensive reporting tools to our users. Please drop me an email or give me a call with any problems or suggestions when "test-driving" the new report.

When you use the new form for the first time you'll notice two significant changes from the last version. We have added a checklist as page 1 of the form, replacing the optional checklist offered with previous versions and have matched the demographics section of the report with the categories used in the 2010 US Census. We have also enhanced the instructions in several sections within the form.

I am always glad to meet 1:1, with a unit, by phone or by email. Please don't hesitate to contact me anytime and we can set a time to meet.

On the Compliance Radar

Sherri Gabbert, Ph.D. Research Compliance Quality Assurance Analyst

This might be news to some of you, but NJH has an official Research Compliance Review Program, complete with a compliance analyst: me! I'm in my 6th year at NJH, having started in Pediatrics clinical research as regulatory specialist. The majority of my work within Research Regulatory Affairs focuses on routine compliance reviews of approved research at NJH and assisting the RRA director, Wendy Charles, in providing education about regulatory requirements, and developing and implementing compliance policies and advice papers to investigators to help them understand their regulatory obligations. On occasion, I am asked by the NJH IRB to investigate a particular study if there is confusion about how the study is being conducted.

My position is immediately under the RRA director and not within IRB, so I'm not much help to you

with issues that IRB-specific. On the other hand, I am here to help you with information about responsible conduct of research, non-human subject research and distinctions between exempt and expedited research eligibility. I can also offer some advice about HIPAA obligations, if Steve or Wendy isn't readily available. Finally, I will use this column to provide you with compliance facts, trends, changes, and applications to help you keep up with government's ever-moving compliance target.

For more information, contact:
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Please Remember ...

The IRB requires the correct number of photocopies for submissions.

- For personnel changes, responses to stipulations, and minor amendments eligible for expedited review, provide the signed originals plus one photocopy of all submitted documents.
- If an amendment requires full committee review, provide the signed originals plus 17 copies of all documents.

If unsure about the review designation, contact the IRB office for guidance. We plan to provide detailed guidance about review designations soon.

The IRB will no longer be making photocopies as a courtesy. Any submission provided with the incorrect number of copies will be returned to the IRB Contact listed on the form.