LSU HEALTH COORDINATOR COMPETENCIES

X

ADHERENCE TO ETHICAL STANDARDS

Informed Consent Process and Procedures for Clinical Research

Objectives

- List and describe supporting documentation of the informed consent process (e.g. consent forms, consent notes, waivers).
- Identify and interpret policies and regulations related to the informed consent process and HIPAA
- Describe requirements related to ensuring participant comprehension of informed consent and ICFs (e.g. translation requirements)
- Describe how the consent process is planned and diagnose errors in consent planning
- Describe the procedure for conducting and documenting consent for participants

Refresher: What is 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."

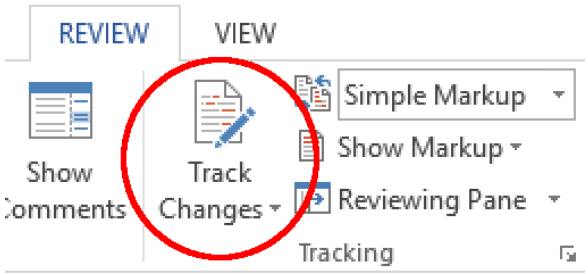
FDA's Guidance for Industry E6 GCP: Consolidated Guidance, Section 1.28

My Informed Consent form was approved by the IRB! Now what?

- The IRB approval letter, relevant communications, and approved ICF should be filed in the site's regulatory binder and saved electronically
- If applicable, send sponsor a copy of the IRB approval letter and approved ICF

Changing the Informed Consent Form

- Any revised written ICF document and written information must be submitted for IRB approval **prior** to use.
  - Revise the ICF whenever important new information becomes available that may be relevant to the subject's consent or willingness to continue participation in the trial.
  - If the IRB of record is not LSUHSC, all new and revised documents relevant to LSUHSC should still be submitted to the LSUHSC IRB, preferably within 30 days.
    - For example, if WIRB is the central IRB, the updated consent for LSU patients would still need to be submitted to LSUHSC IRB.
- Change the document version number and approval date on the updated ICF.
- Submit tracked Word document and clean PDF of the updated ICF.



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Before you get started…

Are you listed as Study Personnel in the IRB submission and Delegation of Authority Log?

What does the protocol say?
E.g., location of consent, in-person vs. phone

Do you have the
UP TO DATE version of the consent?

Consenting is an ongoing process.
Some studies have multiple updates.

Check before you consent.

Informed Consent Process

Investigator or sub-investigator presents 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 (e.g., coordinator) 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 (unless waiver applies)

Signing the 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.

*Remember: LAR cannot sign in the case of nonviable neonates.

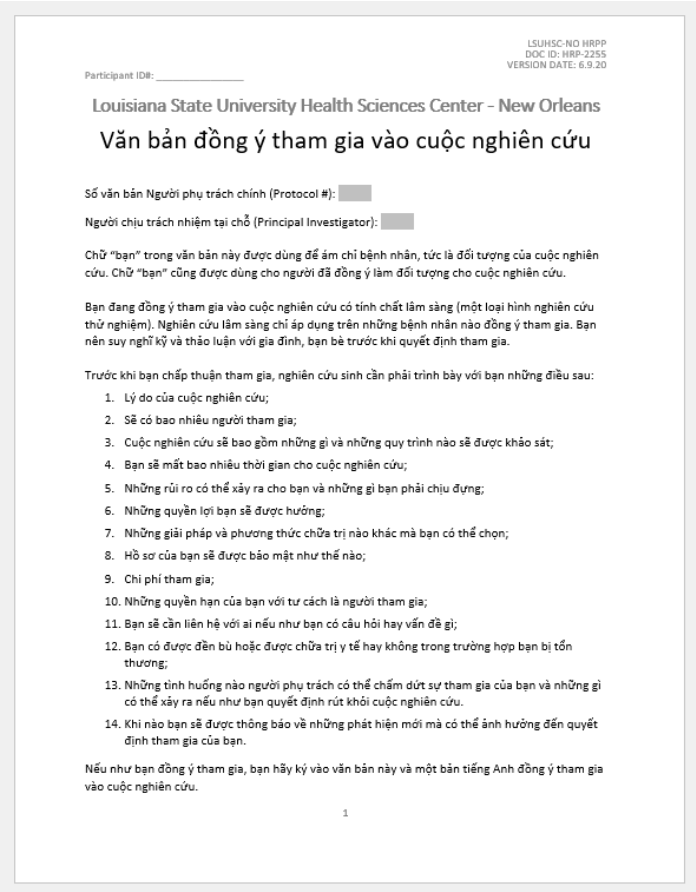
Short Forms for Non-English Speakers

- Used 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.
- **Witness must be present and conversant in both languages** (i.e., English and the language of the subject).
  - If study team member does verbal translation, an **independent witness** must also be present.
- A copy of the short form is given to the subject/LAR.

Short Forms for Non-English Speakers

- **Only sign the forms written in languages that the person understands!**
  - Subject/LAR only sign short form itself.
  - Witness should sign both the short form and copy of the summary
  - The person actually obtaining consent shall sign a copy of the summary.
- If the study team **anticipates enrollment of non-English speaking participants**, it is their responsibility to **get the full consent form certified, translated.**
  - Once the short form has been used **twice**, the study team needs to get the full consent form translated.
- LCMC and UMC use a **translation phone service**. Make sure you document the ID number of the translator used.

Short Form Example: Vietnamese



LSUHSC-NO HRPP
DOC ID: HRP-2255
VERSION DATE: 6.9.20

Participant ID#: _____

Louisiana State University Health Sciences Center - New Orleans

Văn bản đồng ý tham gia vào cuộc nghiên cứu

Số văn bản Người phụ trách chính (Protocol #): [redacted]

Người chịu trách nhiệm tại chỗ (Principal Investigator): [redacted]

Chữ "bạn" trong văn bản này được dùng để ám chỉ bệnh nhân, tức là đối tượng của cuộc nghiên cứu. Chữ "bạn" cũng được dùng cho người đã đồng ý làm đối tượng cho cuộc nghiên cứu.

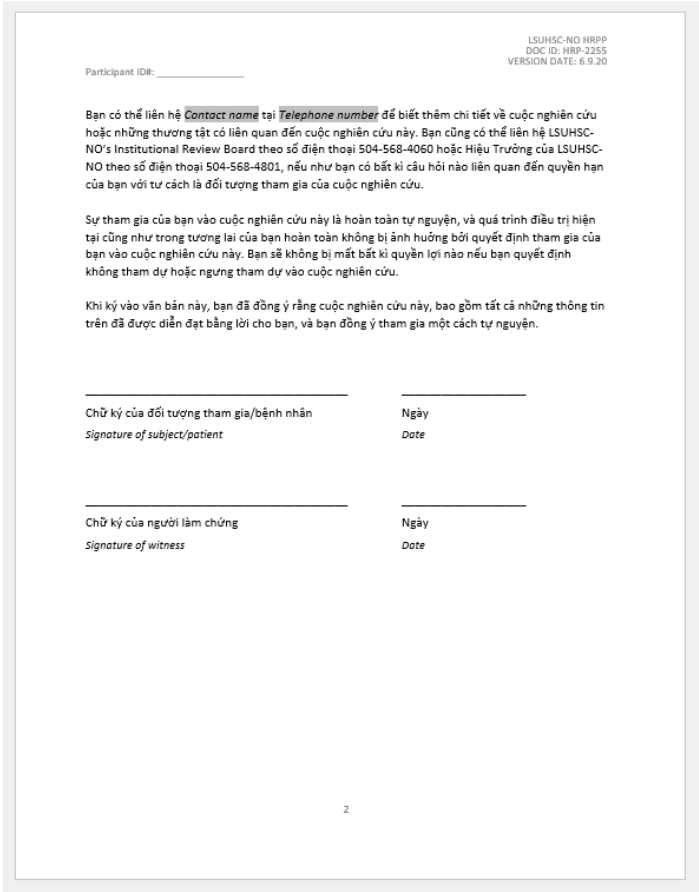
Bạn đang đồng ý tham gia vào cuộc nghiên cứu có tính chất lâm sàng (một loại hình nghiên cứu thử nghiệm). Nghiên cứu lâm sàng chỉ áp dụng trên những bệnh nhân nào đồng ý tham gia. Bạn nên suy nghĩ kỹ và thảo luận với gia đình, bạn bè trước khi quyết định tham gia.

Trước khi bạn chấp thuận tham gia, nghiên cứu sinh cần phải trình bày với bạn những điều sau:

1. Lý do của cuộc nghiên cứu;
2. Sẽ có bao nhiêu người tham gia;
3. Cuộc nghiên cứu sẽ bao gồm những gì và những quy trình nào sẽ được khảo sát;
4. Bạn sẽ mất bao nhiêu thời gian cho cuộc nghiên cứu;
5. Những rủi ro có thể xảy ra cho bạn và những gì bạn phải chịu đựng;
6. Những quyền lợi bạn sẽ được hưởng;
7. Những giải pháp và phương thức chữa trị nào khác mà bạn có thể chọn;
8. Hồ sơ của bạn sẽ được bảo mật như thế nào;
9. Chi phí tham gia;
10. Những quyền hạn của bạn với tư cách là người tham gia;
11. Bạn sẽ cần liên hệ với ai nếu như bạn có câu hỏi hay vấn đề gì;
12. Bạn có được đền bù hoặc được chữa trị y tế hay không trong trường hợp bạn bị tổn thương;
13. Những tình huống nào người phụ trách có thể chấm dứt sự tham gia của bạn và những gì có thể xảy ra nếu như bạn quyết định rút khỏi cuộc nghiên cứu.
14. Khi nào bạn sẽ được thông báo về những phát hiện mới mà có thể ảnh hưởng đến quyết định tham gia của bạn.

Nếu như bạn đồng ý tham gia, bạn hãy ký vào văn bản này và một bản tiếng Anh đồng ý tham gia vào cuộc nghiên cứu.

1



LSUHSC-NO HRPP
DOC ID: HRP-2255
VERSION DATE: 6.9.20

Participant ID#: _____

Bạn có thể liên hệ *Contact name* tại *Telephone number* để biết thêm chi tiết về cuộc nghiên cứu hoặc những thương tật có liên quan đến cuộc nghiên cứu này. Bạn cũng có thể liên hệ LSUHSC-NO's Institutional Review Board theo số điện thoại 504-568-4060 hoặc Hiệu Trưởng của LSUHSC-NO theo số điện thoại 504-568-4801, nếu như bạn có bất kì câu hỏi nào liên quan đến quyền hạn của bạn với tư cách là đối tượng tham gia của cuộc nghiên cứu.

Sự tham gia của bạn vào cuộc nghiên cứu này là hoàn toàn tự nguyện, và quá trình điều trị hiện tại cũng như trong tương lai của bạn hoàn toàn không bị ảnh hưởng bởi quyết định tham gia của bạn vào cuộc nghiên cứu này. Bạn sẽ không bị mất bất kì quyền lợi nào nếu bạn quyết định không tham dự hoặc ngưng tham dự vào cuộc nghiên cứu.

Khi ký vào văn bản này, bạn đã đồng ý rằng cuộc nghiên cứu này, bao gồm tất cả những thông tin trên đã được diễn đạt bằng lời cho bạn, và bạn đồng ý tham gia một cách tự nguyện.

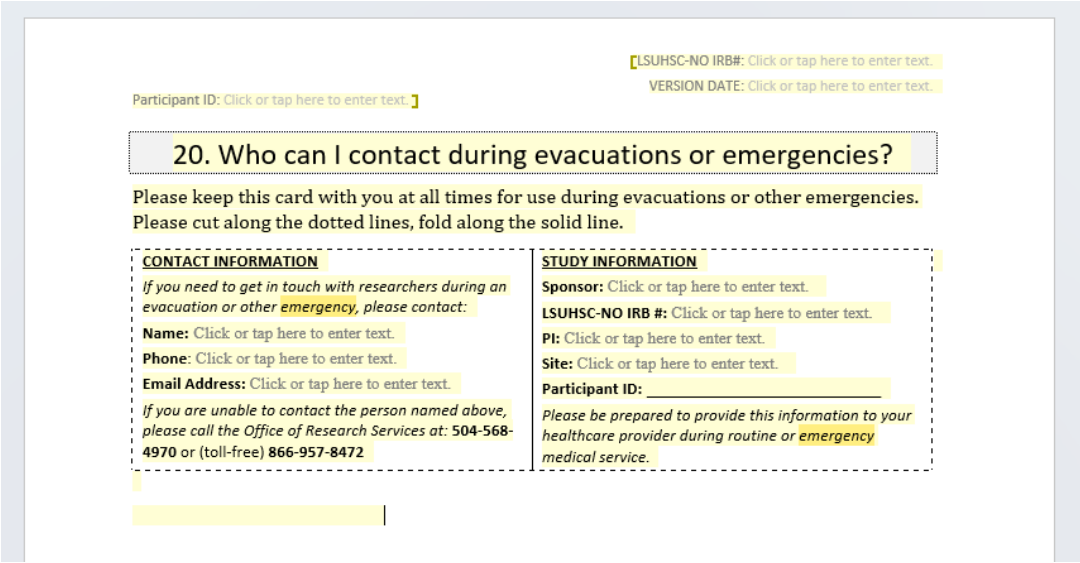
_____	_____
Chữ ký của đối tượng tham gia/bệnh nhân *Signature of subject/patient*	Ngày *Date*
_____	_____
Chữ ký của người làm chứng *Signature of witness*	Ngày *Date*

2

LSUHSC has short forms and HIPAA Authorizations pre-translated into Spanish, French, and Vietnamese.

Emergency Preparedness

- Active participants who are either **taking study drugs or devices** should receive a copy of the **emergency contact number** and the IRB-approved **emergency card** with their study ID number.
- Make sure all the information (principal investigator name, phone number and email address) is accurate prior to giving it to participants



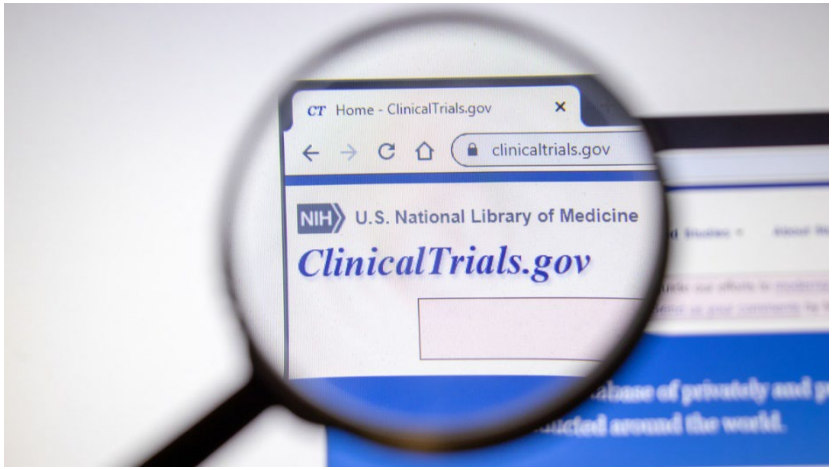
[LSUHSC-NO IRB#: Click or tap here to enter text.
VERSION DATE: Click or tap here to enter text.
Participant ID: Click or tap here to enter text.]

20. Who can I contact during evacuations or emergencies?

Please keep this card with you at all times for use during evacuations or other emergencies.
Please cut along the dotted lines, fold along the solid line.

CONTACT INFORMATION	STUDY INFORMATION
If you need to get in touch with researchers during an evacuation or other emergency, please contact:	**Sponsor:** Click or tap here to enter text.
Name: Click or tap here to enter text.	**LSUHSC-NO IRB #:** Click or tap here to enter text.
Phone: Click or tap here to enter text.	**PI:** Click or tap here to enter text.
Email Address: Click or tap here to enter text.	**Site:** Click or tap here to enter text.
If you are unable to contact the person named above, please call the Office of Research Services at: **504-568-4970** or (toll-free) **866-957-8472**	**Participant ID:** _____
	Please be prepared to provide this information to your healthcare provider during routine or emergency medical service.

Clinicaltrials.gov



- A description of the clinical trial will need to be available at http://www.ClinicalTrials.gov, as required by U.S. Law.
- *ClinicalTrials.gov* is a website that provides information about federally and privately supported clinical trials.
- During the consent process, study team members need to explain what *ClinicalTrials.gov* is to participants, how to access information about their trial, and emphasize that the website will not include information that can identify them.

After the Participant Signs

- **Review the signed form for completeness** BEFORE subject leaves and again BEFORE filing in your files.
  - Ensure that all blanks on the forms are filled out appropriately
  - Research team members may not complete these blanks for the subject
- **The complete original signed copies** are kept by PI and delegated study team members
  - Put the original copy in the regulatory binder and a copy of the signed ICF in the subject file
- **Provide a copy of all signed forms to the subject/LAR**
- Document informed consent process in **source document**
- **Remember! Consent is an ongoing process!**
- Same procedure and process applies for **re-consenting** subjects
  - Re-consent when participant turns 18 years old

Template to Document IC Process in EPIC for UMC/LCMC

Research Informed Consent Documentation Form

@LCMCTODAYDATE@

Protocol Name: ***
Protocol #: ***
IRB #: ***
Principal Investigator: ***
Version: ***
IRB Approval Date: ***

Subject has the ability to give informed consent? {yes/no:310449}

Legal Representative gave informed consent on behalf of the subject and has the authority to act on behalf of the subject? {yes/no:310449}

The Informed Consent was obtained prior to any study procedures being performed? {yes/no:310449}

Was the informed consent discussion in private & did the subject have enough time to read the consent? {yes/no:310449}

Has the subject had enough time to ask questions of qualified staff? {yes/no:310449}

Has the subject expressed comprehension of the Goal of the Research and Protocol? {yes/no:310449}

Has the subject expressed comprehension of the Duration of Participation? {yes/no:310449}

Has the subject expressed comprehension of the Risks with Study Medication and Procedures? {yes/no:310449}

Has the subject expressed comprehension of the Benefits and Compensation? {yes/no:310449}

Has the subject expressed comprehension of Voluntariness? {yes/no:310449}

Has the subject expressed comprehension of the reproductive risks related to study medication or procedures? {yes/no:310449}

Has the subject expressed comprehension of the process for New Information? {yes/no:310449}

Has the subject expressed comprehension of the Privacy & Confidentiality? {yes/no:310449}

Has the subject expressed comprehension regarding compensation for study related injury and whom to contact for study related injury? {yes/no:310449}

Does the subject have all the proper Contact Information required? {yes/no:310449}

Was the subject given a Copy of the completed Consent Form? {yes/no:310449}

Has the subject expressed comprehension regarding compensation for study related injury and whom to contact for study related injury? {yes/no:310449}

Does the subject have all the proper Contact Information required? {yes/no:310449}

Was the subject given a Copy of the completed Consent Form? {yes/no:310449}

Was the subject given information and does the subject acknowledge understanding of www.clinicaltrials.gov? {yes/no:310449}

Patient stated @HIS@ willingness to participate in the study. All questions and/or concerns were answered to the patient and @HIS@ legal representative/guardian's satisfaction by myself and the treating physician, ***.

@ME@, RN

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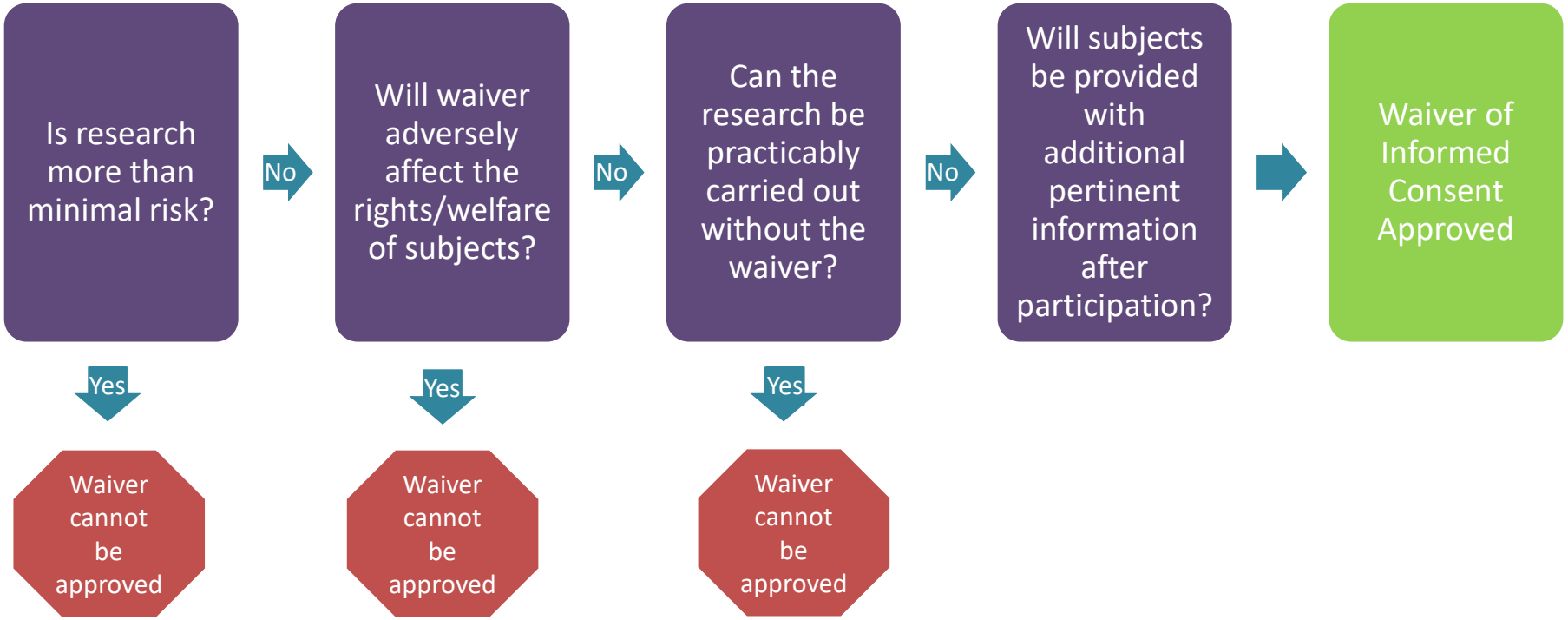
Waivers

- 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 <u>all</u> 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 <u>any</u> 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.

Verbal Informed Consent Information Sheet and Script

- When the documentation requirement is waived and verbal informed consent is allowed, the study team must provide the subject with an **information sheet** (either printed or electronically)
- When verbal consent is obtained over the phone for informed consent, the study team is also required to have a **script to be used by the person obtaining consent**
- When the **waiver is granted under 45 CFR 67.117(c)(i)** (*only record linking subject and research is signed ICF*), person consenting **must provide option for subject/LAR to sign the verbal ICF document** (e.g., script and/or information sheet).
- When waiver is granted under **other categories**, person consenting must **sign the information sheet if consenting in person** or the **verbal script if consenting via phone or via other electronic means**.
- Person consenting should also **document how verbal 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**

Verbal HIPAA Information Sheet and Script

- In cases where HIPAA authorization requirement is altered and verbal HIPAA authorization is allowed, the study team may be required to provide the subject with a **HIPAA Authorization document without subject information lines and signature lines** (either printed or electronically)
- When HIPAA authorization is obtained over the phone for informed consent/HIPAA, the study team is also required to have a **script to be used by the person obtaining consent/authorization**
- When the **waiver is granted under 45 CFR 67.117(c)(i)** (*only record linking subject and research is signed ICF*), person consenting **must provide option for subject/LAR to sign the verbal HIPAA document** (e.g., script and/or information sheet).
- When waiver is granted under **other categories**, person consenting must **sign the information sheet if consenting in person** or the **verbal script if consenting via phone or via other electronic means**.
- Person consenting should also **document how verbal HIPAA was obtained**.

Waiver of Parental Permission
(45 CFR §46.408(c)/45 CFR §46.116(c))

- The research or demonstration project is to be conducted by or subject to the approval of **state or local government officials** and is designed to study, evaluate, or otherwise examine
  i. public benefit or service programs;
  ii. procedures for obtaining benefits or services under those programs;
  iii. possible changes in or alternatives to those programs or procedures; or
  iv. possible changes in methods or levels of payment for benefits or services under those programs.
- The research **could not practicably be carried out without the waiver or alteration**.

Waiver of Parental Permission
(45 CFR §46.408(c)/45 CFR §46.116(d))

- The research involves **no more than Minimal Risk** to the subjects.
- The **waiver or alteration will not adversely affect the rights and welfare** of the subjects.
- The research **could not practicably be carried out** without the waiver or alteration.
- Whenever appropriate, the subjects will be **provided with additional pertinent information after participation**.

Waiver of Parental Permission
(45 CFR §46.408(c))

- The research protocol is **designed for conditions or for a subject population for which parental or guardian permission is not a reasonable requirement** to protect the subjects.
- An **appropriate mechanism for protecting the children** who will participate as subjects in the research is **substituted**.
- The **waiver is not inconsistent with Federal, State, or local law**.

Waiver of Assent
(45 CFR §46.408(a)/45 CFR §46.116(c))

- The research is **not FDA-regulated**.
- The research or demonstration project is to be conducted by or subject to the approval of **state or local government officials**
- The research or demonstration project is designed to study, evaluate, or otherwise examine one or more of the following:
  i. (i) Public benefit or service programs.
  ii. (ii) Procedures for obtaining benefits or services under those programs.
  iii. (iii) Possible changes in or alternatives to those programs or procedures.
  iv. (iv) Possible changes in methods or levels of payment for benefits or services under those programs.
- The research **could not practicably be carried out** without the waiver or alteration.

Waiver of Assent
(45 CFR §46.408(a)/45 CFR §46.116(d)/21 CFR §50.55(d))

- The research involves **no more than Minimal Risk** to the subjects.
- The **waiver or alteration will not adversely affect the rights and welfare** of the subjects.
- The research **could not practicably be carried out** without the waiver or alteration.
- Whenever appropriate, the **subjects will be provided with additional pertinent information** after participation.

Check For Understanding

The study team knows that they need to retain the original signed copy of the consent form. They have kept the last page of the consent document in the study files, since this is the only page with signatures.

What is the issue?

Check For Understanding

The study team knows that they need to retain the original signed copy of the consent form. They have kept the last page of the consent document in the study files, since this is the only page with signatures.

What is the issue?

The study team must retain the full original copy of the signed form, not just the page with signatures.

Check For Understanding

As their IC procedures, the study team member wants to provide the participant with a copy of the consent document and ask them to read it over and ask questions.

What is the issue?

Check For Understanding

As their IC procedures, the study team member wants to provide the participant with a copy of the consent document and ask them to read it over and ask questions.

What is the issue?

The study team member needs to have a dialogue with the participant and go through the entire consent with the subject. The consent acts as a guide for the conversation.

Check For Understanding

True or false?

The regulations strongly suggest but do not require that the informed consent process be delivered in a language that is understandable to the subject.

Check For Understanding

True or false?

The regulations strongly suggest but do not require that the informed consent process be delivered in a language that is understandable to the subject.

FALSE.

The information that is given to the subject or the representative must be in language understandable to the subject or the representative.

Check For Understanding

Can you provide an example of when a waiver of consent/assent may be appropriate?

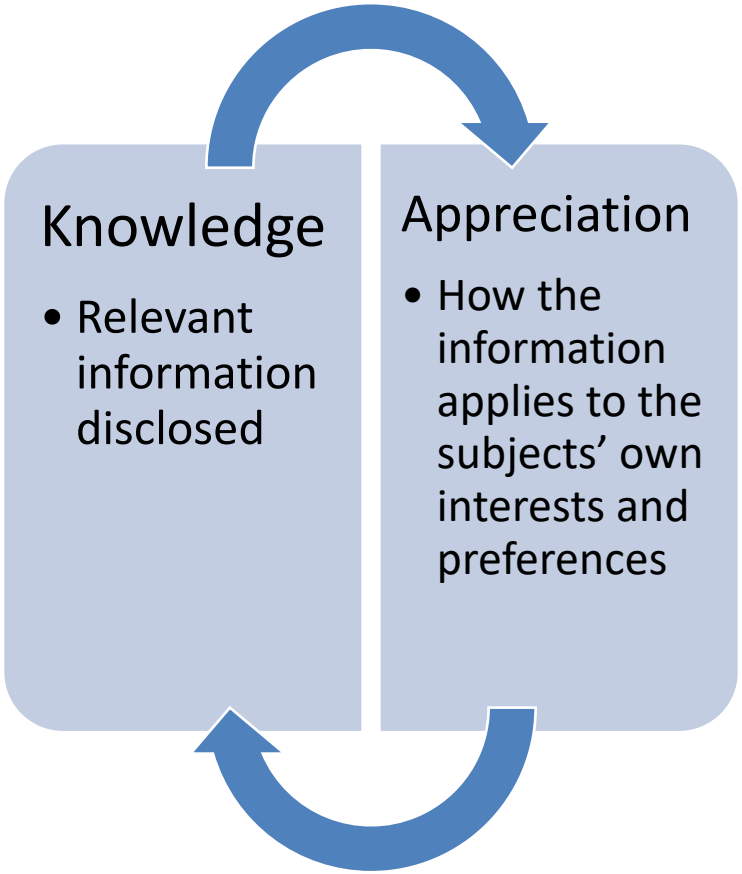
Check For Understanding

Can you provide an example of when a waiver of consent, assent, or parental permission may be appropriate?

Example 1: A medical record chart review study

Example 2: A study with participants under the age of 18 about sexual activity, STDs, use of illegal substances, HIV status, cancel, and child abuse

Implementing Effective Informed Consent



Barriers to Effective Informed Consent

Participant Factors	Study Team Factors
• Low Health Literacy • Limited English Proficiency • Cognitive Impairment • Learning Disabilities or Educational Level • Hearing/Vision Impairment • Confusion about the process & its purpose • Intimidation • Stress or Time Pressure • Memory • Therapeutic Misconception	• Lack of time • Overly complex materials • Lack of interpreter support • Wrong assumptions about patient comprehension

Therapeutic Misconception

Other Barriers: Coercion

Occurs when an overt or implicit threat of harm is intentionally presented by one person to another in order to obtain compliance.

Example: Investigator tells prospective participants that they will lose access to needed health services if they do not participate in the research.

Other Barriers: Undue Influence

Often occurs through an offer of an excessive or inappropriate reward or other overture in order to obtain compliance.

Example: Investigator promises psychology students extra credit if they participate in the research. If that is the only way a student can earn extra credit, then the investigator is unduly influencing potential participants. If, however, she offers comparable non-research alternatives for earning extra credit, the possibility of undue influence is minimized.

Undue Influence can be subtle.

Example: Patients might feel obligated to participate in research if their physician is also the investigator, or students might feel pressure to participate in research if everyone else in the class is doing so.

Minimizing Coercion and Undue Influence

- **Reasonable assessments can be made by the IRB to minimize the likelihood of undue influence or coercion occurring.**
  - Example: restricting levels of financial or nonfinancial incentives for participation, carefully reviewing how incentives are described to potential participants
- **It is up to the IRB to use its discretion in determining which circumstances give rise to undue influence.**
  - Example: an IRB might consider whether the informed consent process will take place at an appropriate time and in an appropriate setting, and whether the prospective participant may feel pressured into acting quickly or be discouraged from seeking advice from others.
- **Known benefits should be stated accurately but not exaggerated, and potential or uncertain benefits should be stated as such.**

Tips for Improving Patient Communication

- **Practice!**
- Be **empathetic** and **honest**
- Keep it **simple** and **do not rush**
- **Speak slowly** and use **easy-to-understand** speech
- Observe the participant's **body language**
- Get a sense of what the participant **already knows** and what the participant **wants to know**
- Recognize **differences in education or literacy**
- Consent document **guides your interactions** and **supports** the consent process
- Consider using **supplementary materials** (must be IRB-approved)

Tips for Improving Patient Communication

- Actively **assess for understanding**
  - Teach-Back
  - Open-ended
- Make sure participants are given **opportunity to decline** and are **aware of their right to do so**
  - Are **confidential procedures** for consent or refusal needed?
- Allow potential participants to **take the forms home** to review
  - Make sure participants do not sign until study team member is present!
- **Principal Investigator or delegate** should be available to answer questions
- Develop a **system to track** consents and re-consents
- After participation is complete, **get feedback** about the consent process

Check for Understanding:

Can you give an example of coercion?

Check for Understanding:

Can you give an example of coercion?

Examples:

Imagine a professor doing survey research about sensitive and private topics who wishes to use their students as participants, and who threatens to fail or penalize any students who do not complete the survey.

Imagine a physician who threatens to withhold access to some service or product unless their patient participates in a research study that they are conducting.

Imagine an investigator threatens to pay a participant less than was promised at initial consent unless they continue in the trial.

The Many Faces of "Coercion" and "Undue Influence"

LSU Health Coordinator Competencies

- ✓ Onboarding
- ✓ Ethical Standards
- ✓ Protocol Compliance
- ✓ Developing the Informed Consent Form
- ✓ Informed Consent Process and Procedures
- ❑ Patient Recruitment & Retention
- ❑ Management of Patients
- ❑ Documentation & Document Management
- ❑ Data Management & Information Technology
- ❑ Financial Stewardship
- ❑ Leadership & Professional Development

Links to Regulations

Belmont Report

Common Rule (45 CFR 46)

FDA Regulations (21 CFR 50 & 56)

ICH Good Clinical Practice

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