

IRB Update

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Refresher on Data Use Agreements

Steve Leibold, MSHA, Corporate Compliance Manager and Privacy Officer

A Data Use Agreement is an agreement described in the HIPAA regulations that provides a way for covered entities, e.g. National Jewish Health, to share a limited data set with other entities or individuals for research purposes.

What's a limited data set? A limited data set is PHI that excludes all personal identifiers except dates and postal information such as town, city, state and zip code.

The Data Use Agreement contains wording that requires the recipient to:

- Not use or disclose the information other than permitted by the agreement or law.
- Use appropriate safeguards to prevent the use or disclosure of the information and require the recipient to report to the covered entity any uses or disclosures in violation of the agreement of which the recipient becomes aware.
- Hold any agent of the recipient (including subcontractors) to the standards, restrictions, and conditions stated in the data use agreement with respect to the information.
- Not identify the information or contact the individuals.

Because the Data Use Agreement is an agreement between the covered entity, (i.e., National Jewish Health) and the recipient, Data Use Agreements involving NJH must be signed by either the Corporate Compliance Officer (Ron Berge) or the Privacy Officer (Steve Leibold).

A Data Use Agreement is not necessary when sharing PHI with outside researchers who are also investigators on the same study as a National Jewish Health investigator.

If you have questions about when a Data Use Agreement should be used please contact me.

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Refresher on Waivers of Authorization

Wendy Charles, MS, CIP, CCRP, Director, Research Regulatory Affairs
Steve Leibold, MSHA, Corporate Compliance Manager and Privacy Officer

What is a waiver of authorization? Many health research projects and protocols cannot be performed using de-identified health information. Also, it may not be practicable for a researcher to obtain signed authorization from all subjects. Therefore, the Privacy Rule allows for waivers of authorization.

The process and criteria for obtaining a waiver of authorization under the Privacy Rule is similar to the process and criteria for waiving informed consent under Human Subject Protection Regulations. Complete the *IRB Waiver of HIPAA Authorization* application form on the IRB website on the *Initial Submissions page*. When reviewing the completed form, the NJH IRB, acting as the Privacy Board, will verify that:

- The use or disclosure of the PHI involves no more than minimal risk to the privacy of individuals
- The research could not practicably be conducted without the waiver or alteration.
- The research could not practicably be conducted without access to and use of the PHI.

The NJH IRB may approve a waiver or an alteration of the authorization requirement in whole or in part. A complete waiver occurs when the IRB determines that no authorization will be required for a particular research project. A partial waiver of authorization occurs when the IRB can waive authorization for some PHI uses and disclosures for research purposes, such as using or disclosing PHI for telephone recruitment purposes. The IRB may also approve a request that removes some PHI, but not

all, or alters the requirements for an authorization (referred to as an alteration of authorization).

Who does the waiver cover? The waiver covers all members of the research team—even if some of those members work at other institutions.

On the application form, what is the difference between “access,” “use,” and “disclosure?”

Access is “contact” with PHI. For example, it is often necessary to view patient records to identify which charts would be suitable to include in a retrospective chart review study. Access is restricted to “viewing” PHI (not “recording” data) for research purposes. [Note: access to PHI for the purpose of developing a research study may be covered by *HIP-018: Request to Access PHI Preparatory to Research* – a simpler form than a Waiver of Authorization.]

Use involves generating, recording, studying, or analyzing PHI for research.

Disclosure involves sharing PHI with other researchers who are not part of the research team or to other organizations (e.g., commercial sponsors) outside of National Jewish Health.

If I am granted a waiver, how long must I keep the documentation? Documentation of that approval must be retained for 6 years from the date of its creation or the date it was last in effect, whichever is later.

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Update on IRB Education Schedule

Deb Clayton, MA, IRB Regulatory Affairs Monitor

In previous newsletters, the IRB published a schedule of monthly educational events hosted by the IRB.

The schedule is currently being modified so the IRB can include instruction pertinent to an exciting new institutional project.

More details will be provided in upcoming newsletters.

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HIPAA Submission, Review, and Acknowledgement at Continuing Review

Deb Clayton, MA, IRB Regulatory Affairs Monitor

Many PIs have seen stipulated changes to HIPAA forms at Continuing Review and have been asking why we are requiring these changes. Some of the stipulations are related to using outdated versions of HIP-001 (Recruitment Authorization to be Contacted about Research) and HIP-004 (the authorization for the study being reviewed). The current versions of the form can always be found on the IRB website. As with all IRB submissions, we are suggesting that a new form is prepared using the provided templates in the event that they have been revised.

Below is a description of what the IRB looks for in each of the HIPAA Authorization forms.

HIP-001 – Permission to Contact

This is an institutional authorization, most recently revised in January 2010. When reviewing the authorization submitted for acknowledgement at Continuing Review, the IRB monitor checks for the following:

- 1) The current version of HIP-001 is being used.
- 2) The applicable boxes are checked in paragraph 3 of the form
- 3) An expiration date is included OR the “Will not expire box” is checked in paragraph 6.
- 4) The box in the lower left corner, “For NJ Research Staff Use” is populated.

HIP-004 – HIPAA Research Authorization*

This authorization is used for the purposes of the research being conducted under a single HS# (IRB identifier). Depending on the nature of the study there could be more than one authorization required for a single study. For instance, if your protocol has a provision for a repository, the repository will have its own HIP-004. If there is any optional component, such as genetics, that would require another HIP-004.

When reviewing the authorization(s) submitted for acknowledgement at Continuing Review, the IRB monitor checks for the following:

- 1) The current version of the HIP-004 is being used.
- 2) That ALL applicable boxes are checked. We most frequently find errors in the second shaded area in Section 3. It is important to note that the only boxes that should be checked pertain to procedures performed exclusively for research participation. If you are required to submit more than one authorization, each authorization submitted should only include in Section 3 those activities covered by the specific authorization.
- 3) Section 5 is for organizations OUTSIDE of National Jewish Health. Also, unless the FDA has access to the data (this is the case for industry sponsored research, research where there is an IND, or research conducted at the direct request of FDA) the FDA box is NOT checked.
- 4) An expiration date is included OR the “Will not expire box” is checked in paragraph 8.

If a PI decides to convert the Informed Consent to the new form that includes the HIPAA authorization, that document can be submitted at continuing review. If it is submitted, it must be in both tracked changes and clean versions. It is also important to note that if there are separate authorizations necessary as discussed above, the informed consent(s) for the optional sub-study(ies) must also either be revised to include the authorization language OR the additional HIP-004 forms must still be submitted for review and acknowledgement.

*HIP-005 is the Spanish version of the authorization for the study being reviewed (version date 11/2009).

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On the Compliance Radar

Sherri Gabbert, PhD, Clinical Research Quality Assurance Analyst
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So many researchers have said to me: “HIPAA is confusing and doesn’t make sense.” I’m sympathetic. There’s no question that it is awkward to apply or, in some cases, difficult to anticipate HIPAA obligation. Since the Office of Civil Rights won’t let us change it to our liking, I and my colleagues will use the newsletter to remind and update you on the twists and turns of HIPAA compliance.

The topic for this newsletter article is on HIPAA authorization as it applies to future, unspecified use; or, in the typical context, authorization required for provision of samples to an approved repository. Just to emphasize, this is the authorization required to deposit a subject’s specimen into a repository, not the authorization required to access and use the specimen after it is deposited. As you already know, study-specific HIPAA authorization can’t be used as authorization to also store samples in a repository that is separate and distinct from the study. [Study-specific repositories are different animals and I won’t cover them in this column].

A separate HIPAA authorization is required to inform the subject that a specimen provided to a repository is for future, unspecified research. Informed consent for the repository can be included

in the approved, study-specific consent document, along with an opt-in option for the subject, to minimize the number of blood draws. Consent and study-specific HIPAA authorization only are not sufficient to cover the repository for future use.

To summarize: required documents for provision of specimens for a future, unspecified use repository that are drawn at the same time blood is collected for study-specific reasons are 1) informed consent for the study and the repository sample, 2) HIPAA Authorization HIP-004 for study-specific use of the subject’s PHI, and 3) a separate HIPAA Authorization HIP-004 for retention of specimen and associated PHI in the repository.

A short reminder: in order to access and use specimens and/or PHI in an approved repository, the research requiring the specimens/PHI must be reviewed by NJH IRB and a Request for IRB Waiver of HIPAA Authorization must be approved.

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Please Remember ...

Michele Gaffigan, BA, IRB Coordinator
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IRB documentation is time sensitive and it is required that original documents are kept on both ends. Using interoffice mail is not always the best way to assure your documents will arrive safely and timely. It can also cause more work for everyone if we are not able to verify that all your items are complete at the time of submission and no one wants to do more work than needed.

We also do not accept submissions electronically, unless your circumstances have been discussed with the reviewer.

If submitting for full board review, include 17 copies + the original are required, and all other submissions (initial or response to stipulations) will require 1 copy + the original.

Questions? Feel free to contact Michele (x 1477) or Emily (x 1011) in the IRB office. We will help make sure you know what is needed for your submissions.

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