

OBTAINING WRITTEN INFORMED CONSENT

Introduction and Purpose

The Principal Investigator (PI) of a clinical research study is responsible to ensure that all human subjects provide voluntary informed consent before participating in the study. Informed consent is an ongoing process that begins at the first contact with a prospective subject and continues throughout their participation. The PI may delegate the task of conducting informed consent to qualified sub-investigators or study staff.

The PI or delegate is required to follow the regulations set forth for obtaining informed consent for the protection of human subjects as found in the Department of Health and Human Services Common Rule (45 CFR §46) and the U.S. Food and Drug Administration (FDA) regulations (21 CFR §50), as applicable.

Additionally, clinical trial investigators should adhere to the International Council on Harmonization (ICH) GCP guidelines, which provide assurance that freely given informed consent is obtained from every subject prior to clinical trial participation.

This SOP applies to all clinical research studies not otherwise exempt from obtaining informed consent outlined in 45 CFR §46 and 21 CFR §50 and which do not fall into the consent without signature or opt-out consent models approved by the IRB.

Definitions and Acronyms

Clinical Research: Clinical research includes all research involving human participants. It does not include secondary studies using existing biological specimens or data collected without identifiers or data that are publicly available.

Clinical Trial: Clinical trials are clinical research studies involving human participants assigned to an intervention in which the study is designed to evaluate the effect(s) of the intervention on the participant and the effect being evaluated is a health-related biomedical or behavioral outcome.

Legally Authorized Representative: An individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the study.

CFR: Code of Federal Regulations

ERICA: Electronic Research Integrity and Compliance Administration

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FDA	United States Food and Drug Administration
GCP:	Good Clinical Practice
ICF:	Informed Consent Form
ICH:	International Council on Harmonization
IRB:	Institutional Review Board
LAR:	Legally Authorized Representative
PI:	Principal Investigator
SOP:	Standard Operating Procedure

Procedure

1. Delegation of Authority

- 1.1. The Principal Investigator is responsible to ensure that informed consent is administered appropriately and effectively to all study subjects prior to enrollment into a study. The PI may delegate this task, or parts of it, to a Sub-Investigator or qualified study staff member prior to participating in the consent process. The delegation of this task must be documented in the study records.
 - 1.1.1. Delegated staff must be appropriately trained to perform informed consent and must be added to the IRB application allowing consent privileges.

2. IRB Approval

- 2.1. Consent form(s) must be reviewed and approved by the IRB prior to consenting study subjects. Any changes made to the consent form(s) after initial IRB approval must also be submitted to the IRB and approved prior to use.
- 2.2. The study consent must be obtained in a language the subject can understand. For non-English speaking subjects, a translated consent form or short form must be IRB approved in order to consent them to the study. No study subject will be asked to sign a consent form in a language they do not understand. Additional guidance for consenting non-English speaking

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subjects can be found on the IRB website or within individual department guidance.

- 2.3. Documentation of the subjects' consent may be done on paper or in electronic format (eConsent). If the study is using eConsents, the process must be approved by the IRB first and additional considerations must be met including validation and assurance that the electronic system meets 21 CFR part 11, if appropriate. Further combined OHRP and FDA guidance on eConsent can be found at:

<https://www.fdanews.com/ext/resources/files/2016/12/12-14-16-FDAOHRPeConsentGuidance.pdf?1520830927>

- 2.4. Depending on the study requirements, cognitive ability, and age of the subjects, different consent forms may be required or may be waived by the IRB as described in 45 CFR 46 and 21 CFR 50. Typically, the required forms are as follows:
- An Informed Consent Form (ICF) is required for adult subjects age 18 or older or for emancipated minors.
 - A Parental Permission Form (PPF) must be signed by a parent or guardian, instead of the adult consent, if the subject is under the age of 18. The IRB will determine if one or two parents are required to sign the PPF, depending on the study and the risk involved. If two parents are required to sign, the IRB will request a second signature block be added to the PPF.
 - An Assent Form may also be required, in addition to the PPF, for subjects between the age of 7-17 or when required by the IRB for adult subjects with diminished decision-making capacity. The IRB determines when written Assent is required taking into account the subjects age, psychological state, and maturity level.

- 2.4.1. The study may require additional consent forms. Examples include supplemental information, specimen repository/tissue banking, or optional sub-study consents when this extra information is not included in the main consent. The PI or delegated staff is required to know which

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consent forms are required for the study and ensure that they are obtained appropriately.

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- 2.5. Unless specifically exempted by the IRB, no study procedures will occur prior to obtaining the required consent(s). Procedures that are performed prior to consent, but are done as standard of care, may be used for study purposes as long as they are allowed by the protocol and meet protocol specifications.
- 2.6. The PI and/or the person delegated to consent will meet with the potential subject or, if applicable, their legally authorized representative, to introduce the study and go over each section of the consent.
 - 2.6.1. To reduce the possibility of consenting with outdated forms, the PI or delegated staff should not keep multiple printed copies of consents for future use. Each time a potential new subject is identified, the person obtaining consent should retrieve the required Informed Consent Form(s) directly from the documents tab in the electronic IRB ERICA application (<http://erica.research.utah.edu>). This will ensure that only the current approved forms are used to consent subjects.
 - 2.6.1.1. For studies where pulling the consent forms directly from ERICA at the time of consent is not feasible or applicable (e.g., eConsents, consenting in community or under-resourced settings), then an alternate process to ensure accurate versions should be implemented for the study and consent forms should be printed as close to the time of consent as possible.
 - 2.6.2. For single-IRB (SIRB) studies where the University of Utah IRB is not the IRB of Record, the study application in ERICA will not be updated with revised consent forms. The study team must develop a documented plan with the coordinating site and IRB of Record to ensure access to the current version of the IRB-approved ICF.

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- 2.6.3. If the study is utilizing eConsents, a process must be documented and implemented to ensure new/updated forms are uploaded to the system immediately after IRB approval.
- 2.7. The subject will be given ample time to read the full consent(s) and have all of their questions answered to their satisfaction prior to signing the form(s).
- 2.8. During the consent discussion, it should be explained to the subject that their participation is voluntary and that they may withdraw from the study at any time.
- 2.9. If the subject agrees to participate, they will sign and date the consent form(s), and answer any additional questions located in the consent form following the instructions provided within the consent.
 - 2.9.1. If study procedures are conducted on the same day consent is obtained, it should be clear that the consent was obtained prior to conducting study procedures. This may be done by documenting the time that consent is obtained on the consent form or otherwise noting in the consent process note.
- 2.10. The person obtaining consent will ensure all sections of the consent form(s) have been completed, all pages of the consent form(s) are present, and that the subject signature block is correctly signed and dated.
 - 2.10.1. If errors are noted, corrections will be made by using a single line through the incorrect information, entering the correct information, initialing and dating the correction, and providing a reason for change (if necessary).
- 2.11. After the subject or LAR signs and dates the consent form, and the person obtaining consent has verified everything is completed correctly, they will sign, date and time (if applicable) the form(s).
- 2.12. If the consent form(s) also require the signature of the investigator, this will be obtained on the day of consent or as soon as possible thereafter. If there is a delay in obtaining the PI's signature, an explanation for the delay should be included in the consent process note.
- 2.13. The subject/LAR will always be provided a copy of the consent form. For studies that adhere to GCP guidelines, the subject should be given a copy of the fully executed signed consent form(s).

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2.14. Remote consenting may be done if the remote consent process is approved by the IRB as part of the consent process described in the study application.

2.14.1. Guidance on remote (telephone) consenting can be found on the IRB website.

<https://irb.utah.edu/resources/documents/pdf/Telephone%20Consent%20Process%20to%20Obtain%20a%20Signed%20Consent%20Form.pdf>

3. Documenting the Consent Process

3.1. The completed and signed ICF alone is insufficient for adequate documentation of the consent process. Details of the full process should be documented in a consent process note or other type of study flowsheet. Examples of information that should be included in the documentation are: that a copy was given to the subject, who was present during the discussion, questions asked and answers given, time of consent, use of a translator or witness, details if remote consent was obtained or any other unique details to the particular subject.

3.1.1. Certain types of studies may be exempt from requiring a consent process note for each subject. For example, it may not be feasible or applicable to document each individual consent for large, high enrolling minimal risk trials, opt in/out consent models, etc.

3.2. No extraneous information should be written on the actual consent form(s) unless noting corrections to the signatures or patient provided answers. Any details that need clarification should be included in the consent process note.

3.3. Individual groups or departments may require a specific template to use for consent process note. Otherwise, the consent process note may be free text or captured otherwise by the person obtaining consent.

4. Where is the Consent Document and Consent Process Note Filed?

4.1. The original signed and dated consent forms will be retained in the subject's research chart along with the consent process note.

4.2. The informed consent form and consent process note are allowed to be placed in research participants' medical records, per University of Utah IRB

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SOP 505. As part of the standard HIPAA authorization language included in consent forms, the research participant consents to the inclusion of research-related documents and data within their medical record. Although allowed, the inclusion of the informed consent form and consent process note within the medical record **is not required** and is at the discretion of the principal investigator and applicable departmental policy. The principal investigator should evaluate the following when considering adding this documentation to the medical record:

- Clinical relevance of study procedures: the potential to effect or interference with the patient's clinical care/treatment and/or place them at a greater risk of harm.
- Sensitivity of consent: the degree to which disclosure of the consent form outside of the study team could result in financial, social, or personal harm to the subject. Financial harm includes, but is not limited to, adverse effects on employment, on the ability to maintain medical insurance, on credit standing, or harm to career opportunities. Social harm includes, but is not limited to, damage to either friendships or memberships in social groups. Personal harm includes, but is not limited to, adverse effects on personal or familial relationships.
 - Certificates of Confidentiality (CoC): IRB guidance regarding CoC becomes relevant when sensitive research records are included in the medical record. The purpose of a CoC is to protect the privacy of research subjects by prohibiting disclosure of identifiable, sensitive information to anyone not connected to the research, except when the subject consents. The CoC will not operate, however, with respect to research information that is included in the medical record of a research participant. Therefore, careful consideration should be made in situations where consenting to a study might be sensitive (e.g., studies collecting data on sexual abuse, drug addiction, suicide, etc.). The IRB guidance on CoC can be found in the "References" section, below.

5. Re-Consenting Subjects

5.1. The subject's consent is ongoing throughout their participation on the study.

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Any new information that may affect their willingness to continue in the study must be IRB approved and given to them for re-consent. The PI or delegated study staff must ensure they are aware of any time a new consent must be IRB approved and given to subjects.

5.2. If required by the IRB, enrolled subjects must be re-consented anytime the consent form is updated to include any of the following changes:

- Addition of new risk(s)
- Increase in the frequency or severity of known risk(s)
- Any change in the treatment or procedures that will directly affect the subject
- Relevant new information about the study or the investigational product
- Any other important change that may affect the subjects willingness to participate

If the changes made to the consent document do not meet any of the above criteria, re-consent is not required, and it should be stated in the amendment application that participants will not be notified.

5.3. Re-consent is required to occur within a timely manner. The terminology, “timely” should be considered with the type of research (e.g. interventional vs. non-interventional), the subject’s condition (e.g. healthy volunteers vs. participants with terminal illness) and the new information in the consent document. Re-consent with the new consent form should be obtained as soon as practicable which may be the next scheduled visit. In general, re-consent should take place no later than 60 – 90 days after IRB approval of the new consent document.

5.3.1. If a different time frame for obtaining re-consent is required by the study sponsor, department, or PI, this should be included in the amendment application for IRB approval.

5.4. If new information becomes available involving increased risk, subjects participating on the trial may be made aware of the information prior to IRB approval of the amended consent documents. Depending on the situation, verbal notification to subjects prior to approval of the amended documents is often necessary to protect participant safety and to provide participants with information that may affect their willingness to participate.

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5.5. During the re-consent process, the changes made to the ICF should be stressed. However, the entire process for obtaining and documenting informed consent should be followed as described above.

6. Additional Considerations

6.1. Additional considerations apply for consenting the following subjects:

- Non-English speaking subjects
- Blind or illiterate subjects
- Subjects using a Legally Authorized Representative
- Remote Location / Telephone Consents
- Children
- Prisoners

6.2. Guidance documents for these consent models can be found on the IRB website or within individual department guidelines.

Materials Required

- Current IRB Approved Consent Form(s)
- IRB Witness Signature Page if applicable
- Delegation of Authority log

References

- 21 CFR Part 50 Subpart B: Protection of Human Subjects
- 45 CFR Part 46: Protection of Human Subjects
- ICH Guidance for Industry E6(R2): Good Clinical Practice
- IRB Telephone Consent Process to Obtain a Signed Consent Form
- IRB Investigator Guidance Series
- IRB Forms: Consent Process Models
- IRB SOP 505: <https://irb.utah.edu/guidelines/irb-sops.php>
- IRB Investigator Guidance, Certificates of Confidentiality: <https://irb.utah.edu/guidelines/investigator.php>

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Document Approval



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DATE

Revision History

Version Date	Change Summary
13Dec2019	Original Version
26Jun2020	Version #2 – minor updates for clarity and ease of reading
05Mar2021	Version #3 – addition of guidance regarding informed consent documentation in the medical record

Printed or photocopied versions are considered unofficial copies unless it is the original signed document.