INFORMED CONSENT

January 10, 2024
Objectives

- Inform study teams about the required elements of informed consent
- Discuss the process of traditional Informed Consent
- Discuss the different waivers related to Informed Consent
- Outline how to handle consenting of non-English-speaking subjects
BELMONT REPORT

- Individuals should be treated as autonomous agents
- Persons with diminished autonomy are entitled to protection

**Application**: Informed Consent

- To each person an equal share
- To each person according to individual need
- To each person according to individual effort
- To each person according to societal contribution, and
- To each person according to merit

**Application**: Assessment of Risks & Benefits

- Do not harm
- Maximize the possible benefits and minimize possible harms
- NOT an act of kindness or charity, but a concrete obligation

**Application**: Selection of Participants
# REQUIRED ELEMENTS OF INFORMED-consent

<table>
<thead>
<tr>
<th>A statement that the study involves research</th>
<th>An explanation of the purpose of the study</th>
<th>A statement about the expected duration of participation</th>
<th>A description of the procedures to be followed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Distinction of experimental procedures vs standard of care</td>
<td>A description of any foreseeable risks/discomforts</td>
<td>A description of reasonable benefits, if any</td>
<td>A disclosure of alternatives to study, if any</td>
</tr>
<tr>
<td>A statement re: extent record will be kept confidential</td>
<td>For more than minimal risk, explanation about compensation</td>
<td>Information regarding research-related injury</td>
<td>Whom to contact about the research, rights, and injury</td>
</tr>
<tr>
<td>A statement that participation is voluntary and refusal is without penalty</td>
<td>A statement about possibility of keeping samples for future use</td>
<td>Participant or Legally Authorized Representative Signature</td>
<td></td>
</tr>
</tbody>
</table>

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**LSU Health NEW ORLEANS Office of Research Services**
<table>
<thead>
<tr>
<th>Optional Elements of Informed Consent</th>
</tr>
</thead>
<tbody>
<tr>
<td>A statement that procedures may involve <strong>unforeseeable risk</strong></td>
</tr>
<tr>
<td>Circumstances under which <strong>participation may be terminated</strong> by the PI</td>
</tr>
<tr>
<td>A statement of any <strong>additional costs to the subject</strong> that may result</td>
</tr>
<tr>
<td>A statement of <strong>consequences of a subject’s decision to withdraw</strong></td>
</tr>
<tr>
<td>A statement that <strong>significant new findings</strong> will be presented to subjects</td>
</tr>
<tr>
<td>Approximate <strong>number of subjects</strong> anticipated to enroll in the study</td>
</tr>
<tr>
<td>A statement that biospecimen may be used for <strong>commercial profit</strong></td>
</tr>
<tr>
<td>A statement regarding disclosure to subject about <strong>clinically relevant results</strong></td>
</tr>
<tr>
<td>A statement if the research will involve <strong>genome sequencing on biospecimen</strong></td>
</tr>
</tbody>
</table>
INFORMED CONSENT
“A process by which a subject voluntarily confirms his or her willingness to participate in a particular trial, after having been informed of all aspects of the trial that are relevant to the subject’s decision to participate. Informed consent is documented by means of a written, signed and dated informed consent form.”

*FDA’s Guidance for Industry E6 GCP: Consolidated Guidance, Section 1.28*
The IRB requires the subject or their LAR to sign the consent form and then the person consenting to sign.
LOCAL INFORMED CONSENT TEMPLATES

- Standard Joint Consent/HIPAA Authorization
- LSUHSC-UMC Joint Consent/HIPAA Template
- LSUHSC-OLOL Joint Consent/HIPAA Template
- CHNOLA-LSUHSC Joint Consent Form
LSUHSC prefers use of our local-approved template; however, if the study team wishes to use the Sponsor template, the LSUHSC ICF Cover Letter must be provided along with the Sponsor consent, or the required language must be embedded into the form.

*If the designated reviewer does not feel that the Sponsor template contains all the appropriate information or that the quality is poor, the reviewer reserves the right to request the team switch to use of the local-approved template.
The IRB may approve a waiver of the requirement to document informed consent provided that one of the following apply:

<table>
<thead>
<tr>
<th>45 CFR 46.117(c)(i)</th>
<th>45 CFR 46.117(c)(ii)</th>
<th>45 CFR 46.117(c)(iii)</th>
</tr>
</thead>
<tbody>
<tr>
<td>• The only record linking the subject and the research would be the consent document</td>
<td>• The research presents no more than minimal risk of harm to subjects</td>
<td>• The subject and/or their LAR are members of a distinct cultural group or community where signing forms is not the norm</td>
</tr>
<tr>
<td>• The principal risk would be potential harm resulting from a breach of confidentiality</td>
<td>• The research involves no procedures for which written consent is normally required outside of the research context</td>
<td>• The research presents no more than minimal risk of harm to the subjects</td>
</tr>
<tr>
<td></td>
<td>• There is an appropriate, alternative method for documenting informed consent was obtained</td>
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</tr>
<tr>
<td></td>
<td>• The oral or written information provided to the subject includes all required and appropriate additional elements of consent disclosure</td>
<td></td>
</tr>
</tbody>
</table>
Verbal informed consent occurs when a member of the research team and a potential subject verbally interact, and the subject gives their consent to participate verbally. The member of the research team and the subject can be in the same location or can be communicating over the phone or through some other electronic means (i.e. Zoom).
The IRB requires the person consenting to sign either the verbal informed consent form if consenting in person or the verbal informed consent script if consenting over the phone or via other electronic means. The person consenting should also document how verbal consent was obtained.

**Signature of Person Obtaining Verbal Consent:**

*I have explained the research to the subject and answered all his/her questions.*

<table>
<thead>
<tr>
<th>Signature of Person Obtaining Consent</th>
<th>Printed Name</th>
<th>Date</th>
</tr>
</thead>
</table>

**Verbal consent was obtained:**

- [ ] In person
- [ ] Over the phone
- [ ] By other electronic means: ________________________________
Can you obtain verbal consent from a subject over the phone?

• Verbal consent from the subject can be obtained over the phone so long as it is an approved consenting method in the IRB protocol.

Can you obtain verbal consent from a subject’s LAR over the phone?

• Verbal consent of an LAR over the phone is only allowed in cases of planned emergency research or when there is a justifiable need to quickly obtain consent. Please contact the IRB before requesting verbal consent via LAR over the phone to discuss.
When a waiver of documentation is granted and verbal consent is not being requested, a study team must present to potential subjects an information sheet to review prior to participating in any research activities. The information sheet allows the subjects to make an informed decision about participating without having to sign a consent.
The IRB may approve a waiver of the requirement to obtain informed consent provided that all of the following apply:

1. Is research more than minimal risk? No
2. Will waiver adversely affect the rights/welfare of subjects? No
3. Can the research be practicably carried out without the waiver? No
4. Will subjects be provided with additional pertinent information after participation? No

**WAIVER OF INFORMED CONSENT APPROVED**
CONSENTING NON-ENGLISH-SPEAKING INDIVIDUALS
CONSENTING NON-ENGLISH-SPEAKING INDIVIDUALS

If the study is ongoing and unexpectedly encounters a non-English speaking subject qualified for enrollment, and study documents are not already translated, the study team may use the Short Forms once to enroll the subject without delay. After this first enrollment of a non-English speaking individual, it is the responsibility of the team to obtain certified translations of all patient-facing materials and submit them to the IRB for approval before enrolling any other non-English speaking individuals.

If the study anticipates in advance of study start-up that one or more potential subjects may be non-English speaking, then it is the responsibility of the team to obtain certified translations of all patient-facing materials and submit them to the IRB for approval. A list of translation companies can be found here.

Translation Companies (Note: The IRB does not endorse any translation service)

- TNOLA Languages
- protranslate
- Northwest Translations
- The Language Bank, Inc.
- Transperfect
The full consent form must be presented to the subject by a translator or a study team member who is proficient in the participant’s primary language.

- LCMC uses a translation phone service. Make sure you document the ID number of the translator used.
- If study team member does the translation, an independent witness conversant in both languages (not study team or family) must also be present.
Save the Date!

February Lunch & Learn

Date: February 7, 2024
Time: 12:00 PM
Topic: Amendments