THE OHIO STATE UNIVERSITY

Waivers of Informed Consent and HIPAA Research Authorization

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Session Objectives

- Provide overview of informed consent requirements
- Explain consent waivers and provide examples
- Provide overview of HIPAA
- Explain authorization waivers/alterations and provide examples
- Explore Buck-IRB application

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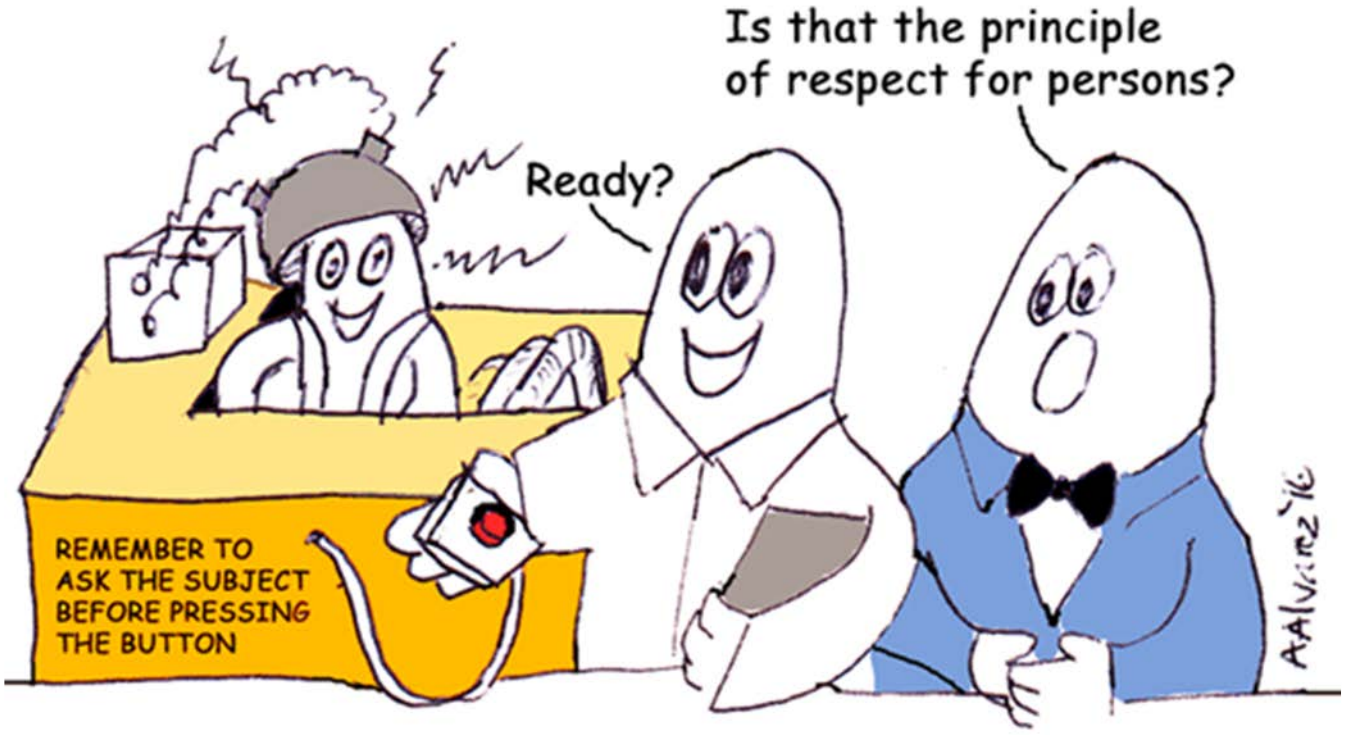
Informed Consent Overview

- Ethical human subjects research
- “Respect for persons”
- Interactive, ongoing process
- Nature and circumstances are important

Informed Consent Attributes

- Written documentation is the default
- Sufficient opportunity to consider participation
- No coercion or undue influence
- Understandable language
- Free of exculpatory language


Is that the principle of respect for persons?
Ready?
REMEMBER TO ASK THE SUBJECT BEFORE PRESSING THE BUTTON

Federal Regulations

21 CFR Part 50, Informed Consent of Human Subjects

45 CFR Part 46, Protection of Human Research Subjects

Waivers

Some or all of the informed consent components are not required

Waiver of Consent Documentation

Definition

The IRB approves a process whereby participants do not provide a legally valid signature on a consent form

Criteria for Determination One

- Minimal risk research
- Contains no procedures typically requiring written consent outside of research

Criteria for Determination Two

- Only record linking participant to research would be consent document
- Principle risk is potential harm from a breach of confidentiality

Note: An approved consent form will be made available should the participant request documentation linking them to the research.

Criteria for Determination Three

- Minimal risk research
- Participants are members of cultural group or community where signing forms is not the norm
- Alternative method in place to document consent was obtained

Examples

- Online survey (recruitment email or first page at survey site contains required elements of consent)
- Verbal consent (e.g., phone interview, in-person interview)
- Cover page for a paper survey (no signature, but the cover page contains required elements of consent)

Case Study

Dr. Smith is conducting research using an online quality of life (QOL) survey. She plans to link the responses to existing medical record data at outside physicians' offices so she can correlate QOL with disease status. She sends the survey link via e-mail.

Question: Does Dr. Smith need to obtain consent?

If so, what options are there for the consent process?

Case Study

Question: Does Dr. Smith need to obtain consent?

Answer: Yes.

Question: If so, what options are there for the consent process?

Answer: Written consent form.

Waiver of Consent

Definition

The IRB approves a process whereby participants do not provide consent

Criteria for Waiver

- Minimal risk research
- Impracticable to conduct the research if consent were required
- If identifiable data/specimens used, impracticable to conduct without data/specimens in identifiable format
- Waiver will not affect participant rights/welfare
- When appropriate, participants provided information after participation

Examples

- Research involving observation of natural behaviors where study outcomes could be influenced if participants knew they were being observed
- Review of existing medical records
- Some research involving secondary data analysis

Case Study

Dr. Buckeye has heard of Dr. Day's study involving a new drug and wishes to conduct a secondary analysis study using his research data.

Question: Would Dr. Buckeye need to request a waiver of consent?

Case Study

Dr. Buckeye has heard of Dr. Day's study involving a new drug and wishes to conduct a secondary analysis study using his research data. Would Dr. Buckeye need to request a waiver of consent?

Answer: It depends.

The IRB would need to review the consent form for Dr. Day's study and decide if it covered the secondary analysis for Dr. Buckeye's study. If so, then no waiver would be necessary. If not, then a waiver would need to be requested and the IRB would also need to decide if the waiver criteria could be met or not.

Group Activity A

Waiver Eligibility

- Classroom written survey - **D**
- Existing medical records - **P**
- Investigational drug - **N**
- Coded dataset analysis - **P**
- Online REDCap survey - **D**


WAKE HIM UP. WE NEED INFORMED CONSENT FOR THE NEXT PART
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HIPAA Authorization & Waivers

Health Insurance Portability and Accountability Act of 1996 (HIPAA)

Governs the way certain health information is collected, maintained, used, and disclosed

Privacy Rule

- Establishes safeguards on certain types of health information
- Created to provide national minimum level of protection for protected health information (PHI)

Protected Health Information

Is individually identifiable Protected Health Information subject to the HIPAA Privacy Rule requirements to be accessed, used, or disclosed in the research study?

- ✓ Are materials *health information*?
- ✓ Are materials *identifiable* (containing HIPAA identifiers)?
- ✓ Are materials obtained from, or held by, a *covered entity*?

HIPAA Identifiers

(1) Names (including initials);
(2) Geographical divisions smaller than state (e.g., zip codes, city, county)
(3) ALL elements of dates (except year) for dates directly related to an individual and all ages over 89 (this would include procedure dates, date of admission, date of lab work, etc.)
(4) Telephone numbers;
(5) Fax numbers;
(6) Electronic mail addresses;
(7) Social security numbers;
(8) Medical record numbers;
(9) Health plan ID numbers;
(10) Account numbers;
(11) Certificate/license numbers;
(12) Vehicle identifiers and serial numbers, including license plate numbers;
(13) Device identifiers/serial numbers;
(14) Web addresses (URLs);
(15) Internet IP addresses;
(16) Biometric identifiers, incl. finger and voice prints;
(17) Full face photographic images and any comparable images; and
(18) Any other unique identifying number, characteristic, or code

Privacy Rule – General Provisions

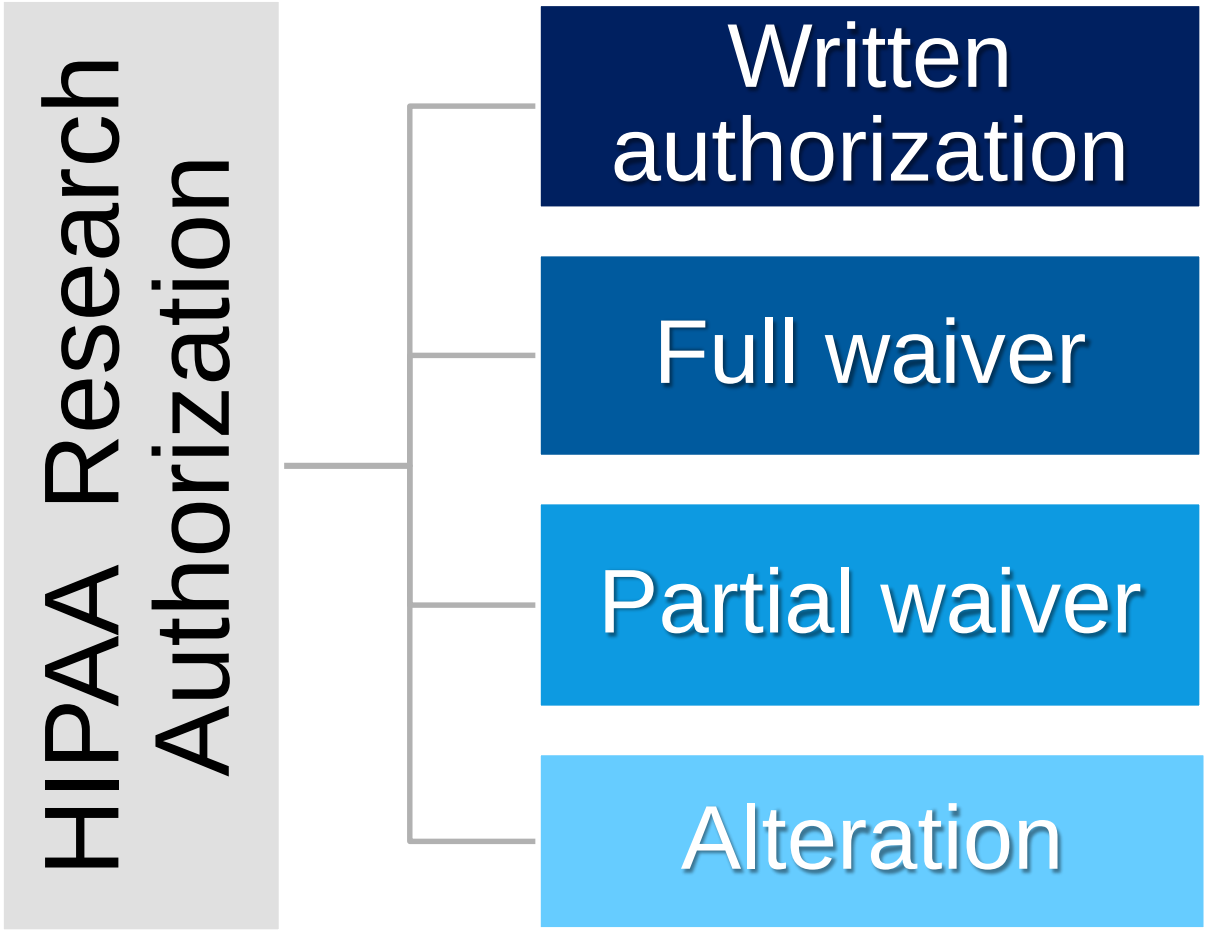
Reasonable Safeguards

- Administrative, technical, and physical protection against unpermitted use/disclosure
- Protects privacy and confidentiality

Minimum Necessary

- Limits *who* may access/use/disclose PHI
- Limits *what* PHI may be accessed/used/disclosed

Your research contains PHI. Now what?



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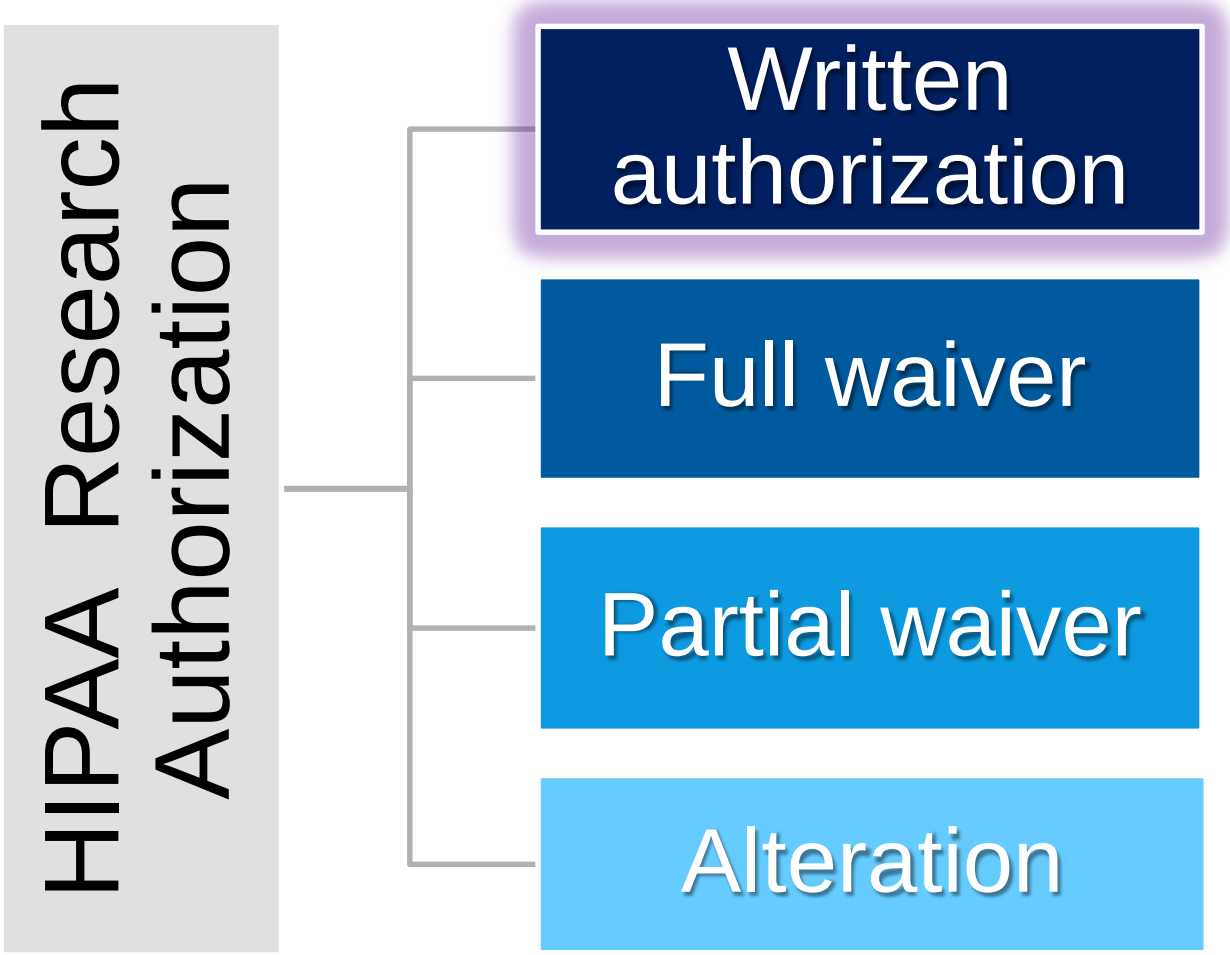


Written Authorization

Individual's legally valid, signed permission to allow the use or disclosure of an individual's PHI for a purpose that would *not otherwise be permitted under the Privacy Rule*

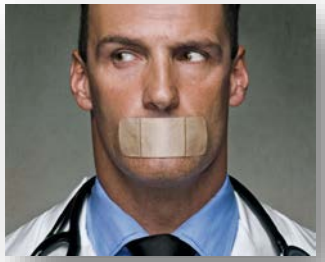
Includes:

- Information to be accessed, used, or disclosed
- Identification of those authorized to use/disclose
- Potential for re-disclosure
- Right to revoke

Alternatives to written authorization:

HIPAA Research Authorization

- ~~Written authorization~~
- Full waiver
- Partial waiver
- Alteration



Waiver/Alteration Criteria (4)

1. The PHI use or disclosure involves no more than minimal risk to **privacy**
   - Plan to **protect** identifiers from improper use/disclosure
   - Plan to **destroy** identifiers at earliest opportunity
   - Written assurance that PHI will not be **reused or disclosed** to any other person/entity

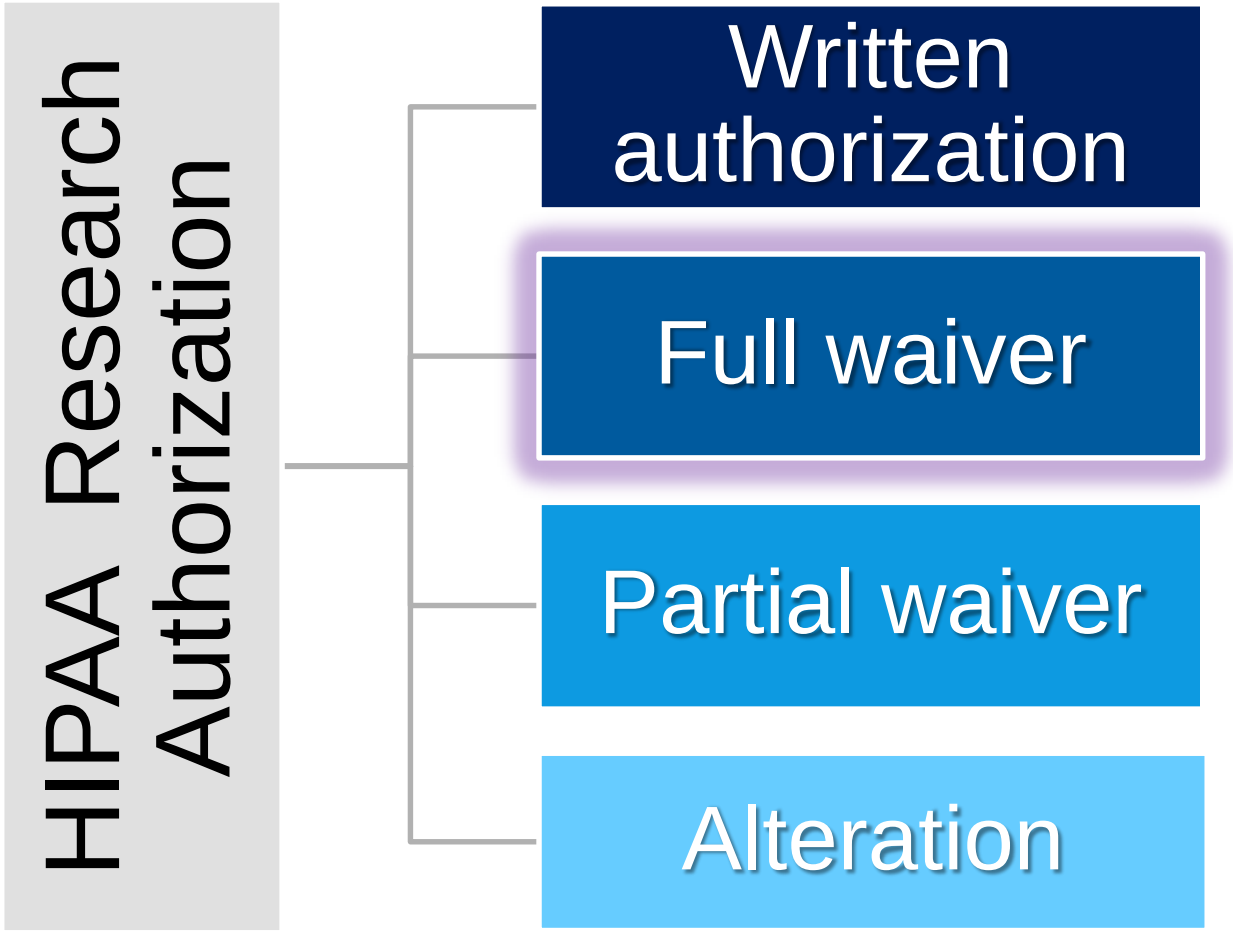
Waiver/Alteration Criteria (4)

2. The waiver or alteration will not adversely affect the **rights and welfare of the subjects**

3. The research could not practicably be conducted **without the waiver or alteration**

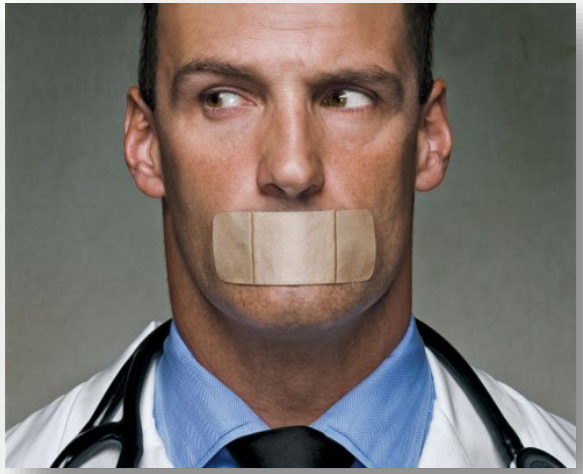
4. The research could not practicably be conducted **without access to and use of PHI**

Remember: The general provisions of the Privacy Rule (reasonable safeguards & minimum necessary) must also be satisfied!


HIPAA Research Authorization
Written authorization
Full waiver
Partial waiver
Alteration

Full Waiver

HIPAA Authorization will not be obtained



- Allows use/disclosure for research purposes
- Impracticability criterion: typically no subject contact

Full Waiver

Most common example:

- Chart review studies
  - Must be entirely retrospective*
  - Clearly state end date of data collection in protocol & application
  - Provide data collection form

**All data/specimens are in existence or "on the shelf" on the date study is submitted to IRB*

Group Activity B: Mock Review

Full Waiver of HIPAA Authorization

- Consider study details (next slide)
- Review Buck-IRB pages: request for full waiver of HIPAA research authorization (handout)
- As a group, use Reviewer Checklist (handout) to determine if the request is approvable

  If not, what else would you need to know?

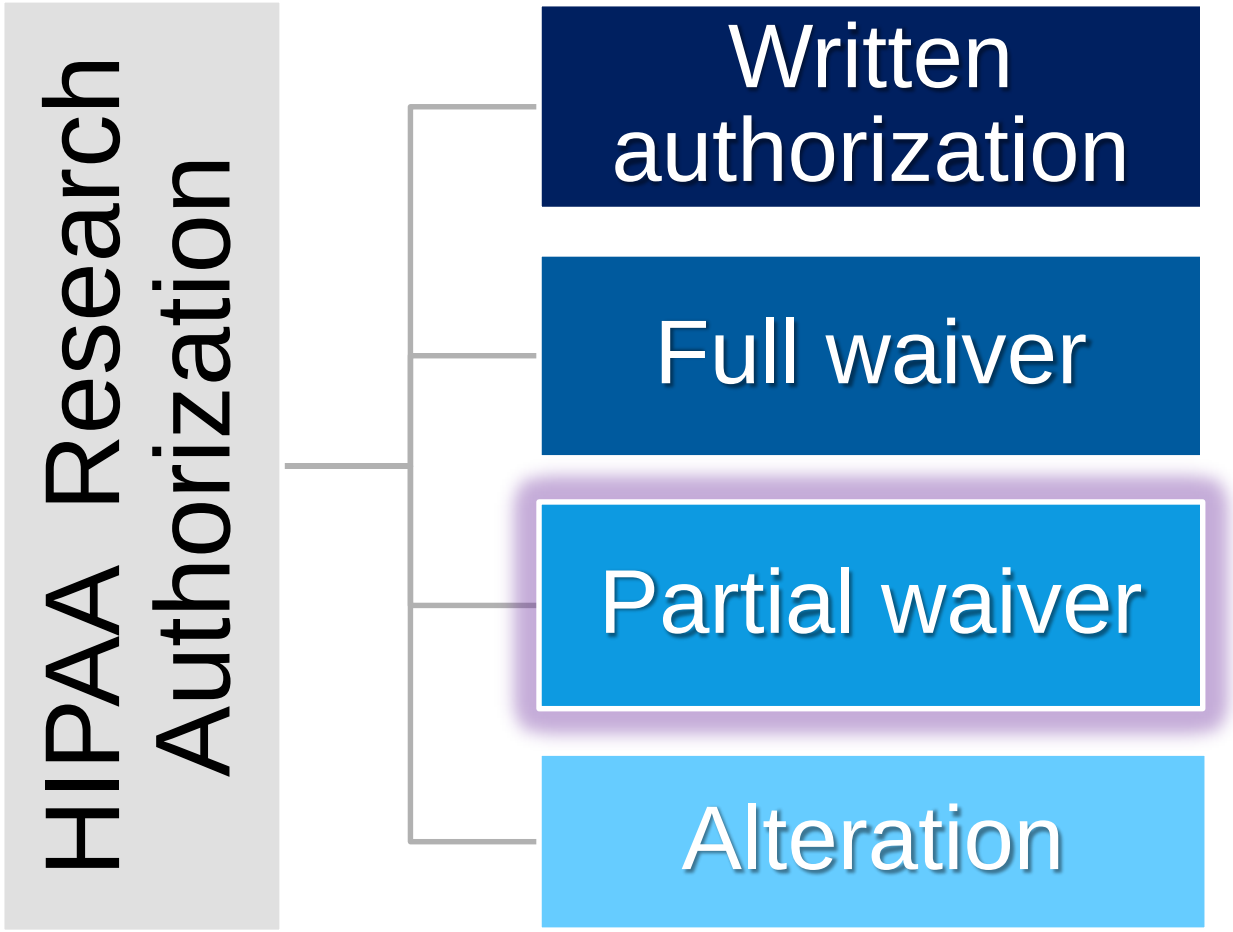
- Be prepared to discuss your group's decision!

Group Activity B: Mock Review

SAMPLE STUDY

- Review of existing medical records
- Purpose: Compare survival data from breast cancer patients who received one of two chemo drugs
- Characteristics: female, 30-75 yrs, stage III breast cancer diagnosis, received chemo between 1/1/12 and 1/1/18 at Stefanie Spielman Breast Center

Is the request for a full waiver approvable?


HIPAA Research Authorization
Written authorization
Full waiver
Partial waiver
Alteration

Partial Waiver

PHI accessed & used for recruitment

Authorization will eventually be obtained

- Allows PHI access/retention for the purposes of identifying potential subjects
- Permission for direct contact may still be required
- Information collected under partial waiver must be destroyed after recruitment is complete unless additional authorization requirements are met

Partial Waiver

What if I want to retain data collected under a partial waiver beyond recruitment?

1. Subjects enrolled on study: **Written authorization**
2. Ineligible individuals (no contact/not approached): **Full waiver**
3. Individuals who decline to participate: **Alteration**

Group Activity C

Request a Partial Waiver of Authorization

- Consider study details (next slide)
- As a group, use Partial Waiver Sample Responses (handout) to choose the best answers for each question

  There may be more than one right answer!

- Be prepared to discuss your group's decision!

Group Activity C

SAMPLE STUDY

- Survey study
- 3 physician-researchers recruiting their own patients on day of clinic appointment
- Recruited from Lung Center at Martha Morehouse
- Eligibility criteria: smoker for 3+ years or never-smoker; male or female; age 18 – 35; diagnosis of asthma; PFT values indicate mild to moderate obstruction

Submission Tips

#1: Determine the appropriate waiver(s)

- Which activities will you conduct without obtaining legally valid consent?
- For which activities will you use PHI without obtaining written authorization?

#2: Buck-IRB: Answer prompts

- Questions designed to elicit specific info (regulatory criteria)

#3: Tailor responses on waiver pages

- To your specific study
- To the specific waiver(s) you are requesting
- Avoid a one-size-fits-all mentality

#4: Check for Consistency

Common Discrepancies

- ✓ Documentation waiver and consent materials
- ✓ Access vs. recording of PHI
- ✓ Data points to be collected vs. data collection sheet

#5: Review of existing medical charts

- Ensure date range of data to be collected is clearly stated (protocol, Buck-IRB)

#6: Care Everywhere reminder

- Care Everywhere cannot be used for research

Today, we covered:

- Types of consent & HIPAA authorization waivers and when each applies
- Regulatory criteria for waiving consent or HIPAA authorization
- Good & bad examples of waiver requests
- Best practices for completing waiver pages: be thoughtful & tailor responses to your study

HRPP Policies

http://orrp.osu.edu/irb/osuirbpolicies/hrpppolicies/

HRPP Glossary

http://orrp.osu.edu/irb/osuirbpolicies/hrppglossary/

IRB Reference Sheets

http://orrp.osu.edu/files/2011/11/IRBReviewerRefSheets.pdf

Contact Us

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