



# The New and Improved HIPAA Research Authorization Process

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# ***HIPAA Research Authorization***

- Privacy Rule requires authorization to use and disclose PHI for research.
- Authorization is separate from and in addition to informed consent.
- Authorization is obtained and documented using an authorization form unless waived by the IRB.
- *We aren't going to cover:*
  - *Prep to Research*
  - *Waivers*
  - *Decedents*

# *What has changed?*

Changes to the language of the Privacy Rule regarding compound authorizations



Changes to OCR's interpretation of the Privacy Rule regarding authorization for future research



Changes to the OHSU IRB's consent and authorization templates:

- combined forms
- one signature

***Wait, again?? I thought you just changed the forms to keep consent and authorization separate!?***

Yes, under the old rules, they needed to be separate in certain circumstances. And yes, we changed the requirements less than a year ago. But, on the bright side....



***Trust me, this is excellent news.***

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# ***Change #1: Compound Authorizations***

- **Old rule:** “Conditioned” authorization could not be combined with an “unconditioned” authorization.
- **New rule:** Authorizations for research studies can be combined with any other type of permission for the same research study, as long as it is clear to the subject what is conditioned and what is unconditioned.
- **Exceptions:** *Psychotherapy notes and marketing*

# *“Conditioned?” Huh?*

- This means conditioning treatment or other benefits on the signing of an authorization form. In other words, if you don’t authorize us to use and disclose your PHI in this way, you can’t receive this treatment.
- Generally, HIPAA prohibits this, but there is an exception for research studies that involve research-related treatment. You can exclude someone from a study if they refuse to authorize the use/disclosure of their PHI.

# *Why did conditioned authorizations need to be separate?*

- It's important to be clear when the refusal to sign an authorization could result in not having access to a type of treatment (including investigational treatment).
- Subjects should also understand what they can refuse to authorize while still having access to the treatment. Example – optional repository.



# *Those are valid concerns. Why the change of heart?*

- That's a lot of paper – too many forms hurt, rather than help, subject understanding.
- There are some new safeguards. Forms can be combined as long as:
  - The distinction is clear between what the subject must authorize in order to receive treatment and what is “optional.”
  - Subjects **opt-in** to the optional parts of the study.

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## *Change #2: Future Research*

- **Old OCR interpretation:** Asking subjects to authorize unspecified future research did not meet the requirement to describe “each purpose of the requested use or disclosure.”
- **New OCR interpretation:** Unspecified future research can be considered authorized if the authorization adequately describes the future research purposes “such that it would be reasonable for the individual to expect that his or her protected health information could be used or disclosed for such future research.”
- *Note that the actual language of this rule did not change.*

# *How does this affect my studies?*

- More consistent with Common Rule and FDA concepts of informed consent; must still describe future research in sufficient detail to meet required elements, but not limited to the present study.
- May not need a waiver of authorization for future research if sufficiently described up front.
- Old consent/auth forms are “grandfathered in” if they contain language that adequately describes the future research.

# *Authorization Core Elements and Required Statements*

- Description of PHI (“specific and meaningful”)
- Persons who may use and disclose, and receive PHI
- Purpose(s) of use or disclosure
- Expiration date/event, or lack thereof
- Signature and date, plus description of LAR’s authority if applicable
- Right to revoke in writing and how
- Ability or inability to condition treatment or other benefits on signing the authorization and, if applicable, consequences of not signing
- Potential for redisclosure by recipients

# *Integration of Forms*

| <b>Authorization Elements</b>                    | <b>Location in New Template</b> |
|--|---------------------------------|
| Description of PHI (specific and meaningful)     | Purpose/Procedures              |
| Who can use, disclose, and receive?              | Confidentiality                 |
| Purpose(s) for use or disclosure                 | Confidentiality                 |
| Expiration date/event                            | Confidentiality                 |
| Signature and date                               | Signatures                      |
| Right to revoke                                  | Participation                   |
| Conditioning of treatment/benefits; consequences | Participation/Confidentiality   |
| Potential for redisclosure                       | Confidentiality                 |

# *Requirements for Purpose/Procedures Sections*

- Must describe health information to be collected/created in a **specific and meaningful** way.
- Must clearly differentiate between required and optional components.

# ***Confidentiality Section: DOs and DON'Ts***

**DO** customize language according to instructions and [*bracketed italics*].

**DO** supply additional information where relevant.

**DO** call the IRB if you have questions about the requirements for your study.

**DON'T** modify or remove any required template language.

**DON'T** add duplicative information.

**DON'T** add exculpatory or legalistic language (watch out for industry sponsors).



# *Requirements for Participation*

## *Section*

- Customize according to instructions and [*bracketed italics*]. Pay careful attention if your study has optional components.
- Supply contact information in case subject wants to withdraw authorization.

# *Requirements for Signatures*

- List options in the box if applicable. Note that this includes any options to restrict the use/disclosure of PHI. Delete the box if there are no optional components.
- Subjects must receive a SIGNED copy of the consent/authorization form (HIPAA requirement).
- If an LAR signs, a description of his/her authority to act for the subject must be included.

# *When do I have to start using the new forms?*

- Required for all new studies submitted on or after **May 15**.
- Exceptions: Knight, NCI CIRB, Shriners
- You may use the new forms now!
- You **do not** have to switch to the combined form if you have separate forms already approved, but you may switch (with a mod or CR) if you think it would be helpful.

# FAQs

- What if I've been working with a sponsor on the old template, but my study won't be submitted before May 15?
  - Ask us nicely if you can still use the old template. We'll probably say yes.
- What if I still need a separate HRA form for my study?
  - These cases should be rare, but you can get one by contacting the IRB.

# FAQs

- What if I got authorization for a repository before it was possible to authorize for future unspecified research? Do I still need to get a waiver for my secondary research project?
  - Nope, as long as the consent form discussed the potential future research in sufficient detail.
- What if my study doesn't involve PHI?
  - Use the Non-Clinical template. It contains some sections that you are instructed to include only if the study involves PHI. You can delete these.

# FAQs

- What if I want to obtain authorization to use psychotherapy notes or PHI for marketing purposes?
  - CALL US! You will likely need an additional form , which we will help you draft.
- What if I want to do something crazy, like store drug treatment records in a repository?
  - CALL US!
  - Or, you could...nope, just call us. 4-7887, option 1.



Integrity Week

May 6-10, 2013



# Cultivating Integrity

Breaches happen: protect your  
patients, your research, and you

Tuesday May 7<sup>th</sup>  
9:00 am to 10:30 am  
UHS 8B60

Presenters: Kathryn Schuff, IRB Chair  
John Rasmussen, Chief Information Security Officer

- Tables around campus all week
- Spin-to-win wheel with trivia questions
- Giveaway goodies
- Schedule online
- [www.ohsu.edu/integrity](http://www.ohsu.edu/integrity)

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*Mark your  
calendars!*

**Request for  
Determination**

May 23<sup>rd</sup>

11:30am to 12:30pm

UHS 8B60

Melinda Allie



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