Northwestern | OFFICE FOR RESEARCH

Crafting Consent

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Informed Consent

- Providing a potential subject with adequate information about the research to allow for an informed decision about the subject's voluntary participation in a research study.
- A process that continues beyond obtaining the subject's initial consent at the time of enrollment and may involve providing additional information as the research progresses or as the subject or situation requires.
- The consent document (or form) is not the same as informed consent.

- 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, but rather facilitates the prospective subject's or legally authorized representative's understanding of the reasons why one might or might not want to participate.
  - See the SOP 13 on Legally Authorized Representatives

Elements of Informed Consent
45.CFR.46.116 and 21.CFR.50.21

(1) A statement regarding the research, an explanation of the purpose, expected duration, procedures to be followed, and identification of any procedures that are experimental

(2) A description of any reasonably foreseeable risks to the subject

(3) A description of any benefits to the subject or to others that may be expected

(4) A disclosure of alternative procedures or courses of treatment

(5) A statement describing the extent to which confidentiality of records identifying the subject will be maintained

Elements of Informed Consent 45.CFR.46.116 and 21.CFR.50.21

(6) Explanation as to whether there is compensation and an explanation as to whether any medical treatments are available if injury occurs (for greater than minimal risk research)

(7) 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 injury to the subject

(8) 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

(9) One of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens:

- (i) A statement that identifiers might be removed from the collected data or biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or;

- (ii) A statement that the subject's information or biospecimens collected as part of the research will not be used or distributed for future research studies.

Consent Process and Documentation

- Make sure that consent is obtained prior to the start of any data collection or study procedures.
- Verify that the person obtaining consent has up to date CITI training and is listed on the approved IRB personnel list.
- Verify that you are using the most up to date and IRB approved and stamped consent form. This can be found in the “Final” column in the Documents tab of eIRB.
- Offer the potential participant access to the consent prior to the participant prior to the discussion whenever possible.
- Offer a copy of the signed consent to the participant after completing both sets of signatures.
- Detail the consent process and documentation of consent in the protocol.

  – See the IRB guidance to describe the consent process: https://irb.northwestern.edu/docs/website-process-obtaining-consent-1q7i6ut.pdf

  – See the IRB Form to document informed consent.

Translations and Short Form

- The consent document needs to be written and presented in a language understandable to the participant.
- If presented with a person whose primary language is other than English, you may use the Short Form process described on the IRB website. (23 languages available)
- A written summary of what is to be said to the participant or the participant's legally authorized representative (English version of the IRB-approved informed consent document)
- The short form document that will be signed by the potential participant.
- Confirmation that:
  - The oral presentation will be conducted in a language understandable to the participant.
  - The person obtaining consent is authorized by the IRB.
  - There will be a witness to the oral presentation (this cannot be the same person who is obtaining consent). The witness should be fluent in both English and the language of the participant. When the person obtaining consent is assisted by a translator, the translator may serve as the witness.
  - The short form will be signed by the participant and the witness.
  - The written summary will be signed by the witness and the person actually obtaining consent.
  - A copy of the oral summary and the short form will be given to the participant.

- After a couple uses of the Short Form, seek out a complete translation of the consent form. This can be done by a person who is fluent in both languages and can attest to their qualifications and the accuracy of the translation.

Consent Document in Perspective

- Polishing the wording in the consent form does not meaningfully improve the protection of subjects.

- Most subjects get the information they need about participating in research by discussing the study with the research team and with family and friends.

Readability

- Avoid legal-sounding language
- Avoid repetition
- Avoid large blocks of printed text
- Avoid using contractions
- Avoid using exculpatory language. These are statements that often use the phrase “I understand.”
  - Any language that waives or appears to waive the rights of the participant
  - Any language the waives or appears to waive the liability of those conducting the research (investigators, sponsors, institutions, etc.)

Readability

- Use active verbs (the subject of the sentence does the action)
- Use terms such as “investigational” instead of “new” (do not over-promise potential benefits)
- Explain whether the drug or device under study is FDA approved
- Use words familiar to a non-medical reader, see the lay language glossaries in the Resources section at the end.
- Use the second person “you” instead of third person “participant”
- Use 12-point font and avoid using bold, underline, or italic font
- Specify the amounts of blood or tissue to be taken for study purposes in teaspoons or ounces/milliliters

Readability

- Use photos, graphics, or tables if they will help clarify procedures
  - If tables are large and complicated, consider placing them at the end of the consent. Also, make sure that any acronyms or abbreviations are explained either before or just below the table.
- Be consistent with the use of all terminology and abbreviations
- Spell out acronyms and abbreviations at first use, except abbreviations such as DNA. HIV, AIDS, that are accepted as standard by the proposed study population may not need to be spelled out
- Check the text to see if each idea is clear and logically sequential
- Use the word processing tools available to measure grade level readability score
- Read the form out loud to a colleague or test it in a target audience

Organization/Format:

- Use a version date in the footer and matching date in the document file name and update it every time you make a change
- Use a descriptive title for the consent file name
- Don’t add anything to the header of the consent to avoid obscuring the IRB approval stamp
- Use tracked-changes when submitting revised documents or responding to requested edits from the IRB
- Only list one PI in the header
- Replace currently approved forms with new versions and delete outdated documents
- There is no need to submit both clean and tracked versions

Sections of the Template

- Conflict of Interest
- Reproductive Risks
- Research Related Injury (What else do I need to know?)
- HIPAA
- Signature Sections

Research Related Injury

What else do I need to know?

[Include for greater-than-minimal research. Otherwise, delete. The language should not be changed except as indicated.]

[Include if study is industry sponsored. If you need to deviate from this language, then please contact Sponsored Research (SR) and obtain written documentation that the template language is not consistent with the clinical trial agreement and that the language must be altered. The written documentation should then be uploaded into the eIRB+ application.]

If you have an injury or illness from the study device, taking the study drug, or the procedures required for this study, the reasonable medical expenses required to treat such injury or illness may be paid for by the study sponsor.

The coverage for such injury or illness is only available if the Northwestern University principal investigator and study sponsor, if applicable, have decided that the injury/illness is directly related to the study drug, device, or procedures and is not the result of a pre-existing condition or the normal progression of your disease, or because you have not followed the directions of the study doctor. If your insurance is billed, you may be required to pay deductibles and co-payments that apply. You should check with your insurance company about any such payments.

Certificate of Confidentiality

[If your study is NIH funded, include the following statement as the research is being conducted under a Certificate of Confidentiality. Otherwise, delete.]

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or suit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena.

There are some important things that you need to know. The Certificate does not stop reporting that federal, state or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate cannot be used to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate does not stop disclosures required by the federal Food and Drug Administration (FDA). The Certificate also does not prevent your information from being used for other research if allowed by federal regulations.

Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other persons not connected with the research. The Certificate of Confidentiality does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information.

Signature Section for Mental Health Information

Signature Block for Witness for Use of Mental Health Information, Developmental Disability Services, Genetic Counseling, or 'All information in the Medical Record:

[**A witness signature is required for studies accessing mental health or developmental disability services information, and genetic counseling information, from the participant's medical record or if "all information in a medical record" is listed in the consent form as the data being accessed.** Otherwise delete.]

[**The consent form shall be signed by the person entitled to give consent and the signature shall be *witnessed by a person who can attest to the identity of the person so entitled* (note that the 'witness' signature on the NU consent template may or may not be the same as the study team member who signs to 'obtain' consent, depending on pre-existing relationship and/or established processes in place that can confirm identity).**]

I attest that the identity of the individual giving consent has been verified.

_____ _____

Signature of Witness to Consent Process Date

_____

Printed Name of Person Witnessing Consent Process

Consent Witness Signature Section

Signature Block for Witness of Consent Process:

[Add the following if a witness will observe the consent process, e.g., participant is illiterate, participant is visually impaired, or the participant is physically unable to sign. Otherwise delete.]

My signature below documents that the information in the consent document and/or assent process and any other written and verbal information was accurately explained to, and apparently understood by, the participant, and that consent was freely given by the participant.

_____ _____

Signature of Witness to Consent/Assent Process Date

_____

Printed Name of Person Witnessing Consent/Assent Process

Electronic Consent

- Electronic informed consent refers to the use of electronic systems and processes that may employ multiple electronic media, including text, graphics, audio, video, podcasts, passive and interactive web sites, biological recognition devices, and card readers, to convey information related to the study and to obtain and document informed consent.
- FDA and HHS joint guidance on electronic consent

Electronic Informed Consent (eIC)

- Whether the eIC is obtained from the subject on-site or remotely, the eIC process must provide sufficient opportunity for the subject to consider whether to participate.

- Per FDA, if any or all of the consent process takes place remotely and is not personally witnessed by study personnel, the electronic system must include a method to ensure that the person electronically signing the informed consent is the subject who will be participating in the research study or is the subject's LAR. Examples of various methods that could be used include verification of a state-issued identification or other identifying documents or use of personal questions, biometric methods, or visual methods.

Electronic Informed Consent (eIC)

- In order to be considered equivalent to full handwritten signatures, electronic signatures must comply with all applicable requirements under 21 CFR part 11 (per FDA regulations).
- Northwestern RedCap electronic signature process is part 11 compliant!
- The electronic system must also capture and record the date that the subject or subject's LAR provides consent.
- To assist the subject in understanding the material, the eIC may use interactive electronic-based technology, which may include diagrams, images, graphics, videos, and narration. The eIC should be appropriate for the intended audience, taking into consideration the subject's age, language, and comprehension level.

Consent As An Ongoing Process (example)

- A research team wants to do a baseline survey and interview with participants and then interview each participant every 6 months for 2 years. The initial interviews will take place in-person, while follow-up interviews will take place over Zoom.

- After an initial explanation of the project over the phone, the research team emails the consent form to the participant prior to their scheduled meeting. This allows the participant to read through the form at their leisure. At the scheduled first interview, the research team goes through the consent form with the participant and provides time and space for questions before signing.

Consent As An Ongoing Process (example)

- Every 6 months, as follow-up interviews approach, the study team emails participants a reminder with the project's consent document. This ensures that participants are still fully informed of their rights as participants and know that they can ask more questions or withdraw from the study at any time. At the beginning of each follow-up interview, the researcher confirms the participant still would like to continue participating in the study and answers any questions or concerns they have.

- Informed consent is an active process, it doesn't end with a signature.

Informed Consent Is Necessary For Exempt Studies

- Researchers sometimes think that if a study is determined be Exempt, then informed consent is not necessary
  - This is FALSE
  - Informed consent is necessary even when a study seems ‘low risk’
  - The expectation for informed consent for Exempt studies is derived from from the Belmont Principle of “Respect for Persons”

Informed Consent Is Necessary For Exempt Studies

- Example – Anonymous, online survey is posted on MTurk
  - After reading the recruitment post, participants click on a link that takes them to the consent document, hosted on Qualtrics
  - After reading the consent document, participants must click the "I agree" button before they are able to take the survey
  - This ensures that participants are fully informed about the research study, of their rights, how the data will be used, and who to contact if they have questions or concerns
- Researchers are encouraged to use the NU consent templates to ensure participants are fully informed about the study

Things to Keep In Mind

- Always check the NU IRB Website for most up to date templates and guidance.
- Use the language provided in the NU template as much as possible and read through the directions carefully. Delete the language that is not applicable.
- Avoid including Industry Sponsor language that is overly complicated, redundant, or conflicting with NU language, and avoid any exculpatory language like statements using “I understand”.

Resources

- HHS Consent FAQs
- Glossary of medical words: http://kidshealth.org/kid/word/)
- Glossary of lay terms: http://humansubjects.stanford.edu/general/glossary.html
- FDA and HHS joint guidance on electronic consent
- Acknowledgement of John's Hopkins IRB guidance on consent: https://www.hopkinsmedicine.org/institutional_review_board/guidelines_policies/guidelines/informed_consent_ii.html
- FDA Part 11 Guidance for use of Electronic Signatures
- Process for Obtaining Consent
- Documentation of Consent Process Form
- Short Form Guide

Contact Information

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QUESTIONS?