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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

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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

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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**

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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

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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.

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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.

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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/YYY)	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/entites** who **will use the PHI**

Description of **specific purpose** of the requested disclosure

Authorization expiration date

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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

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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 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

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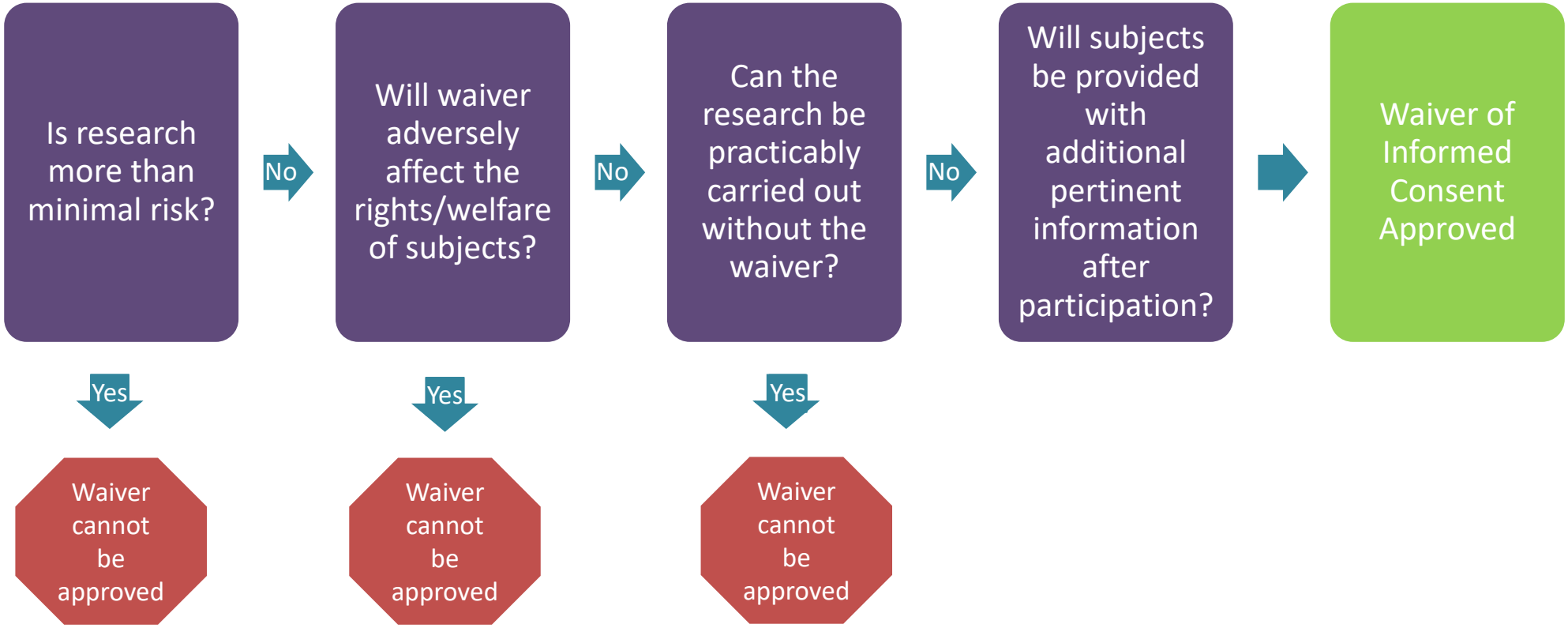
WAIVER OF INFORMED CONSENT

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



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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 <u>any</u> 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.

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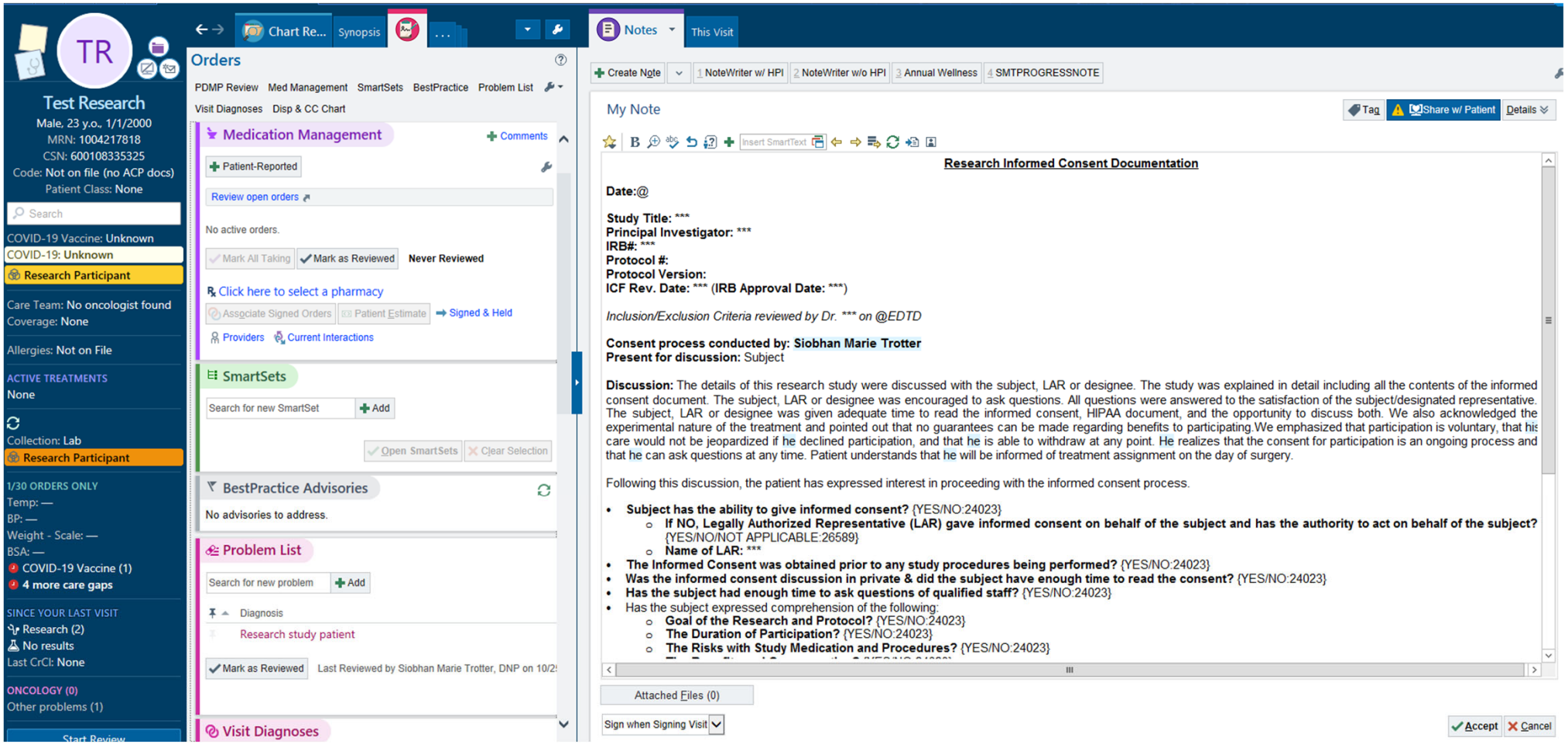
Informed Consent Discussion Process Documentation- EPIC NOTE



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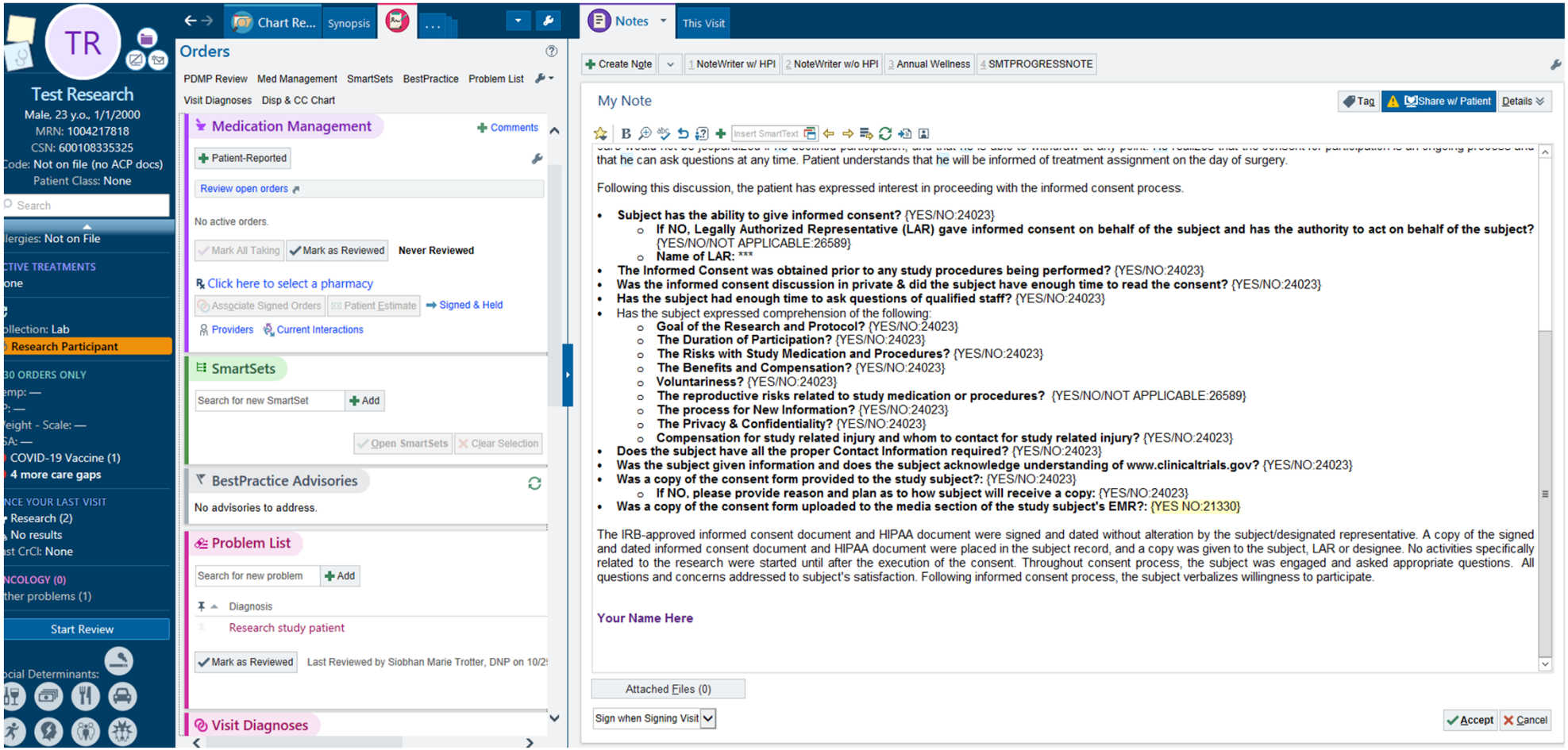
Informed Consent Discussion Process Documentation- EPIC NOTE



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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:
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