


[« Back](#)

Save

Exit

Hide/Show Errors

Print

Jump To ▾

[Continue »](#)

Waiver or Alteration of HIPAA Authorization Requirements

Instructions for board members:

- *If you answer "yes," the required criterion is satisfied.*
- *If you answer "no," the required criterion is not satisfied. You may request modifications in the "Specified Concerns" section.*
- *In order to approve the waiver or alteration, the IRB must determine that all of the criteria are satisfied.*

Select the type of review (you may select more than one):

- Waiver of Authorization for One or More Phases/Cohorts of the Research
-
- Waiver of Authorization for Recruitment Only (this also covers the determination for a waiver of consent for recruitment only)
-
- Alteration of Authorization (one or more components of authorization are altered or removed)

Yes No Does the proposed use or disclosure of PHI involve no more than a minimal risk to the privacy of individuals?

[Clear](#)

Yes No Does the investigator provide adequate justification that the research could not be practicably conducted without the waiver or alteration?

[Clear](#)

Yes No Does the investigator provide adequate justification that the research could not be practicably conducted without access to and use of the PHI?

[Clear](#)

Yes No Does the investigator provide an adequate plan to protect the identifiers from improper use and disclosure?

[Clear](#)

Yes No Does the investigator provide an adequate plan to destroy the identifiers at the earliest opportunity consistent with the conduct of research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law?

[Clear](#)

Yes No Does the investigator provide adequate written assurances that the PHI will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of PHI would be permitted by the HIPAA Privacy Rule?

[Clear](#)

Specific Concerns:

If any, explain any concerns you may have and WHY they are of concern. You must be very specific. If you have none, please state "None."

Resolutions to Concerns:

Provide specific resolutions to concerns listed above. Your requested clarifications, suggestions, and revisions must be specific.

Reminder: If you need more information than is in the current application to resolve issues related to the approval criteria, the IRB encourages you to contact the PI before the Board meeting. Your IRB coordinator can contact the PI on your behalf (if you wish to remain anonymous).

DETERMINATION: Is the requirement for obtaining authorization waived or altered?

Yes.

Yes, if the above stipulation is met.

No.

[Clear](#)

« Back

 Save

 Exit

 Hide/Show Errors

 Print

 Jump To ▾

Continue »