OBTAINING CONSENT IN RESEARCH

Consent is a vital part of the research process. A subject’s consent should be given freely, without coercion and must be based on a clear understanding of what their participation involves. Obtaining informed consent, the contents of the informed consent document, and the process are governed by federal regulations and institutional policy.

The Principal Investigator (PI) has several responsibilities in ensuring that the informed consent process is carried out correctly. The FDA does not require the PI to personally conduct the consent process or sign the consent form, but the PI is ultimately responsible for all aspects of the research including informed consent.

Who can obtain informed consent?

Those obtaining consent in a research study should be appropriately trained and delegated by the PI. The PI should ensure all those delegated the task of obtaining consent have completed the Ochsner required CITI course, that they have been trained on the protocol and this training is documented. Documentation of completion should be maintained in a regulatory binder. In addition, those staff members must be noted in the Ochsner IRB electronic system and/or a delegation of authority log.

How is consent obtained?

The most recently approved version of the informed consent must always be used. To ensure the most recent version of the consent is used it is recommended that you always pull the consent form from eIRB.

The following are the basic procedures and elements for an informed consent to be valid (FDA, 21CFR50 Subpart B/ HHS, 45CFR46 Subpart A):

- Informed consent will be obtained from each subject prior to any study related activities being performed.
- The PI or designee will fully inform the potential subject or the Legally Authorized Representative (LAR) of all pertinent aspects of the study in language that is as non-technical as possible (lay-terms).
- The PI or designee must disclose all relevant information to the potential subject. The information must be sufficient to allow the potential subject to decide whether to participate or not. If the study is federally funded or regulated by HHS the consent document must begin (for research starting after 1/21/2019) with a key information section.
The following elements of the informed consent, if applicable should be discussed with the subject (FDA, 21 CFR 50.25/ HHS, 45 CFR 46.116) during the consent process:

<table>
<thead>
<tr>
<th>Regulatory Agency</th>
<th>Required Elements</th>
</tr>
</thead>
<tbody>
<tr>
<td>FDA + HHS</td>
<td>purpose of the study, to include a statement that the study involves research, the expected duration and description of the procedures</td>
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<tr>
<td>FDA + HHS</td>
<td>risks</td>
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<td>FDA + HHS</td>
<td>benefits</td>
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<td>FDA + HHS</td>
<td>reasonable alternatives to the proposed intervention</td>
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<td>FDA + HHS</td>
<td>confidentiality of subject records will be maintained</td>
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<tr>
<td>FDA + HHS</td>
<td>compensation or medical treatment available due to injury</td>
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<tr>
<td>FDA + HHS</td>
<td>contact information</td>
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<tr>
<td>FDA + HHS</td>
<td>participation is voluntary; the subject may withdraw at any time without penalty; data captured up until the date of withdrawal can be used in the study</td>
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<tr>
<td>FDA + HHS</td>
<td>clinicaltrials.gov</td>
</tr>
<tr>
<td>HHS</td>
<td>future research on identifiable information/biospecimens collected during the study</td>
</tr>
</tbody>
</table>

**Additional Elements**

| FDA + HHS         | Unforeseeable risks |
| FDA + HHS         | Unforeseeable risks to a fetus |
| FDA + HHS         | Participant cost |
| FDA + HHS         | Consequences of withdrawal |
| FDA + HHS         | How to withdrawal or end participation early |
| FDA + HHS         | New findings that impact their decision to participate |
| FDA + HHS         | Approximate number of total participants |
| ICH-GCP           | Explanation of placebo, randomization and/or treatment assignment |
| HHS               | If biospecimens will be used for commercial profit and if the profit will be shared |
| HHS               | If clinically relevant research results will be shared |
| HHS               | If genetic sequencing will be done on biospecimens |

- Ample time and opportunity will be given to the potential subject or LAR to read the consent form. It may be taken home to discuss with family members and signed at the next visit.

- The PI or designee will be available to respond to all questions about the study and each question should be answered to the subject’s satisfaction. Additional medical related questions should be referred to the PI or Sub-Investigator (Sub-I) and documented as appropriate.

- Ensure the subject’s agreement to participate is free from coercion.
• The subject or LAR should personally print their name, sign and date the form. In addition, the person obtaining consent should also personally sign, print name and date in the designated area. The consent form should be checked for completeness prior to leaving the designated area.

• A copy of the signed and dated consent must be given to the subject or LAR. The original consent will be kept with the regulatory binder or the subject record and a copy should be scanned into the subject’s electronic medical record within 24 hours. If the subject is hospitalized at the time of consent, a copy should be placed on the medical chart.

• The consent process is an ongoing process throughout the course of the study. At each visit the PI or designee should ask the subject if he/she wishes to continue on the study and document this in the visit note.

When should a subject be re-consented for participation?

Revisions to the protocol or other study documents are often changed during the study by the sponsor, which may require the consent form to be updated. The consent form as well as the most current documents should be submitted in eIRB as an amendment. The Institutional Review Board (IRB) approval letter will state the requirement for re-consent when applicable. The sponsor may require re-consent to take place regardless of the IRB approval.

How do I consent a subject if they are illiterate or visually impaired?

If a subject (or LAR) cannot read or write (illiterate) or are visually impaired, the consent form must be read to him/her in full, in the presence of an impartial witness. The subject (or LAR) must be competent and be able to comprehend the information presented to him/her.

An impartial witness is someone who is not part of the study team and it is preferred that they are also not a family member. The impartial witness will sign the consent form attesting to the fact that the subject (or LAR) was provided sufficient opportunity to consider whether or not to participate, the possibility of coercion was minimized, and that the information was presented in a language easily understood by the subject (or LAR).

In cases where the subject is illiterate the following should occur prior to the impartial witness signing the consent:

1. the consent form and any other written information must be read and explained to the subject;
2. the subject must orally consent to participate;
3. if capable, the subject should sign or make his/her mark on the consent form
4. The witness should sign in the witness section
For visually impaired subjects or subjects who cannot read the consent by themselves, the following should occur:

1. the consent form and any other written information must be read and explained to the subject or LAR;
2. the subject or LAR must orally consent to participate
3. The witness must sign

A note must be included in the research record stating the method used for communicating with the subject and the means by which the subject communicated agreement. This is in addition to the standard requirements for consent documentation as discussed later in this guidance.

**How do I consent physically challenged subjects?**

A subject, who is physically unable to talk or write, can be entered into a study if they are competent and able to indicate approval or disapproval by other means.

If the person retains the ability to understand the concepts of the study and evaluate the risk and benefit of being in the study when it is explained verbally and is able to indicate approval or disapproval to study entry. An impartial witness must be used in this process.

1. the consent form and any other written information must be read and explained to the subject or LAR if their impairment leaves them unable to read otherwise they may read the consent form;
2. the subject or LAR must consent to participate, and the method of their consent must be documented on the consent form in place of their signature
3. The witness must sign

This entire process must be documented in the Ochsner electronic medical record including the means of consent.

**How do I consent cognitively impaired subjects?**

Cognitively impaired refers to subjects who have a psychiatric disorder, an organic impairment or a developmental disorder (this is not a limited list) that affects a subject’s judgment or reasoning. It is the responsibility of the investigator to designate a subject to be cognitively impaired. Only a LAR is able to provide consent for a subject who has been designated cognitively impaired by the investigator. Should the subject regain or develop the capacity to consent, then his/her consent must be obtained for any further research. This law and method for obtaining consent for these subjects is discussed in our [Legally Authorized Representatives guidance](#).

This entire process should be documented in the Ochsner electronic medical record.
How do I consent non-English speaking subjects?

Subjects whose preferred language is not English can and should be consented to participate in research studies so long as they are not explicitly excluded by the protocol. For further information refer to the Use of Short Forms Guidance.

How do I consent a child to participate in research?

In research children are not consented rather their assent is obtained. Assent is a child’s affirmative agreement to participate in research. Mere failure to object, absent affirmative agreement, should not be construed as assent. Permission means the agreement of parent(s) or guardian to the participation of their child or ward in research.

When research involving children is reviewed by the IRB it is required to make a determination about the category of the research. These categories along with the IRB determine if 1 or both parents/LAR are required to consent to the research. State law determines who the Legally Authorized Representative is.

The following are the categories that the IRB can determine for the research. You should read your IRB determination letter to known if one or both parents must sign the consent form.

- Category 1 (45 CFR 46.404, 21 CFR 50.51)—Research not involving greater than minimal risk; 1 or both parents as determined by the IRB
- Category 2 (45 CFR 46.405, 21 CFR 50.52)—Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual subject; 1 or both parents as determined by the IRB
- Category 3 (45 CFR 46.406, 50 CFR 50.53)—Research involving a minor increase over minimal risk and no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject’s disorder or condition; both parents as per federal regulations
- Category 4 (45 CFR 46.407, 21 CFR 50.54)—Research not fitting into categories 1 through 3, which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children; both parents as per federal regulations.

Who is an adult and who is a child?

This is determined by LA State Law. Less than 18 years of age is a child. 18 years of age or greater is an adult.

Marriage does emancipate a minor in LA, but pregnancy does not (except as to capacity to consent to anesthesia in childbirth). An unmarried minor may not have capacity to consent for her own medical treatment but does for her child's.
Obtaining Consent

What happens if a child becomes an adult during a research study?

If a child gave assent and his/her LAR gave consent to be in a research study, then upon becoming an adult, the subject must give consent and should execute and sign a consent form as an adult. This presumes they are an active part of the study. If the study is completed except for data analysis, etc. then there is no need to obtain an adult consent from them at that point.

What are the Consent and Assent Rules used by the IRB?

The consent and assent rules used by the IRB (unless otherwise determined at a meeting for a specific study) are as follows:

- Consent is provided and signed by the parent(s)/LAR first.
- For children, assent depends on the age of the child:
  - For subjects 12 years and under, assent is obtained by the investigator or designee to the extent possible and documented by the signature of the person obtaining assent on the IRB’s Pediatric Assent Form 12 and under form.
  - It is required for subjects ages 13 through 17 years using the Assent Box at the end of the consent form.

Can I conduct phone consent and what is the process?

Consent facilitated by telephone or videoconference when a subject/LAR is otherwise unable to be physically available is allowable. When conducting consent over the telephone or videoconference with a subject or LAR all requirements described in the federal regulations are still applicable. Refer to the beginning of this document for all necessary parts of the consent process.

If a patient/LAR is unable to be consented in person, then the study team needs to:

- Provide the subject with a consent form via fax, email, postal mail, digital copy, or it may have been provided in person previously, but you must ensure this is the most current version.
- Confirm to the extent that they reasonably can, the positive identity of the patient/LAR
- Have the subject/LAR personally sign/date the consent or apply an electronic signature captured in accordance with 21 CFR 11 using compliant software (e.g. DocuSign). The signed consent form must be returned to the study team as fax, email or postal mail and must be received and signed by the person who obtained consent prior to any study related procedures being performed
- A signed copy must be provided back to the subject/LAR which can be done as fax, email, or postal mail if they are not available to accept this in person.

In addition to the normal process the use of the telephone or videoconference to obtain consent must be documented in the subject’s medical record.
Can I consent subjects using an electronic consent and what is the process?

Electronic informed consent (eIC) can be used in research studies. All requirements described in the federal regulations must still be followed. An eIC may be used to provide information usually contained within the written informed consent document, evaluate the subject’s comprehension of the information presented, and document the consent of the subject or the subject’s LAR.

eIC differs from simply providing a consent form by emailing and asking the subject to sign and return that form. The description of supplemental procedures in telephone consent are appropriate for this type of process. The procedures for eIC are described below.

eIC may take place when the study team and subject are in the same physical location. In this case the study team is available to confirm the identity of the subject, answer questions, and be party to signing the consent document. However, eIC indicates that the consent materials are not 100% paper based and that the subject would be signing the consent utilizing an electronic method (e.g., interactive tablet, digital signature).

- If the eIC is intended to take place remotely without study personnel for direct support then it is expected that subjects would have a method to communicate with the study team to ask questions such as a telephone number, electronic messaging or chat support, live video support, or other means to reach the study team.
- Absent a study team member there should be a method to ensure subject comprehension. For example, this may be accomplished by having pertinent questions throughout the consent that must be answered by the subject.
- There must be a way to confirm the identity of the subject.
- The electronic signature of the subject must be captured in accordance with 21 CFR 11
- A process to provide a copy of the signed consent back to the subject must be in place

As with any consent process the method and normal documentation of consent must be recorded in the subject’s medical record.

What are the requirements for electronic signatures?

FDA regulations found at 21 CFR 11 set forth the criteria under which FDA considers electronic records, electronic signatures, and handwritten signatures executed to electronic records to be trustworthy, reliable, and generally equivalent to a handwritten signature executed on paper. In order to be considered equivalent to full handwritten signatures, electronic signatures must comply with all applicable requirements. The electronic system must also capture and record the date that the subject or subject’s LAR provides consent. This is commonly referred to as Part 11 compliance. Compliance with these regulations is required for all FDA-regulated research that is greater than minimal risk. FDA guidance on electronic consent provides additional information about the requirements. DocuSign is the only Part 11 complaint electronic system that is institutionally approved at Ochsner.
How do I document informed consent?

Once the consent form has been signed, dated and checked for completeness, the PI or designee must ensure a note is captured in the Ochsner electronic medical record (OHS.RES.006). This note should be entered the same day that the consent was obtained. Remember the consent form must be scanned into EPIC!

The note should include:

- IRB number
- That a signed copy was given to the subject
- That no study related procedures were conducted prior to obtaining the consent
- That the subject/LAR was given adequate time to review the consent, to ask questions, and that those questions were answered to their satisfaction
- Who was present for the discussion (e.g., PI, SubI, other study team members, family or friends of subject)
- That the subject agreed to participate voluntarily
- Discussion of:
  - Procedures – subject should verbalize understanding of all procedures and related timelines
  - Discussion of risks, benefits and alternative therapies
  - HIPAA

Example of consent process note in EPIC

Informed Consent Process
IRB #
Date

The subject and his wife were seen in the DEPARTMENT clinic treatment room. The experimental nature of the research was fully explained to the potential subject. The purpose of the study, length of the study, study visits and procedures, risks, benefits, responsibilities, alternative treatments, costs, compensation for injury, contact information, voluntary participation, withdrawal notices, ClinicalTrials.gov and HIPAA authorization were fully discussed. The subject was given ample time to review the consent for consideration. All questions were answered to the subject’s satisfaction. The subject was able to verbalize study information back and states he/she has an understanding of the study and agrees to participate. The consent was signed, and a copy was given to the subject. No study related activity was initiated prior to obtaining consent.
**Ochsner Research HRPP**  
**Guidance Document**  
**Obtaining Consent**  
**Date Last Reviewed: November 2022**

<table>
<thead>
<tr>
<th>Date</th>
<th>Change</th>
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<tbody>
<tr>
<td>November 2022</td>
<td>Added section on regulatory requirements for electronic signatures</td>
</tr>
<tr>
<td>May 2022</td>
<td>Added to phone consent that electronic signature and/or use of videoconference is acceptable.</td>
</tr>
<tr>
<td>April 2021</td>
<td>Added that a digital copy being provided is acceptable for telephone consent</td>
</tr>
<tr>
<td>January 2019</td>
<td>Guidance published</td>
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</tbody>
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