Form C-1: Components of Informed Consent Documentation

The NCWU consent form must include:

1. A statement that the study involves research, a readily understood explanation of the purpose(s) of the research and the expected duration of the subject's participation, a simple description of the procedures to be followed, , and if deception will be involved. If deception is involved, there should be an indication that the research cannot be fully described at this time, but that at the conclusion of the subject's participation an explanation will be provided.

2. A description of any risks or discomforts to the subject that can be reasonably foreseen. These include not only physical injury, but also possible psychological, social or economic harm, discomfort or inconvenience.

3. A description of any benefits to the subject or to others which may reasonably be expected from the research.

4. A statement concerning costs or compensation to the subject, if any.

5. Identification of the person to contact for answers to pertinent questions about the research and research subject's rights, and who to contact in the event of a research-related injury to the subject. Phone numbers should be provided.

    a. **NOTE:** Questions about the research should be directed to the PI; questions about the rights of research subjects or research-related injuries should be addressed to the IRB Chair. This information must be stated in the consent form, together with phone numbers for the PI and the IRB Chair.

6. Description of the extent, if any, to which confidentiality of records identifying the subject will be maintained.

7. A statement that participation is voluntary and that refusal to participate or discontinuation of participation will involve no penalty or loss of benefits to which the subject is otherwise entitled.

8. The consent form should close by indicating that:

    a. The subject agrees to participate in this research
    b. An acknowledgement that the subject has received a personal copy of the consent form, signed and dated by the subject.

9. If subjects are minors, use the following guidelines for obtaining consent:

    a. Six years and younger - only parent(s)/guardian/legal representative must sign. Secure oral assent from the subject.
    b. Seven and eight years - signature of minor is optional, signature of parent(s)/guardian/legal representative is required. Secure oral assent from the subject.
    c. Nine through seventeen years - requires signature of minor on assent form and signature of parent(s)/guardian/legal representative on consent form.

10. A sample consent form is provided. It is <u>required</u> that this template be used for all NCWU research studies. On the sample consent form, fill out bracketed sections. All other text should remain as is on the form.