AGENDA

- Discuss the Belmont Report
- Talk through the elements of Informed Consent
- Provide tips for drafting the Informed Consent
- Discuss HIPAA Authorizations
- Talk through the elements of HIPAA Authorization
- Outline the Informed Consent process
- Review the different waivers for Informed Consent & HIPAA Authorization
- Review UMCNO Policy regarding Consent Process
BELMONT REPORT

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

**Application:** Assessment of Risks & Benefits

- Beneficence
  - 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

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

**Application:** Informed Consent

- Justice
## INFORMED CONSENT: CORE ELEMENTS

<table>
<thead>
<tr>
<th>Element</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>A statement that the study involves research</td>
<td>Distinction of experimental procedures vs standard of care</td>
</tr>
<tr>
<td>An explanation of the purpose of the study</td>
<td>A description of any foreseeable risks/discomforts</td>
</tr>
<tr>
<td>A statement about the expected duration of participation</td>
<td>A description of reasonable benefits, if any</td>
</tr>
<tr>
<td>A description of the procedures to be followed</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>
</tr>
<tr>
<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>
</tr>
<tr>
<td>Participant or Legally Authorized Representative Signature</td>
<td></td>
</tr>
</tbody>
</table>
## INFORMED CONSENT: OTHER ELEMENTS

<table>
<thead>
<tr>
<th>A statement that procedures may involve <strong>unforeseeable risk</strong></th>
<th>Circumstances under which <strong>participation may be terminated</strong> by the PI</th>
<th>A statement of any <strong>additional costs to the subject</strong> that may result</th>
</tr>
</thead>
<tbody>
<tr>
<td>A statement of <strong>consequences of a subject’s decision to withdraw</strong></td>
<td>A statement that <strong>significant new findings</strong> will be presented to subjects</td>
<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>
<td>A statement regarding disclosure to subject about <strong>clinically relevant results</strong></td>
<td>A statement if the research will involve <strong>genome sequencing</strong> on biospecimen</td>
</tr>
</tbody>
</table>
**TIPS FOR DRAFTING THE CONSENT**

**Reading Level:** 8th grade - Use Flesch-Kincaid* to text the readability of your document

**File Names:** Be Consistent

**Templates:** Use the local IRB template

**Second or Third Person:** Use “you” or “he/she/they”

**Statement of Agreement:** Conclude with this

**Verbs:** Tell your audience what they will be doing

*Flesch-Kincaid - The Flesch/Flesch–Kincaid readability tests are designed to indicate comprehension difficulty when reading a passage of contemporary academic English. There are two tests: the Flesch Reading Ease, and the Flesch–Kincaid Grade Level both that measure word length and sentence length. Both available in Word.
TIPS FOR EXECUTING THE CONSENT

(If you are working on an industry study or a sponsor that has written consent)

Before you get started- do you have the UP TO DATE version of the consent?

Consenting is an ongoing process and some studies have multiple updates. Check before you consent.
HIPAA AUTHORIZATION

An individual's signed permission to allow a covered entity to use or disclose the individual's protected health information (PHI) that is described in the Authorization for the purpose(s) and to the recipient(s) stated in the Authorization.

18 Identifiers as defined by HIPAA:

<table>
<thead>
<tr>
<th>Name</th>
<th>URL Address</th>
<th>Health Plan Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Street Address</td>
<td>IP Address</td>
<td>Device Identifiers</td>
</tr>
<tr>
<td>Dates (MM/DD/YYYY)</td>
<td>Social Security Number</td>
<td>Vehicle Identifiers</td>
</tr>
<tr>
<td>Phone Number</td>
<td>Account Numbers</td>
<td>Biometric Identifiers</td>
</tr>
<tr>
<td>Fax Number</td>
<td>License Numbers</td>
<td>Full Face Photos</td>
</tr>
<tr>
<td>Email Address</td>
<td>Medical Record Number</td>
<td>Other Identifying Characteristics</td>
</tr>
</tbody>
</table>
HIPAA AUTHORIZATION: 
CORE ELEMENTS

- Description of PHI to be used
- Identification of persons/entities who will make the disclosure
- Identification of persons/entities who will use the PHI
- Description of specific purpose of the requested disclosure

Authorization expiration date
Investigator or designee reads through the consent form with the potential participant, and allows ample time for the potential participant to ask questions.

The potential participant may be provided with a copy of the consent and given time to consider whether they want to participate.

After allowing the participant time to decide, the Investigator or designee must answer any additional questions the subject may have.

When the potential participant is ready, the Investigator or designee must obtain signatures on the consent & HIPAA Authorization or document verbal consent.
Who Can Sign? Participant or their Legally Authorized Representative

What if the Participant Cannot Write? The participant can sign with an “X”

What if the Participant Cannot Read? An independent witness must be present for the reading of the consent & HIPAA Authorization. There is a signature block on the consent form for the witness.

What of the Participant Does Not Speak English? LSUHSC allows for the use of a Short Form when consenting a subject unexpectedly that does not speak English. The full consent form must be translated verbally to the subject by a translator or a study team member who is proficient in the participant’s primary language. An independent witness must be present if the consent is translated by a study team member. If the study team anticipates enrollment of non-English speaking participants, it is their responsibility to get the full consent form certified, translated.
WAIVERS

- Waiver of Informed Consent
- Waiver of Documentation of Informed Consent / Permission for Verbal Consent
- Waiver or Alteration of HIPAA Authorization
The IRB may approve a waiver of the requirement to obtain informed consent if **all** of the following apply:

1. **Is research more than minimal risk?**
   - **No**
   - **Yes**
     - **Waiver cannot be approved**

2. **Will waiver adversely affect the rights/welfare of subjects?**
   - **No**
   - **Yes**
     - **Waiver cannot be approved**

3. **Can the research be practically carried out without the waiver?**
   - **No**
   - **Yes**
     - **Waiver cannot be approved**

4. **Will subjects be provided with additional pertinent information after participation?**
   - **No**
   - **Yes**
     - **Waiver of Informed Consent Approved**
WAIVER OF DOCUMENTATION / PERMISSION FOR VERBAL CONSENT

The IRB may approve a waiver of documentation of informed consent and/or grant permission to obtain verbal consent if any of the following apply:

45 CFR 67.117(c)(i)

- The **only record** linking the subject and the research would be the *signed informed consent form*;
- The **principal risk** would be potential harm resulting from a *breach in confidentiality*; and,
- Each subject or LAR will be asked whether the subject wants documentation linking them.

45 CFR 67.117(c)(ii)

- The research **presents no more than minimal risk** of harm to subjects; and,
- The research involves **no procedures for which written consent is normally required** outside of the research context.

45 CFR 67.117(c)(iii)

- The subject or LAR is a **member of a distinct cultural group** or community in which signing forms is not the norm;
- The research presents **no more than minimal risk** of harm to subjects; and,
- There is an **appropriate, alternative mechanism** for documenting that informed consent was obtained.
WAIVER OR ALTERATION OF HIPAA AUTHORIZATION

The IRB may approve a waiver of or alteration to HIPAA Authorization if any of the following apply:

45 CFR 164.512(i)(ii)(A)

• The use or disclosure of protected health information involves no more than minimal risk to the privacy of the subjects based on, at least, one of the following:
  i. An adequate plan to protect the identifiers from improper use or disclosure; and/or,
  ii. An adequate plan to destroy the identifiers at the earliest opportunity, unless there is a health, legal, or research justification for retaining the identifiers; and/or,
  iii. Adequate written assurances that the protected health information will not be used or disclosed to any other person or entity, except as required by law for authorized oversight of the research project, or for other research for which the use or disclosure of protected health information would be permitted.

45 CFR 164.512(i)(ii)(B)

• The research could not practicably be conducted without the waiver or alteration

45 CFR 164.512(i)(ii)(C)

• The research could not practicably be conducted without access to and use of the protected health information
AT UMC, researchers and affiliates need to be credentialed and obtain EPIC access. The coordinators are required to document that the informed consent was completed.

For credentialing, please call or email:

504-702-02440 umc-researchcredentialing@lcmehealth.org

Consent Documentation must be entered into EPIC within 24 hours. Standard language should be used. Include eligibility in same note for ease.

Both UMC Office of Research and LSU have smart phrases on EPIC to help researchers fulfill requirements. The smart phrases can be customized to your study and saved to EPIC.
Informed Consent Discussion Process Documentation - EPIC NOTE

Research Informed Consent Documentation

Date: [ ]

Study Title: [***]
Principal Investigator: [***]
IRB #: [***]
Protocol #: [***]
Protocol Version: [***]
ICF Rev. Date: [***] (IRB Approval Date: [***])

Inclusion/Exclusion Criteria reviewed by Dr. [***] on [EDTD]

Consent process conducted by: Siobhan Marie Trotter
Present for discussion: Subject

Discussion: The details of this research study were discussed with the subject, LAR or designee. The study was explained in detail including all the contents of the informed consent document. The subject, LAR or designee was encouraged to ask questions. All questions were answered to the satisfaction of the subject/designated representative. The subject, LAR or designee was given adequate time to read the informed consent, HIPAA document, and the opportunity to discuss both. We also acknowledged the experimental nature of the treatment and pointed out that no guarantees can be made regarding benefits to participating. We emphasized that participation is voluntary, that no care would not be jeopardized if he declined participation, and that he is able to withdraw at any time. He realized that the consent for participation is an ongoing process and that he can ask questions at any time. Patient understands that he will be informed of treatment assignment on the day of surgery.

Following this discussion, the patient has expressed interest in proceeding with the informed consent process.

- Subject has the ability to give informed consent? [YES/NO] 24023)
  - If NO, Legally Authorized Representative (LAR) gave informed consent on behalf of the subject and has the authority to act on behalf of the subject? [YES/NO/NOT APPLICABLE 24589]
  - Name of LAR: [***]
- The informed consent was obtained prior to any study procedures being performed? [YES/NO] 24023)
- Was the informed consent discussion in private & did the subject have enough time to read the consent? [YES/NO] 24023)
- Has the subject had enough time to ask questions of qualified staff? [YES/NO] 24023
- Has the subject expressed comprehensive understanding of the following:
  - Goal of the Research and Protocol? [YES/NO] 24023
  - Duration of Participation? [YES/NO] 24023
  - The Risks with Study Medication and Procedures? [YES/NO] 24023

Attached Files (0)

Sign when Signing Visit [ ]

Accept [ ]

Rejection [ ]
Informed Consent Discussion Process

Documentation - EPIC NOTE

The IRB-approved informed consent document and HIPAA document were signed and dated without alteration by the subject/designated representative. A copy of the signed and dated informed consent document and HIPAA document were placed in the subject record, and a copy was given to the subject, LAR or designee. No activities specifically related to the research were started until after the execution of the consent. Throughout consent process, the subject was engaged and asked appropriate questions. All questions and concerns addressed to subject’s satisfaction. Following informed consent process, the subject verbalizes willingness to participate.
Informed Consent Training Required

AT UMC, all persons conducting research in our facility are required as part of their credentialling to participate in this informed consent training.

You will be given a certificate of participation after the informed consent training, and it will be stored with your credentials.

Resource for FAQs:
## Save the Date!

<table>
<thead>
<tr>
<th>Date</th>
<th>Time</th>
<th>Topic</th>
</tr>
</thead>
<tbody>
<tr>
<td>03/01/2023</td>
<td>12:00PM</td>
<td>Expanded Access Use of a Test Article</td>
</tr>
<tr>
<td>04/05/2023</td>
<td>12:00PM</td>
<td>Regulatory Binders</td>
</tr>
<tr>
<td>05/03/2023</td>
<td>12:00PM</td>
<td>Renewals</td>
</tr>
<tr>
<td>06/07/2023</td>
<td>12:00PM</td>
<td>Non-Human Subjects Research Determinations</td>
</tr>
</tbody>
</table>