UNIVERSITY of MARYLAND
SCHOOL OF NURSING

Informed Consent in Human Subjects Research

Part 5: Untangling Consent Waivers

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Goals

By the end of this seminar, you should have an increased knowledge of:

- What research consent waivers are/are not
- The types of research consent waivers and what they may be applied to
- Consent waiver considerations in CICERO
- Documentation considerations with consent waivers

Disclaimer

- This seminar is not an endorsement of the use of waivers for inappropriate circumstances; the Belmont report is the guiding principle
- Every protocol is unique and requires special considerations, therefore the material expressed in these slides may not apply to all studies
- This seminar is not discussing exempt research, assent waivers, or waivers under public benefit and service programs

Pop quiz!

A waiver of documentation of consent means:

A) There is no need to conduct the consent process

B) There is no need to document the consent process

C) There is no need to obtain a signature on the consent form

D) Electronic consent

Research Consent Waivers

let's clarify some misconceptions

- Not required for exempt studies (exception- HIPAA authorization)
- Can only apply to certain scenarios
- Must have strong rationale for requesting one
- Does not negate the consent process
- It is NOT a request for electronic consent
- UMB does not support broad consent

Types of Research Consent Waivers

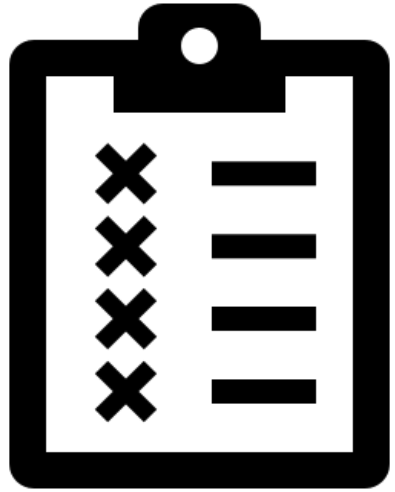
Apply to non-exempt studies

- Waiver of Consent (whole process)
- Alteration of Consent (waive some elements)
- Waiver of Documentation of Consent
- Assent Waiver – *will be discussed in next months' seminar*

Apply to exempt and non-exempt studies

- HIPAA authorization partial waiver (for recruitment)
- HIPAA authorization full waiver
- HIPAA authorization alteration

Request to Waive Consent



What is it?

Waiver of the consent process (all of it!)

To what does it apply? 45CFR46.116 (f)(3)

All of the following must be true:

- Cannot involve more than minimal risk
- Without the waiver, the research could not be practicably done
- The waiver cannot adversely affect subjects' rights/welfare
- The research wouldn’t be feasible without using identifiers/identifiable samples (if applicable)
- Subjects/LARs should be provided with information after participation, where appropriate

Request to Waive Consent (cont.)

Examples

- Emergency situation studies (minimal risk)
- Deception studies

Studies where a waiver of consent would NOT apply

-Greater than minimal risk studies

-FDA regulated studies*

-Research involving non-viable fetuses

Request to Waive Consent (cont.)

Considerations

Study File Documentation

Study records should be incredibly detailed with regards to subject interactions (progress notes)

Participants

Earliest opportunity to inform participants/LAR should be taken

Staff

Trained on documentation needs

Request to Waive Consent (cont.)

CICERO Required Explanations

- why the research involves no more than minimal risks to the subjects:
- why a waiver or alteration of the consent process would not adversely affect the rights and welfare of the subjects
- why you cannot carry out the research unless you are granted a waiver or alteration of the consent process
- why the research could not practicably be carried out without using identifiable information or biospecimens in an identifiable format (if applicable)
- how will subjects receive additional pertinent information?-Or- why would a subject not receive additional pertinent information?

Request to Alter Consent

What is it?

A request to waive/alter certain elements of consent

To what does it apply? 45CFR46.116 (f)(3)

Same requirements as waiver of consent

Example

Deception study where disclosure of study purpose would introduce bias

Request to Alter Consent (cont.)

Considerations

Situation specific (depends on what was altered) and similar to consent waiver in terms of documentation, staff training

CICERO Required Explanations

Same as consent waiver, however you must identify specifically what is being altered or changed in the consent process AND why the alteration request is needed for the conduct of the research

Request to Waive Documentation of Consent

What is it?

Waives participant signature requirement only- all other consent requirements must be followed

What does it look like?

Verbal/oral consent, check box/non-verified agreement, "click to agree", etc.

Request to Waive Documentation of Consent

To what does it apply? (45 CFR 46.117)

- Minimal risk studies with procedures that wouldn't normally require consent –OR-
- The consent signature is the only link to subject identifiers; main risk in study is breach of confidentiality

Examples

- Studies only using standard of care procedure data (blood draw, buccal swab, etc.)
- Survey of clinician employees with substance use disorder

Request to Waive Documentation of Consent (cont.)

Considerations

Documentation: Documentation of the consent *process* must still be in research records (verbal consent log, progress notes, etc.)

Participants: Provision of study contacts and info (copy of consent must be made available to participants)

Staff: Ensure proper training- remember the waiver is for participant signature only, not waiving your need to document consent process in the study file!

Request to Waive Documentation of Consent (cont.)

CICERO Required Explanations

Waiver of Documentation of Consent

You indicated that a waiver of documentation of consent (verbal/oral consent) is requested.

1 * Indicate why a waiver of documentation of consent is being requested for the study:

- ○ The only record linking the subject and the research would be the consent document, and the principal risk would be potential harm resulting from a breach of confidentiality.
- ○ The research presents no more than minimal risk of harm to subjects, and involves no procedures for which written consent is normally required outside of the research context.

Clear

2 * Provide a justification/explanation for the choice above:

HIPAA Authorization Waiver

What is it?

A request to waive HIPAA authorization to access medical records for research purposes

Partial= access request, but no retention of PHI without written authorization

Full= access and retention of PHI without written authorization

To what does it apply?

Studies which access patient data from a HIPAA covered entity

(note! PII vs PHI)

HIPAA Authorization Waiver (cont.)

Examples

- Hospital studies targeting a specific disease
- Retrospective chart review studies

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HIPAA Authorization Waiver (cont.)

Considerations

Documentation: Be mindful of why you would need to **record/retain** identifiers in your research records (access vs. recording/retaining). Confidentiality plan.

Participants: Think about confidentiality as if you were the participant

Staff: Know difference between PHI and PII. Assess resources and data access capabilities before requesting the waiver

HIPAA Authorization Waiver (cont.)

CICERO Required Explanations

-why privacy risks are minimal

-plan for protection of PHI against improper use, disclosure

-plan for destroying PHI as soon as feasible in the research (or rationale for need to keep PHI)

-why the research wouldn't be practical without access and use of PHI

-why the research wouldn't be practical without access and use of a HIPAA waiver

-contact details of anyone who will receive the PHI (if applicable)

Case Study #1

A researcher at a cancer center is conducting a study on a new drug to treat a very specific form of myeloma which involves many in-person tests and clinic visits. What types of waiver(s) could be applicable?

-HIPAA waiver for recruitment

What about considerations during a pandemic?

-Potentially waiver of documentation of consent

Case Study #2

A hospital researcher wishes to collect a one-time saliva samples from HIV+ patients to study for non-diagnostic/health related purposes. The only record linking potential participants to the study would be the consent form. What types of waiver(s) could be applicable?

-Waiver of documentation of consent

-HIPAA authorization waiver for recruitment

Final Thoughts

- Waivers are not applicable to all studies
- Strong rationale for requesting waivers
- Vet your request thoroughly before requesting (consult HRPO)
- No need to consider for exempt studies (unless HIPAA)
- Understand PII vs PHI
- Documentation is a two-way street!

Stay Tuned for Further Research Seminars!

March 2022- Research Consent Part 6:
Vulnerable populations, assents, and short form consents

April 2022- Research Consent Part 7:
Electronic consent - what is it and what is it not?

Resources

UMB HRPO Resources for Researchers

https://www.umaryland.edu/hrp/for-researchers/study-conduct/

CICERO

http://cicero.umaryland.edu/

OSU Waivers of Consent Presentation

http://orrp.osu.edu/files/2012/03/Waivers-BSS-2016.pdf

Link to previous SON research seminars

https://www.nursing.umaryland.edu/research/seminar-series/

Questions?