



Clinical Research Support Center

OFFICE OF REGULATORY COMPLIANCE

UNIVERSITY OF COLORADO

DENVER | ANSCHUTZ MEDICAL CAMPUS

SOP #	CRSC-106
Effective Date	10-22-2013
Version #	1
Version Date	8-21-2013

Standard Operating Procedure Informed Consent

Purpose:

This SOP details the appropriate procedures for obtaining and documenting the informed consent process for applicable populations in accordance with the process approved by the IRB.

Procedure:

Check ALL that apply:

Competent adults **only**

LAR possibly

Competent adults

Proxy consent possibly

Non-English speakers possibly

Children

Note: only persons appropriately delegated on the delegation log can obtain informed consent under this SOP

Adult Informed Consent Process

- 1) The research team identifies a potential study subject, and informed consent must be obtained prior to any study-specific (non-standard of care) procedures including fasting or research data collection (Note: Certain kinds of pre-screening, verbal screening, medical record reviews may proceed with a waiver of the documentation of consent, and/or waiver of consent)
- 2) The research team initiates a preliminary discussion with the subject about the study and performs an initial subject screen for basic study eligibility requirements based on brief subject history only
- 3) If the research team deems the subject preliminarily eligible, the consent process is initiated
- 4) A member of the research team sees the subject in a quiet, private area and initiates the informed consent process:
 - a. The IRB-approved, current consent form is thoroughly reviewed with the subject, including the study treatments/interventions, procedures, risks, study schedule, expenses (if applicable)



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- b. The research team provides the subject with adequate time to read the ICF/HIPAA combined document (May require more than one visit, and this may occur prior to the review of the consent form with the subject)
- c. The research team and subject exchange information (question/answer, clarification, other). The PI should be available to answer technical or complex questions
- d. The research team will verify that the subject understands the study as described in the ICF by asking appropriate questions or by utilizing the Document of Consent Process Questionnaire Template (attached)
- e. The subject will be invited to voluntarily sign the ICF with the understanding that the subject can withdraw from the study at any time, without penalty at the same or subsequent visit
- f. The designated member of the research team will ensure that each page of the ICF is initialed by the subject, that the last page is signed and dated by the subject and the person obtaining consent signs and dates the ICF as well
- g. The PI signs and dates the ICF after reviewing, within 30 days of the date the subject signing the ICF (or sooner if required by the IRB)
- h. The designated member of the research team will give the subject a copy of the signed and dated ICF
- i. The designated member of the research team will put a copy of the signed ICF in the subject's official medical record and a brief summary of the consent process should be documented in the medical record
- j. The designated member of the research team will ensure the original, signed ICF is placed in the site-specific, research-specific study record
- k. The designated member of the research team completes the Adult Informed Consent Documentation Checklist (attached) and files it with the original, signed ICF
- l. The designated member of the research team adds the subject to the screening and enrollment log



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Legally Authorized Representative (LAR) Informed Consent Process (adult)

Determination of decisional capacity will be based on:

- Clinical Assessment
- Review of the Medical Record
- For research purposes as outlined in the IRB approved protocol

Definition of Legally Authorized Representative:

Any individual person, judicial body or other body of individuals who are authorized under state and federal laws to consent on behalf of a legally designated person.

Procedure:

- 1) The research team identifies a potential decisionally-impaired study subject, and informed consent must be obtained prior to any study-specific (non-standard of care) procedures including fasting or research data collection
- 2) The research team performs a preliminary assessment of the subject for basic study eligibility requirements and initiates a discussion regarding the study with the subject’s LAR.
- 3) The LAR must provide appropriate documentation that they have the legal authority to make health and health research related decisions for the potential subject. A copy of this material should be maintained with the research-specific study record
- 4) If the research team deems the subject preliminarily eligible then the consent process is initiated
- 5) The delegated member of the research team meets with the subject’s LAR in a quiet and private area and initiates the informed consent process. The informed consent process for the LAR is the same as outlined above under Adult Informed Consent Process

Assent Process:

The decision whether or not to assent individuals who are decisionally challenged rests with the IRB. If required, the assent process should be conducted in accordance with the IRB approved process using the IRB approved assent document

Proxy Informed Consent Process

Determination of decisional capacity will be based on:

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303-724-1111

<http://www.ucdenver.edu/academics/research/AboutUs/regcomp/ClinicalResearchSupportCenter/Pages/default.aspx>



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- Clinical Assessment
- Review of the Medical Record
- For Research purposes as outlined in the IRB approved protocol

Process for determining the Surrogate Decision Maker:

The “interested parties” must decide who among them will make decisions regarding the care of the patient. The “interested parties” are defined as “the patient’s spouse, either parent of the patient, any adult child, sibling, or grandchild of the patient, or any close friend of the patient.” The medical record must document the specific procedures that are followed in this determination of a proxy decision-maker.

Procedure:

- 1) The PI identifies a potential decisionally-impaired study subject, and informed consent must be obtained prior to any study-specific (non-standard of care) procedures including fasting or research data collection
- 2) The PI performs a preliminary assessment of the subject for basic study eligibility requirements
- 3) The PI confirms that a LAR does not exist
- 4) The PI follows the procedure for identifying the proxy if not already done by the primary care team.
- 5) The PI contacts the surrogate decision maker that has been identified for clinical purposes or follows the process for determining the surrogate decision maker detailed above or as approved by the IRB
- 6) The delegated member of the research team meets with the subject’s Surrogate Decision Maker in a quiet and private area and initiates the informed consent process. The informed consent process for the Surrogate Decision Maker is the same as outlined above under *Adult Informed Consent Process*
- 7) Upon such time as the subject’s decision making capacity is restored/regained, the subject will be re-consented following the “Adult Informed Consent Process” procedures or as approved by the IRB

Assent Process:

The decision whether or not to assent individuals who are decisionally challenged rests with the IRB. If required, the assent process should be conducted in accordance with the IRB approved process using the IRB approved assent document



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Short-Form Informed Consent Process

Procedure:

- 1) The research team identifies a potential study subject, and informed consent must be obtained prior to any study-specific (non-standard of care) procedures including fasting or research data collection
- 2) An interpreter must be an individual who meets the applicable institution's policy for serving as an interpreter. At a minimum, the interpreter should not be a member of the family, should be fluent in the appropriate language and understand medical vocabulary
- 3) The research team performs an initial subject screen, with the assistance of an interpreter, for basic study eligibility requirements
- 4) If the PI deems the subject preliminarily eligible, the study coordinator is contacted and the consent process is initiated
- 5) A short-form ICF is obtained in the subject's native language from the COMIRB website and the current IRB approved consent form is used as the summary document.
- 6) The coordinator, and interpreter (with a separate impartial witness if needed) see the subject in a quiet and private area and the informed consent process is initiated:
 - a. The applicable short-form consent form is thoroughly reviewed with the subject
 - b. The coordinator provides the subject with adequate time to read the short form ICF document
 - c. The current IRB approved consent form is translated verbally into the appropriate language
 - d. The delegated member of the research team and subject exchange information (question/answer, clarification, other) through the interpreter
 - e. The delegated member of the research team will verify via the interpreter that the subject understands the study as described in the ICF
 - f. The subject will be invited to voluntarily sign and date the short-form ICF with the understanding that the subject can withdraw from the study at any time, without penalty
 - g. The delegated member of the research team will also sign and date the short-form ICF

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- h. The delegated member of the research team will ensure that each page of the current approved ICF is initialed by the **translator**, that the last page is signed and dated by the translator and the delegated member of the research team obtaining consent signs
- i. The PI signs and dates within 30 days of the date the subject signs the ICF or as required by the IRB
- j. The delegated member of the research team will give the subject a copy of the signed short form ICF and the summary consent document in English; the coordinator will put a copy of the signed short form ICF and the signed summary consent document in the subject's official medical record; and the delegated member of the research team will ensure the original, signed short form ICF and summary consent form is placed in the site-specific, research-specific study record
- k. The delegated member of the research team completes the Short-Form Informed Consent Documentation Checklist (attached) and files it with the original, signed ICF
- l. The delegated member of the research team adds the subject to the screening and enrollment log
- m. The delegated member of the research team will also note the use of the short form carefully to ensure that the short form is used no more than three (3) times per non-English language

Parental Permission and Assent Process:

Check ALL that apply:

No assent form approved

One parent signature required

Written assent form approved

Both parent signatures required

Verbal assent process

Assent using consent form

Parental Permission Process:

- 1) Verify that the persons who are with the child are the parents or LAR. Document the verification process

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- 2) If parental permission is required from both parents, the process for obtaining permission can be conducted with both parents together or separately as appropriate for the family. Both parents should sign the same consent form and the child's name should be added to the consent form
- 3) The process for obtaining parental permission for their child to be enrolled in a study follows the same format as outlined for obtaining *Adult Informed Consent* as outlined earlier in this SOP

Assent Informed Consent Process:

- 1) Follow the assent process as outlined in the IRB approved protocol.
- 2) COMIRB presumes that children ages 7 and older should provide assent; adolescents (generally ages 13-17) show capacity for understanding similar to an adult so can assent using the approved consent form with an additional signature line for assent
- 3) Verify that the child is under the age of 18 years. Document the verification and note if the individual will turn age 18 while on study as re-consenting will be necessary
- 4) For older adolescents, assent can be obtained without the parent(s) being present. Note: a child's dissent "no" usually overrides a "yes" from a parent (there are individual exceptions to this that must be prospectively approved by the IRB)
- 5) Document why the determination was made that assent was obtained using the Assent checklist. If written assent is obtained, have the child sign and date the assent form
- 6) The delegated member of the research team will give the subject or parents a copy of the signed assent; a copy of the signed assent will be placed in the child's official medical record; and the original, signed assent is placed in the site-specific, research-specific study record
- 7) If verbal assent is to be obtained, the parent(s), person obtaining assent and independent witness should observe the assenting process and document that appropriate assent was obtained and how this assessment was made using the appropriate IRB verbal assent document
- 8) A copy of this assent document should be placed in the child's official medical record; and the original, signed assent assessment form placed in the site-specific, research-specific study record

Attachments:

1. Screening Log
2. Enrollment Log
3. ICF Documentation Checklist – Adult/LAR/Proxy
4. ICF Documentation Checklist – Assent
5. ICF Documentation Checklist – Short Form Consent

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APPLICABLE REGULATIONS AND GUIDELINES

US Department of Health & Human Services	45 CFR 46.116; 45 CFR 46.117; 45 CFR 46.117 (a); 45 CFR 46.115 (b); 45 CFR 46.117 (c)
HHS FAQ	http://answers.hhs.gov/ohrp/categories/1566
OHRP Tips	http://www.hhs.gov/ohrp/policy/ictips.html
ICH GCP	E6 Good Clinical Practice: Consolidated Guidance, section 4.8 Informed Consent of Trial Subjects
FDA Guidance Document	Q&A on Informed Consent Elements 21 CFR 50.25 (c) http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM291085.pdf
FDA Regulation	21 CFR 50.20; 21 CFR 50.25 (c); 21 CFR 50.23 (e); 21 CFR 50.27
Colorado Statute	15-18.5-103
Belmont Report	http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html
UCD Human Research Protection Program	Investigator Responsibilities for the Protection of Human Subjects Section 17.3 Education Section 20.1 HIPAA Education
COMIRB Policy	12.11; 13.11; 14 http://www.ucdenver.edu/academics/research/AboutUs/comirb/Pages/comirb-home.aspx

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