

Demystifying Partial Waivers of Consent and Authorization

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Session Overview

The concept of a “partial” waiver of consent or authorization is common in IRB review, despite not appearing in the HHS, FDA, or HIPAA regulations.

Objectives

- Examine the regulatory criteria for waivers and alterations of consent and authorization and learn how they may apply to different portions of a study.
- Explore strategies for collecting information from researchers to facilitate clear and compliant waiver determinations by the IRB.

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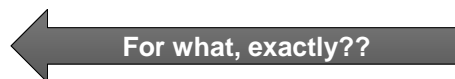
Agenda



Partial vs. Full Waiver

HIPAA Authorization

- ☐ Signed Authorization
- ☐ Partial Waiver
- ☐ Full Waiver



Most commonly refers to a waiver of consent and/or HIPAA authorization for the screening portion of a study, where subjects will sign a full consent and authorization form at the time of enrollment into the full study.

What is a partial waiver?

No regulatory definition!!



However, we do have **regulatory clues** that:

1. A waiver may apply only to a portion of the study, and
2. The waiver criteria are to be evaluated with respect to the portion of the study to which the waiver applies.

The Fine Print...

HIPAA - 45 CFR 164.512(i) Standard: Uses and disclosures for research purposes

(1) Permitted uses and disclosures. A covered entity may use or disclose protected health information for research, regardless of the source of funding of the research, provided that...

(i) Board approval of a waiver of authorization. The covered entity obtains documentation that an **alteration to or waiver, in whole or in part, of the individual authorization** required by §164.508 for use or disclosure of protected health information has been approved by either: (A) An Institutional Review Board (IRB)... or (B) A privacy board...

The Fine Print...

OHRP Informed Consent FAQ: Can records or databases be reviewed to identify potential subjects without obtaining informed consent or parental permission?

In order to permit investigators to obtain and record identifiable private information for the purposes of identifying potential subjects, OHRP expects that IRBs routinely will waive the requirement for informed consent for such activities. In assessing the level of risk to determine whether a waiver of informed consent or parental permission is permissible for the identification of potential subjects, **the IRB need only consider the risk of investigators accessing the subjects' identifiable private information, not the risks of the research in total.**

The Fine Print...

OHRP Revised Common Rule FAQ: What are the new flexibilities to the requirement for informed consent for screening, recruiting, or determining eligibility under the revised Common Rule?

Under the revised Common Rule, an IRB may approve a proposal for the investigator to obtain information or biospecimens to **screen, recruit, or determine eligibility of prospective subjects for a research study without informed consent.** **In other words, the revised Common Rule removes the pre-2018 Common Rule requirement for an IRB to approve a waiver of informed consent for these types of activities.** This is applicable if (1) the information is obtained through oral or written communication with the subject or the subject's legally authorized representative, or (2) identifiable private information or identifiable biospecimens are obtained by accessing records or stored identifiable biospecimens. This change harmonizes with FDA. [45 CFR 46.116(g)]

What is “Full” Informed Consent?

All participants are provided with information

containing **all elements of informed consent**,

as they apply to **all parts of the study**,

and each participant **documents consent with a signature** before the study procedures take place.

What is “Full” HIPAA Authorization?

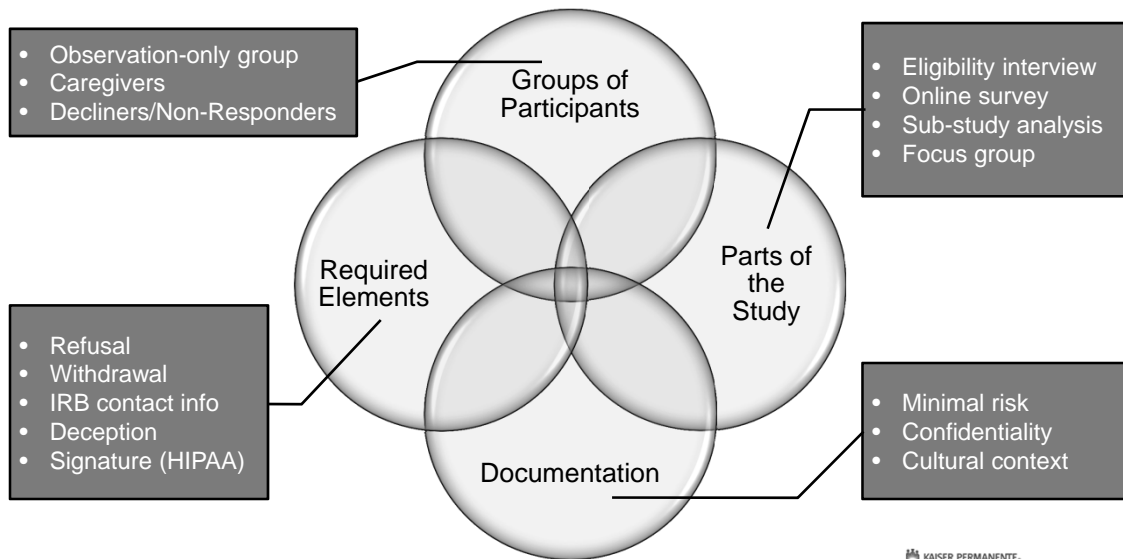
All participants whose Protected Health Information (PHI) will be used or disclosed are provided with information

containing **all elements of HIPAA authorization**,

as they apply to **all uses and disclosures of PHI**,

and each participant **documents authorization with a signature** before PHI is used or disclosed.

Waivers may apply to...

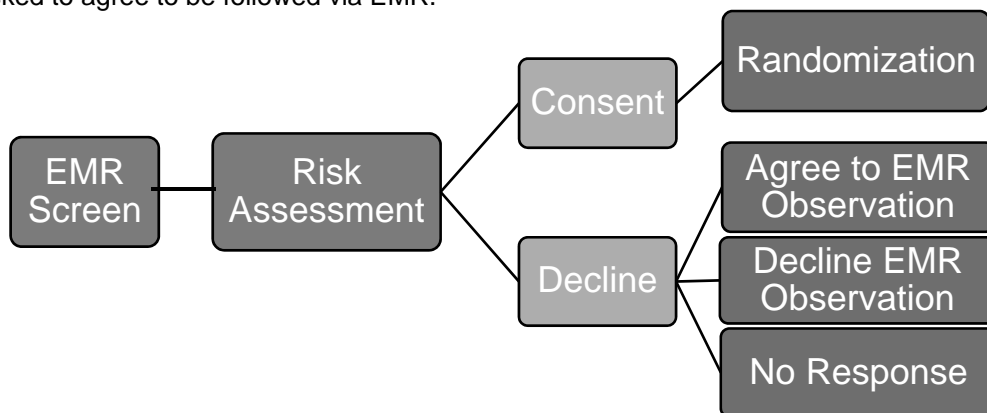


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Example

Study involves EMR screening followed by a risk assessment for certain genetic conditions, conducted by telephone. High-risk participants are invited to join the next part of the study, which includes genetic testing and randomization to different genetic counseling methods. Decliners are asked to agree to be followed via EMR.



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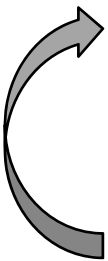
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Scope First, Analysis Second

1. To what participants, information, parts of the study, or documentation requirements does the waiver apply?
2. How do the waiver criteria apply to the defined scope?

Screening Activities Without a Waiver

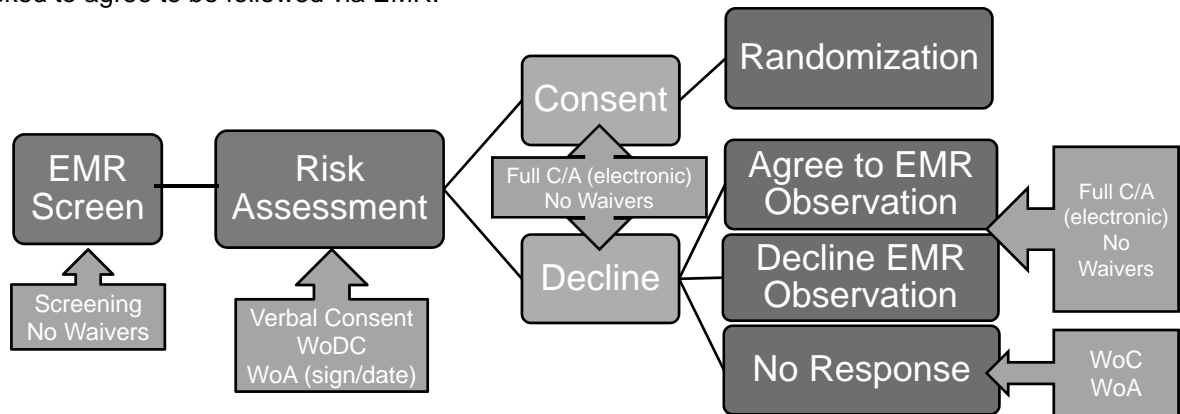
Screening Activity	Common Rule / FDA	HIPAA
Reviewing medical records for eligibility prior to contact	No waiver	No waiver
Checking availability of stored biospecimens	No waiver	No waiver
Collecting information directly from potential subject – verbal or written	No waiver	Waiver
Prospective testing or procedures to determine eligibility	Waiver	Waiver
Collecting medical record data for retrospective review	Waiver	Waiver



NEW! Revised Common Rule

Example

Study involves EMR screening followed by a risk assessment for certain genetic conditions, conducted by telephone. High-risk participants are invited to join the next part of the study, which includes genetic testing and randomization to different genetic counseling methods. Decliners are asked to agree to be followed via EMR.



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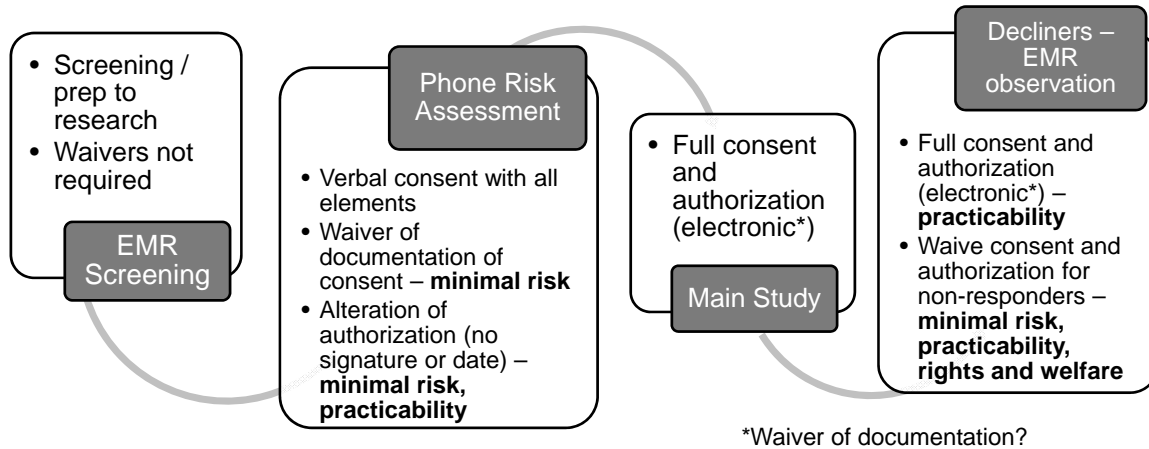
Waiver or Alteration Criteria

Informed Consent	Authorization	Documentation of Consent
<ul style="list-style-type: none"> • Minimal Risk • Impracticability <ul style="list-style-type: none"> • Study • Identifiers • Rights/Welfare • Follow-up Info 	<ul style="list-style-type: none"> • Minimal Risk to Privacy <ul style="list-style-type: none"> • Security • Destruction • Re-use/disclosure • Impracticability <ul style="list-style-type: none"> • Study • Identifiers 	<ul style="list-style-type: none"> • Minimal Risk <i>or</i> • Confidentiality <i>or</i> • Cultural considerations

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Waiver Determinations for Example Study



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The Forest through the Trees

Think about the **whole encounter** from the potential participant's perspective:

- What **makes sense** in the conversation?
- What is **practicable** for the study?



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Case Study #1

Study Overview: Large pragmatic trial that compares two standard-of-care protocols for asthma surveillance. Random assignment to intervention groups will occur at the level of the hospital or health system. Study will compare patient-reported outcomes of emotional distress, anxiety, general health status, and satisfaction with the intervention, and provider satisfaction with the intervention.

Procedures:

1. 3-month observation of medical records – participants notified by mail and may opt out
2. Web-based patient survey at 3 and 12 months following intervention using validated measures of emotional distress, anxiety, and general health status
3. Provider survey (web or in-person) at the start of patient enrollment and 12 months following

Case Study #1 – Waiver Scope

Part of Study	Participant Group	Information Provided	Permission Obtained	PHI Used or Disclosed?	Waiver?
Chart Review	Patients	All Elements	Opt-Out	PHI Use	Consent: Waive HIPAA: Waive
Survey	Patients	All Elements	Verbal or Action	PHI Use	Consent: Waiver of documentation HIPAA: Alteration, no signature or date
Survey	Physicians	All Elements	Verbal or Action	No	Consent: Waiver of documentation

Case Study #2

Study Overview: Three-arm randomized controlled trial with adolescents aged 12 to 17 with a confirmed ADHD diagnosis in the EMR.

Procedures

1. Chart review to identify potential participants
2. Telephone screening to further confirm eligibility
3. One of three intervention arms:
 - A. Standard behavioral intervention delivered by phone with a coach;
 - B. Self-administered behavioral intervention downloaded and installed on participants' home computers; or
 - C. The same intervention installed on a home computer plus telephone calls from a coach.
4. Parents complete surveys

Case Study #2 – Waiver Scope

Part of Study	Participant Group	Information Provided	Permission Obtained	PHI Used or Disclosed?	Waiver?
Chart Review for Eligibility	Teens	None	None	PHI Use	None
Phone Screening	Parents (12-14) Teens (14-17)	Some Elements	Verbal or Action	PHI Disclosure	Consent: None (not required) HIPAA: Alteration, no signature or date
Interventions	Parents (12-14) Teens (14-17)	All Elements	Verbal or Action	PHI Disclosure	Consent: Waiver of documentation HIPAA: Alteration, no signature or date
Parent Surveys	Parents	All Elements	Verbal or Action	PHI Disclosure	Consent: Waiver of documentation HIPAA: Alteration, no signature or date

Help Researchers Help You!

In your waiver form (or application or protocol template)...



Do

Include clear instructions

Provide a framework to describe waiver scope

Create shortcuts for common requests

Don't

Ask trick questions

Ask for redundant information

Instructions

↓ READ ME FIRST! ↓


What is Full Informed Consent?


All participants are provided with information containing **all elements of informed consent**, as they apply to **all parts of the study**, and each participant **documents consent with a signature** before the study procedures take place.

What is HIPAA Authorization?

All participants whose Protected Health Information (PHI) will be used or disclosed are provided with information containing **all elements of HIPAA authorization**, as they apply to **all uses and disclosures of PHI**, and each participant **documents authorization with a signature** before PHI is used or disclosed.

Any deviation from the above two standards requires a waiver from the IRB. Use this form to describe the waiver you are requesting and provide your rationale, as applicable. Review the restrictions and cautions below before completing this form:

 **Emergency Research:** Certain types of interventional emergency medicine studies qualify for a waiver of informed consent even though they are greater than minimal risk. If you think this applies to your study, please contact the IRB office. Do not use this form.

 **Other Research that is Greater than Minimal Risk:** With few exceptions, research must be minimal risk in order to qualify for any type of waiver. If your study is greater than minimal risk and you believe it would be impracticable or inappropriate to obtain full informed consent, please consult the IRB for guidance before completing this form.

Shortcuts



5a. Common Waiver Requests: *If one or more of these options apply, check the box(es) below and do not fill out the rest of this form. The IRB will contact you if they need more information.*

- ☐ **Data-only study** with no participant interaction
- ☐ **Data-only screening** (e.g. medical record review) for eligibility followed by full informed consent (and authorization, if applicable) for the rest of the study
- ☐ **Verbal or online eligibility questionnaire/interview** followed by full informed consent (and authorization, if applicable) for the rest of the study
- ☐ **No signature**, but all elements of informed consent (and authorization, if applicable) are provided verbally or in writing *and* the study meets at least one of the following criteria:
 - ☐ The research involves no procedures for which written consent is normally required outside of the research context.
 - ☐ Signing a consent form is the main confidentiality risk in the study and the only record linking the subject to the research would be the consent form.
 - ☐ Signing a consent form would be culturally inappropriate.

Waiver Scope

5b. If none of the above apply, or if the above choices apply to only part of the study, complete the following table to describe the scope of the waiver request. Add/delete rows as needed.

Part of Study	Participant Group	Information Provided*	Permission Obtained**	PHI Used or Disclosed?***
		Choose an item.	Choose an item.	Choose an item.
		Choose an item.	Choose an item.	Choose an item.
		Choose an item.	Choose an item.	Choose an item.

Waiver Scope

Information Provided*	Permission Obtained**	PHI Used or Disclosed?***
None	None	No
Some Elements	Opt-Out	PHI Use
All Elements	Verbal or Action Signature	PHI Disclosure

***Information Provided** means which elements of informed consent will be provided to participants. If the part of the study will include the use or disclosure of PHI, this also includes the elements of HIPAA authorization.

****Permission Obtained** means how, if at all, participants will indicate their agreement to participate in the study.

*****PHI Used or Disclosed:** PHI is used if it is accessed or collected by the research team but is not sent to or accessed by anyone outside the institution. PHI is disclosed when it is viewed, accessed, or received by anyone outside the institution. There is no option for "both" because a disclosure includes a use of PHI.

More Shortcuts

7. Explain why it would not be practicable to conduct the study if you had to obtain full informed consent (and HIPAA authorization, if applicable) from every participant, for all parts of the study.

- ☐ Study includes too many individuals to contact for consent and authorization.
- ☐ Participants' contact information is unavailable or may be outdated.
- ☐ Participants may be deceased and there is no way to confirm.
- ☐ Some elements of consent/authorization are not helpful (or may be confusing) to the potential participant in making an informed decision about participation.
- ☐ The research setting is not appropriate for a full consent/authorization discussion.
- ☐ The study design requires 100% participation to answer the research question.
- ☐ Other, describe below:

Other Considerations

- What determinations are you asking researchers to make? What determinations “belong” to the IRB?
- Document waiver scope on IRB side, too (e.g. in review checklists)
- Can’t follow the participants’ path through the study? Ask for a visual!
- Take advantage of new regulatory flexibility in Revised Common Rule. Don’t grant a waiver when you don’t need one!

Questions or Comments?

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