

# Waivers of Informed Consent and HIPAA Research Authorization

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Office of  
Responsible Research Practices



- Review regulatory requirements for HIPAA research authorization and informed consent
- Explore possible exceptions to authorization and consent requirements through waivers
- Discuss Ohio State Human Research Protection Program (HRPP) policies and relevant regulations

# Objectives

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- Basic Definitions
- Use of PHI or health information not involving IRB review
  - Not Human Subject Research determinations
  - Exemption from IRB review
- Use of PHI or health information requiring IRB review
  - Recruitment
  - Collecting/analysis of data
  - Banking/retaining research data for future unspecified analysis
- Informed consent requirements and waivers

# Overview of Presentation 3

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# DEFINITIONS

## **Research**

Systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge

## **Human subject**

Living individual about whom an investigator obtains:

- Data through intervention or interaction
- Identifiable private information

## **Clinical investigation**

Experiment involving test article and one or more human subjects

## **Human subject**

Individual (healthy individual or patient) who is a subject in research; either test article recipient or control; also a specimen in device research

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) and its regulations, including the Privacy Rule and the Security Rule, govern the way certain health information is collected, maintained, used, and disclosed. The Privacy Rule establishes a set of safeguards on certain types of health information known as *protected health information*, or PHI. The Privacy Rule was created to provide a national minimum level of protection for PHI.

# HIPAA



Health information that is *individually identifiable* (contains at least one of 18 HIPAA identifiers) and created or held by a covered entity

PHI

- A Privacy Rule authorization is an individual's signed permission to allow a covered entity to use or disclose the individual's PHI that is described in the authorization for the purpose(s) and to the recipient(s) stated in the authorization
  - Information to be accessed, used, or disclosed
  - Identification of those authorized to use/disclose
  - Potential for re-disclosure; right to revoke
- The requirement for an authorization may be waived (full or partial) or altered as outlined in the regulations

# Authorization

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# NO IRB REVIEW REQUIRED

Not Human Subjects and Exempt Research

- Data collection/analysis of publically available data sets without special permission requirements
- Investigators receiving existing data from banks/repositories or honest brokers with IRB approved processes to allow release of de-identified data sets
- Projects conducted for the sole purpose of quality improvement/quality assurance with no research intent

# No Review Requirement

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You wish to compare the use of approved Drug A to approved Drug B in patients with certain types of infections.

- All data currently exists
- All data can be obtained via the Information Warehouse's IRB-approved honest broker process
- Investigator will not access or receive HIPAA identifiers

# Not Human Subjects Research Example

- Research involving human subjects that is not subject to regulations requiring IRB review and approval
- Six categories of research; requires an application and determination by ORRP
- Minimal Risk

# Exempt Research

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- Conducted as submitted
- New application required for changes beyond simple personnel changes
- All activities to be conducted for a project must qualify as exempt
- Cannot collect PHI on known prisoners
- Cannot use PHI to contact participants
- FDA-regulated research cannot be exempt (except category #6)

# Exempt Research

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DHHS:

Research involving the collection or study of **existing** data, documents, records, pathological specimens, or diagnostic specimens if these sources are **publicly available** or if the information is recorded by the investigator in such a manner that **subjects cannot be identified directly or through identifiers linked to the subjects**

Exempt Category 4

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- Research on existing data or specimens (must be “on the shelf” at the time the research is submitted)
- All data must exist at the time that the research is conceived, no ongoing research or serial applications
- Must be de-identified, including removal of all HIPAA identifiers (e.g., dates)
- More than 25 potential subjects must fit the inclusion criteria to be considered de-identified
- All data must come from a single source; it cannot be combined from completely separate data sources

## Category 4 (cont.)

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- Exempt research involving PHI requires Privacy Board review to obtain a full waiver of HIPAA authorization
- ORRP facilitates the review process; no additional action by the investigator is necessary

# Privacy Board Review

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- The PHI use or disclosure involves no more than minimal risk to privacy
- The waiver or alteration will not adversely affect the rights and welfare of the subjects
- The research could not practicably be conducted without the waiver or alteration
- The research could not practicably be conducted without access to and use of the PHI

# Waiver Requirements

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You wish to compare the use of approved Drug A to approved Drug B in patients with certain types of infections.

- Not FDA-regulated
- All data currently exists
- Investigators need to access IHIS for data collection
- Investigators will not record HIPAA identifiers or create codes that would link data back to subjects

## Category 4 Example

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IRB REVIEW REQUIRED

- Minimal Risk
- One or more of 7 categories
- Reviewed by IRB Chair or designees
- Create new study in Buck-IRB application

# Expedited IRB Review

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Research involving materials (data, documents, records, or specimens) that have been collected or will be collected solely for **nonresearch** purposes (such as medical treatment or diagnosis). (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects [45 CFR 46.101\(b\)\(4\)](#). This listing refers only to research that is not exempt.)

\*Data/specimens previously collected for research purposes do not qualify for this category

## Expedited Category 5

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You wish to compare the use of approved Drug A to approved Drug B in patients with certain types of infections.

- All data currently exists
- Investigators need to access IHIS for data collection
- Investigators need to record HIPAA identifiers (e.g., dates, zip codes) and wish to retain a code that would allow additional data collection if needed

## Category 5 Example

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- Greater or potentially greater than minimal risk
- Does not fit into one or more of the seven expedited categories
- Reviewed by full IRB
- Create new study in Buck-IRB application

## Convened IRB Review

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You wish to compare the use of approved Drug A to approved Drug B in patients with certain types of infections.

- All data currently exists
- Investigators need to access both, data previously obtained during a clinical trial and medical information from IHIS
- Investigators need to record HIPAA identifiers (e.g., dates, zip codes)

# Convened IRB Review Example

- Individuals involved in recruitment of participants, beyond providing information about study availability and investigator contact information, are “engaged in research”
- Engaged personnel must:
  - have IRB approval for involvement with each protocol
  - meet institutional education (CITI) and conflict of interest disclosure requirements

## Personnel Engagement

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- Investigators may not directly contact potential participants identified from privately held sources (e.g., physicians' practices, previous research participation) without the participants' (or their legally authorized representatives') permission
- Methods of contact that are the “least intrusive” should be considered

# Respect Privacy

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- Study subjects who agreed to future contact via the informed consent process for a different protocol may be contacted as outlined in the consent document/process
- Listservs or other lists without a reasonable expectation of privacy (e.g., magazine subscribers, professional organization members) do not require permission

Direct Contact Allowed 28

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- A Privacy Rule authorization is an individual's signed permission to allow a covered entity to use or disclose the individual's PHI that is described in the authorization for the purpose(s) and to the recipient(s) stated in the authorization
  - Information to be accessed, used, or disclosed
  - Identification of those authorized to use/disclose
  - Potential for re-disclosure; right to revoke
- The requirement for an authorization may be waived (full or partial) or altered as outlined in the regulations

# Authorization

- The PHI use or disclosure involves no more than minimal risk to privacy
- The waiver or alteration will not adversely affect the rights and welfare of the subjects
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# Waiver Requirements

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- 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 authorization or additional waiver/alteration is obtained

## Partial Waiver of Authorization

Written documentation and/or all core elements/required statements as contained in the research authorization template are not required

Alteration of Authorization 32

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- Must meet waiver requirements
- Allows PHI access/retention for research conduct and data analysis

## Full Waiver of Authorization

- Dr. Who wishes to recruit patients who see Dr. No in another department.
  - How can Dr. Who access/obtain PHI for the purpose of recruiting Dr. No's patients?
  - Can Dr. Who contact Dr. No's patients directly?
  - What does Dr. Who need to do to maintain a do not contact list?

## Scenario #1

- Partial Waiver is not required if the research is a possible treatment option for patients, Dr. No is a collaborator on the protocol, and Dr. No (or his clinical staff) is accessing PHI to assess eligibility
- Partial Waiver is required if the research is a possible treatment option for patients, Dr. No is a collaborator on the protocol, but Dr. Who (or research staff) is accessing PHI to identify potential participants
- Partial Waiver is required if the research is not therapeutic, regardless of clinical relationship

## PHI Access

- Dr. Who may send a joint letter with Dr. No to potential subjects from Dr. No's practice
- Dr. No may send a study introduction letter to his patients that either:
  - provides them with protocol-specific and/or research team contact information, or
  - informs them that the research team will contact them

If second approach is used, the letter should also include an opt-out telephone number

# Recruitment Contact

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- Waiver request should include a description of the identifiable information retained for a “do not contact” list
- Destroy when recruitment ends (unless full waiver/alteration requested)
- Inform individuals of the list and maintain appropriate confidentiality

## Do Not Contact List

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Dr. Who wishes to analyze data to characterize eligible individuals who refused study participation. What steps should be taken to permit analysis?

Scenario #2

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- Identifiable “refuser” data may be used for research purposes when prospective informed consent is obtained
- Waiver of informed consent documentation and alteration of HIPAA research authorization may be appropriate based on the sensitivity/type of the data collected

## “Refuser” Data

- Individuals who provide informed consent and HIPAA research authorization can be contacted for future research
- Recruitment PHI retention/access will be described in the protocol and informed consent document
  - single data collection (e.g., name, telephone number)
  - ongoing data updates (e.g., lab values, medications)

- An essential part of ethical human subjects research
- Founded on the Belmont principle of “respect for persons”
- More than a form; an interactive ongoing process
- Nature and circumstances of process are important aspects: who will provide consent, timing, place, etc.

# Informed Consent

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- FDA 21 CFR Part 50, Informed Consent of Human Subjects
- DHHS 45 CFR Part 46, Protection of Human Research Subjects

# Federal Regulations

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- The study involves research; explanation of purpose, expected duration, and study procedures
- Description of risks and benefits
- Disclosure of alternatives, if any
- Confidentiality of records (regulations insist that subjects be told extent of disclosure, if any)

# Federal Requirements for Informed Consent

- Contacts for research questions, rights, and injury/harm (must be explicitly stated)
- Voluntary participation and withdrawal
- For greater than minimal risk research, available medical treatments & compensation for injury
- FDA regulated research; FDA may inspect records
- Applicable clinical trials are entered into ClinicalTrials.gov databank

## Requirements (cont.)

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- There may be unforeseeable risks
- Participation may be terminated without consent
- Additional costs
- Consequences of withdrawal & procedures for orderly termination by participant
- Significant new findings will be provided
- Approximate number of study participants

# Additional Elements

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- The consent document provides key information and serves as a reference for participants or legally authorized representatives (LAR)
- Although a signed form is usually required, it alone does not constitute an adequate informed consent process

## Documentation of Informed Consent

## **Risk of breach of confidentiality**

- Only record linking participant & research
- Principal risk is harm from breach
- Each participant will be asked if they want documentation linking them to research
- Research is not FDA regulated

## **Minimal Risk Research**

- Minimal risk of harm
- No procedures require written consent outside of research context

# Waiver of Documentation 47

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- IRB must review a written script containing required elements and any applicable additional elements
- IRB may require an investigator to provide: consent forms without signature lines, contact information cards, or information sheets outlining study procedures

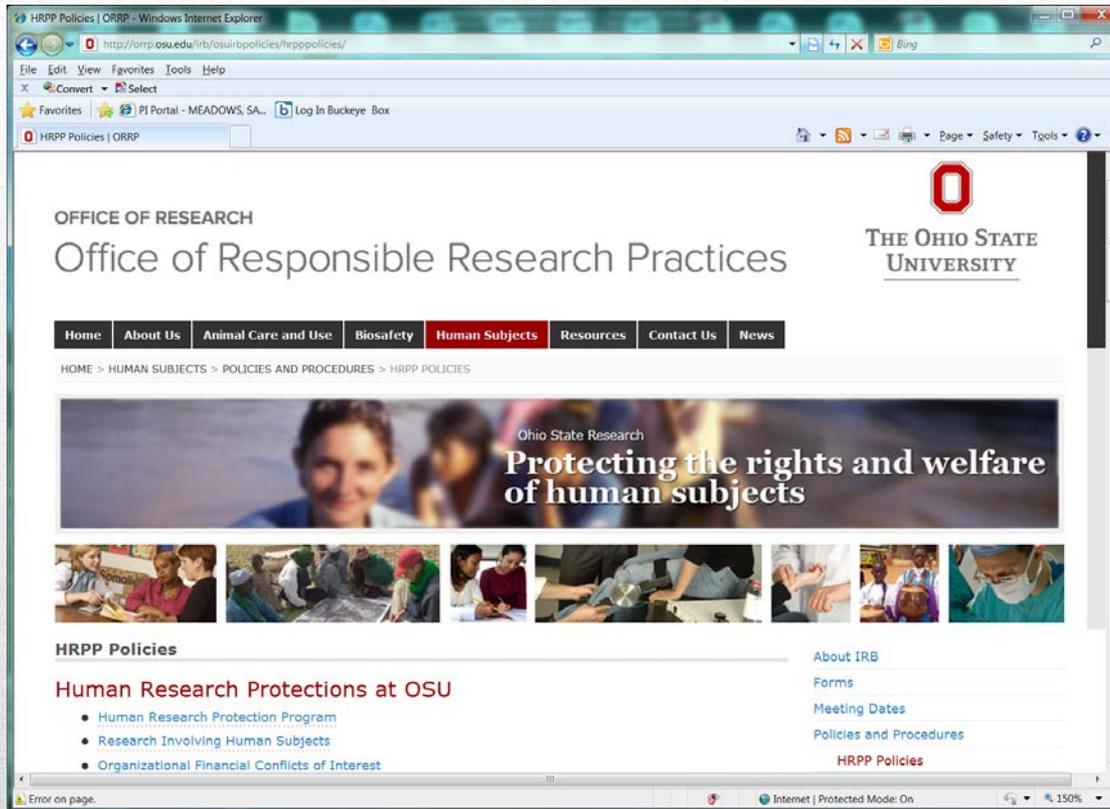
## Waiver of Documentation (cont.)

- **Waiver:** IRB has determined that investigators do not need to obtain informed consent (e.g., planned emergency research, research involving natural behavior, retrospective chart review)
- **Alteration:** IRB allows some or all elements of informed consent to be altered.
- The research could not practicably carried out without the waiver or alteration

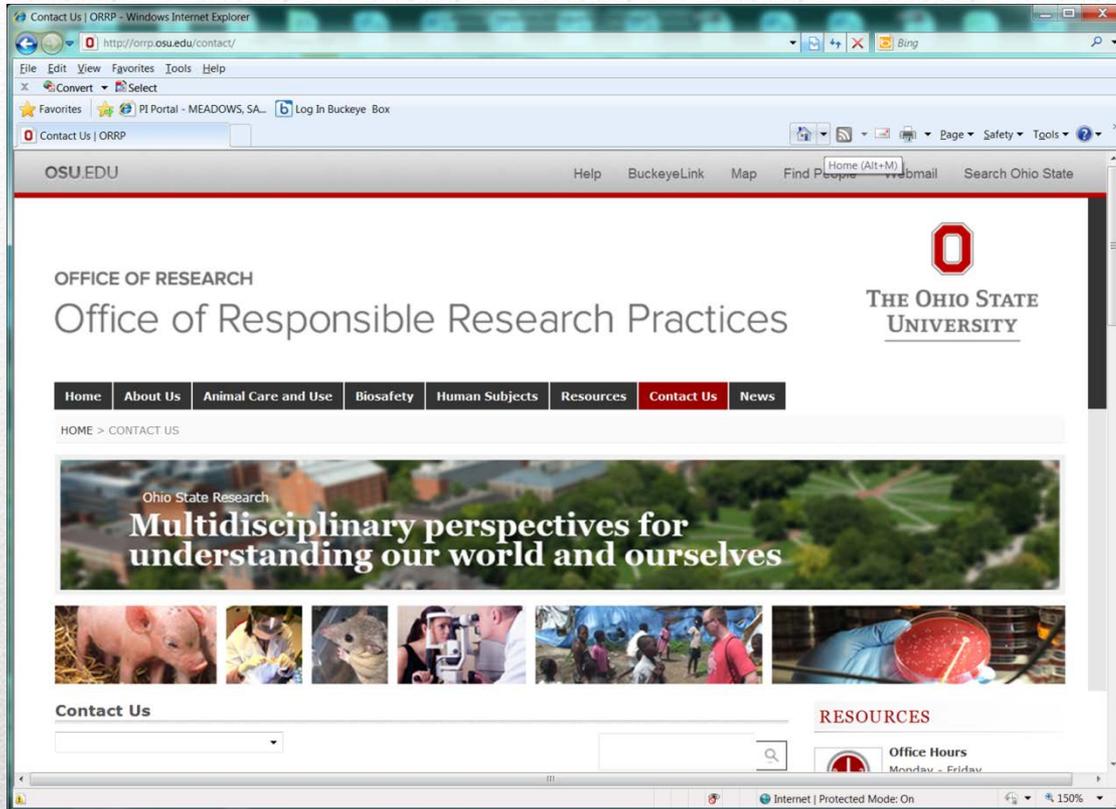
## Waiver or Alteration of Informed Consent

- Collection of data and/or specimens for *future unspecified research uses* and/or distribution for research purposes are activities that meet the definition of “research involving human subjects,” and IRB review is required.
- Specific informed consent must be obtained for future unspecified research involving specimens and/or data; HIPAA authorization is also required for data that include PHI
- HRPP policy, *Research Involving Data and/or Biological Specimens*

# Banking



# HRPP Policies



orpp.osu.edu

614-688-8457

# Contact Us

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