A **process** by which a subject **voluntarily** confirms his or her willingness to participate in a particular study, after having been **informed** of all aspects of the study that are relevant to the subject’s decision to participate. The method of obtaining and documenting informed consent must be outlined in the study protocol and approved by the LSUHSC-NO IRB.

1. [**Written Informed Consent**](#ICF)
2. [**Verbal Informed Consent**](#Verbal)
3. [**Information Sheets**](#InfoSheet)
4. [**Waiver of Informed Consent**](#Waiver)
5. [**Consenting Non-English-Speaking Subjects**](#NonEnglish)

**INFORMED CONSENT**

What is written informed consent?

Informed consent is typically documented by means of a written, signed and dated informed consent form.

What is the process for obtaining written informed consent from a subject?

1. Investigator or sub-investigator presents the consent form with the potential participant and allows ample time for the potential participant to ask questions.
2. The potential participant must be provided with a copy of the consent and given time to consider whether they want to participate.
3. After allowing the participant time to decide, the Investigator or designee (e.g., coordinator) must answer any additional questions the subject may have.
4. When the potential participant is ready, the Investigator or designee must obtain signatures on the consent (and HIPAA Authorization/Acknowledgement of Notice of Privacy and Practices (NPP), if applicable).

What do you need to provide to the subject/LAR when consenting?

The IRB requires the investigator to provide the subject and/or their LAR with the IRB-approved informed consent form (and HIPAA Authorization/Acknowledgement of NPP, if applicable) during the consenting process. Upon execution, a copy of the signed documents should be made and given to the subject or their Legally Authorized Representative (LAR).

What consent template do you use and when?

* [Standard Joint Consent/HIPAA Template [HRP-2250, 2251]](https://www.lsuhsc.edu/administration/academic/ors/irb/consent_form_templates.aspx): used for research activities conducted by LSUHSC personnel, with the exceptions listed below.
* [LSUHSC-UMC Joint Consent/HIPAA Template [HRP-2251UMC]](https://www.lsuhsc.edu/administration/academic/ors/irb/consent_form_templates.aspx): used when some/all research activities will be conducted at UMC.
* [LSUHSC-OLOL Joint Consent/HIPAA Template [HRP-2251OLOL]](https://www.lsuhsc.edu/administration/academic/ors/irb/consent_form_templates.aspx): used when some/all research activities will be conducted on an FMOLHS campus.
* [CHNOLA-LSUHSC Joint Consent Form](https://www.lsuhsc.edu/administration/academic/ors/irb/consent_form_templates.aspx): used when some/all research activities will be conducted at Children’s Hospital

**VERBAL INFORMED CONSENT (Waiver of Documentation of Informed Consent, Request for Verbal)**

What is verbal 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).

When is verbal consent allowed?

One of the following must apply:

1. The only record linking the subject and the research would be the signed informed consent form, and the principal risk would be potential harm resulting from a breach in confidentiality. In this instance, you must give the subject or their LAR the opportunity to sign the Verbal Consent if they want to.
2. The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.
3. 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; and there is an appropriate, alternative method for documenting informed consent was obtained.

\*Please note that the FDA will only allow for verbal consent under category ii above.

When is it necessary to draft a verbal consent form versus a verbal consenting script?

All studies requesting verbal consent should draft a [verbal consent information sheet [HRP-2263]](https://www.lsuhsc.edu/administration/academic/ors/irb/consent_form_templates.aspx). When verbal consent will be obtained over the phone or via other electronic means, the IRB also requires that the study team draft a [verbal consenting script [HRP-2264]](https://www.lsuhsc.edu/administration/academic/ors/irb/consent_form_templates.aspx) to be used by the person obtaining consent.

The same rules apply to drafting the verbal HIPAA Authorization form and verbal HIPAA Authorization script.

What is the process for obtaining verbal informed consent from a subject (in-person)?

1. Investigator or sub-investigator presents the verbal consent information sheet (and verbal HIPAA Authorization form), if applicable with the potential participant and allows ample time for the potential participant to ask questions.
2. The potential participant are provided with a copy of the verbal consent information sheet (and verbal HIPAA Authorization form, if applicable) and given time to consider whether they want to participate.
3. After allowing the participant time to decide, the Investigator or designee (e.g., coordinator) must answer any additional questions the subject may have.
4. When the potential participant is ready, the Investigator or designee must sign on the verbal consent information sheet (and verbal HIPAA Authorization form, if applicable), and document how verbal consent was obtained.
5. Upon execution, a copy of the signed documents should be made and given to the subject or their LAR when verbal consent occurs during in-person interactions.

What is the process for obtaining verbal informed consent from a subject (virtual – e.g., phone, Zoom)?

1. Investigator or sub-investigator reads the verbal consenting script (and verbal HIPAA Authorization script, if applicable) to the participant via phone and/or through some other electronic means (i.e., Zoom) and allows ample time for the potential participant to ask questions.
2. The potential participant are provided electronically or by mail with a copy of the verbal consent information sheet (and verbal HIPAA Authorization form, if applicable) and given time to consider whether they want to participate.
3. After allowing the participant time to decide, the Investigator or designee (e.g., coordinator) must answer any additional questions the subject may have.
4. When the potential participant is ready, the Investigator or designee must sign on the verbal consenting script (and verbal HIPAA Authorization script, if applicable), and document how verbal consent was obtained.
5. The Investigator or designee must then sign on the verbal consenting script (and verbal HIPAA Authorization script, if applicable), and document how verbal consent was obtained.

What do you need to provide to the subject/LAR when consenting?

In cases where the documentation requirement is waived and verbal informed consent is allowed, the IRB requires the investigator to provide the subject and/or their LAR, either printed or electronically, with the verbal consent information sheet (and verbal HIPAA Authorization form, if applicable). Upon execution, a copy of the signed documents should be made and given to the subject or their LAR when verbal consent occurs during in-person interactions. A copy of the signed documents does not need to be sent to participants when verbal consent occurs virtually.

When can you obtain verbal consent 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.

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.

How do you document verbal consent was obtained?

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

**INFORMATION SHEET ONLY (Waiver of Documentation of Informed Consent, No Request for Verbal)**

What is a Waiver of Documentation of Informed Consent?

Waivers of documentation are granted when studies meet certain criteria. This waiver would allow study teams to 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.

When is a waiver of documentation granted/When is an information sheet appropriate?

One of the following must apply:

1. The only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality.
2. The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.
3. The researcher will obtain information through oral or written communication with the prospective participant or legally authorized representative (ex. Surveys).
4. 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; and the oral or written information provided to the subject includes all required and appropriate additional elements of consent disclosure.

What do you need to provide to the subject/LAR before the study?

In cases where the documentation requirement is waived and verbal consent is not being requested, the IRB requires the investigator to provide the subject and/or their LAR, either printed or electronically, with an  [verbal consent information sheet [HRP-2259]](https://www.lsuhsc.edu/administration/academic/ors/irb/consent_form_templates.aspx).

Is a signature ever needed from the subject/LAR when doing verbal consent?

Yes, when the verbal consent was granted under 45 CFR 67.117(c)(i), meaning that the only record linking the subject and the research would be the signed informed consent form, and the principal risk would be potential harm resulting from a breach in confidentiality. If the verbal consent was granted under 45 CFR 67.117(c)(i) and the subject or LAR wants documentation linking them to the research, the the subject or LAR need to be asked whether or not they want documentation linking them to the research. If they indicate that they want this documentation, the subject or LAR should sign in the appropriate signature block on the verbal consent information sheet. The subject or LAR should send this signed copy to the study team electronically or via mail. The Investigator or designee must then sign on the verbal consent information sheet and provide a copy of the signed document to the subject or their LAR.

**WAIVER OF INFORMED CONSENT**

What is a Waiver of Informed Consent?

Waivers are granted when studies meet certain criteria. This waiver would allow study teams to conduct research activities without having to inform the subjects of the activities.

When is a Waiver of Informed Consent granted?

All of the following must apply:

1. The research involves no more than minimal risk to the subjects;
2. The waiver or alteration will not adversely affect the rights and welfare of the subjects;
3. The research could not practicably be carried out without the waiver or alteration, even if the research involves use of identifiable private information or identifiable biospecimens; and
4. Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

**CONSENTING NON-ENGLISH-SPEAKING INDIVIDUALS**

What if you want to enroll a non-English speaking subject?

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 at the bottom of the page [here](https://www.lsuhsc.edu/administration/academic/ors/irb/consent_form_templates.aspx).

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 [HRP-2252, 2253, 2254, 2255]](https://www.lsuhsc.edu/administration/academic/ors/irb/consent_form_templates.aspx) once to enroll the subject without delay. LSUHSC IRB has short forms pre-translated into Spanish, French, and Vietnamese. LSUHSC also has HIPAA Authorizations pre-translated in those languages as well.

Short forms are ONLY to be used when consenting a subject that unexpectedly does not speak English. When using a short form, 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. If a study team member is proficient in the participant’s primary language, the study team member may do the verbal translation. However, an independent witness must also be present for the consent process and conversant in both languages (i.e., English and the language of the subject). By signing the consent form, the witness attests that the information in the consent form, and any other written information, was accurately explained to and understood by the subject or the subject's LAR, and that informed consent was freely given by the subject or the LAR. The independent witness should be a person who is conversant in both languages (i.e., English and the language of the subject), who is independent of the study, who is not a member of the patient’s healthcare team, who is not a family member, and who cannot be unfairly influenced by people involved with the study. If an independent translator is used for the consent process, then a separate witness is not needed.

Individuals should only sign the forms written in languages that the person understands. The subject/LAR only sign short form itself. The witness and/or independent translator should sign both the short form and copy of the long form English ICF. The person actually obtaining consent (i.e., study team member) shall sign a copy of the long form English ICF. A copy of the short form is given to the subject/LAR.

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 a participant’s primary language is not Spanish, French, or Vietnamese, the short form cannot be used and the consent must be fully translated prior to enrollment.

**Figure 1.** Short Form Procedures for Different Types of Translators