# Module 4: Informed Consent Communication

After completing this module, you should be able to identify the required elements of informed consent, have a set of tools to use to prepare for and conduct informed consent, and be aware of special situations that may have different consent requirements (e.g., children).

## The Informed Consent Process

*Informed consent ensures that participants know exactly what is going to happen within a study, so they can make an educated decision about their participation.*

Below is the list of critical elements in an informed consent document that were outlined in this module. Are there any other elements you should, or would like to, include in your own document?

- Introduction (Study title, names, credentials)
- Purpose (Study goals)
- Qualifications (Eligibility and exclusion criteria)
- Design (Study expectations, procedures, assessments, timeframes)
- Voluntary (Highlights voluntary nature of research and how to withdraw)
- Alternative Treatments
- Risks (Expected participant risks and discomforts)
- Benefits
- Compensation (Financial compensation and responsibility)
- Policies (How to report illness, injury, or other problems)
- Privacy and Confidentiality (Who has access to data and how it is protected)
- Contact Information (Address, phone, email for study members and contact information for IRB)

Take a moment to find and review your IRB's version of an informed consent template. Make note of the website address. Write down any questions or comments you have in the space below. You can contact your IRB later to get the answers.

One of the most important things to convey is the difference between research and clinical care and what that means for the participant. What things can you say to explain this difference?

## Preparation

*Whoever is conducting the informed consent process must be able to explain every element. This will help ensure that participant questions can be addressed. Remember, the informed consent process is a dialogue!*

Preparing for your first potential participant visit is critical to the informed consent process. What are some ways you can prepare yourself and your environment for a successful conversation?

## Participant Conversations

*The first visit with potential participants sets the stage for the entire study.*

What are some key phrases or wording that will be important for you to include in your own studies? We've given you a general checklist below of the items you'll need to cover:

- Ensure privacy during the conversation and protect privacy and confidential data
- Review all of sections of the consent document in full with participants
- Use the actual consent document as a guide, translate any legalese or medical terms into lay language
- Use open-ended questions and summarization methods to ensure participant comprehension
- Make sure you use the most current informed consent document
- Make sure you obtain a signature and date from the participant
- Provide a copy of the consent to the participant and document that the process is complete according to your institutional or sponsor requirements
- When consenting potential participants who are non-English speakers, what considerations should be made?

## Other Considerations

*Be mindful of individuals and populations at risk for coercion including children, teenagers, cognitively impaired individuals, prisoners, and pregnant women.*

Take a moment to review your IRB's guidelines surrounding vulnerable populations. Take notes below. What other questions do you have?

List your IRB's guidelines surrounding appropriate financial incentives and compensation plans.

## Other Notes

## Resources

CDC Health Literacy Plain Language
http://www.cdc.gov/healthliteracy/developmaterials/plainlanguage.html