

Participants' Rights and Responsibilities	Effective Date	05.20.2010
	Revisions Date	01.21.2019

1.0 Purpose: The purpose of this rule is to establish guidelines for recognizing research participants' rights and responsibilities.

2.0 Persons Affected: Research participants (e.g., individuals who volunteer their time and efforts in research activities).

3.0 Standard Operating Practice: This rule is to ensure that the rights and responsibilities of research participants are defined. The ethical conduct of research is a shared responsibility between the institution, investigators and their research staff, the participants who enroll in research, and the UMCIRB.

4.0 Definitions:

4.1 **Research Participant:** Also known as "human subject" in federal regulations; an individual participating in human research activities. A living individual about whom an investigator conducting research: (a) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or (b) Obtains, uses, studies, analyzes, or generates identifiable information or identifiable biospecimens. An individual who is or becomes a participant in research, either as a recipient of a test article, an intervention, or as a control. A research participant may be either a healthy individual or a patient/client with a particular problem, issue, or disease.

5.0 Responsibilities:

5.1 **Research Participants** have certain responsibilities which include:

- 5.1.1 Making every effort to gather sufficient information that will allow them to make an informed decision about their participation, in good faith;
- 5.1.2 While participating, they should also make every reasonable effort to comply with protocol requirements and inform the investigators of unanticipated problems. Participants always have the right to withdraw from their participation in research at any time and for any reason without penalty or loss of benefits to which they would otherwise be entitled.

5.2 **Investigators, the UMCIRB, ECU and Vidant Health** have the responsibility to protect participants' rights and welfare. The investigator should ensure the participant:

- 5.2.1 Has enough time to decide whether or not to be in the research study;
- 5.2.2 Is allowed to make that decision without any pressure from the people who are conducting the research;
- 5.2.3 Understands his/her right to refuse to be in the study at all, or to stop participating at any time after beginning the study;
- 5.2.4 Is told the purpose of the study, what will happen during the research, and what the participant will be asked to do if he/she is in the study in a level of language that is easily understood;

- 5.2.5 Be told about known and reasonably foreseeable risks of being in the study, including the chances of experiencing those risks and the possible severity of the risks;
- 5.2.6 Be told about the possible benefits of being in the study.
- 5.2.7 Be told whether there are any costs associated with being in the study and whether the participant will be compensated for participating in the study;
- 5.2.8 Be told whom will have access to information collected during or after the study, to what extent confidentiality can be assured, and how his/her confidentiality will be protected;
- 5.2.9 Be told who to contact with questions about the research, who to tell about a research-related injury, and who to ask about his/her rights as a research participant;
- 5.2.10 If the study involves treatment or therapy:
 - 5.2.10.1 Be told about other non-research treatment choices; and.
 - 5.2.10.2 Be told where treatment is available should a research-related injury occur, and who will pay for research-related treatment.

Revision History:

Date	Change	Reference Section(s)
05.20.2010	New Policy	All Sections
06.30.2013	Formatting and change to SOP	All Sections
01.21.2019	Common Rule revisions	

References:

- 45 CFR 46
- 21 CFR 50
- 21 CFR 56