TOPIC 5. HOW TO INFORM THE PARTICIPANTS ABOUT THEIR RIGHTS AND RISKS ASSOCIATED WITH A STUDY?

What is the Informed Consent Process in Recruitment

Informed Consent Process

Course Objective:

- Demonstrate understanding of the process for *legally effective* informed consent

Making an Informed Decision

- Several steps in the process:

Introduction → Questions → Discussion → Deliberation → Decision Making → **Signed Consent Form** → Ongoing Conversation about Consent

Making an Informed Decision

- Tell participants all they need to know.
- Make sure they understand.
- It's their own choice; resist giving your opinion *even if they ask for it!*
- Tell them who are you/what organization or group you represent, specially if they have met you before at another location or in the community, even if it feels strange!
- Don't exaggerate benefits nor minimize risks or discomforts.
- Tell people they can withdraw, *even AFTER signing ICF.*

Waivers

- What about **people who are not able to decide for themselves** about being a human subject/participant in a study?
  - Children because they are too young
  - Adults that are too sick, either mentally or physically to make their own decisions.
- **For children:** parents give their permission, the child has to agree and the IRB has approved it.

Role Play 1: Inclusion/Exclusion Criteria

Martha:

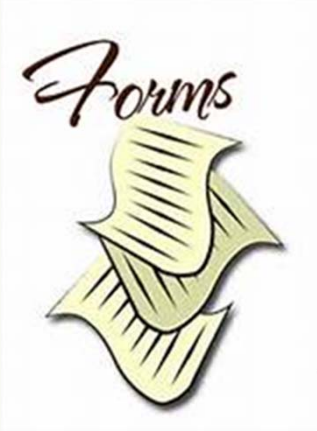
- CHW responsible for obtaining informed consent

Joseph:

- Does not have diabetes and therefore does not meet inclusion/exclusion criteria. Still wants to participate because the research study provides $100. Lies about having diabetes in order to try to qualify. Tries to persuade Martha that she should "let you sign up because you really need the money".

Observer:

- Note questions that Martha can ask to ensure that Joseph meets the study's inclusion/exclusion criteria. Note ways that Martha can explain to Joseph why he cannot participate. Note strategies that Martha can use to tell Joseph no without being rude.



Role Play 2: Voluntary ≠ Forced Decision

Fred:

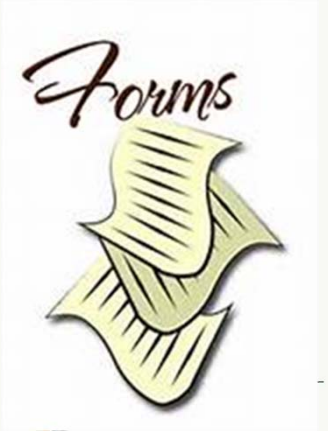
- Responsible for enrolling participants and obtaining informed consent. Has not successfully recruited anyone today. Begs, pleads, bribes, and uses guilt – i.e., tries everything! to get Rick to sign the consent form. Tells Rick that the research is really going to help him and going to do a lot of good for the community. Tells Rick that he will lose his job if he doesn't sign up enough people. Tells Rick that if he is concerned about privacy, he doesn't have to use his real name or answer questions honestly.

Rick:

- Does not want to participate because he does not have time and is also concerned about his privacy and the confidentiality of the information he will share.

Observer:

- Note what is wrong with the ways that Fred tries to persuade Rick to sign the consent form. Note the various things that Rick does and says to demonstrate that he is not interested. Note what might be some more appropriate ways of dealing with Rick's concerns about privacy.



Role Play 3: Participant Questions

Kim:

- Responsible for obtaining informed consent.

Janet:

- Is interested in the study, but also has a lot of concerns, questions, and ideas about research. She wants to know:
  - Why is this research being conducted in my neighborhood?
  - Who is this research going to help? What changes can she expect in her community?
  - Is she going to be used as a guinea pig? Are scientists going to experiment on her?
  - How is her information going to be kept private? Her cousin signed up for a research study, and his identity was stolen 2 weeks later.
  - Where is the money for this research coming from? Why isn't that money being used to provide community services?

Observer:

- Note the answers Kim provides in response Janet's questions. Are they accurate and persuasive? What are some other potential responses?

Role Play 4: Understanding

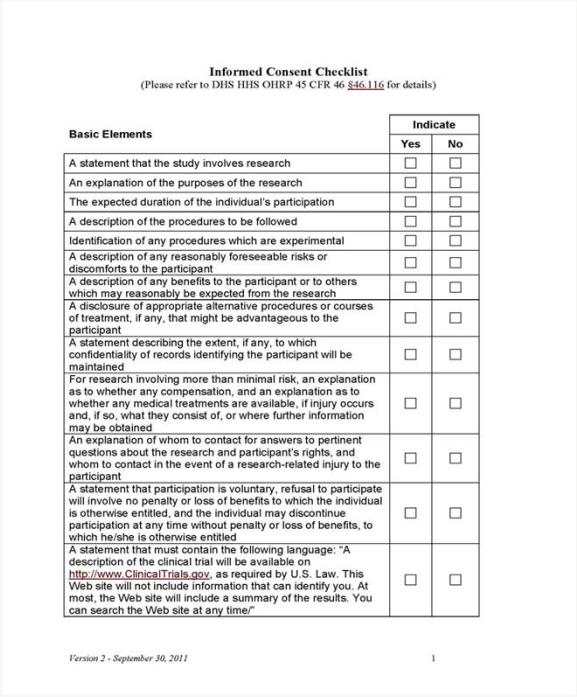
George:
Responsible for obtaining informed consent.

Rita:
60-year old woman. Has diabetes and meets other inclusion criteria. Has limited reading skills and poor eyesight. Makes excuses about why she does not want to read the form. Makes incorrect statements about the research. Asks questions that show that she does not understand what is involved in research participation.

Observer/Discussion:
Note different strategies that George can use to help Rita understand the study without making her feel uncomfortable.

Let's Take a Look

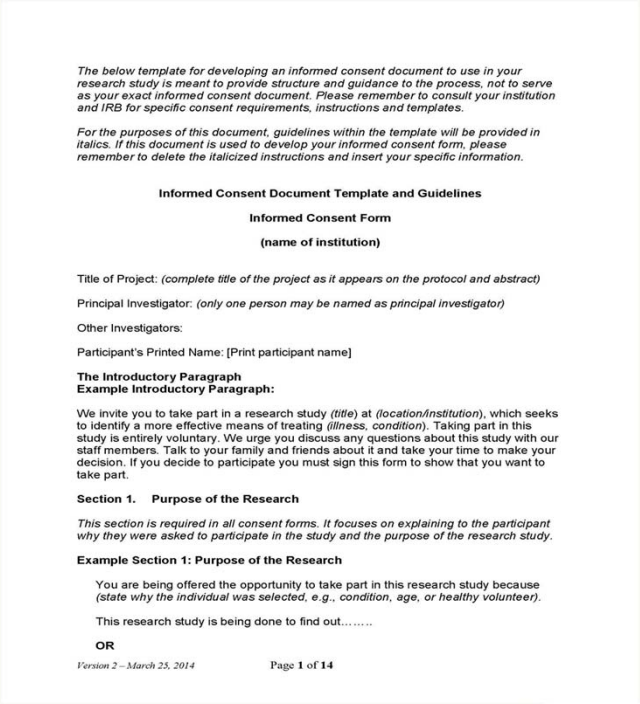
- Informed Consent Checklist and Template



Informed Consent Checklist
(Please refer to DHS HHS OHRP 45 CFR 46 §46.116 for details)

Basic Elements	Indicate	
	Yes	No
A statement that the study involves research	☐	☐
An explanation of the purposes of the research	☐	☐
The expected duration of the individual's participation	☐	☐
A description of the procedures to be followed	☐	☐
Identification of any procedures which are experimental	☐	☐
A description of any reasonably foreseeable risks or discomforts to the participant	☐	☐
A description of any benefits to the participant or to others which may reasonably be expected from the research	☐	☐
A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the participant	☐	☐
A statement describing the extent, if any, to which confidentiality of records identifying the participant will be maintained	☐	☐
For research involving more than minimal risk, an explanation as to whether any compensation, and an explanation as to whether any medical treatments are available, if injury occurs and, if so, what they consist of, or where further information may be obtained	☐	☐
An explanation of whom to contact for answers to pertinent questions about the research and participant's rights, and whom to contact in the event of a research-related injury to the participant	☐	☐
A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the individual is otherwise entitled, and the individual may discontinue participation at any time without penalty or loss of benefits, to which he/she is otherwise entitled	☐	☐
A statement that must contain the following language: "A description of the clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search the Web site at any time/"	☐	☐

Version 2 - September 30, 2011 1



The below template for developing an informed consent document to use in your research study is meant to provide structure and guidance to the process, not to serve as your exact informed consent document. Please remember to consult your institution and IRB for specific consent requirements, instructions and templates.

For the purposes of this document, guidelines within the template will be provided in italics. If this document is used to develop your informed consent form, please remember to delete the italicized instructions and insert your specific information.

Informed Consent Document Template and Guidelines

Informed Consent Form

(name of institution)

Title of Project: *(complete title of the project as it appears on the protocol and abstract)*

Principal Investigator: *(only one person may be named as principal investigator)*

Other Investigators:

Participant's Printed Name: [Print participant name]

The Introductory Paragraph
Example Introductory Paragraph:

We invite you to take part in a research study *(title)* at *(location/institution)*, which seeks to identify a more effective means of treating *(illness, condition)*. Taking part in this study is entirely voluntary. We urge you discuss any questions about this study with our staff members. Talk to your family and friends about it and take your time to make your decision. If you decide to participate you must sign this form to show that you want to take part.

Section 1. Purpose of the Research

This section is required in all consent forms. It focuses on explaining to the participant why they were asked to participate in the study and the purpose of the research study.

Example Section 1: Purpose of the Research

You are being offered the opportunity to take part in this research study because *(state why the individual was selected, e.g., condition, age, or healthy volunteer).*

This research study is being done to find out……..

OR

Version 2 – March 25, 2014 Page **1** of **14**

Questions?

- Next topics:
  - How does a CHW track data and report data collected?
  - How to report study results and to whom?