



IRB Newsletter:

Review of HIPAA Process Changes September 2009

NEW ICD template

The ETSU/VA IRB has determined that required HIPAA Authorization language must be embedded in the informed consent document, rather than in a stand-alone document.

Advantages:

1. Research participants will

only have to sign one document. The document will include both the required consent elements and the required HIPAA elements. The revised template clearly states that their signature documents their consent to both the research and

the use/disclosure of their protected health information as outlined.

Please ensure that your informed consent process clearly communicates this to participants.



For Initial Studies

If your study will access or use protected health information, use the Informed Consent Document (ICD) Template with HI-

PAA Authorization incorporated to create your ICD. If your study will not access, use or disclose protected health information,

create your ICD using the the previous template, Informed Consent Document (ICD) for Full or Expedited Review.

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For continuing reviews

As you prepare your Form 107 to submit to the IRB for continuing review, review your documents.

IF you currently have a stand-alone HIPAA Authorization **AND** you are still enrolling participants, do the following:

1. Revise your currently approved ICD to embed the required HIPAA Authorization language (copy and paste the language from your stand-

alone HIPAA into the ICD).

2. Additionally, revise the document to incorporate the new paragraph above the signature line

“In addition, by signing below, you are authorizing the use and disclosure of your protected health information for research purposes as described above.”

3. Complete a modification request noting the changes you made and submit this with your form 107.

IF you are no longer enrolling participants you are not required to make this revision at the time of your continuing review.



Privacy Rule

In general, the Privacy Rule requires an individual to provide his/her signed permission, known as an *Authorization* under section 164.508 of the Privacy Rule, before a covered entity can use or disclose the individual's PHI for

research purposes. Under certain circumstances, however, the Privacy Rule permits a covered entity to use or disclose PHI for research without an individual's Authorization. One way a covered entity can use or disclose PHI

for research without an Authorization is by obtaining proper documentation of a waiver of the Authorization requirement by the IRB, or another type of review body, known as a Privacy Board. The ETSU/VA IRB shall serve as the Privacy Board.

Questions ?

Contact Janine Richardson at 439-6054 or Teresa Doty at 439-6055.

