CUNY HRPP
Informed Consent Process and Documentation Tip Sheet

Preparing Informed Consent Documents

- Formatting
  - Leave the footer blank so that the UI-IRB approval stamp may be appended
- Reading Level
  - Use language that is understandable to the subject population
    - General rule of thumb = 8th grade reading level
    - Define technical/scientific terminology into lay language
    - Use available comprehension tools for assistance
      - Ex: PRISM Readability Toolkit

Informed Consent Process

- Basic steps of obtaining consent:
  - Explain the research verbally
  - Answer any questions
  - Provide written document
  - Allow sufficient time to consider participation
  - Answer any additional questions
  - Assess subject comprehension
- Be sure that the person obtaining consent is UI-IRB approved to do so, is qualified to explain the research and to assess comprehension
- Obtain consent prior to initiating research activities, including screening procedures

Assessing Subject Comprehension

- Ask open-ended questions – Examples:
  - Describe the purpose of the study
  - Explain what you have to do to participate
  - What is a possible benefit of this research?
  - Where will the research take place?
- Avoid directed or yes/no questions
- Use best judgment based on questions asked to decide whether the potential subject understands the research and their participation

Informed Consent by Telephone

- Would the UI-IRB ever approve this?
  - Yes, when it is appropriate given the nature of the study and the subject population
  - PI should justify why in-person consent process is not feasible
- What if the criteria for the waiver of documented informed consent is not met?
  - Send potential subject a copy of the consent document in advance of the telephone discussion
  - Informed consent process takes place via telephone
  - Subject signs and returns the document to the researcher (by fax, mail, etc.)