# Informed Consent and the Consent Form

- What is informed consent?
- What does the process look like?
- Who can obtain consent?
- Where can I find more information?

# Consent Form ≠ Informed Consent

They are NOT the same!

Why?

The consent form is a document.

Informed consent is a process that includes the consent form.

The consent form should be used as part of the informed consent process.

# What is Informed Consent?

The process requires three key components to be ethically valid:

- Information;
- Understanding;
- And Voluntary Agreement

Documentation that the consent process has been handled correctly is crucial.

# Who is responsible?

IRBs, investigators, and research sponsors all share responsibility for ensuring that the informed consent process is adequate.

# Who can obtain Informed Consent?

- Currently approved study staff that are familiar with the informed consent process and current on all required training.  If someone other than the PI will be obtaining consent, then the PI must formally delegate this responsibility and that person with a delegation of duties log.

The PI is responsible for ensuring that informed consent is obtained from each subject before participation in the study.  Even though the PI is not required to personally obtain consent, the PI is ultimately responsible, even when delegating the task to another member of the study team

# What does the process look like?

There are three stages to this process:

- Before
- During
- After

# What does the process look like?
# Before

Before the subject is to arrive, the following should be done:

- Check the regulatory binder to make sure you have the currently approved consent form
- Make sure the document is legible

# What does the process look like? During

During the consent process, the following should be done:

- Make sure the appropriate staffer is obtaining consent
- Explain the purpose of the study, procedures, duration, benefits, risks, voluntariness, etc., in accordance with Federal regulations
- Encourage questions
- Allow the potential subject time to review the consent form alone or with study staff
- Assure appropriate steps are taken for those who are non-English speaking, illiterate, cognitively impaired, minors, etc.

*Continued…*

# What does the process look like?
# During

During the consent process, the following should be done:

- Encourage subjects to discuss the consent form with family and significant others and allow them to take the unsigned or signed consent form with them
- Be sure to obtain all signatures and initials from subject or LAR and appropriate staff and don’t forget the date
- Obtain authorization in addition to consent

# What does the process look like?
# After

After the consent process, the following should be done:

- Review the consent form for completeness and accuracy—it's best to do this before the subject leaves if possible
- A copy of the document should be given to the subject and the original should be placed in the subject's file
- Re-consent should occur as necessary

# Common Problems in the Consent Form

- Forgetting to add a version date or update a version date when changes are made
- Using an outdated template
- Leaving the template text as-is
- Study staff listed is not consistent with the submission, protocol, etc.
- Not breaking down risk information by probability
- Listing more than one PI

# General Tips

- The subject (not the POC) should enter the date of his/her signature.
- If consent is obtained the same day that the subject begins the study, the POC should document that consent was obtained prior to participation in the research.
- A copy of the consent document must be provided to the subject.
- The consent process begins when a potential subject is initially contacted.

# Where can I find more information?

- FDA Information Sheets – Guide to Informed Consent
- OHRP Informed Consent Tips
- OHRP Informed Consent – Legally Effective and Prospectively Obtained
- 45 CFR 46.116 General Requirements for Informed Consent
- 21 CFR 50.20 FDA Informed Consent of Human Subjects

# Confirmation of Completion

Please have all staff sign and date to confirm completion of this training. **Your Non-Compliance Case will not be closed out until the IRB receives this signature sheet.** The sheet may be emailed to sarahmarie.huban@choa.org or faxed to 404-785-9470. If additional space is needed, use the table on the following slide.

| Role | Printed Name | Signature | Date |
|---|---|---|---|
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |

| Role | Printed Name | Signature | Date |
| --- | --- | --- | --- |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |