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IRB Update

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THIS ISSUE

Material Transfer Agreements

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The transfer of tangible materials between investigators is an essential aspect of scientific research. Material Transfer Agreements (MTA) are legally binding contracts used to define the terms and conditions for the exchange of materials, and therefore to protect the rights of both the recipient and the provider.

Whether the MTA is incoming (NJH faculty receiving materials) or outgoing (NJH faculty sending out materials), the Technology Transfer Office is in charge of negotiating, reviewing and signing the document.

If you intend to transfer materials to another academic institution, we highly recommend that an MTA be put in place first. This is particularly important if the materials are patient samples.

There are several reasons why MTAs are needed:

- To define what is being transferred
- To control the use of the material by the recipient
- To further limit the distribution of the material by the recipient
- To hold confidential any confidential information transferred with the material
- To not transfer title of the material to the recipient
- To assure the recipient will comply with HIPAA regulations and will report to the provider any breach of Protected Health Information (if health information is being transferred)
- To permit publication of the results obtained from the use of the material
- To establish intellectual property rights of the provider and the recipient in the event an invention is created from the use of the material

If you intend to transfer materials to a for-profit entity, please contact the Technology Transfer Office first. Often, the company requests the materials for its internal research, and a fee-bearing license agreement can be negotiated instead of an MTA. Any revenue produced by these license agreements are shared with the creators of the materials and NJH according to the NJH intellectual property policy.

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Is it Coercion or Undue Influence?

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

Many IRBs note that researchers confuse the terms, “coercion” and “undue influence,” and also may be unfamiliar with the ways these forms of pressure reduce subjects’ perception of voluntary participation in research. We hope that the following definitions and examples clarify these concepts.

Coercion occurs when an overt or implicit threat of harm is presented to an individual to influence decision-making or behavior. Restated simply, it is considered coercion for a researcher to say or imply that something bad may happen (punishment, shame, study failure, etc) if the subject does not act in a particular way.

As examples,

- A coordinator tells a subject that the Investigator would be disappointed if the subject dropped out of the research study.
- An Investigator mails a recruitment letter, informing recipients that he is conducting a very important study and their participation is needed for the study to succeed.
- A subject is told that he or she will not receive payment for any visit unless he or she finishes two more study visits.

Undue influence (also called **undue enticement**), occurs through an offer of an excessive or inappropriate reward in order to achieve a particular outcome. Similar to a bribe, it is considered undue influence for a researcher to say or imply that something very desirable may happen if the subject acts in a particular way. The concern is that an enticing opportunity may influence people to agree to circumstances that they would otherwise find unacceptable.

As examples:

- An Investigator offers a large payment to entice prospective subjects to undergo a high risk procedure for research.
- A professor promises students extra credit if they participate in the research, when there is no other way to obtain extra credit.
- An Investigator tells subjects that the research study offers the best chance for treating the subjects’ disease.

Of course, researchers cannot predict how an individual may perceive an interaction, but we hope that this article raises awareness. From both coercion and undue influence, subjects may perceive pressure to act differently.

For each submission, the IRB will examine the study population, recruitment plans, and payment plans to minimize the likelihood of coercion or undue influence.

The Office for Human Research Protections (OHRP) provides additional guidance on these topics: http://answers.hhs.gov/ohrp/questions/7250

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Research Tips…

IRB Staff

No color copies, please: National Jewish Health has provided new copy machines that provide remarkably clear color photocopies. The IRB office asks researchers not to provide color photocopies of research submissions at this time. 1) It is difficult for IRB staff to distinguish color copies from original signed documents. 2) There is additional (unnecessary) cost to the institution for color.

Reminder: New consent/authorization template: The National Jewish Health IRB created a new consent/authorization template that can allow HIPAA authorization for more than one purpose. Researchers can now “compound” some optional research activities with the main consent form. Be sure to download the most recent version from the Informed Consent page on the IRB website.

Site Monitors' Access to National Jewish Health Medical Records

Wendy Charles

The U.S. Food and Drug Administration permits site monitors access to consent forms and source documents that directly support information entered into case report forms (CRFs). Monitors also need access to medical information that supports participant eligibility and ongoing safety—information typically found in medical records.

While National Jewish Health is required to provide site monitors access to pertinent medical records, some site monitors request access to participants' *complete* medical records. This article provides reasons why our institution may not grant a request to review participants' complete medical records and instructions on how to work with Kathy Flesher in Health Information Management to find a solution.

Honoring the terms of our consent forms:

In the HIPAA authorization sections, both the NJH IRB and COMIRB consent/authorization templates are written to inform participants that various organizations may view information collected about them. When discussing medical records in this section, the consent templates request permission to access "*Portions of your previous and current medical records that are* ***relevant to this study*** *[emphasis added] …*"

Further, each consent/authorization form specifies the type of information that may be seen, used, collected, or disclosed as part of the study. The list of bullet points is customized by the research team (and reviewed by the IRB) to ensure that the nature of access is necessary and appropriate for the study.

Because a consent/authorization form outlines our commitments to research participants, we need to honor the terms of the consent/authorization form. Therefore, it would be inappropriate for a site monitor to examine health information outside the scope listed in the consent/authorization form.

Perceptions of Privacy:

This concept is tied to the principle of what a "reasonable person" would understand about the privacy of his or her study records. As noted above, participants are told that several individuals or organizations will look at their research and/or medical records to verify safety and study compliance. By agreeing to these terms, participants agree to give up *some* privacy to participate in a study. However, there are limits to the degree of privacy participants are willing to relinquish.

Medical records may contain sensitive or stigmatizing information that subjects would not be comfortable sharing. Medical records may contain psychiatric history, diagnoses of sexually-transmitted diseases, details of sensitive conversations between a patient and provider, and may even involve discussions of criminal activity. Participants typically assume that this type of private information is not relevant to participation in their study.

Therefore, if a site monitor reviewed a participant's complete medical record and accessed information that a participant would not believe to be related to the study, this access would likely be perceived as an invasion of privacy.

Fairness to all participants:

Most clinical research studies seek to enroll participants representative of the demographics in the Denver area. Some prospective participants may learn about the study through advertisements, some through community outreach programs, and some participants are referred by their National Jewish Health treatment providers.

A participant who has been a National Jewish Health patient for many years may have extensive medical history available for review, whereas a person who responded to an advertisement might not have any medical records. It seems unfair to treat these groups of participants differently. Our long-standing patients should not be afforded less privacy just because their private medical history is available.

Institutional Compliance with HIPAA Privacy Rule:

As a covered entity, National Jewish Health must comply with all regulatory requirements of the HIPAA Privacy Rule. In 45 CFR 164.502(b), the

Privacy Rule states that "*…a covered entity must make reasonable efforts to limit protected health information to the* ***minimum necessary to accomplish the intended purpose of the use, disclosure, or request*** [emphasis added]."

The "minimum necessary" regulation is intended to reduce the risk of unauthorized disclosures. With consideration of the minimum necessary standard, it would be difficult for a site monitor to argue that a participant's complete medical record is the minimum amount of health information necessary to accomplish the monitoring visit.

What should you do when a site monitor requests full access to the EMR?

Please respond that our institution does not grant full, independent access to National Jewish Health medical records, but our institution has developed other ways of providing pertinent medical records for review.

When a site monitor schedules a visit to National Jewish Health, please contact Kathy Flesher in Health Information Management. Specifically, please send Kathy an email with a list of participants' names, information needed, and date desired.

Kathy can arrange for restricted access to the EMR to make sure the site monitor only looks at specific reports/records. As an alternate option, she can print records about specific individuals.

Conclusion:

In summary, National Jewish Health will provide site monitors with reasonable access to medical records. But our institution has both a legal and ethical responsibility to limit the extent and nature of access to this information.

Source:

This guidance was inspired by an article written by Paul Latimer in the Journal of Clinical Research Best Practices, Vol 9, No. 9. September 2013. Dr. Latimer provided additional excellent reasons why researchers should not allow site monitors access to research subjects' complete medical records. His article is publicly accessible at the JCRBP website: http://www.firstclinical.com/journal/2013/1309_Medical_Records.pdf.

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