INFORMED CONSENT, HIPAA AND WAIVERS

GENERAL REQUIREMENTS FOR INFORMED CONSENT
(45 CFR 46.116)

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

General Requirements for Informed Consent

§46.116

1) Before involving a human subject in research covered by this policy, an investigator shall obtain the legally effective informed consent of the subject or the subject's legally authorized representative.
2) An investigator shall seek informed consent only under circumstances that provide the prospective subject or the legally authorized representative sufficient opportunity to discuss and consider whether or not to participate and that minimize the possibility of coercion or undue influence.
3) The information that is given to the subject or the legally authorized representative shall be in language understandable to the subject or the legally authorized representative.
4) The prospective subject or the legally authorized representative must be provided with the information that a reasonable person would want to have in order to make an informed decision about whether to participate, and an opportunity to discuss that information.
5) Broad Consent
6) No informed consent may include any exculpatory language through which the subject or the legally authorized representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence

Key Information:
5 Factors Identified in The Common Rule

1. A statement that the project is research, and that participation is voluntary
2. Summary: Purpose, duration, overview
3. Reasonable, foreseeable risks or discomforts
4. Reasonable expected benefits
5. Alternative procedures, if any

Required for federally funded studies

IRB may request for any study

No informed consent may include any exculpatory language through which the subject or the legally authorized representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence

Exculpatory

- By agreeing to this use, you should understand that you will give up all claim to personal benefit from commercial or other use of these substances

Acceptable

- Tissue obtained from you in this research may be used to establish a cell line that could be patented and licensed. There are no plans to provide financial compensation to you should this occur

https://www.hhs.gov/ohrp/regulations-and-policy/guidance/exculpatory-language-in-informed-consent-documents/index.html#:~:text=Examples%20of%20Exculpatory%20Language%3A&text=I%20voluntarily%20and%20freely%20donate,and%20interest%20to%20said%20items.

BASIC ELEMENTS OF INFORMED CONSENT

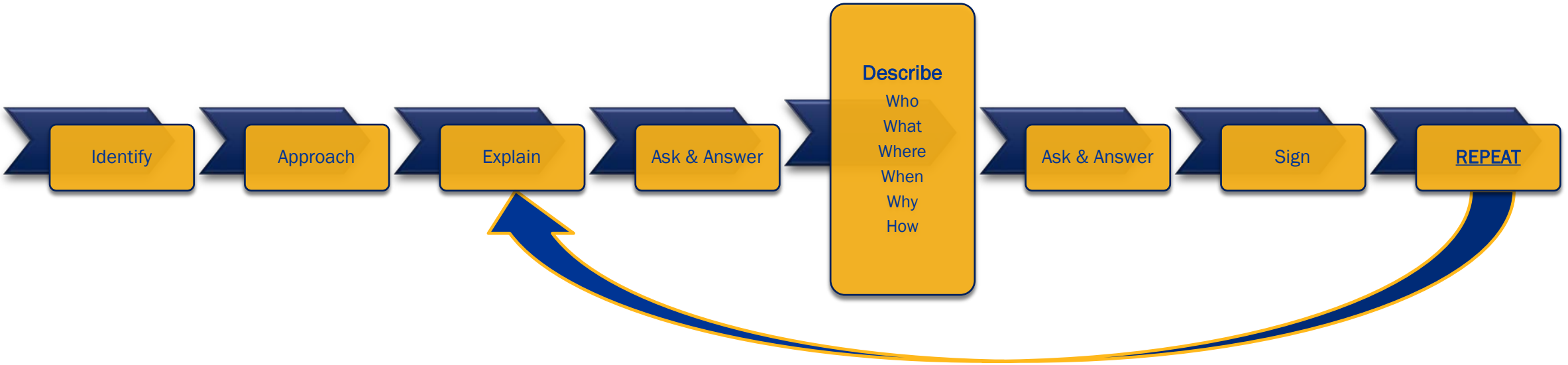
- A clear statement of research, purpose, duration, and procedures;
- A description of any risks or discomforts to the subject;
- A description of any benefits to the subject or to others;
- Alternative procedures;
- A statement describing how confidentiality will be maintained;
- Compensation for injury (> min risk);
- Research subjects' rights, and whom to contact in the event of a research-related injury;
- A statement that participation is voluntary
- Whether or not identifiable private information or biospecimens will be used in future studies

ADDITIONAL OF INFORMED CONSENT

45 CFR 46.116(6)(C)

- The treatment or procedure may involve risks that are currently unforeseeable;
- Circumstances when participation may be terminated by the investigator without subject or LAR consent
- Additional costs that may result from participation
- Consequences of a subject's decision to withdraw and how to orderly terminate
- A statement that new findings that may affect subject's willingness to continue will be provided
- The approximate number of subjects in the study
- A statement that biospecimens may be used for commercial profit & if the subject will share in profit
- A statement whether clinically relevant research results will be disclosed to subjects and when
- For biospecimen research, whether the research will or might include whole genome sequencing

CONSENT IS A PROCESS, NOT JUST THE FORM



Informed consent is not a single event or document. It is an ongoing process involving the study team and the research subject. Informed consent consists of a full discussion of the research:

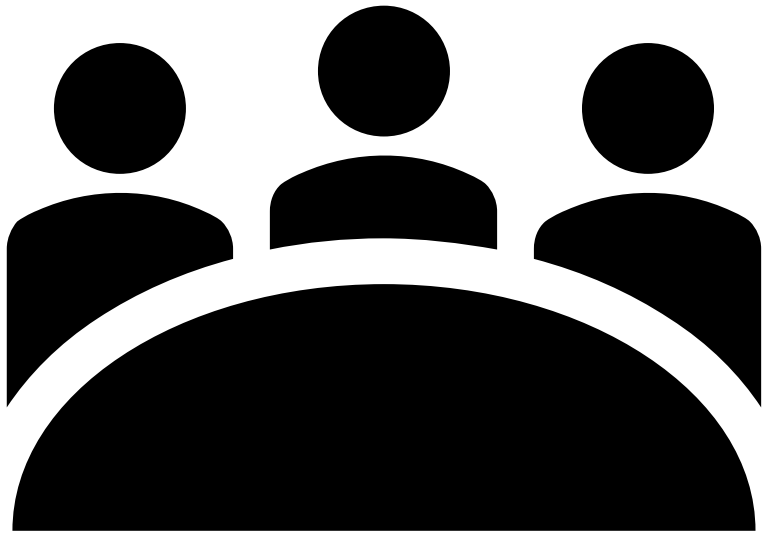
- nature of the research
- subject's role in that research
- understanding of that role by the potential subject
- subject's voluntary choice to join the study

INVESTIGATOR'S ROLE

PI has ultimate responsibility to determine how and who conducts the process. Plan who needs to be present on both sides of the table:

- Subject only?
- One parent or two parents?
- Proxy?
- Primary Investigator?
- Co-Investigator?
- Others?

Subjects may want family or friends involved



Investigator may want colleague, coordinator, or other research staff involved

WHEN DO I HAVE TO NOTIFY OR RECONSENT SUBJECTS?

Consent as an ongoing process demands dissemination of new information concerning the subject's participation

New Findings:

1. Could it affect current subjects desire to participate? (if yes, reconsent)
2. Is it something that former subjects would need to know? (notification)

Study Procedure Change:

If subjects are unaffected by the change (i.e. past that point of the study), they do not need to reconsent for the new procedures. They may need notification depending on the reason

Risk (new or changed):

1. Completed subjects may need notified of late developing risks
2. Current subjects may need reconsent if they haven't yet assumed the risk

Reconsent: use when subjects have to decide whether or not to proceed with additional study procedures
Notification: use when information needs to be conveyed but there is nothing to "reconsent" to

NON-ENGLISH SPEAKING PARTICIPANTS

Expected
(recruiting those who do not speak English)

- Recruitment process written into approved protocol
- Consenting process, including who will carry it out, written into the approved protocol
- Consent documents (and other relevant study documents) translated into a language understandable to potential subjects

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

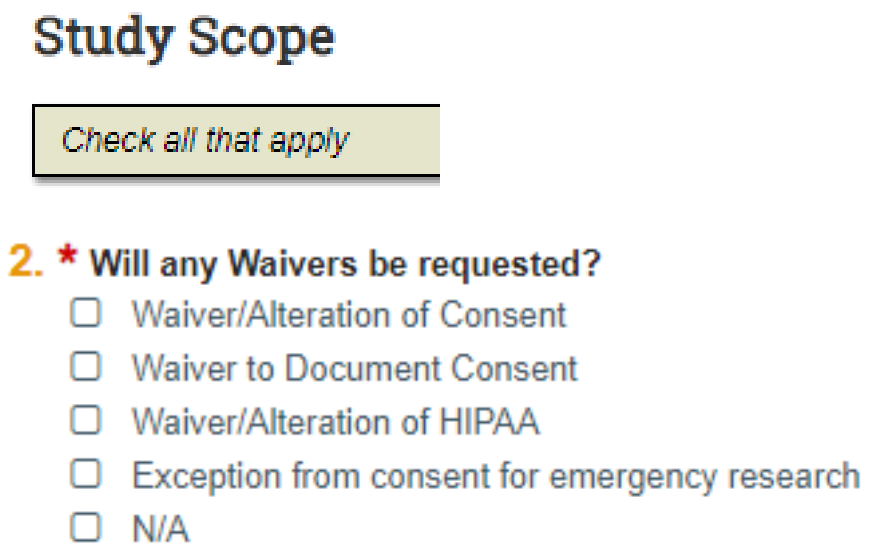
Details can be found in A-Z Guidance: https://www.hrpo.pitt.edu/non-english-speaking-participants

WAIVERS OF INFORMED CONSENT

45 CFR 46.116(f): An IRB may waive the requirement to obtain informed consent for research…

WAIVERS: FEW OPTIONS, MANY APPLICATIONS

- Waiver/Alteration of Informed Consent
- Waiver to Document Informed Consent
- Waiver of HIPAA
- Emergency Exception from Informed Consent



EMERGENCY EXCEPTION FROM INFORMED CONSENT (EFIC)

- Used for planned emergency research
- Eg: trauma research, cardiac arrest in the field
- Extensive process that includes community consultation
- Notify the IRB in advance when planning this type of research

Minimum Criteria:

- Potential subjects are in a life-threatening situation, and
  - available treatments are unproven or unsatisfactory and
  - collection of scientific data is required to determine the safety and effectiveness of the experimental intervention
- Obtaining informed consent is not feasible because:
  - the potential subject is not able to consent due to his/her medical condition
  - the intervention must be administered before consent from the potential subject's authorized representative is feasible and
  - there is no reasonable way to prospectively identify potential eligible subjects
- Participation in the research study holds out the prospect of direct benefit to the subjects because:
  - the subjects are facing a life-threatening situation
  - appropriate pre-clinical and prior clinical research studies support the potential for direct benefit and
  - the risks associated with the research are reasonable relative to the risks of the subjects' condition and the risk/benefit ratio of standard therapy for the condition
- The research could not be practicably carried out without the waiver.

SCREENING, RECRUITING, DETERMINING ELIGIBILITY

§116(G)

An investigator can obtain information or biospecimens for screening, recruiting, or determining eligibility without informed consent:

- Information is obtained through oral or written communication with the prospective subject or LAR, or
- The investigator will obtain private identifiable information or identifiable biospecimens by accessing records or stored identifiable specimens

- Effectively eliminates the need for the IRB to grant waivers for screening and recruitment, consistent with FDA regulations and HIPAA
- **IRB must approve the procedure as a part of the recruitment plan**

Waiver to Document Informed Consent

What is verbal consent?

- Dialog occurs between the subject and investigator that contains all of the required elements of informed consent.
- Subject states their verbal agreement to participate and does not sign anything
- Investigator documents the conversation in the research record

Is it binding?

Yes. The Common Rule states than an IRB may waive the requirement for the investigator to obtain a signed informed consent form for some or all subjects

45 CFR 46.117(c)(1)

Scripts must include all elements of consent!

When can I use it?

In **minimal risk situations** when:

- The principal risk is breach of confidentiality, and the consent form is the only link to the study
- The study involves no procedures for which written consent is normally required outside of research
- Cultural or community norms do not support individuals signing forms

Common Uses of a Waiver to Document

- Research activities over the phone
- “Click to consent”
- Request to fast prior to obtaining written consent
- Consent form could put subject at risk
- Low risk psychosocial research
- Other minimal risk activity (focus groups, surveys, interviews)

WAIVER OF INFORMED CONSENT §46.117(F)

Must be able to justify waiver criteria

i. Research involves no more than minimal ris

ii. Research could not be practicably carried out without the waiver

iii. If using identifiable private info or identifiable biospecimens, the research could not be carried out without using the identifiable info or specimens

iv. Waiver will not adversely affect the rights and welfare of subjects, and

v. Whenever appropriate, the subjects will be provided with additional pertinent information after participation

COMMON USES OF A FULL WAIVER

- Parental permission
- Other minimal risk activity
  - Obtain samples for later analysis
- Alteration to omit one or more required elements
- Activities where no interaction will take place (e.g. chart review)

HIPAA AUTHORIZATIONS AND WAIVER

The Health Insurance Portability and Accountability Act (HIPAA) includes a Privacy Rule that provides Federal standards for safeguarding the privacy of individually identifiable health information that is held by a "covered entity"

PROTECTED HEALTH INFORMATION (PHI)

- Is individually identifiable health information, whether oral or recorded in any form or medium (e.g., narrative notes; X-ray films or CT/MRI scans; EEG / EKG tracings, etc.), that may include demographic information, and
- Is created or received by a 'covered entity,', and
- Relates to the past, present, or future physical or mental health or condition of an individual, to the provision of health care to that individual, and/or to payment for health care services and
- Identifies the individual directly or contains sufficient data so that the identity of the individual can be readily inferred

HIPAA

- Researchers are obligated comply with HIPAA when they access, use, disclose, and/or create “Protected Health Information” (PHI)

- Accessing identifiable medical records for research requires a signed HIPAA Authorization or a waiver
  - Exempt studies using PHI require authorization or waiver

Elements of HIPAA Authorization

Who is requesting the PHI for research?	We are also requesting your authorization or permission to review your medical records.
Why is this information needed?	To determine whether you meet the conditions for participation in this study, to compare your earlier test results to the findings from this study, and if possible, to use your previous exam results in place of, or in addition to, some of the exams needed for this study.
What will be disclosed?	We will obtain the following information: your diagnosis, age, past medical history, diagnostic procedures, and results of any tissue biopsies or blood tests, including results of genetic tests that were already done as part of your standard evaluation at the Cancer Center.
Will research data be placed in the medical record? If yes, describe.	As part of this research study, some information that we obtain from you will be placed into your medical records held at UPMC, including the results of pregnancy tests (for women of childbearing potential) and other medical tests.
How long will this information be made available to the researchers?	This identifiable medical record information will be made available to members of the research team for an indefinite period of time.
Who (other than the investigators) will receive the PHI, and how will they use it? Note: highlighted element must be included in every consent form.	Your medical information, as well as information obtained during this research study, may be shared with other groups, possibly including authorized officials from the Food and Drug Administration, the Cancer Oncology Group, the National Cancer Institute, and the University of Pittsburgh Office of Research Protections, for the purpose of monitoring the study. Authorized representatives of UPMC or affiliated health care providers may also have access to this information to provide services and address billing and operational issues.

Statement of the potential risk that PHI will be re-disclosed by a recipient:	We will make every attempt to protect your privacy and the confidentiality of your records, as described in this document, but cannot guarantee the confidentiality of your research records, including information obtained from your medical records, once your personal information is disclosed to others outside UPMC or the University.
How long will this authorization be valid?	This authorization is valid for an indefinite period of time.
Right to revoke authorization; how to revoke:	However, you can always withdraw your authorization to allow the research team to review your medical records by contacting the investigator listed on the first page and making the request in writing.
Implications of revocation of authorization	If you do so, you will no longer be permitted to participate in this study. Any information obtained from you up to that point will continue to be used by the research team.
Implications of not signing form	Note: this need not be stated in the consent form but must be in the IRB application: subjects who do not sign this hybrid consent form (that includes the HIPAA authorization) cannot participate in the study
Signature line should include last phrase (highlighted here)	By signing this form I consent to participate in this research study and provide my authorization to share my medical records with the research team.

https://www.hrpo.pitt.edu/sites/default/files/hipaa_auth_text8.21.18_0.pdf

REQUIREMENTS FOR WAIVER OF HIPAA

1. Plan to protect the identifiers from improper use or disclosure
2. Plan to destroy ID at the earliest opportunity, unless justified to retain
3. Written assurances that the PHI will not be used or disclosed to others (entity or person), except by law, authorized oversight, or other permitted use or disclosure
4. Why the research couldn't practicably be conducted without the waiver
5. Why the research couldn't practicably be conducted without access and use of the PHI
6. Why the nature and amount of PHI is felt to be the minimum necessary

Waiver of HIPAA uses

- Rarely used on a full board study
- Not required when using medical records to identify subjects for recruitment
  - Preparatory to research
- Common on chart reviews

POSSIBLE QUESTIONS FROM AAHRPP:

- What are the required elements of informed consent?
- Explain the process of consent for your study (how do you engage with the subject)
- Explain how you obtain informed consent and who is involved
- How do you determine subject comprehension of consent and encourage questions?
- What do you do if you feel someone does not understand?
- How would you proceed if you had an eligible subject who did not speak English?
- When would you use a waiver of consent?
- Explain when HIPAA applies to a study and what that means

QUESTIONS?

Specialized education available upon request: askirb@pitt.edu