LSU HEALTH COORDINATOR COMPETENCIES

X

ADHERENCE TO ETHICAL STANDARDS

Developing the Informed Consent Form

Objectives

- Discuss the purpose of informed consent and of documentation
- Identify and define the elements of the informed consent form
- Identify and interpret policies and regulations related to the informed consent process and Health Insurance Portability and Accountability Act (HIPAA)
- Describe requirements related to ensuring participant comprehension of informed consent and ICFs (e.g., reading level and translation requirements)

Refresher: 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

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

What is Informed Consent?

A process …

- Informed consent begins with the potential participant's **first encounter** with information regarding the clinical research and ends when they are discharged from the study.
- All information disseminated between those two dates, whether written or verbal, is part of the informed consent process.

What is Informed Consent?

…a subject **voluntarily** confirms willingness to participate…

The legal rights of participants may not be waived, and participants may not be asked to release or appear to release the investigator, the sponsor, the institution or its agents from liability for negligence.

An investigator should seek consent only under circumstances that:

- ✓Provide the prospective participant sufficient opportunity to consider whether to participate
- ✓Minimize the possibility of coercion or undue influence.

What is Informed Consent?

…having been **informed** of all aspects…

The overall goal is to **provide sufficient information so that a participant can make an informed decision** about whether to enroll in a study or to continue participation.

- Explain the overall experience to the participant
- Written document which documents the basis for consent and, also provides future reference for the participant
- Thoroughly discuss all elements of the consent to ensure a clear understanding and allow ample time for questions to be addressed.

Educate the participant in terms they can UNDERSTAND

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: Additional 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 (e.g., standard of care vs. study procedures)

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

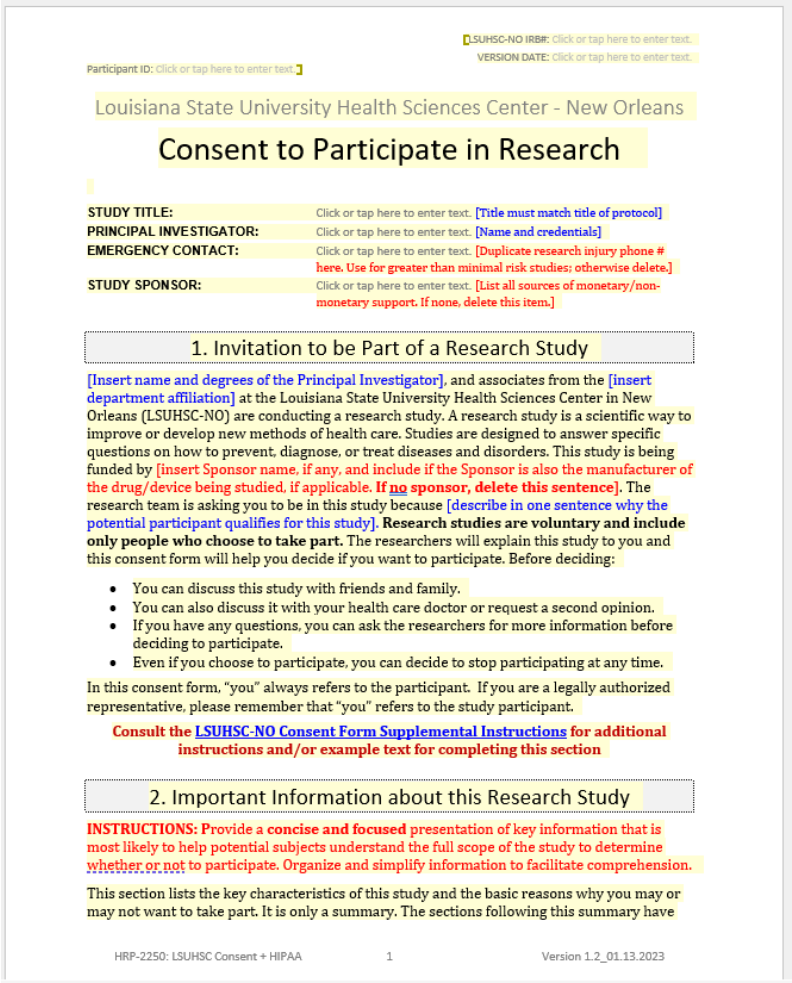
A statement that biospecimen may be used for **commercial profit**

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

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

Informed Consent Templates

- Templates are available on the LSUHSC website.
- Take the template directly from the website every time to ensure you use the most up-to-date version.
- LSUHSC prefers use of our local-approved template.
  - 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.
- Templates are a semi-locked form (only some text is editable) and contain instructions.
- Note: Some templates are site-specific (e.g., UMCNO, CHNOLA, OLOL)



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.

Louisiana State University Health Sciences Center - New Orleans

Consent to Participate in Research

STUDY TITLE:	Click or tap here to enter text. [Title must match title of protocol]
PRINCIPAL INVESTIGATOR:	Click or tap here to enter text. [Name and credentials]
EMERGENCY CONTACT:	Click or tap here to enter text. [Duplicate research injury phone # here. Use for greater than minimal risk studies; otherwise delete.]
STUDY SPONSOR:	Click or tap here to enter text. [List all sources of monetary/non-monetary support. If none, delete this item.]

1. Invitation to be Part of a Research Study

[Insert name and degrees of the Principal Investigator], and associates from the [insert department affiliation] at the Louisiana State University Health Sciences Center in New Orleans (LSUHSC-NO) are conducting a research study. A research study is a scientific way to improve or develop new methods of health care. Studies are designed to answer specific questions on how to prevent, diagnose, or treat diseases and disorders. This study is being funded by [insert Sponsor name, if any, and include if the Sponsor is also the manufacturer of the drug/device being studied, if applicable. **If no sponsor, delete this sentence**]. The research team is asking you to be in this study because [describe in one sentence why the potential participant qualifies for this study]. **Research studies are voluntary and include only people who choose to take part.** The researchers will explain this study to you and this consent form will help you decide if you want to participate. Before deciding:

- You can discuss this study with friends and family.
- You can also discuss it with your health care doctor or request a second opinion.
- If you have any questions, you can ask the researchers for more information before deciding to participate.
- Even if you choose to participate, you can decide to stop participating at any time.

In this consent form, "you" always refers to the participant. If you are a legally authorized representative, please remember that "you" refers to the study participant.

Consult the LSUHSC-NO Consent Form Supplemental Instructions for additional instructions and/or example text for completing this section

2. Important Information about this Research Study

INSTRUCTIONS: Provide a concise and focused presentation of key information that is most likely to help potential subjects understand the full scope of the study to determine whether or not to participate. Organize and simplify information to facilitate comprehension.

This section lists the key characteristics of this study and the basic reasons why you may or may not want to take part. It is only a summary. The sections following this summary have

HRP-2250: LSUHSC Consent + HIPAA 1 Version 1.2_01.13.2023

The HIPAA Privacy Rule as It Relates to Research

What is the HIPAA Privacy Rule?

- Aka *Health Insurance Portability and Accountability Act: Standards for Privacy of Individual Identifiable Health Information* [45 CFR Parts 160 and 164]
- Establishes conditions under which protected health information (PHI) may be used or disclosed by overed entities.
- Failure to implement and comply with the Privacy Rule may, under certain circumstances, trigger the imposition of civil or criminal penalties.

What is a Covered Entity?

- Those who must comply with HIPAA are called covered entities.
- Include:
  1) Health plans
  2) Clearinghouses
  3) Health care providers who electronically transmit any health information
- Because LSUHSC is involved in health care delivery, it is a covered entity.

The HIPAA Privacy Rule as It Relates to Research

What is Protected Health Information?

- Individually identifiable health information transmitted or maintained in any form or medium, including paper records.

How can PHI be used and disclosed?

- With written Authorization from the subject
- With a Waiver of Authorization from the Privacy Board
- As a limited data set pursuant to a data use agreement
- Preparatory to research
- Research on Decedents

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 collected and 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**	**Right to revoke** Authorization
Statement: **Eligibility may be conditioned** on Authorization	Notice: **Re-disclosure** may occur	**Signatures & Dates**

CONSENT OF VULNERABLE POPULATIONS

Special considerations for:

- **Pregnant Women & Fetuses**
  (Subpart B, 45 CFR 46.204)
- **Neonates**
  (Subpart B, 45 CFR 46.205)
- **Children**
  (Subpart D, 45 CFR 46.4XX)
- **Adults with Decisional Impairments**

CONSENT OF VULNERABLE POPULATIONS: Pregnant Women & Fetuses (Subpart B, 45 CFR 46.204)

Consent of the pregnant woman is obtained when:

- Research holds out the **prospect of direct benefit to the pregnant woman**, OR
- The prospect of a direct benefit **both to the pregnant woman and the fetus**, OR
- **No prospect of benefit** for the woman nor the fetus when **risk to the fetus is NOT greater than minimal** and the purpose of the research is the development of **important biomedical knowledge** that cannot be obtained by any other means

Consent of the pregnant woman and the father is obtained when:

- Research holds out the **prospect of direct benefit solely to the fetus**,
  - Except the **father's consent need NOT be obtained** if he is unable to consent because of **unavailability, incompetence, or temporary incapacity or the pregnancy resulted from rape or incest**.

CONSENT OF VULNERABLE POPULATIONS: Neonates (Subpart B, 45 CFR 46.205)

- **<u>Neonates of Uncertain Viability</u>**:
  - Obtain consent of **either parent** of the neonate or, **if neither parent is able to consent** because of unavailability, or temporary incapacity, **consent from either parent's Legally Authorized Representative (LAR)**
  - Consent of the father or his LAR need not be obtained if the pregnancy resulted from rape or incest.

- **<u>Nonviable Neonates</u>**:
  - Obtain consent of **both parents**, **unless one parent is unable to consent** because of unavailability, incompetence, or temporary incapacity and the consent of the father need not be obtained if the pregnancy resulted from rape or incest.
  - **Cannot use LAR**

CONSENT OF VULNERABLE POPULATIONS: Children (Subpart D, 45 CFR 46.4XX)

A. Adequate provisions are made for soliciting the **assent of the children** and **permission of their parents or guardians**;

OR

B. **Justification for waiver or partial waiver** of the assent of the children and permission of their parents or guardians

Permission can be required from:

- **Both parents** (unless one parent is deceased, unknown, incompetent, or not reasonably available, or when one parent has legal responsibility for the care and custody of the child.)
- **One parent** (even if other parent is alive, known, competent, reasonably available, and shares legal responsibility)
- Parental permission is **waived** (less common)

CONSENT OF VULNERABLE POPULATIONS: Children (Subpart D, 45 CFR §46.408)

Assent can be required from:

- **All children**
- **Some children**
  - (i) The capability of some of the children is so limited that they cannot reasonably be consulted.
  - (ii) The intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the children and is available only in the context of the research
  - (iii) Assent is waived for some of the children
- Assent is **waived** for all children

CONSENT OF VULNERABLE POPULATIONS: Children (Subpart D, 45 CFR §46.408)

Additional Information:

- It is best practices to obtain assent for children aged 7-17 years old.
- LSUHSC IRB has templates for assent for children between the ages of 7-12 and children between the ages of 13-17.
- For children from 14-17 years of age, an assent line may be used on the informed consent document of the study.
- Waiver of assent for some or all children is study-specific
  - Examples:
    - Assent may be waived for all participants under the age of 7 in a clinical drug trial due to lack of capacity to understand.
    - Assent may be waived for some children if they have a debilitating illness that affects their capacity to assent.
- Please consult the IRB if you are uncertain if assent is appropriate in your study.

CONSENT OF VULNERABLE POPULATIONS: Adults with Decisional Impairments

- Research involving adults with decisional impairment is not regulated by DHHS; however, DHHS has provided guidance on their involvement in research:
  - Assent is required from all participants; or,
  - Assent is required only from subjects capable of being consulted; or,
  - Assent is waived (same requirements as those for subpart D waiver)

Check for Understanding

Name one of the key elements of informed consent.

Check for Understanding

Name one of the key elements of informed consent.

- Study involves research
- Purpose of the research
- Expected duration
- Description of research procedures
- Distinction of research vs SOC
- Foreseeable risks/discomforts
- Possible reasonable benefits, if any
- Alternatives to participation
- Confidentiality of information
- Point of contact for injury
- Point of contact for questions or concerns
- Statement: Voluntary Participation
- Statement: Right to Withdraw
- Signatures & Dates

Check for Understanding

What does it mean when we say, "Informed consent is a process"?

Check for Understanding

What does it mean when we say, "Informed consent is a process"?

Obtaining signatures on the consent form is just the beginning of the process.

Informed consent begins with the potential participant's first encounter with information regarding the clinical research and ends when they are discharged from the study. At each visit, the study team should confirm with the subject that they still understand the details of their participation and are still willing to participate.

Check For Understanding

For research involving pregnant women, participation requires:

A. That women have completed the first trimester

B. That the study be conducted first in men

C. Permission of the father

D. Consideration of risks and potential benefits for the fetus and the pregnant woman

Check For Understanding

For research involving pregnant women, participation requires:

A. That women have completed the first trimester

B. That the study be conducted first in men

C. Permission of the father

D. Consideration of risks and potential benefits for the fetus and the pregnant woman

Permission of the father is only required when the research holds out the prospect of benefit solely to the fetus.

Check For Understanding

In order to participant in research, children must:

A. Provide written informed consent.
B. Provide written permission.
C. Provide assent in all cases.
D. None of the above.

Check For Understanding

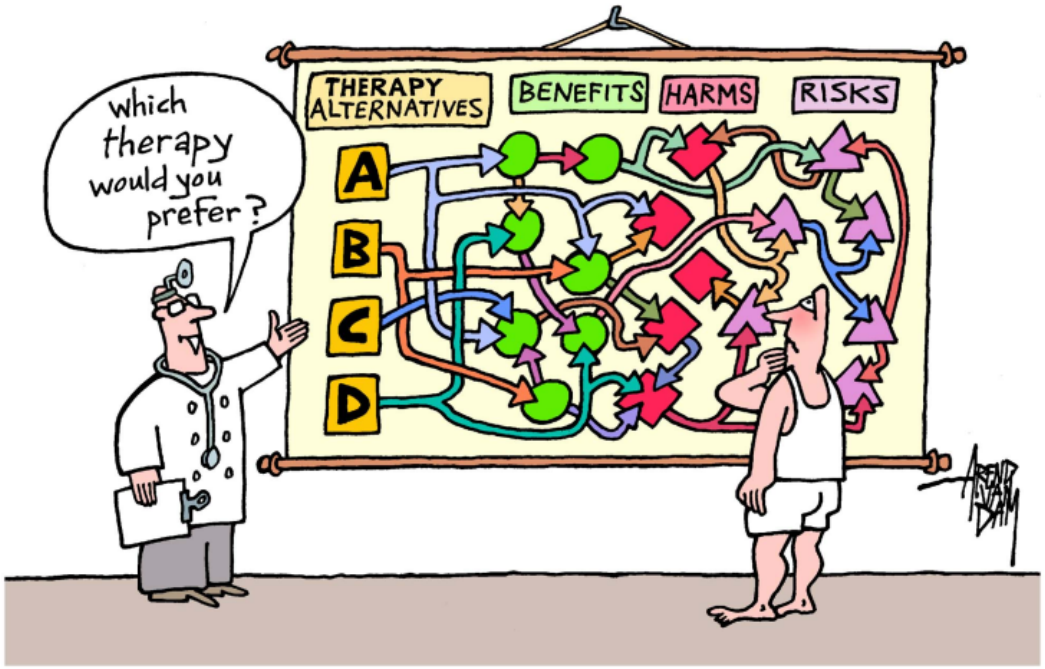
In order to participant in research, children must:

A. Provide written informed consent.
B. Provide written permission.
C. Provide assent in all cases.
D. None of the above.

Assent of some or all children may be waived if the study meets the criteria.

Failure to Achieve Informed Consent

- Despite Informed Consent procedures, subjects often have **variable understanding of the study at best**
- Example: Tam et al., 2015
  - Meta-analysis on subject understanding of components of informed consent in clinical trials
  - NONE of the required elements of informed consent was understood by more than 75% of subjects, including that participation was voluntary
  - Only about 50% of subjects understood the concepts of randomization or placebo



informed consent

Developing an Effective Informed Consent Form

"The manner and context in which information is conveyed is as important as the information itself."

(Belmont Report, 1979)

LSU Health NEW ORLEANS
Office of Research Services

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

*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 Drafting the Consent

- **Length:** Be concise; More is not always better
- **Complexity:** Short paragraphs, sentences, and words; Same term for same concept
- **Know your Audience**: Take into account age, education, language, and culture of subjects
- **Format:** Use headings; Avoid small font, single-spaced text, and large chunks of text without headings; Put key information first
- **Concrete ideas or images**: Charts, pictures, flowcharts, graphics
- **Technology:** Multimedia formats (e.g., webcasts, podcasts, DVDs) can help bolster understanding

Check for Understanding

Which example is best?

Example 1:

You voluntarily consent to participate in this research investigation. You may refuse to participate in this investigation or withdraw your consent and discontinue participation in this study without penalty and without affecting your future care or your ability to receive alternative medical treatment at the university.

Example 2:

Participation in this study is entirely voluntary. You have the right to leave the study at any time. Leaving the study will not result in any penalty or loss of benefits to which you are entitled.

Adapted from www.plainlanguage.gov and Stockton 2004
Six Steps for Creating Simple and Effective Disclosure Forms

Example 3:

You don't have to be in this research study. You can agree to be in the study now and change your mind later. Your decision will not affect your regular care. Your doctor's attitude toward you will not change.

Check for Understanding

Which example is best?

Example 1: College level

You voluntarily consent to participate in this research investigation. You may refuse to participate in this investigation or withdraw your consent and discontinue participation in this study without penalty and without affecting your future care or your ability to receive alternative medical treatment at the university.

Example 2: 8th grade level

Participation in this study is entirely voluntary. You have the right to leave the study at any time. Leaving the study will not result in any penalty or loss of benefits to which you are entitled.

Adapted from www.plainlanguage.gov and Stockton 2004
Six Steps for Creating Simple and Effective Disclosure Forms

Example 3: 4th grade level ← BEST CHOICE***

You don't have to be in this research study. You can agree to be in the study now and change your mind later. Your decision will not affect your regular care. Your doctor's attitude toward you will not change.

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

References

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