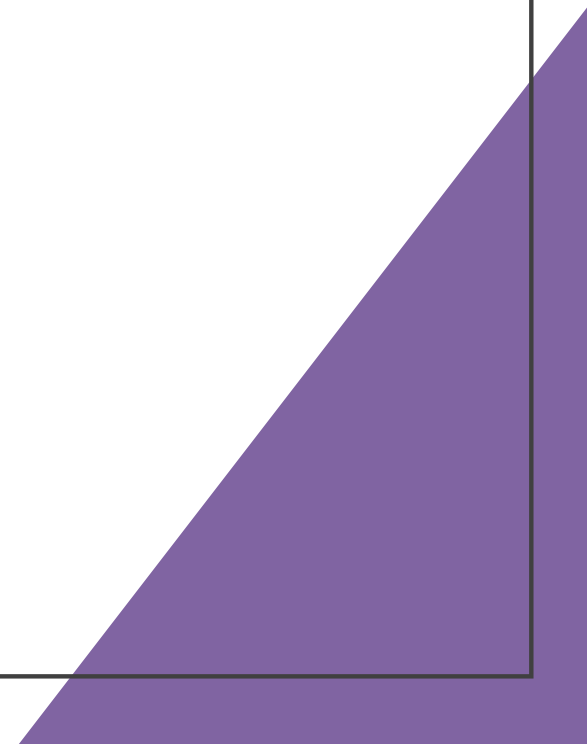




INFORMED CONSENT & HIPAA AUTHORIZATION

February 1, 2022



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



- 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: Selection of Participants

INFORMED CONSENT: CORE ELEMENTS

A statement that the **study involves research**

An explanation of the **purpose of the study**

A statement about the **expected duration** of participation

A description of the **procedures to be followed**

Distinction of **experimental procedures** vs standard of care

A description of any foreseeable **risks/discomforts**

A description of reasonable **benefits**, if any

A disclosure of **alternatives to study**, if any

A statement re: **extent record will be kept confidential**

For more than minimal risk, **explanation about compensation**

Information regarding **research-related injury**

Whom to **contact** about the research, rights, and injury

A statement that **participation is voluntary** and refusal is without penalty

A statement about possibility of **keeping samples for future use**

Participant or Legally Authorized Representative **Signature**

INFORMED CONSENT: OTHER ELEMENTS

A statement that procedures may involve **unforeseeable risk**

Circumstances under which **participation may be terminated** by the PI

A statement of any **additional costs to the subject** that may result

A statement of **consequences of a subject's decision to withdraw**

A statement that **significant new findings** will be presented to subjects

Approximate **number of subjects** anticipated to enroll in the study

A statement that biospecimen may be used for **commercial profit**

A statement regarding disclosure to subject about **clinically relevant results**

A statement if the research will involve **genome sequencing** on biospecimen

TIPS FOR DRAFTING THE CONSENT

Reading Level: 8th grade - Use Flesch-Kincaid* to test 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:

Name	URL Address	Health Plan Number
Street Address	IP Address	Device Identifiers
Dates (MM/DD/YYYY)	Social Security Number	Vehicle Identifiers
Phone Number	Account Numbers	Biometric Identifiers
Fax Number	License Numbers	Full Face Photos
Email Address	Medical Record Number	Other Identifying Characteristics

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

INFORMED CONSENT PROCESS



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

SIGNING CONSENT & HIPAA AUTHORIZATION

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.

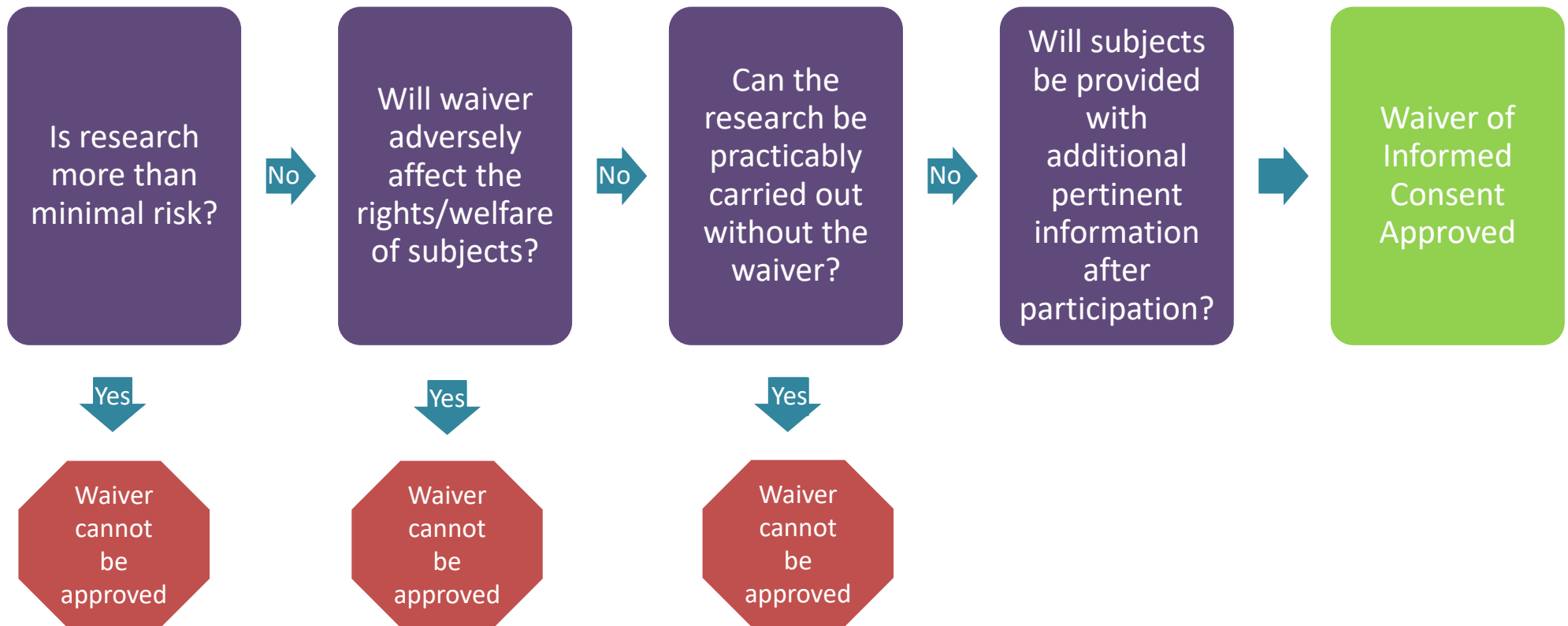
What if the Participant Does Not Speak English? LSUHSC allows for the use of a Short Form when consenting a subject unexpectedly that does not speak English. The full consent form must be translated verbally to the subject by a translator or a study team member who is proficient in the participant’s 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

WAIVER OF INFORMED CONSENT

The IRB may approve a waiver of the requirement to obtain informed consent if all of the following apply:



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**

Informed Consent Discussion Process Documentation

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@lcmchealth.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

The screenshot displays the EPIC EHR interface. On the left, a patient summary for 'Test Research' (Male, 23 y.o., 1/1/2000) is shown, including MRN, CSN, and patient class. The main chart area includes sections for Medication Management (no active orders), SmartSets, BestPractice Advisories, and a Problem List with one entry: 'Research study patient'. The right pane shows a note titled 'Research Informed Consent Documentation' with the following content:

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 his care would not be jeopardized if he declined participation, and that he is able to withdraw at any point. He realizes 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:26589}
 - **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 comprehension of the following:**
 - **Goal of the Research and Protocol?** {YES/NO:24023}
 - **The Duration of Participation?** {YES/NO:24023}
 - **The Risks with Study Medication and Procedures?** {YES/NO:24023}

At the bottom of the note, there are buttons for 'Accept' and 'Cancel', and a 'Sign when Signing Visit' dropdown menu.

Informed Consent Discussion Process Documentation- EPIC NOTE

TR

Test Research
Male, 23 y.o., 1/1/2000
MRN: 1004217818
CSN: 600108335325
Code: Not on file (no ACP docs)
Patient Class: None

Search

Medication Management

SmartSets

BestPractice Advisories

Problem List

Visit Diagnoses

My Note

Create Note

1 NoteWriter w/ HPI 2 NoteWriter w/o HPI 3 Annual Wellness 4 SMTPROGRESSNOTE

My Note

Tag Share w/ Patient Details

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:26589}
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Has the subject expressed comprehension of the following:

- Goal of the Research and Protocol? {YES/NO:24023}
- The Duration of Participation? {YES/NO:24023}
- The Risks with Study Medication and Procedures? {YES/NO:24023}
- The Benefits and Compensation? {YES/NO:24023}
- Voluntariness? {YES/NO:24023}
- The reproductive risks related to study medication or procedures? {YES/NO/NOT APPLICABLE:26589}
- The process for New Information? {YES/NO:24023}
- The Privacy & Confidentiality? {YES/NO:24023}
- Compensation for study related injury and whom to contact for study related injury? {YES/NO:24023}

Does the subject have all the proper Contact Information required? {YES/NO:24023}

Was the subject given information and does the subject acknowledge understanding of www.clinicaltrials.gov? {YES/NO:24023}

Was a copy of the consent form provided to the study subject?: {YES/NO:24023}

- If NO, please provide reason and plan as to how subject will receive a copy: {YES/NO:24023}

Was a copy of the consent form uploaded to the media section of the study subject's EMR?: {YES NO:21330}

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.

Your Name Here

Attached Files (0)

Sign when Signing Visit

Accept Cancel

Informed Consent Training Required

AT UMC, all persons conducting research in our facility are required as part of their credentialing 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:

<https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/informed-consent/index.html>

Save the Date!

Date	Time	Topic
03/01/2023	12:00PM	Expanded Access Use of a Test Article
04/05/2023	12:00PM	Regulatory Binders
05/03/2023	12:00PM	Renewals
06/07/2023	12:00PM	Non-Human Subjects Research Determinations

