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Newsletter Focus on HIPAA

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

There is so much involvement of the Health Insurance Portability and Accountability Act (HIPAA) in research that the Institutional Review Board (IRB) is devoting an entire newsletter to help researchers understand HIPAA obligations. In this newsletter, the terms “HIPAA” and “Privacy Rule” are used interchangeably.

Q&A About the National Jewish Health HIPAA Training Requirement

Greg Downey, MD, FRCP(C), Executive Vice President for Academic Affairs and Institutional Official

Ron Berge, Executive Vice President, Chief Operating Officer, and Chief Compliance Officer

Steve Leibold, MSHA, Corporate Compliance Manager and Privacy Officer

In recent months there have been a number of inquiries directed to Steve Leibold and the IRB staff about additional HIPAA training via the CITI Program. When we initiated the additional HIPAA training modules effective July 1, we did it because many research studies were conducted without complying with the HIPAA regulations. Because of the non-compliance we felt compelled to do what we could to make sure we as an organization do a better job in maintaining compliance with HIPAA. We decided the least disruptive method to do this was to require a few extra hours of HIPAA training for all research staff.

Researchers have asked several good questions about the training requirements. The questions posed have primarily fallen into three main areas- researchers exempted from the requirement, National Jewish vs. IRB requirement, and temporary removal of investigators from the study.

Q: Why do I have to perform HIPAA training if I don't access PHI?

A: Several individuals listed on human research protocols requested exemptions from HIPAA training based on the argument that they did not access or use protected health information (PHI). Although this is often true, we have several reasons for not allowing exemptions. First, those individuals who might not look at identifiable information have a right to see it as a listed member of the research staff. Second, some research staff change roles, and those who previously did not need to see PHI initially may need to see and access it at a later time. Third, tracking exceptions would be overly burdensome to the IRB staff.

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Institutional HIPAA Training Requirement (Cont)

Q: Why is the IRB involved in HIPAA compliance?

A: Although the IRB oversees research at National Jewish Health, it's actually the National Jewish Health Privacy Officer's responsibility to make sure HIPAA requirements are followed. Although the IRB staff is not responsible for requiring the additional educational requirement they have been very helpful in monitoring and reminding researchers that they must take the additional HIPAA modules before new studies and continuing review studies are approved. When an organization such as National Jewish discovers that its workforce is not complying with HIPAA regulations, it's required to take action to correct non-compliance. The requirement to add a few hours of additional training for research staff is believed to be the least burdensome to both the institution and the research staff in order to improve HIPAA compliance.

Q: If researchers haven't completed their HIPAA training, can they simply be removed from the study until it's complete?

A: The IRB staff has noticed several occasions in which researchers have been removed from the

study staff only to be re-added to the study after a continuing review deadline has been reached and they have completed their additional HIPAA training. We strongly recommend that you refrain from this practice and complete the HIPAA training by the continuing review due date. Making these personnel changes creates additional work for both you and the IRB staff and may be a red flag in an audit. The training requirement was announced on April 1, 2010 and has been in place since July 1, 2010. Researchers have had ample time to complete the requirement.

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.

For more information, contact:

Steve Leibold
leibold@njhealth.org
303-398-1466

Requesting National Jewish Health Patient Medical Information for an IRB-Approved Study

Kathy Flesher, BS, Health Care Management, Records Health Information Technology

There are times when a researcher will need to request information from a NJH patient's chart who is in a research study. Researchers may also request patient information in the form of a report. Information Services can create these reports.

The above scenarios require one of the following for the request:

- Verification that signed HIPAA authorization forms were received for personal health information
- Verification of Waiver of Authorization
- Preparatory to Research approval document is required in order to access medical information.

The following is the correct process for requesting this information:

- Complete the *Request for Medical Information Form* (HIM 001). This can be retrieved from [Forms Management website on the Spyderweb](#).
- Send the type of verification above with the HIM 001 Form.
- Please send (or hand-deliver) this request to the Manager of Health Information Management for National Jewish Health, L07 B or fax to my attention at #303-398-1987.

For more information, contact:

Kathy Flesher
flesherk@njhealth.org
303-398-1985
303-398-1987 (fax)

HIPAA Definitions

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

When enacted in 2003, the Privacy Rule introduced many unique regulatory terms. National Jewish Health introduced additional terms for its HIPAA forms. Below is a short tutorial on terms and forms researchers should be familiar with.

Protected Health Information (PHI): Individually identifiable health information, created or maintained by a covered entity (such as National Jewish Health), relating to the past, present, or future physical or mental health or condition of an individual. The following details are considered PHI:

1. Names.
2. All geographic subdivisions smaller than a state, including street address, city, county, precinct, ZIP Code.
3. All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older.
4. Telephone numbers.
5. Facsimile numbers.
6. Electronic mail addresses.
7. Social security numbers.
8. Medical record numbers.
9. Health plan beneficiary numbers.
10. Account numbers.
11. Certificate/license numbers.
12. Vehicle identifiers and serial numbers, including license plate numbers.
13. Device identifiers and serial numbers.
14. Web universal resource locators (URLs).
15. Internet protocol (IP) address numbers.
16. Biometric identifiers, including fingerprints and voiceprints.
17. Full-face photographic images and any comparable images.
18. Any other unique identifying number, characteristic, or code, unless otherwise permitted by the Privacy Rule for re-identification.

De-identified: Refers to a data set that doesn't contain any of the 18 identifiers listed above. Note that many researchers mistakenly use the term "de-identified" when they simply mean that data are not readily identifiable.

Limited Data Set: Refers to a data set that excludes the identifiers listed above except for dates, town/city, state, and ZIP Code. If a researcher

enters into a Data Use Agreement, he or she can conduct research with this limited data without obtaining either an individual's HIPAA Authorization or a Waiver of Authorization.

Data Use Agreement: An agreement between a covered entity (e.g., National Jewish Health) and the intended recipient (an investigator) for research involving a Limited Data Set. The agreement establishes ways in which the limited data set may be used and how it will be protected.

HIPAA Authorization (HIP 004): An authorization is an individual's written permission to allow a covered entity to use or disclose specified PHI for a particular purpose. It is different from an informed consent form because the consent form asks the subject to be in a research study, while an authorization asks the subject for permission to use or disclose health information. National Jewish Health created a fill-in-the-blank template that includes all required elements of an authorization.

Authorization to be Contacted for Research Recruitment (HIP 001): This NJH template, nicknamed a "Recruitment Authorization" form includes all elements of a HIPAA authorization but is customized for recruitment. If an individual signs this form, a researcher can contact him/her for participation in research even if there is not an existing treatment relationship.

Waiver of Authorization (HIP 020): Using this form, a researcher can request that the IRB--acting as the Privacy Board--waive or alter the Privacy Rule's requirement for obtaining an individual's written permission for use or disclosure of PHI. Note that the researcher must meet strict criteria to demonstrate that it is not practicable to obtain individuals' authorization.

All forms referenced on this page are available on the IRB website or the Forms Management list.

For more information about the Privacy Rule, the NIH created a very informative website: <http://privacyruleandresearch.nih.gov/>.

HIPAA and Continuing Review

Deb Clayton, M.A. IRB Monitor

We have been monitoring studies for HIPAA documentation and HIPAA training for about 6 weeks now. I think the biggest impact of this effort on continuing review for the clinical site is that the study cannot be renewed until everyone listed as study staff for the protocol has completed HIPAA training. This is the most frequent HIPAA finding I have stipulated since July 1, 2010.

If any staff member is using HIPAA training from a source other than CITI, the Principal Investigator will be asked to verify training for the individual, and to include a paper copy of the training record with the response to stipulations. NJH IRB staff will enter the training information into the NJH IRB database for future reference. If you have questions about your HIPAA training status, please contact Michele Gaffigan @ ext. 1477.

Another requirement at continuing review is that a redacted copy of the last, signed HIPAA Authorization (HIP 004) or Recruitment Authorization (HIP 001) signed by a subject during the review period be included in the submission. If no subject signed a HIPAA form during the review

period, do not submit a redacted copy. This will happen when there is no enrollment for a specific review period.

The last HIPAA requirement at continuing review is that the submission must include a clean copy of the current HIP 004/HIP 001 forms for review and acknowledgement. It is important to be sure that if you have revised the protocol and/or informed consent form that the clean copy of the HIPAA form you submit also reflects any applicable changes.

And for all your effort, you will receive with your approval letter (as long as the study is still enrolling) a clean, stamped “acknowledged” HIPAA form with a handwritten, acknowledgement date, but no expiration date. You should always use the most recently IRB acknowledged form when obtaining HIPAA Authorization from study subjects.

For more information, contact:

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

Please Remember ...

- The IRB updated all submission forms on July 1, 2010. The forms were updated to clarify questions (with the hope of reducing stipulations based on misunderstandings) and to ask more questions about privacy and confidentiality practices.

The IRB asks all researchers to download and complete the latest form versions from the IRB website.

- HIPAA forms are also updated periodically so please check the [Forms List](#) intranet site for current versions.
- The new informed consent templates contain the option of including pre-approved HIPAA authorization language in the consent form. If

using a combined consent/authorization form, a separate HIPAA authorization form is not required.

Remember that the IRB is offering more options. Researchers retain the choice of keeping consent and authorization forms separate or combining them into one form.

- The National Jewish Health IRB can only track the CITI HIPAA training performed under National Jewish’s course outline. We will accept research-specific HIPAA training performed with affiliation to other institutions, but we ask researchers to provide us with a copy of the completion certificate.