SEVEN QUESTIONS TO GUIDE
the informed consent process

WHO DO YOU CONSENT?

A person with the **legal** and **mental** capacity to give consent or their **legally authorized representative (LAR).**

A LAR can be a **court appointed legal guardian**, a **healthcare power of attorney**, or a **durable general power of attorney** (priority given in that order).

always obtain a copy of the records supporting LAR status for the study record.

WHO DOES THE CONSENTING?

A study team member, listed on the IRB, that:

Is **delegated** by the investigator to consent

Has received appropriate protocol **training**

Has **knowledge** regarding the consent process

Speaks the language of the subject (unless an interpreter is available)

WHAT CONSENT FORM DO YOU USE?

Always use the **current approved version** of the consent, downloaded from IRBIS.

Don't forget the informed consent process documentation!

WHEN SHOULD YOU CONSENT?

You must consent subjects prior to:

Entering a subject into a study	**Collecting any samples** from the subject
Gathering data about a subject	Conducting any **research procedures**

WHERE DO YOU CONSENT?

You should consent in an area that allows the subject to...

- **Read** the consent document
- **Ask** questions
- **Consider** whether or not to participate
- **Evaluate** the risks and benefits of the study
- **Receive** answers to all questions

This area must also be **private** (no public waiting rooms!)

WHY DO WE NEED CONSENT?

Belmont Report

"...respect for persons requires that subject...be given the opportunity to choose what shall or shall not happen to them..."

Nuremberg Code

"The voluntary consent of the human subject is absolutely essential"

HOW SHOULD YOU CONSENT?

Minimize coercion. Don't try to "sell" a person a study- if someone tells you no, thank them for their time and end the discussion.

Pause to allow the subject to ask questions. Some people will not want to interrupt you as you're speaking, but they may have questions as you discuss the study.

Don't talk too quickly. If you know that you're a fast talker, keep that in mind when you consent.

Don't use jargon. As research professionals, we use jargon a lot in normal conversation. Try to avoid jargon when consenting.

Always thank people for their time, regardless of the outcome!

RESOURCES

UNC Office of Human Research Ethics SOP Documents:

http://ohresop.web.unc.edu/

Electronic Code of Federal Regulations (specifically 21CFR50 and 45CFR46):

https://www.ecfr.gov

FDA Guidance Document on Informed Consent:

https://www.fda.gov/RegulatoryInformation/Guidances/ucm404975.htm

FDA "For Patients" Document on Informed Consent:

https://www.fda.gov/ForPatients/ClinicalTrials/InformedConsent/

UNC Office of Clinical Trials Templates and Forms (specifically the informed consent process documentation):

https://research.unc.edu/clinical-trials/forms/

UNC Research Coordination and Management Unit

https://rcmu.tracs.unc.edu/