Informed Consent & HIPAA Authorization-Required Elements

Summary

Unless a waiver or alteration of consent is granted by the IRB, the Investigator and IRB ensure that informed consent documents include the basic required elements and, if appropriate, the additional elements of consent specified in 45 CFR 46.116 , 21 CFR 50.25 and the applicable additional elements of consent and requirements related to presentation of understandable key information described in the HHS Final Rule (2018 Revised Common Rule - 45 CFR 46).

Basic Elements of Informed Consent:

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1. Statement that the study involves research;
2. Explanation of the purposes of the research;
3. Expected duration of the subject's participation;
4. Description of procedures to be followed;
5. Identification of any procedures that are experimental;
6. Description of any reasonably foreseeable risks or discomforts to the subject;
7. Description of benefits to the subject or others that may be reasonably expected from the research;
8. Disclosure of appropriate alternative procedures or course of treatment, if any, that might be advantageous to the subject;
9. Statement describing the extent to which confidentiality of records identifying the subject will be maintained;
10. For medical research involving more than minimal risk, an explanation as to if any compensation or any medical treatments are available if injury occurs and, if so, what they consist of, or where further information can be obtained;
11. The identification of an individual who can be contacted for answers to questions related to the research, research-related injury, or their rights as a research subject;
12. 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 s/he is otherwise entitled.

Additional Elements of Informed Consent (45 CFR 46.116 (b) or 21 CFR 50.25(b)), if appropriate for this study:

1. A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable;
2. Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;
3. Any additional costs to the subject that may result from participation in the research;
4. The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;
5. A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject;
6. The approximate number of subjects involved in the study.
7. Genetic Information Nondiscrimination Act of 2008 (GINA) language, if the study includes genetic testing
8. Clinicaltrials.gov language, if the study is an applicable clinical trial (LINK TO GUIDANCE)
9. COC (Certificate of Confidentiality) language, if the study has a COC or meets NIH criteria for automatically granting a COC

Additional Elements of Informed Consent (Final Revised Common Rule 45 CFR 46 Subpart A - Basic HHS policy of Protection of Human Research Subjects (January 18, 2017) - 45 CFR 46.116(c) if the study collects identifiable private information or biospecimens:

1. Statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens
    - could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the LAR, if this might be a possibility - OR –
    - Statement that the subject's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies
2. Statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit
3. Statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions; and
4. For research involving biospecimens, whether the research will (if known) or might include

whole genome or exome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen)

Key Information Requirement

The informed consent must include a **clear, concise explanation of Key Information** in the beginning of the consent that can assist a reasonable person in deciding about whether to participate in this research. The following points and order are recommended in *Final Revised Common Rule 45 CFR 46 Subpart A - Basic HHS policy of Protection of Human Research Subjects (January 18, 2017)*:

- Statement that the project is research and participation is voluntary
- A summary of the research, including purpose, duration, and list of key activities
- Reasonable, foreseeable risks or discomforts
- Reasonable, expected benefits
- Alternatives, if any

Informed consent must begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or legally authorized representative in understanding the reasons why one might or might not want to participate in the research. This part of the informed consent must be organized and presented in a way that facilitates comprehension, and provide sufficient information that a "reasonable person" would want to have. Informed consent must present information in sufficient detail relating to the research and must be organized and presented in a way that does not merely provide lists of isolated facts.

"Key information" might be different for different studies or different types or studies. For example, information a person might need to decide whether or not to participate in a study randomizing participants to receive investigational drug/device v. placebo for a serious health condition is probably very different from what is important to a person asked to take part in a minimal risk observational study. It is the principal investigator's responsibility to determine what information should be considered "key information" for a study. That "key information" should be presented to participants first.

The following is an example of key information presentation:

1. A statement that the project is research and that participation is voluntary	*EXAMPLE: "You are being asked to take part in a research study. Research Studies include only people who choose to take part. The study team members will explain the study to you and will answer any questions you might have. You should take your time to make your decision."*
2. A summary of the research, including...	• *Purpose of the research* • *Duration, number of study visits* • *Overview of study procedures*

	• *Other study specific information*
3. Reasonable, foreseeable risks or discomforts	*EXAMPLE: "Risks and side effects related to the [procedures, drugs, interventions, devices] include those which are:* *Likely: _____* *Less Likely: _____* *Rare but serious: _____*
4. Reasonable, expected benefits	*EXAMPLE: "There will be no direct benefit to you from participating in the study. However, this study will help doctors learn more about X disease and it is hoped that this information will help in the treatment of future patients with conditions like yours."*
5. Alternative procedures to course of treatment, if any	*EXAMPLE: "If you decide not to participate in this research, your other choices may include:* • *Getting treatment or care for [disease] without being in a study* • *Taking part in another study* • *Getting no treatment"*

If the ICF includes HIPAA authorization (or if stand-alone HIPAA authorization is used), the following elements are required:

1. A specific/meaningful description of PHI that will be collected for research and the purpose of collecting this information (e.g., *for this research*)
2. The person or class of persons who may use or disclose the PHI collected for research (e.g. *study doctor and study staff*)
3. The person or class of persons to whom PHI collected for research may be disclosed and the purpose of such disclosure (e.g., *We will share your information with the study sponsor and its partners for this research*)
4. Potential for disclosed PHI to be redisclosed by the recipient and no longer protected by Privacy Rule (e.g., *Geisinger (or AtlantiCare) is required by law to protect your health information. Some laws that protect your health information only apply to hospitals, doctors' offices, and other healthcare providers. When your information is shared outside of Geisinger, some federal privacy laws might not apply.)*
5. The expiration date of the authorization (e.g., *may use or use and share your health information until the end of study* or … *indefinitely for this study's purpose*)

6. Consequences to the individual of a refusal to sign the authorization (e.g., *cannot take part in the study/receive research-related treatment* (if applicable) *without signing consent/authorization)*
7. The individual's right to revoke authorization, process to revoke and consequences of such revocation (e.g., *By signing this form, you are giving Geisinger or AtlantiCare [select appropriate one] permission to use and share your health information indefinitely. If you change your mind, tell us in writing to stop using and sharing your information. Write to: [Enter name of study, internal zip code and address] Information already collected will still be used. We will only use and share new information if it is needed to protect your safety or follow with the law.*)
8. Participant or LAR signature and date

Readability statistics & Format

Readability statistics and format of the informed consent should comply with Geisinger standards, considering the population to be studied. Exceptions to these requirements might be considered if understandability is deemed reasonable by the IRB.

- Flesch-Kincaid Grade Level = 6-8
- Flesch Reading Ease > 60
- Font = Arial 14
- Spacing = multiple @ 1.15