

INFORMED CONSENT TEMPLATE

Study Title (must match IRB application) _____

Principal Investigator's Name _____

I. Background & Purpose of Study.

Should include a statement that the study involves research.

Why it is being conducted.

Length of study.

If the study involves review of patient records, the statement must say that researchers will review patients' records;

II. Qualification to Participate and Right to Refuse or Discontinue.

A statement concerning how participants were chosen for possible participation and that participants may choose to discontinue participation at any time during the study without penalty from Dominican (or whatever institution/agency may be sponsoring the research).

III. Study Procedures.

Must include a description of the procedures to be followed, including an identification of any procedures which are experimental (including possible random assignment to treatment and control groups if study is health related (e.g., Nursing, O.T. or P.T. studies).

A description in layperson's terms of any medical terms/procedures;

IV. Possible Physical or Psychological Risks & Benefits (or none).

A description of the associated discomforts and risks reasonably to be expected;

If no risks or benefits to the participant are expected, this should be stated.

V. Confidentiality.

A statement describing the extent to which confidentiality of records identifying the participant will be maintained.

VI. Alternative Methods of Treatment (generally medical studies only).

A disclosure of appropriate alternative procedures that might be advantageous for the participant if he or she chooses not to participate;

VII. Illness or Injury (medical studies only).

IF RESEARCH INVOLVES PSYCHOLOGICAL OR MEDICAL RISK, a statement indicating that Dominican University will not be responsible for any treatment if participant is injured or becomes ill and that participant is responsible for any treatment. If any participating agency/institution chooses to provide medical treatment in the case of injury, indicate so.

VIII. Compensation.

A statement on compensation indicating the type and amount if there is compensation (e.g., research credits for research participation);

IX. Contact Information.

A statement concerning who to contact with questions or problems that includes the names, titles (e.g., undergraduate student or Ph.D.) and contact information for researchers, faculty advisors, and the IRB (IRB@duny.edu).

An offer to answer any questions about the procedure.

A statement that participant will receive a copy of the informed consent to keep (for written consent forms only);

X. Separate Signature Area.

A statement that signature indicates participant is making a decision to participate.

That the signature indicates he or she has read the consent, decided to participate, and questions have been answered.

If potential participants may be minors, as in the case of undergraduate students, there must be a statement that participant's signature indicates he or she is also at least 18 years of age.

A statement that, although the participant may sign the form, he or she may withdraw at any time without prejudice.

An area for participant's written name, signature and date.

<Please be sure to visit the IRB website to download & read full instructions for completing your Informed Consent.>