University Hospitals
Clinical Research Center

UH CLINICAL RESEARCH CENTER
11100 Euclid Avenue, Lakeside 1400
Cleveland, Ohio 44106
ClinicalResearch@UHhospitals.org

Informed Consent Tip Sheet

Federal regulations mandate, participants are fully informed of any research activity in which they will participate. Informed Consent is more than a signed document, it is an ongoing educational exchange of information during the entire duration of the person's participation in the research project. Below are some tips to keep in mind while conducting the informed consent process, even virtually.

Storage

- Maintain a convenient, central location for the most recent IRB approved consent for all study staff to access. This will help prevent version control issues.

Process

- Each potential study participant should have adequate time to review the consent. Keep in mind how complex the study is and how long the document is to allow adequate time for review.
    - Encourage potential study participants to write, highlight, and make notes on the informed consent form they receive before being consented.
- Schedule the informed consent meeting so it is long enough for the person consenting to explain the entire informed consent and to have time to address questions from the participant.
    - Using the teach-back method with the informed consent process will confirm participant's understanding.
- Communication is key. Make sure the potential study participant knows where to meet for the informed consent meeting, notify the study physician, and confirm the rest of the study team is aware of the potential study participant being consented.

Training

- Confirm the appropriate study staff are IRB approved to consent for the research project, delegated the task on the study delegation log, and are *medically qualified* to discuss sections of the consent form for which this is relevant.
- Ensure adequate training has taken place and that the document is understood by study staff prior to consenting the potential study participant.

Documentation

- Documentation of the informed consent process required as part of the informed consent process. Consider a narrative note or using the Informed Consent Documentation Checklist.
    - Remember to include whether the participant is competent to consent and understood the consent document.
- Make a copy of the signed consent and give to the study participant.
    - The consent form with wet-ink is retained in the research participant record and uploaded to EMR per Clinical Research SOP SC-403 - Research Documentation

Remember, informed consent is a process.

- Assess the study participant's willingness to continue participation at each study visit.
- Continue to educate and encourage the participant to ask questions during study visits.

References

- Informed Consent Documentation Checklist
- Informed Consent Elements – Basic and Additional
- Investigator Manual for IRB Submissions, page 45
- Education: Clinical Research – The Basics, Module 6: Informed Consent & Re-consent (UH Employee GPS Link | Non-Employee GPS Link)