LSUHSC IRB Presents:

LUNCH & LEARN

INFORMED CONSENT

January 10, 2024

Objectives

- Inform study teams about the required elements of informed consent
- Discuss the process of traditional Informed Consent
- Discuss the different waivers related to Informed Consent
- Outline how to handle consenting of non-English-speaking subjects

BELMONT REPORT

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

Application: Informed Consent

- 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

- 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

REQUIRED ELEMENTS OF INFORMED CONSENT

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**

OPTIONAL ELEMENTS OF INFORMED CONSENT

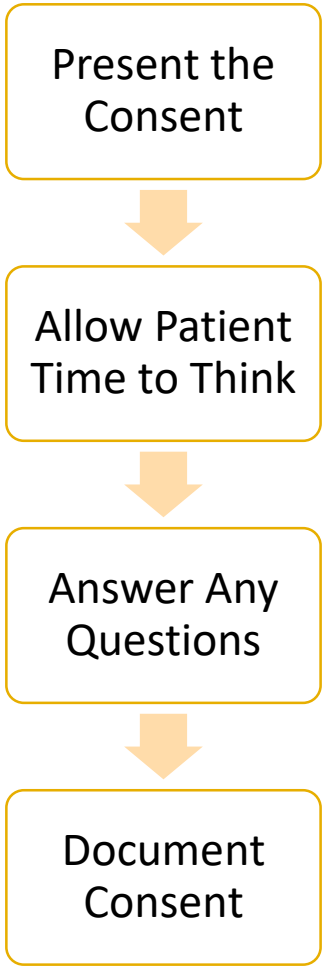
A statement that procedures may involve **unforeseeable risk**	Circumstances under which **participation may be terminated** by the PI	A statement of any **additional costs to the subject** that may result
A statement of **consequences of a subject's decision to withdraw**	A statement that **significant 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

INFORMED CONSENT

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



DOCUMENT INFORMED CONSENT

The IRB requires the subject or their LAR to sign the consent form and then the person consenting to sign.

INSTRUCTIONS: Include this signature block when informed consent and authorization for participation of some or all subjects will be obtained directly from the subjects. **Otherwise, delete.**

Signature of Participant:

I agree to take part in this study.

Participant Signature | Printed Name | Date

INSTRUCTIONS: This signature block is mandatory.

Signature of Person Obtaining Consent:

I have explained the research to the subject and answered all their questions. I will give a copy of the signed consent form to the subject.

Signature of Person Obtaining Consent | Printed Name | Date

INSTRUCTIONS: Include this signature block when informed consent and authorization for participation of some or all adult subjects will be obtained from a legally authorized representative (LAR) of the subject. **Otherwise, delete.**

Signature of Legally Authorized Representative for Adult:

I am a legally authorized representative of the person named below. I agree for this person to take part in this study.

Name of Participant (Please print)

Type of LAR (Check applicable box):

- ☐ Court-appointed Guardian
- ☐ Health Care Proxy
- ☐ Durable Power of Attorney
- ☐ Family Member/Next-of-Kin. Relationship: _____
- ☐ Other: _____

LAR Signature | Printed Name | Date

LOCAL INFORMED CONSENT TEMPLATES

Standard Joint Consent/HIPAA Authorization

LSUHSC-UMC Joint Consent/ HIPAA Template

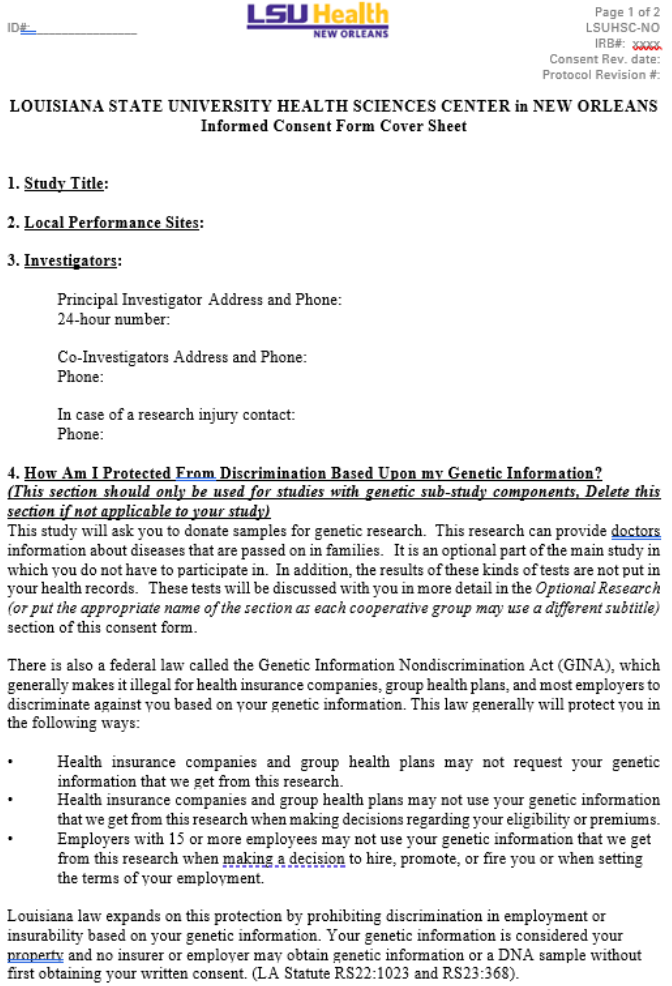
LSUHSC-OLOL Joint Consent/ HIPAA Template

CHNOLA-LSUHSC Joint Consent Form

SPONSOR INFORMED CONSENT TEMPLATES

LSUHSC prefers use of our local-approved template; however, 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.

**If the designated reviewer does not feel that the Sponsor template contains all the appropriate information or that the quality is poor, the reviewer reserves the right to request the team switch to use of the local-approved template.*



ID#:_____

LSU Health NEW ORLEANS

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LSUHSC-NO
IRB#: xxxx
Consent Rev. date:
Protocol Revision #:

LOUISIANA STATE UNIVERSITY HEALTH SCIENCES CENTER in NEW ORLEANS
Informed Consent Form Cover Sheet

1. Study Title:

2. Local Performance Sites:

3. Investigators:

Principal Investigator Address and Phone:
24-hour number:

Co-Investigators Address and Phone:
Phone:

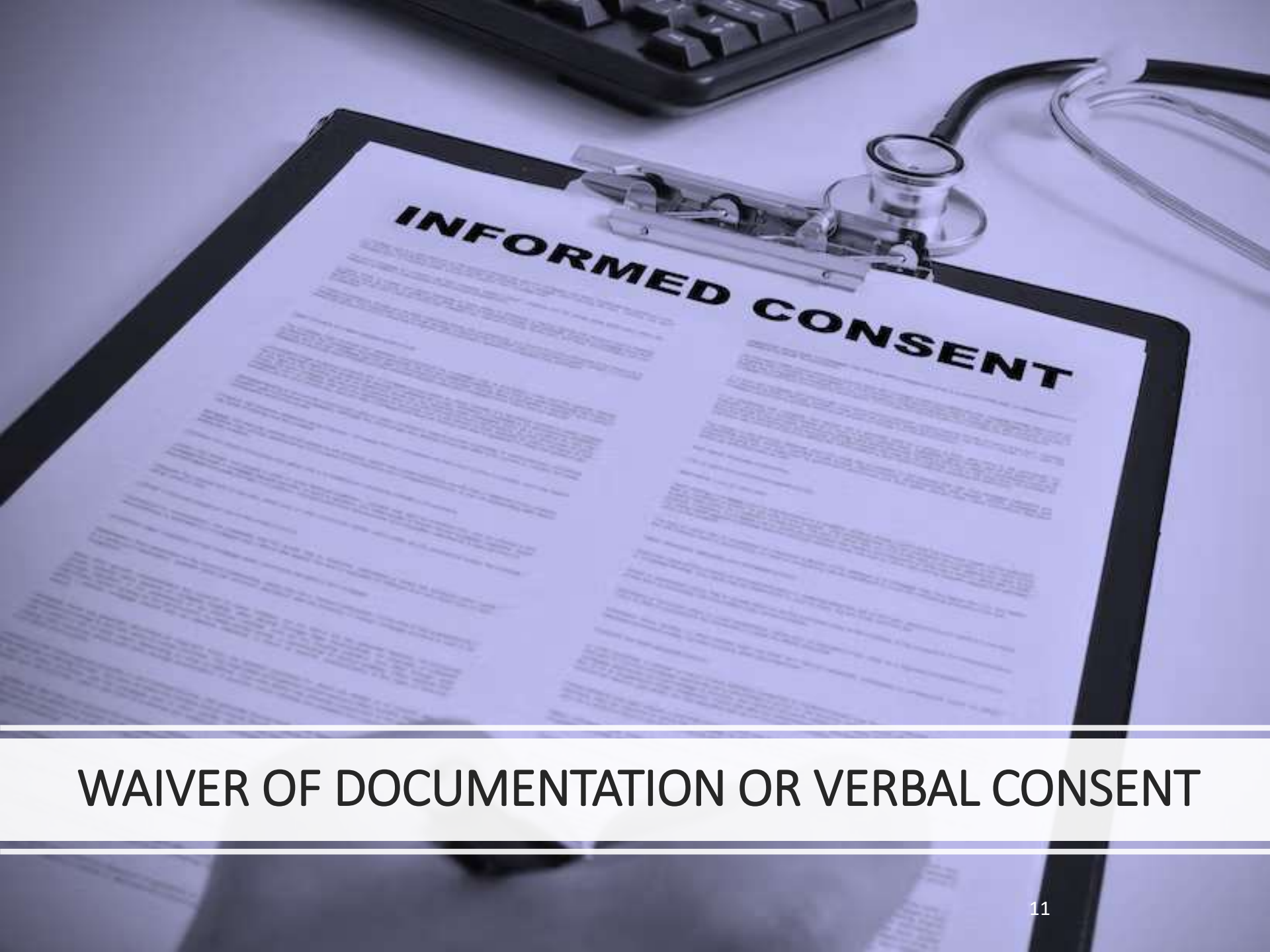
In case of a research injury contact:
Phone:

4. How Am I Protected From Discrimination Based Upon my Genetic Information?
(This section should only be used for studies with genetic sub-study components, Delete this section if not applicable to your study)
This study will ask you to donate samples for genetic research. This research can provide doctors information about diseases that are passed on in families. It is an optional part of the main study in which you do not have to participate in. In addition, the results of these kinds of tests are not put in your health records. These tests will be discussed with you in more detail in the *Optional Research (or put the appropriate name of the section as each cooperative group may use a different subtitle)* section of this consent form.

There is also a federal law called the Genetic Information Nondiscrimination Act (GINA), which generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law generally will protect you in the following ways:

- Health insurance companies and group health plans may not request your genetic information that we get from this research.
- Health insurance companies and group health plans may not use your genetic information that we get from this research when making decisions regarding your eligibility or premiums.
- Employers with 15 or more employees may not use your genetic information that we get from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

Louisiana law expands on this protection by prohibiting discrimination in employment or insurability based on your genetic information. Your genetic information is considered your property and no insurer or employer may obtain genetic information or a DNA sample without first obtaining your written consent. (LA Statute RS22:1023 and RS23:368).



WAIVER OF DOCUMENTATION OR VERBAL CONSENT

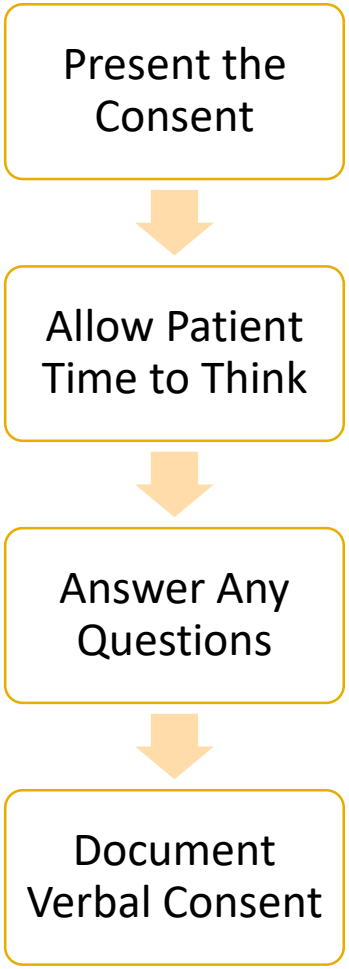
PERMISSION TO OBTAIN VERBAL CONSENT
WAIVER OF DOCUMENTATION OF INFORMED CONSENT

The IRB may approve a waiver of the requirement to document informed consent provided that <u>one</u> of the following apply:

45 CFR 46.117(c)(i)	45 CFR 46.117(c)(ii)	45 CFR 46.117(c)(iii)
• The only record linking the subject and the research would be the consent document • The principal risk would be potential harm resulting from a breach of confidentiality	• The research presents no more than minimal risk of harm to subjects • The research involves no procedures for which written consent is normally required outside of the research context	• The subject and/or their LAR are members of a distinct cultural group or community where signing forms is not the norm • The research presents no more than minimal risk of harm to the subjects • There is an appropriate, alternative method for documenting informed consent was obtained • The oral or written information provided to the subject includes all required and appropriate additional elements of consent disclosure

VERBAL INFORMED CONSENT

Verbal informed consent occurs when a member of the research team and a potential subject verbally interact, and the subject gives their consent to participate verbally. The member of the research team and the subject can be in the same location or can be communicating over the phone or through some other electronic means (i.e. Zoom).



DOCUMENT VERBAL INFORMED CONSENT

The IRB requires the person consenting to sign either the verbal informed consent form if consenting in person or the verbal informed consent script if consenting over the phone or via other electronic means. The person consenting should also document how verbal consent was obtained.

Signature of Person Obtaining Verbal Consent:

I have explained the research to the subject and answered all his/her questions.

_____

Signature of Person Obtaining Consent Printed Name Date

Verbal consent was obtained:

- ☐ In person
- ☐ Over the phone
- ☐ By other electronic means: _____

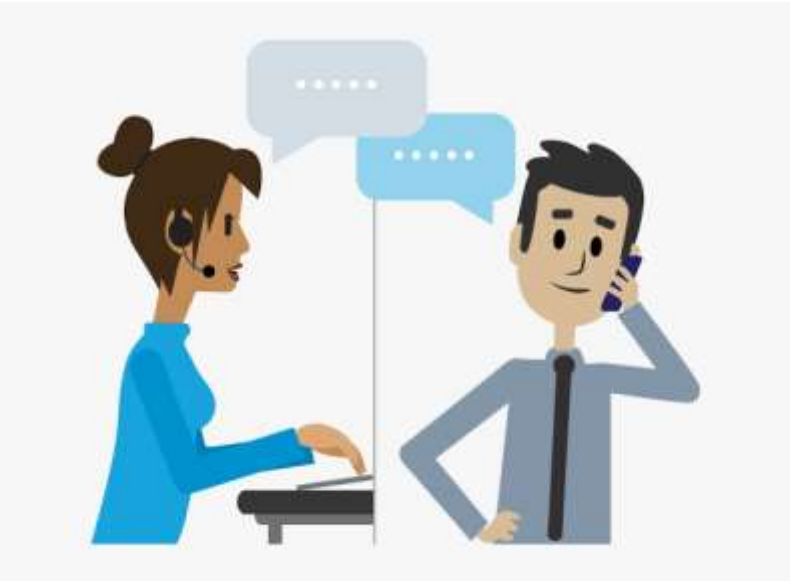
VERBAL INFORMED CONSENT OVER THE PHONE

Can you obtain verbal consent from a subject over the phone?

- Verbal consent from the subject can be obtained over the phone so long as it is an approved consenting method in the IRB protocol.

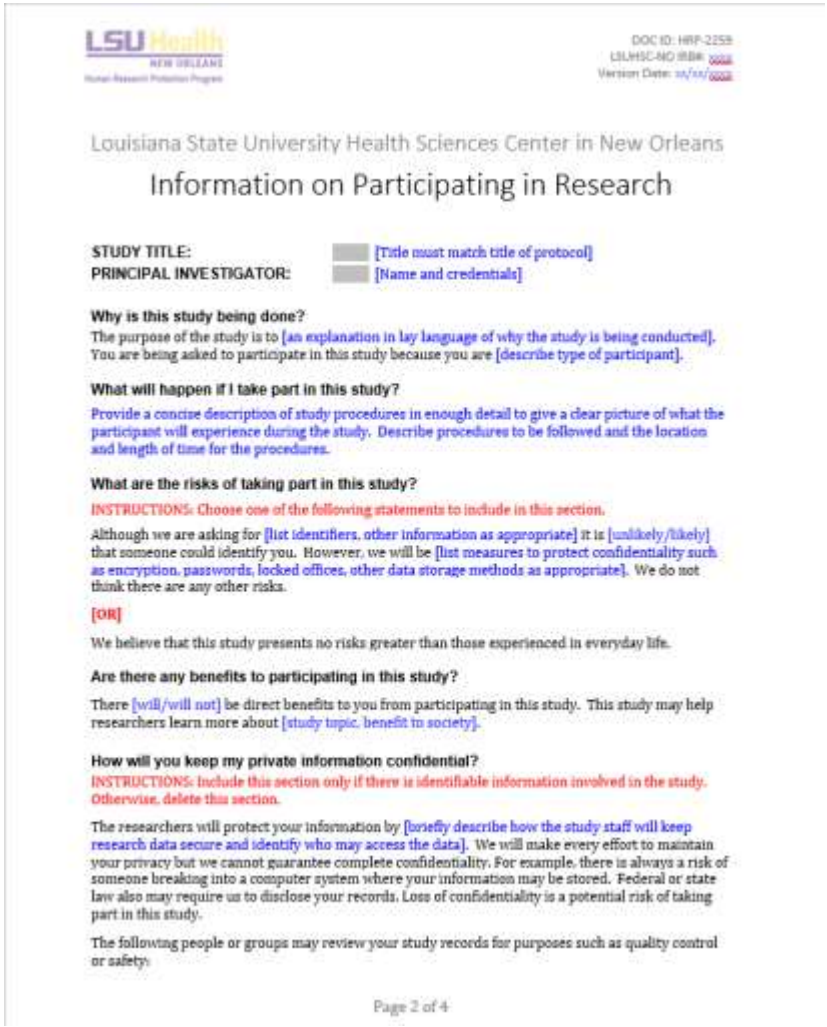
Can you obtain verbal consent from a subject's LAR over the phone?

- Verbal consent of an LAR over the phone is only allowed in cases of planned emergency research or when there is a justifiable need to quickly obtain consent. Please contact the IRB before requesting verbal consent via LAR over the phone to discuss.



LSU Health NEW ORLEANS
Office of Research Services

INFORMATION SHEET



LSU Health NEW ORLEANS

DOC ID: HRP-2259
LSUHSC-NO IRB#: [redacted]
Version Date: xx/xx/[redacted]

Louisiana State University Health Sciences Center in New Orleans

Information on Participating in Research

STUDY TITLE: [redacted] [Title must match title of protocol]
PRINCIPAL INVESTIGATOR: [redacted] [Name and credentials]

Why is this study being done?

The purpose of the study is to [an explanation in lay language of why the study is being conducted]. You are being asked to participate in this study because you are [describe type of participant].

What will happen if I take part in this study?

Provide a concise description of study procedures in enough detail to give a clear picture of what the participant will experience during the study. Describe procedures to be followed and the location and length of time for the procedures.

What are the risks of taking part in this study?

INSTRUCTIONS: Choose one of the following statements to include in this section.

Although we are asking for [list identifiers, other information as appropriate] it is [unlikely/likely] that someone could identify you. However, we will be [list measures to protect confidentiality such as encryption, passwords, locked offices, other data storage methods as appropriate]. We do not think there are any other risks.

[OR]

We believe that this study presents no risks greater than those experienced in everyday life.

Are there any benefits to participating in this study?

There [will/will not] be direct benefits to you from participating in this study. This study may help researchers learn more about [study topic, benefit to society].

How will you keep my private information confidential?

INSTRUCTIONS: Include this section only if there is identifiable information involved in the study. Otherwise, delete this section.

The researchers will protect your information by [briefly describe how the study staff will keep research data secure and identify who may access the data]. We will make every effort to maintain your privacy but we cannot guarantee complete confidentiality. For example, there is always a risk of someone breaking into a computer system where your information may be stored. Federal or state law also may require us to disclose your records. Loss of confidentiality is a potential risk of taking part in this study.

The following people or groups may review your study records for purposes such as quality control or safety:

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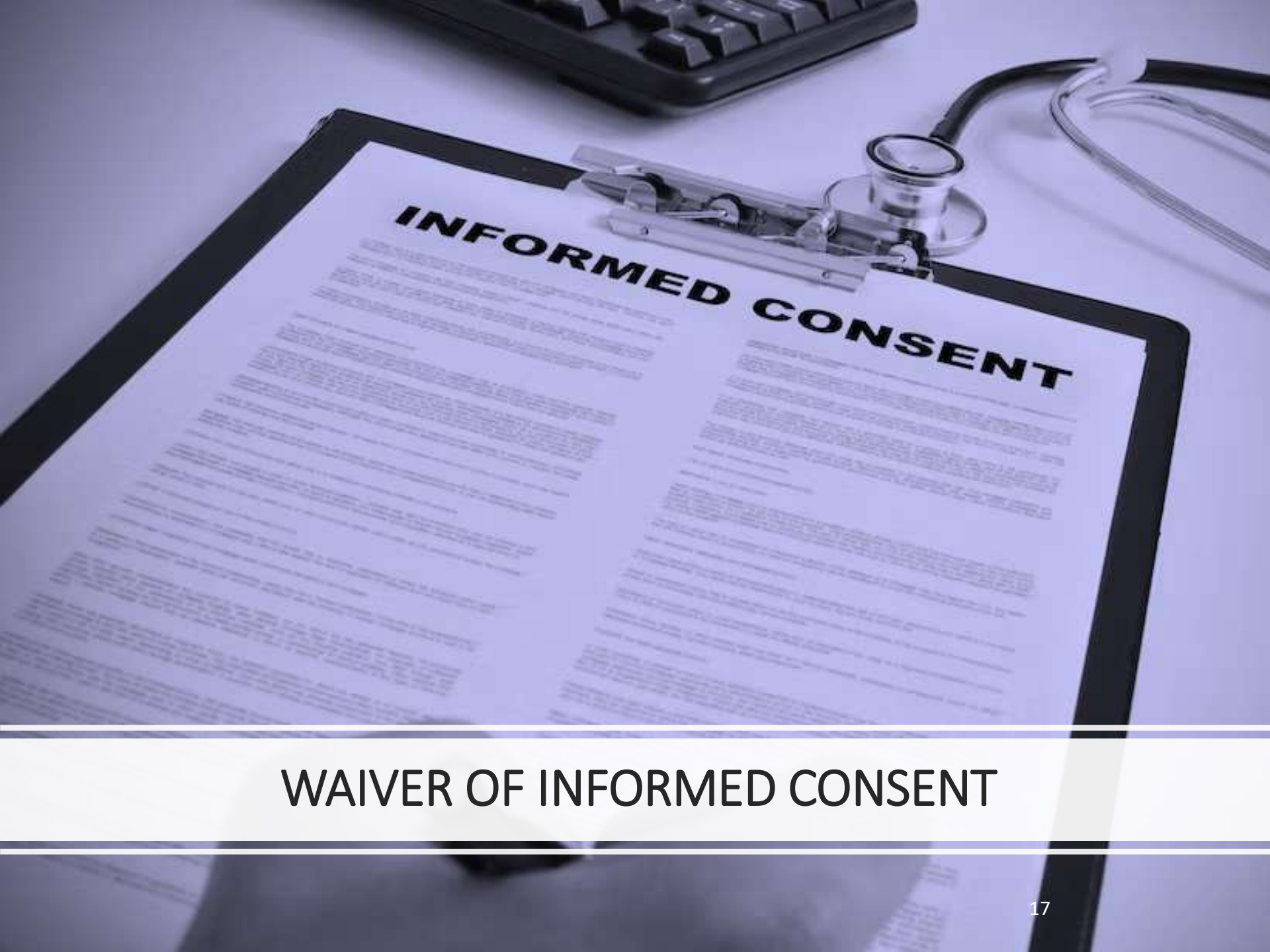
When a waiver of documentation is granted and verbal consent is not being requested, a study team must present to potential subjects an information sheet to review prior to participating in any research activities. The information sheet allows the subjects to make an informed decision about participating without having to sign a consent.



WAIVER OF INFORMED CONSENT

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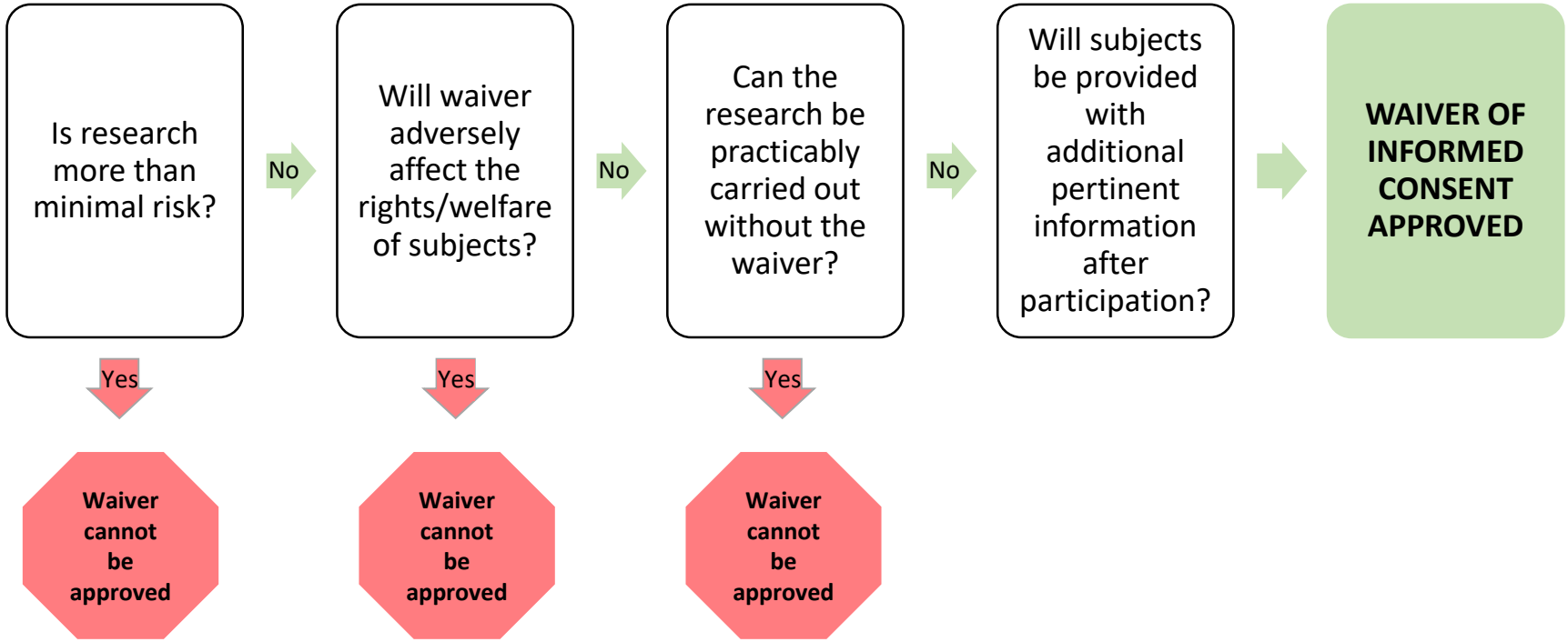
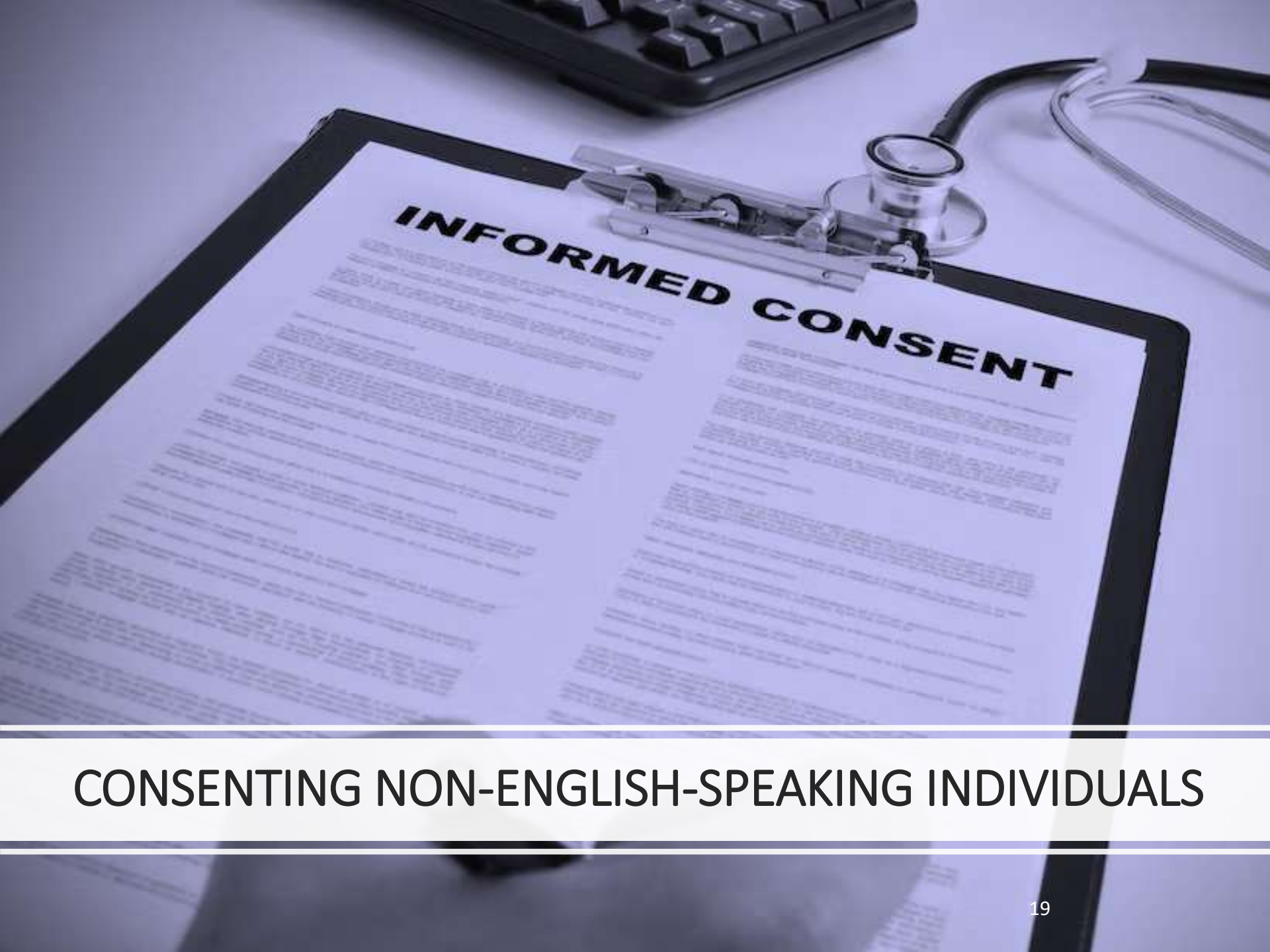
The IRB may approve a waiver of the requirement to obtain informed consent provided that <u>all</u> of the following apply:





CONSENTING NON-ENGLISH-SPEAKING INDIVIDUALS

CONSENTING NON-ENGLISH-SPEAKING INDIVIDUALS

If the study is ongoing and unexpectedly encounters a non-English speaking subject qualified for enrollment, and study documents are not already translated, the study team may use the Short Forms once to enroll the subject without delay. After this first enrollment of a non-English speaking individual, it is the responsibility of the team to obtain certified translations of all patient-facing materials and submit them to the IRB for approval before enrolling any other non-English speaking individuals.

If the study anticipates in advance of study start-up that one or more potential subjects may be non-English speaking, then it is the responsibility of the team to obtain certified translations of all patient-facing materials and submit them to the IRB for approval. A list of translation companies can be found here.

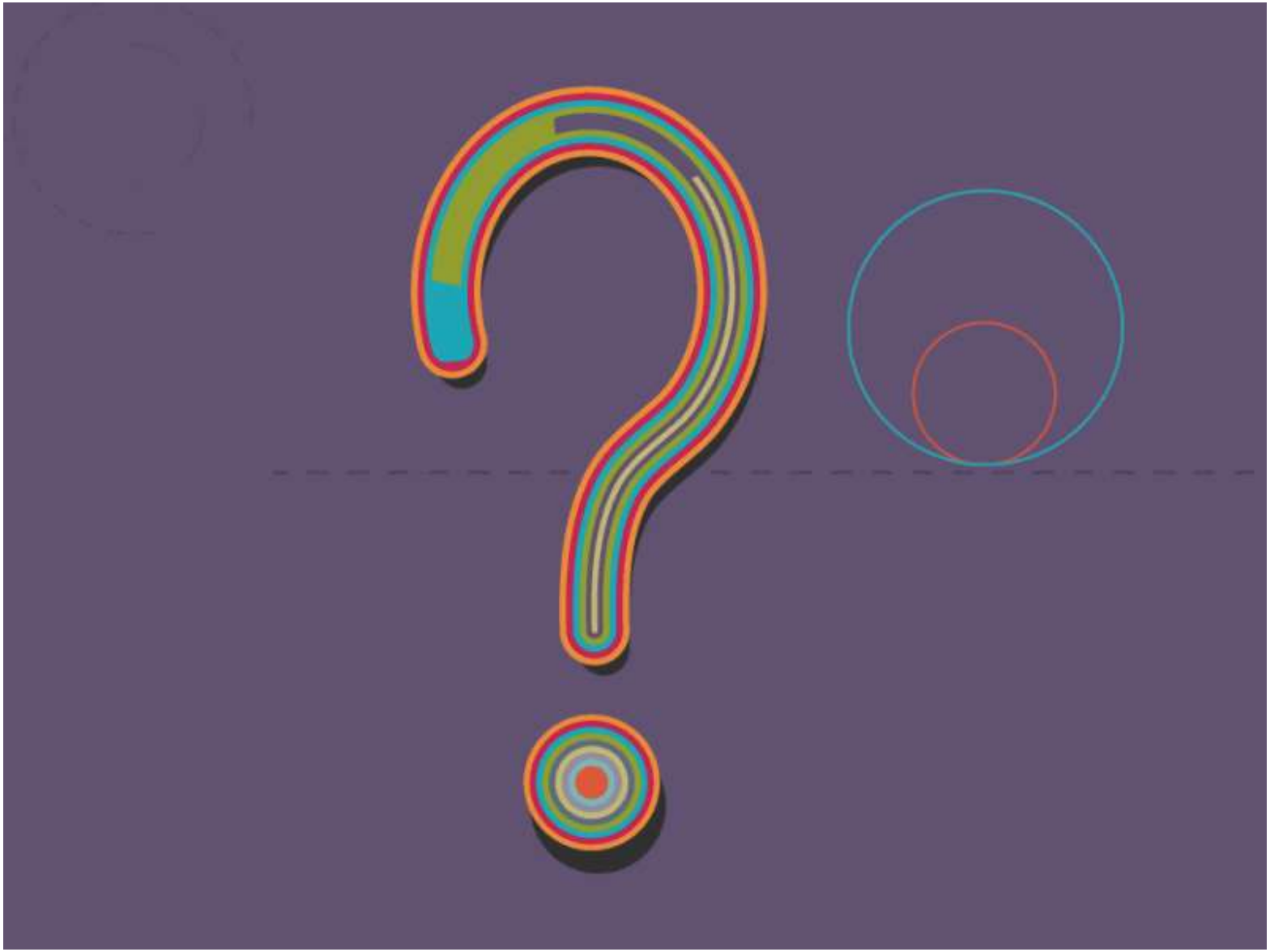
Translation Companies (Note: *The IRB does not endorse any translation service*)

- TNOLA Languages
- protranslate
- Northwest Translations
- The Language Bank, Inc.
- Transperfect

CONSENTING NON-ENGLISH-SPEAKING INDIVIDUALS

The full consent form must be presented to the subject by a translator or a study team member who is proficient in the participant's primary language.

- LCMC uses a **translation phone service**. Make sure you document the ID number of the translator used.
- If study team member does the translation, an independent witness **conversant in both languages** (*not study team or family*) must also be present.



Save the Date!

February Lunch & Learn

Date: February 7, 2024
Time: 12:00 PM
Topic: Amendments