Informed Consent and Waivers of Informed Consent
General Requirement for Informed Consent

No investigator may involve a human being as a subject in research covered by this policy unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative.

45 CFR 46.116
Basic Elements of Informed Consent

1. A clear statement that it is a research study, purposes and the expected duration, procedures to be followed, and identification of any procedures which are experimental;

2. A description of any risks or discomforts to the subject;

3. A description of any benefits to the subject or to others;

4. Alternative procedures or courses of treatment

5. A statement describing how confidentiality will be maintained;

6. For research involving more than minimal risk, compensation for injury;

7. Research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject;

8. A statement that participation is voluntary

45 CFR 46.116, General requirements for informed consent
More Than a Form, a PROCESS

Identify → Approach → Explain

Read → Describe
- Who
- What
- Where
- When
- Why
- How

Ask → Leave

Answer → Sign

REPEAT

Answer
Who Needs to Be at the Table?

- Think in advance who needs to be present:
  - Subject
  - Family member
  - Primary Investigator
  - Research Coordinator
  - Interpreter
  - Others

- Build attendees into the consent process
Non–English Speaking Participants

**Expected** (recruiting those who do not speak English):

- use a consent document that is translated into a language understandable to potential subjects
- Process written into protocol

**Unexpected** (recruiting a subject who happens not to speak English):

- Submission of Exception Request
- Use of an IRB–approved "short form" consent document, written in a language that the person understands and that is combined with an oral presentation of the English version of the consent document using an interpreter.

http://hrpo.pitt.edu/non–english–speaking–participants
Possible questions from AAHRPP

- Do you know the elements of consent?
- What process does your team use to obtain consent?
- What methods do you use to determine subject comprehension?
- What do you do if you feel someone does not understand?
- What if your subject doesn’t speak English?
Types of Waivers

- Waiver of the requirement to obtain a signed consent (waiver to document consent)
- Waiver of informed consent
- Waiver of HIPAA Authorization for the collection of PHI from a UPMC/Pitt covered entity
What is it: The consent process takes place but signatures of participants are not required. The research team will make a note in the research record of the conversation.

When is it commonly used: Phone screening, online consent, or other situations where written consent doesn’t make sense.
Researchers must justify one of the following:

- **45 CFR 46.117(c)(1)** That 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. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or

- **45 CFR 46.117(c)(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 Informed Consent

- **What is it:** No consent process takes place

- **When is it commonly used:**
  - Medical record review for recruitment
  - Chart review research
  - Parental permission
  - Other Minimal Risk activity
Waiver of Consent – OSIRIS 4.7

- Research activity involves no more than minimal risk
- Waiver will not adversely affect the rights and welfare of the subjects
- Research activity could not practicably be carried out without the waiver
- Whenever appropriate, the subjects will be provided with additional pertinent information after participation
What is it: HIPAA authorization is not obtained for access to protected health information (PHI)

When is it commonly used: in conjunction with a waiver of consent for a chart review

When is it not used: A medical record review for recruitment does not require HIPAA waiver because it is considered “preparatory to research”
Waiver of HIPAA Authorization – OSIRIS 2.14

- Investigators accessing, recording, and/or obtaining identifiable information must have normal legitimate access.

- The University of Pittsburgh IRB cannot grant a HIPAA waiver for medical records from entities outside of UPMC/Pitt.
Use or disclosure of PHI involves no more than a minimal risk to the privacy of individuals based on:

- Plan to protect the identifiers from improper use and disclosure;
- Plan to destroy the identifiers at the earliest opportunity consistent with the conduct of the research;
- Written assurances that the PHI will not be reused or disclosed to any other person or entity;
- Research could not practicably be conducted without the waiver or alteration;
- Research could not practicably be conducted without access to and use of the PHI.
Possible questions from AAHRPP

- What is a waiver of informed consent?

- How does a waiver of informed consent differ from a waiver to document consent?

- If you have a waiver to document consent, how do you memorialize the process?
Questions?

Specialized education available upon request: askirb@pitt.edu