Elements of Informed Consent and Consent Form Requirements

Consent forms document that the research project has been adequately explained to the subject. Consent forms need to be written in clear, concise, non-technical language, and must follow these guidelines:

(1) Be duplicated on institutional or department letterhead.

(2) Have spaces to enter the approval date in the upper right hand corner:

Approved: __/__/__, IRB, Saint Martin's University.

After approval by the IRB, the approval date must be placed in the upper right corner of the original copy by the IRB chair.

(3) Have one of these general titles:

Consent to Act as a Subject in an Experimental Study,

Consent to Act as a Subject in a Research Study, or

Consent to Act as a Subject in a Clinical Study.

(4) Have the same official title as the title on the protocol.

(5) List all investigators with names, addresses, and telephone numbers. Non-faculty members must list their faculty sponsor(s).

(6) List the source of support, if applicable.

(7) Provide a space for the subject's initials in the lower right corner of each page except for the page containing the subject's signature. Pages must be numbered.

(8) Informed Consent for Competent Adults and Adolescents must be formatted with the following standard paragraph subtitles: (Description, Risks and Benefits, Alternative Treatments, etc.). This format assists the reviewers and the investigator to insure that all required information is included.

The following template may be used for all **active subject participation**.

If subjects are under 18 years old then the INFORMED CONSENT FOR MINORS AND INCOMPETENT ADULT SUBJECTS must be used **in addition** to this consent form.

If subject participation is via survey/questionnaire only, then you may use the IMPLIED CONSENT statement **in place of** this form.

Saint Martin's University OMB Control number:_____

IORG number:_____

IRB Approval Date_____

Saint Martin's University
Consent to Act as a Subject in a Research Study

Title of the Project:
Investigators:
Advisor:
Department:
Email of the Investigator:
Phone # of the advisor:

DESCRIPTION: The first two sentences should give a brief, non-technical explanation of the study and identify why a particular subject is asked to be in the study. (Example: The purpose of this research is to determine if people of various ages and with different types of illnesses have different problem-solving skills.) The remainder of the description should include the following:

- Purposes and Goals
- Approximate number of subjects (sex and age range)
- Duration of participation
- Time sequences for stages or steps in participation
- Rest periods when indicated
- Tests or diagnostic procedures, and/or questionnaires
- Volume of blood to be drawn, in terms of tablespoons or ounces (tablespoon=15 ml.); maximum allowable amount-450.ml. during eight weeks.

RISKS AND BENEFITS: Include all reasonably foreseeable risks and discomforts. Such risks could be physical, psychosocial, or legal. Also mention precautions taken to avoid such hazards. If blood is to be drawn, then, if appropriate, mention in the consent form the possibility of a bruise or soreness at the site of venipuncture, or a spasm with loss of blood flow at the site of arterial puncture. Include any benefits to the subject or to scientific knowledge.

ALTERNATIVE TREATMENTS: This is applicable to research in which there is a choice of therapeutic interventions.

NEW INFORMATION: If applicable, the form should include the statement*: New information gained during the time the research is in progress and which is relevant to*

participation will be provided. (NOTE: Such new information and any change in the project should be sent to the IRB for review and approval prior to discussion with subject.)

COST AND PAYMENTS: Include any cost or payment to the subject, or reimbursement for related expenses. Mention any conditions affecting payment and time of payment. If appropriate, include a statement such as the following:

> *All costs not related to the research will be charged to me just as though I were not part of this study. –or– I will receive___ (explain the incentive) as an incentive for participating in this study. (Explain when disbursement will occur and condition of payment, and consequences for early withdrawal from the study.)*

CONFIDENTIALITY: Assurance of protection of confidentiality must be included.* Describe your plans, then include appropriate sections of the following:

> *I understand that any information about me obtained from this research, including answers to questionnaires, history, laboratory data, findings on physical examination, or audio or videotapes will be kept strictly confidential. Information that will carry personal identifying material will be kept in locked files. I do understand that my research records, just like hospital records may be subpoenaed by court order. It has been explained to me that my identity will not be revealed in any description or publication of this research. Therefore, I consent to such publication for scientific purposes.*

*Modification of this basic rule may be made in the case of deception studies and other extraordinary circumstances. It is not yet clear whether the courts will allow researchers to keep research records confidential in criminal proceedings.

RIGHT TO REFUSE OR TO END PARTICIPATION: The following is a suggested paragraph, which should be adapted to your protocol.

> *I understand that I am free to refuse to participate in this study or to end my participation at any time and that my decision will not adversely affect my care at this institution or cause a loss of benefits to which I might be otherwise entitled.*

******** Use asterisks to separate the section using "you" from that using "I."

VOLUNTARY CONSENT: (This paragraph should be on the same page as the signature.)

> *I certify that I have read the preceding or it has been read to me and that I understand its contents. Any questions I have pertaining to the research have been and will be answered by _____. Any questions I have concerning my rights as a research subject will be answered by the Office of the Vice President for Academic Affairs (360-438-4310). A copy of this consent form will be given to me. My signature below means that I have freely agreed to participate in this experimental study.*

_____ _____

Date Subject Signature

_____

Witness

_____

Permission to contact corroborator, i.e., teacher, counselor, etc.

INVESTIGATOR'S CERTIFICATION:

> *I certify that I have explained to the above individual the nature and purpose, the potential benefits, and possible risks associated with participating in this research study, have answered any questions that have been raised, and have witnessed the above signature.*
>
> Signature of Investigator or Member of Research Staff:
>
> Date: _____
>
> _____
>
> Investigator/Research Staff

All consent forms must be signed by the subject. If possible, the subject should be allowed to study the consent form for 24 hours before signing. The investigator is responsible for explaining the research and the form to the subject. One copy of the consent form must be placed in the project file, and another copy must be given to the subject.