# **IRB Guidance:** Research Participant Rights

As a participant in a human research project through Campbell University, you have the following rights:

1. To be informed of the nature and purpose of the research including all procedures to be performed/followed.
    - *The Belmont Repor*t-B1 - respect for persons demands that subjects enter into the research…with adequate information; *C-1* - the research procedure, their purposes
    - *45 CFR 46.116(b)(1)* - A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed and identification of any procedures which are experimental.
2. To be given time to decide if being in the project is right for you and to ask questions about the project before and during your participation.
    - *The Belmont Report-C-1* - statement offering the subject the opportunity to ask questions; *C-1* - allowing too little time for consideration or curtailing opportunities for questioning, all my adversely affect a subject's ability to make an informed choice.
    - *45 CFR 116(a)(1) - sufficient opportunity to consider whether or not to participate.*
3. To decide whether to participate in the research project without force, fraud, deceit, duress, coercion, or undue influence.
    - *The Belmont Report B1* - To respect autonomy is to give wight to autonomous persons' considered opinions and choices while refraining from obstructing the actions; *C-1* - This element of informed consent requires conductions free of coercion and undue influence.
    - *45 CFR 46.116*(a)(1) - minimize the possibility of coercion or undue influence.
4. To be given a description of any risks, discomforts, and/or inconveniences reasonably expected from participation.
    - T*he Belmont Report B1* - awareness of possible adverse consequences; C1 risks: *C1* - Even when some direct benefits to them is anticipated, the subjects should understand clearly the range of risk.
    - 4*6 CFR 46.116(b)(2)* - A description of any reasonably foreseeable risks or discomforts to the subject.[i]
5. To be given a description of benefits, if any, you may reasonably expect for participation.
    - *The Belmont Report-B2* – beneficence is understood in a stronger sense, as an obligation. Two general rules have been formulated as complementary expressions of beneficent actions is this sense: (1) do not harm and (2) maximize the possible benefits and minimize possible harms; *C1* – anticipated benefits.
    - *46 CFR 46.116(b)(3)* – A description of any benefits to the subject or to others which may reasonably be expected from the research.
6. To be told about how you may be withdrawn, (if applicable) and that you may ask to withdraw, at any time, without changing your rights.
    - *The Belmont Report-C1* – statement offering the subject the opportunity to…withdraw at any time from the research.
7. To refuse to participate. Being in the project is voluntary. You can also change your mind even after you start the project.

- *The Belmont Report-B1* – respect for persons demands that subjects enter into the research voluntarily; *C1* – voluntary nature of participation.
- *45 CFR 46.116(b)(8)* – A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

8. To be informed about who to contact with questions about the research, about research-related injury, and about your rights as a research subject.
    - *The Belmont Report-C1* – the person responsible for the research.
    - *45 CFR 46.116(b)(7)* – An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the even of a research-related injury to the subject; and.
9. Be provide a copy of the signed and dated consent form, (when it is required).
    - *45 CFR 46.117(a), (b)(2)* – A copy of the summary shall be given to the subject or the representative. In addition to a copy of the short form; A copy shall be given to the person signing the form.

Additional Rights When the Project Involves Treatment or Therapy:

10. To be provide an explanation of any alternative procedures and/or treatment that might be available to you; to include risks and benefits of these alternatives
    - *The Belmont Report-C1* – alternative procedures (where therapy is involved).
    - *45 CFR 46.116(b)(4)* – A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.
11. To be told where treatment is available should you have a research-related injury, and who will pay for research-related treatment.
    - *The Belmont Report-C2* – Beneficence thus requires that we protect against risk of harm to subjects.
    - *45 CFR 46.116(b)(6)* – 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.

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The Belmont Report
45 CFR 46 (2018 Common Rule)

Adapted from the University of Idaho: Bill of Rights for Research Participants.