

IRB Update

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IRB Newsletter will be Published Monthly

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

When the IRB issued the first newsletter in July, we had intended to provide a bi-monthly publication. However, based on your feedback and our realization that there is nearly unlimited potential content, we decided to publish a newsletter each month.

There is now a "Newsletter" tab on the IRB website for access to the current and archived issues. The direct link is: <http://www.nationaljewish.org/research/support/compliance/irb/newsletter.aspx>.

IRB Educational Training Sessions

Deb Clayton, MA, IRB Regulatory Affairs Monitor

In September 2010, the Department of Research Regulatory Affairs (RRA) launched a one year education program focused on advanced topics in research. Modeled after the RRA program offered in 2007-2008, we are offering contact hours necessary for some credentialing at no charge to participation through the Department of Nursing at NJH.

The level of the curriculum assumes that participants have some research background, however all who are interested are welcome to attend.

The presenters are subject matter experts on whatever topic is being discussed, selected to enhance the quality and depth of each session. Some of the upcoming topics include: Investigator Responsibilities, Good Clinical Practice, Research Determinations, and a variety of topics addressing a myriad of regulatory compliance subjects. The sessions are usually the first Tuesday of the month from 10:30 – 11:30 AM in Heitler Hall. Flyers are posted around the institution prior to the session. If you would like to receive updates and notifications, just send me your request via email and I'll add you to the electronic distribution list.

Looking forward to see many of you at future sessions!

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Subjects' Perspectives on Informed Consent for Future Research Uses

Wendy Charles

Subjects are routinely asked to provide informed consent for their data or specimens to be banked for future research, but how do these subjects feel about re-consent for specific future uses?

Research on informed consent perspectives

In an recently-released article titled, *Glad you Asked: Participants' Opinions of Re-Consent for dbGaP Data Submission*, the Group Health Research Institute and the University of Washington described research subjects' opinions about the 2008 NIH policy for genome-wide association studies (GWAS) funded by the NIH to be submitted to its database of genotypes and phenotypes (dbGaP).

To gather subject opinions, adults participating in a longitudinal aging study were re-consented for the prospect of submitting their data to dbGaP. Of 1340 persons contacted, 1159 (86%) agreed. When surveyed about how important it was to be asked for their permission before data was submitted, 90% said it was important to be asked (69% responded it was *very important* and 21% indicated it was *somewhat important*).

Subjects were further asked about alternatives to informed consent for submission to dbGaP.

- 40% responded that an opt-out process was unacceptable.
- 67% stated that it was unacceptable to notify them after data was already submitted.
- 70% said it was unacceptable for data to be submitted to dbGaP without any form of explicit permission or notification.

In a similar study titled *Public Perspectives on Informed Consent for Biobanking*, a survey of 4659 subjects demonstrated overwhelming preference to be contacted for informed consent before each research project where their banked data or specimens would be used. Further, 81% of respondents stated that it was necessary to be contacted for informed consent in order to feel respected and involved.

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What do these results mean for future research?

It is encouraging that subjects generally agree to allow their data or specimens to be banked and studied for future research. However, we should be cognizant of how important it is to them to be asked for permission before their data/specimens are studied or shared.

When it is impractical to ask permission prior to each future use of their banked data or specimens, researchers can still implement practices that demonstrate respect for the individuals represented in the databases/repositories.

1. In the consent form section on banking, provide prospective subjects choices for how their data or specimens will be used. Sometimes called a "menu consent form," subjects may select among narrow to broad research areas. Be advised that subjects feel more comfortable making selections when provided with detailed information about potential research directions.
2. When asking subjects to provide specimens for future banking, ask subjects to *opt-in* to each option, rather than *opt-out* or be *required* to have their specimens banked for future research.
3. Enhance the informed consent discussion regarding banking. Promote an open discussion about future use of specimens and ensure that subjects clearly understand the choices and conditions for participation.
4. Create reliable methods, such as spreadsheets or databases, to track subject choices for future uses. This is particularly relevant when subjects may select among multiple choices for future research areas. Subject preferences must be honored when using the banked data or specimens in future research.

Sources

Ludman, E.J., Fullerton, S.M., Spangler, L., et al. (2010). Glad you asked: Participants' opinions of re-consent for dbGaP data submission. *Journal of Empirical Research on Human Research Ethics*, 5(3), 9-16.

Murphy, J., Scott, J., Kaufman, D., et al. (2009). Public Perspectives on Informed Consent for Biobanking. *American Journal of Public Health*, 99(12): 2128-2134.

On the Compliance Radar

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

During my site visits, I'm finding that investigators and their research staff are struggling with HIPAA requirements, especially in the context of data and/or specimens. Here are a few questions – with answers – from conversations I've had with you:

Q: Why do I have HIPAA obligations if I'm working on tissues from deceased individuals?

A: HIPAA doesn't end at the point of an individual's death, like informed consent does. You may have HIPAA obligations if your research involves deceased subjects based on whether direct or indirect identifiers are associated with the cadaver or its organ constituents.

Q: Sometimes I send specimens to collaborators; sometimes I receive specimens from them. I can't figure out who does what about HIPAA in these cases.

A: If you are sending specimens/data to another institution, you are responsible for complying with any NJH HIPAA requirements associated with the specimens/data. If you are receiving specimens/data from another institution, you should expect HIPAA compliance paperwork, if any, from that institution. Sample/Data Sharing Agreements are not HIPAA documents, but are the NIH convention for protecting privacy and reducing loss of confidentiality risk in the context of shared identified or coded datasets.

Q: I am collecting the same medical information for every study I'm doing. Why can't one signed HIP-004 cover all my studies?

A: That would be convenient for subject and investigator alike, but we weren't given that choice. HIPAA authorizations must be study-specific. You can't execute a single HIPAA authorization for multiple studies. Think of it in terms of intent. Your

intention when you review subject medical records and use their clinical data will probably be slightly different for each study, so just as each study must have its own consent to describe the intention of the research, so a study-unique HIPAA authorization supports a slightly different emphasis to the chart review. You can combine HIPAA authorization and the study-specific consent, which would minimize the number of documents for both you and the subject and builds HIPAA authorization into the consent process.

Q: Why can't I pull data from own patients' charts? I look at these charts all the time.

A: True, but your patient expects you to look at them for their clinical care, not for your research interests. You can't collect and record PHI from your own patients' charts for research purposes without IRB approval or determination. You can review your patients' charts for summary or aggregation of clinical characteristics, but without recording direct or indirect identifiers.

Q: I just need to compile anonymous data about certain clinical parameters. Do I need IRB permission to do that?

A: You're in luck. What you want to do is already a "permitted use" under HIPAA and doesn't require IRB oversight. You do need to submit HIP-018, Request to Access PHI Preparatory to Research to Steve Leibold, Privacy Officer, to document the purpose of your access to identifiable information for institutional reporting requirements.

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Please Remember ...

As a courtesy, the IRB had looked up research education performed through a COMIRB affiliation by checking the COMIRB website. Unfortunately, the COMIRB website no longer offers this search

feature. If relying on education performed through COMIRB's affiliation with the CITI program, researchers are now asked to print or copy documentation for submission to the NJH IRB.

HIPAA Training Implications at Continuing Review

Deb Clayton

On July 1, 2010, successful completion of the CITI HIPAA certification became National Jewish Health institutional policy for individuals engaged in research. The requirement and related policy were issued by Ron Berge, Chief Compliance Officer and is administered by Steve Leibold, Privacy Officer.

The NJH IRB, acting as the Privacy Board, has been tasked by the institution to enforce the HIPAA certification requirement. Enforcement occurs most frequently at Continuing Review. Studies submitted for renewal approval will not receive approval until all stipulations are addressed and proof (if stipulated) of completion of HIPAA certification are received by the NJH IRB. This will be in the cases for any person listed on the protocol as study staff for whom the IRB does not have on file with the IRB, a HIPAA certification training record. It is

important to note that this requirement may include study staff listed who are appointed at other institutions but are listed on the protocol.

The IRB encourages PIs to make sure the members of their study staffs have completed this institutional requirement. We also strongly discourage removing a member of the study staff only because he or she has not completed HIPAA training. Unlike human subject protection certification, which has to be renewed every 3 years, HIPAA certification only needs to be completed and proof of training provided to the NJH IRB once.

Feel free to contact me or Michele Gaffigan, Education Coordinator in the NJH IRB Office, with questions or concerns.

