**Biomedical Applications**

**General Guidelines for Preparing the Consent Form**

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The purpose of this document is to provide research personnel with some general rules or guidelines to be followed when preparing a consent form for research studies involving human participants. The usual elements included in consent are outlined in a separate document, *Elements to be Included in a Consent Form*.

**a. Eighth Grade Reading Level**

The primary goal of a consent form is to provide all required information about a research study in language and format that is easily comprehensible, and presented at the most likely level of understanding of the subject population. For most studies, it is recommended that the consent forms be written at an eighth grade reading level. Non-technical terminology and simple sentence structure should be used throughout the form. While investigators always have the option of describing the study in more detail and in more scientific language during the consent process itself, the initial written description of the study should be simple and straightforward so that potential research subjects will have a fair and reasonable opportunity to make an informed decision as to whether to participate or not.

**b. Lay Language**

Scientific or technical terms should either be replaced or defined in lay language. For example, "blood draw" is preferable to "venipuncture," "X-ray" to "radiographs," "upset stomach" to "GI upset," "obstruction" to "occlusion."

**c. No Legalistic Language**

Legalistic or contractual sounding language such as "You hereby agree," "You certify that," "You, the undersigned, do acknowledge that" should not be used. Nor should any phrases similar to the following be used: "You realize that," "You attest that", "It has been explained to you that." Not only do these phrases make subject comprehension more difficult, they also lend the appearance of a legal document to the consent form, which it is not. Such phrases should be avoided in the consent document or replaced with simplified statements of fact about the study.

**d. Person of the Form**

The informed consent process requires the investigator to transfer information to the participant. Thus it is more appropriate for the subject/participant information and consent document to be written in the second person; that is, "You have been asked to participate in a research study." The REB will accept subject/participant information and consent forms that are written in the first person if used consistently throughout, but second person is preferred. If the subject is referred to as "I," the investigators should not refer to themselves as "we" but rather as "the researchers." If some of the subjects of the study will be minors, there should be a statement in the purpose section that the following information applies to the individual or to his/her child. This statement can also be adapted as appropriate for studies involving other subjects unable to consent for themselves. Such a statement is preferable to writing the entire form using "I/my child" as subject as this dual usage is confusing and cumbersome.

**e. Section Headings**

It is preferred that section headings be used. The information in the form is more clearly organized and more easily read if each section is identified appropriately. However, for very simple consent forms that can fit on one page headings may be omitted.

**f. Proofreading**

The entire form should be carefully proofread for correct spelling and grammar before it is submitted for REB review.

**g. Terminology**

Avoid the term "patient"; use instead the term “research subject or research participant". Use the phrase “study doctor” to distinguish the principal investigator from the primary care physician.

**h. Font Size**

The entire consent form should be in a font size of not less than 12 point.

i. **Required Footers for Consent Forms**

Every consent document (consent forms, assent forms, information sheets) must include the most recent version date (month, day, year) in a lower corner of each page. If multiple consent documents are used for the study, a short identifier should be included in the footer on each page to distinguish between the various consent documents. The pages of every consent document must be numbered, preferably in the format of "1 of 2," "2 of 2," etc. in the footer of the document.

**j. Letterhead**

The use of office letterhead is appropriate only if all of the individuals listed are participating as investigators or sub-investigators in the study. If this is not the case, office letterhead should not be used.

k. **Use of the word "INFORMED"**

The REB considers the inclusion of the word INFORMED on the consent form to be inappropriate because its use presumes the objective of the consent process. A participant could sign the consent at any time, but his/her consent only becomes an informed consent as a result of a process that cannot be presumed on the basis of the form itself.

l. **Canadianize the document**

Usually consent forms originating in the US must be modified by the Canadian investigators to make the document reflect the legal and health care systems in Canada.

m. **Use of the University of Regina Logo**

The use of the University of Regina Logo implies that this study is by and of the University of Reginan. The University Logo will be allowed on all advertisements and consent forms for those researchers that are affiliated with the University.

n. **Endorsement by the REB**

REB review and approval is a requirement for all research involving human subjects and may be stated as in the subject/participant information and consent document.

o. **Abbreviations**

If the title of the research protocol or the name of a disease has an acronym or abbreviation, use the full name first with the acronym or abbreviation in brackets. The next time it is used in the document, use the acronym.

p. **Investigator Qualifications**

This REB is obliged to assess the investigators' qualifications and resources to ensure the safe and proper conduct of the project. For first time submissions, the REB may require a statement of assurance, including a CV, from the principal investigator that s/he has the available time, the qualified staff and facilities necessary to conduct the study safely and properly at the study site. The REB must be satisfied that the principal investigator has the necessary skills to complete the project.