



THE OHIO STATE UNIVERSITY

Waivers of Informed Consent and HIPAA Research Authorization

Cheri Pettey, MA, CIP
Quality Improvement Specialist
Regulatory & Exempt Determinations

Jacob Stoddard, BA, CIP
Quality Improvement Specialist
Exempt & IRB Review



Objectives

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



Overview

- Definitions related to consent
- Waivers related to consent requirements
 - waiver of documentation, full waiver, alteration, and exempt study requirements
- Definitions related to HIPAA
- Waivers related to HIPAA authorization requirements
 - partial waiver, alteration, full waiver, and exempt study requirements
- Related Ohio State Human Research Protection Program (HRPP) policies and guidance



Definitions (Consent-Related)



Informed Consent

Agreement to participate in research expressed by an individual (or his/her legally authorized representative) authorized under applicable law to make such decisions, based on sufficient information (e.g., regarding possible risks and benefits of the research) and adequate opportunity to consider voluntary participation



Informed Consent

- 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 the process are important aspects (e.g., who will provide consent, timing, place, etc.)



Informed Consent

Regulations listing the consent requirements for non-exempt human subjects research:

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



Basic Elements of Informed Consent (IRB)

- a statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;
- a description of any reasonably foreseeable risks or discomforts to the subject;
- a description of any benefits to the subject or to others which may reasonably be expected from the research;



Elements of Informed Consent (IRB), cont.

- a disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
- a statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;
- for research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;



Elements of Informed Consent (IRB), cont.

- an explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related harm or injury to the subject; and
- a statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled



Elements of Informed Consent (Exempt Research)

For research that qualifies for exempt research, the required elements are set by Ohio State policy. Policy requires that, as applicable, consent be obtained by a process that will disclose adequate information, including that the activity involves research, participation is voluntary, a description of the purpose and procedures, sponsor information (if any), and investigator contact information



Assent

Agreement to participate in research expressed by an individual (e.g., a child) who cannot provide legally effective informed consent to participate on his/her own behalf

Note: Failure to object does not constitute assent





Waivers Related to Consent Requirements



Waiver of Documentation of Informed Consent (IRB)

Potential participants, or the parents of children who are potential participants, are presented (either verbally or in writing) with the same information required in a written consent document, but documentation of the process (i.e., the signing of the consent or parental permission form) has been waived by the IRB



Waiver of Documentation of Informed Consent (IRB) Requirements

An IRB may waive the requirement for an investigator to obtain a signed consent form for some or all subjects if it finds either

1. that the only record linking the subject to the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality, or
2. that 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



Waiver of Documentation of Informed Consent (IRB) Requirements, cont.

For research requesting a waiver of documentation under the first criteria (i.e., main risk is harm resulting from breach of confidentiality and consent form is the only link to research):

- Cannot apply to FDA-regulated research
- Each subject will be asked whether the subject wants documentation linking the subject with the research and the subject's wishes will govern



Waiver of Documentation of Informed Consent (IRB), Materials

- In some cases, a written form with signature lines must be created and offered to participants
- The IRB must review any materials/scripts containing required elements and any additional elements
- The IRB may require an investigator to provide: consent forms without signature lines, contact information cards, or information sheets outlining study procedures



Waiver of Documentation of Informed Consent (IRB), Examples

Example under 1:

- Research involving sensitive interviews about potentially illegal behaviors where the signed consent document would be the only element linking a participant to the research
 - A consent form would still need to be created, and each subject asked if they would like documentation of the process



Waiver of Documentation of Informed Consent (IRB), Examples, cont.

Examples under 2:

- minimal risk research with adults involving the administration of online surveys
 - All required elements of consent will be presented online, and participants will be informed that by continuing to complete the questionnaire, they are consenting to participate in the research
- Minimal risk research involving surveys of children where parents are present to give verbal parental permission



Waiver of Consent (IRB)

Waiving the requirement for obtaining informed consent or parental permission means that the IRB has determined that investigators need not obtain the subjects' informed consent to participate in research

Note: Informed consent is required for almost all FDA-regulated research



Waiver of Consent (IRB), Requirements

An IRB may waive the requirements to obtain informed consent or parental permission provided the IRB finds and documents that

- The research involves no more than minimal risk to the subjects
- The waiver will not adversely affect the rights and welfare of the subjects
- The research could not practicably be carried out without the waiver, and
- Whenever appropriate, the subjects will be provided with additional pertinent information after participation



Waiver of Consent (IRB), Impracticability

The most important justification is why it is not practicable (not possible) to conduct the research without the waiver. The justification must provide a reasonable rationale for why the research would not be possible without the waiver.

The following are not, on their own, sufficient justifications for granting a full waiver under the regulations:

- The fact that the research is retrospective
- The fact that the data to be used will be created regardless of the research
- Cost or time required to obtain consent
- Inconvenience to the investigators



Waiver of Consent (IRB), Impracticability, cont.

Some acceptable reasons the research could not practicably be carried out without the waiver:

- No current contact information for participants whose records/information will be accessed
- The requirement to obtain consent would threaten the scientific validity of the research results
- Because of the subjects' medical condition and the unavailability of legally authorized representatives of the subjects, no legally effective informed consent can be obtained
- Parental or guardian permission is not a reasonable requirement to protect the subjects and could put them at risk



Waiver of Consent (IRB), Examples

- Planned emergency research
- Research involving natural behavior
- Retrospective chart review
- Some research examining state or local public benefit or service programs
- Research designed to study conditions in children or a subject population for which parental or guardian permission is not a reasonable requirement to protect the subjects (e.g., neglected or abused children)



Can consent or parental permission ever be “passive” or “opt out?”

“Opt out” procedures are not consistent with the regulatory requirement for obtaining consent or parental permission. The IRB must determine that the conditions for a waiver of consent or parental permission can be met in order for a study to use an “opt out” process



Alteration of Consent (IRB)

In limited circumstances, the IRBs can approve a consent process that does not include, or alters, some or all of the elements of informed consent





Alteration of Consent (IRB), requirements

An IRB may approve an alteration of consent or parental permission provided the IRB finds and documents that:

- The research involves no more than minimal risk to the subjects
- The alteration will not adversely affect the rights and welfare of the subjects
- The research could not practicably be carried out without the alteration, and
- Whenever appropriate, the subjects will be provided with additional pertinent information after participation



Deception or Incomplete Disclosure

The most common use of an alteration is for studies involving deception or incomplete disclosure.

For all studies involving deception, investigators must document the nature of the deception where appropriate within the Buck-IRB application, including

- What information is being withheld or how participants are being misled
- How risks to the participants will be minimized
- Scientific rationale for deceiving the participants (speaks to impracticable requirement)



Deception or Incomplete Disclosure, cont.

- Description of the debriefing process or justification if requesting the debriefing requirement be waived
- Details on whether or not there is an opportunity for participants withdraw the use of their data from the research

Note: A debriefing process is generally required unless it would negatively impact the safety or welfare of the study participants. The script or documents to be used during the debriefing process must be submitted



Waivers Related to Assent (IRB)

Although children cannot provide valid informed consent to participate in research, they may be able to assent to participation. In general, investigators should obtain the assent of children to participate in research whenever children are capable of assenting. Assent may also be appropriate for adults with decisional impairment and other adults unable to consent for themselves, for whom a legally authorized representative will provide informed consent

- A waiver of assent may be granted under the same conditions as a waiver of consent/parental permission



Waivers Related to Assent (IRB), cont.

- The IRB is responsible for determining when assent is required in proposed research and the appropriate method for documenting assent (if any)
- Documentation of assent is generally required, based on the age and literacy level of the participant and nature of the research
- If verbal assent will be obtained, the IRB must review a written description of the information (e.g., a script) that will be provided to the participants during the assent process



Exempt Research and Consent-Related Waivers

- No official regulatory requirements to meet when requesting waivers
- When possible, assent, consent, and/or parental permission should be obtained
- Request process desired for the project
- Describe the process and justification in the appropriate sections
- No additional pages in Buck-IRB to complete in order to request waivers
- Projects may be referred to the IRB process if waivers are requested and sufficient justification is not provided



Definitions (HIPAA-Related)



HIPAA

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



PHI

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





Covered Entity

Covered entities are defined in the HIPAA rules as (1) health plans, (2) health care clearinghouses, and (3) health care providers who electronically transmit any health information in connection with transactions for which HHS has adopted standards

- Covered entities can be institutions, organizations, or persons
- Ohio State is a Hybrid Entity; this designation establishes which parts of the entity must comply with the Privacy Rule



HIPAA Identifiers

1. Names;
2. All geographical subdivisions smaller than a State, including street address, city, county, precinct, zip code, and their equivalent geocodes, except for the initial three digits of a zip code in certain circumstances.
3. All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older;
4. Phone numbers;
5. Fax numbers;
6. Electronic mail addresses;



HIPAA Identifiers, cont.

7. Social Security numbers;
8. Medical record numbers;
9. Health plan beneficiary numbers;
10. Account numbers;
11. Certificate/license numbers;
12. Vehicle identifiers and serial numbers, including license plate numbers;
13. Device identifiers and serial numbers;
14. Web Universal Resource Locators (URLs);
15. Internet Protocol (IP) address numbers;
16. Biometric identifiers, including finger and voice prints;
17. Full face photographic images and any comparable images; and
18. Any other unique identifying number, characteristic, or code



HIPAA Authorization

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



Privacy Board

A Privacy Board is a committee established to review requests for a waiver or alteration of the Authorization requirement for uses and disclosures of PHI in a particular research study. A Privacy Board may waive or alter all or part of the Authorization requirements. Under the Privacy Rule, an IRB may serve as a Privacy Board



Privacy Board, cont.

At The Ohio State University, the Privacy Board reviews requests for waivers or alterations of Authorization in exempt research. ORRP facilitates the review process; no additional action by the investigator is necessary.

- The IRBs serve as Privacy Boards for non-exempt research



Waivers Related to HIPAA Requirements



Remember to make sure HIPAA actually applies to your research:

- There are many datasets that contain (and surveys that collect) health-related information—not all of them are created or held by a covered entity
- Investigators may be receiving existing data from banks/repositories or honest brokers with IRB approved processes to allow release of de-identified or limited data sets
- ORRP can assist in determining if HIPAA applies to your project



HIPAA Waiver of Authorization Requirements (all types)

- 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



Partial Waiver of Authorization

Allows PHI access/retention for the purposes of identifying potential subjects

- Information collected under partial waiver must be destroyed after recruitment is complete unless authorization or additional waiver/alteration is obtained



Partial Waiver of Authorization, cont.

Do I need a partial waiver to access my own patients' records?

- A partial waiver is not required when the study is being considered for therapeutic purposes and the records are accessed by the patient's clinical team (i.e., clinical team that normally sees the patient, not research staff)
- If potentially therapeutic, but charts are being accessed/screened by another doctor or staff member who is not part of the regular clinical team, then a partial waiver is required
- A partial waiver is required if the research is not therapeutic, regardless of any clinical relationship



Partial Waiver of Authorization, cont.

- 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



Example of a Partial Waiver

Investigators need to access their clinic records in order to identify adults with a certain immune disorder who meet the inclusion criteria for a non-therapeutic research study

- Once identified, potential participants will be contacted by members of the study team at their next visit and asked to participate in the study
- The partial waiver is only for recruitment purposes—all data collected must be destroyed once someone declines or is found ineligible unless authorization is obtained or a full waiver or alteration is granted



Alteration of HIPAA Authorization

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

- Same criteria as full waiver must be met—including that the research could not practicably be conducted without the waiver or alteration
- Cannot waive documentation unless it is actually impracticable to obtain (there is not as much flexibility to waive the signature requirements under HIPAA as there is to waive documentation of consent)



Example of an Alteration of Authorization

Investigators need to access medical records in order to identify adults with a certain immune disorder who meet the inclusion criteria for a research study that involves collecting some existing PHI and linking it to a telephone survey

- Once identified, potential participants will be contacted by phone and asked to participate
- Since treatment is complete and all contact is over the phone, it is not practicable to obtain a signature
- Authorization obtained verbally over the phone
- In this study, both a partial waiver and an alteration would be requested



Full Waiver of HIPAA Authorization

Allows PHI access/retention without authorization for the entire research study (collection and data analysis)

- The fact that the research is retrospective or that the data to be used will be created regardless of the research are not sufficient justifications for granting a full waiver under the regulations
- In general, studies involving prospective access/collection of PHI should include a plan to obtain authorization



Full Waiver of HIPAA Authorization, cont.

- Authorization must be impracticable to obtain—for example:
 - no longer in regular contact with patients and significant time has passed since treatment, so there is likely not current contact information available
 - because of the nature of the population/disease, many potential participants may have died
 - scientific validity necessitates collecting all records (with specific justification provided)



Example of a Full Waiver of HIPAA Authorization

You wish to compare the use of approved Drug A to approved Drug B in elderly patients with certain types of infections over the last 10 years.

- Not FDA-regulated
- All data currently exists
- Investigators need to access the electronic medical record for data collection
- Investigators need to collect some of the 18 HIPAA identifiers as part of the research (e.g., dates of treatment, zip codes)



HIPAA Waivers and Exempt Research

In general, the only waiver of authorization request seen in exempt research is for a full waiver of authorization for research proposed under exempt category #4 (e.g., access to PHI for a retrospective chart review where no identifiable data is collected/recorded).

The regulatory requirements and Buck-IRB application pages are the same as those completed for IRB-reviewed research when requesting a full waiver of HIPAA authorization. The Ohio State Privacy Board reviews the request.



HRPP Policies



HRPP Policies

<http://orpp.osu.edu/irb/osuirbpolicies/hrpppolicies/>

HRPP Glossary

<http://orpp.osu.edu/irb/osuirbpolicies/hrppglossary/>





Examples of Related HRPP Policies:

- Exempt Research
- IRB Submission and Pre-Review
- Recruiting Methods, Recruitment Materials, and Participant Compensation
- Informed Consent Process and the Elements of Informed Consent
- Documentation of the Informed Consent Process
- Privacy and Confidentiality
- Assent and Parental Permission
- Short Form Informed Consent
- Research Involving Children
- Research involving Data and/or Biologics, or Devices



Investigator Guidance

<http://orpp.osu.edu/irb/investigator-guidance/>

- Consent, assent, and parental permission templates and guidance
- Includes verbal consent template
- Exempt research
- HIPAA guidance
- QA/QI vs. research



HIPAA Guidance

<http://orrp.osu.edu/irb/investigator-guidance/hipaa/>

Ohio State University Privacy Officers

http://orrp.osu.edu/files/2011/10/privacyofficers_060115.doc



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Protecting Human Subjects in Research at Ohio State



Human Subjects

The Human Research Protection Program is responsible for all Ohio State research involving human subjects. The HRPP's primary responsibility is to protect the rights and welfare of human research subjects, in accordance with Department of Health and Human Services (DHHS) and Food and Drug Administration (FDA) regulations.

NEWS

[Spring 2015 IRB Newsletter now available](#)

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[New System for IRB and Exempt Submissions](#)