Guidelines for Creating Informed Consent Forms

According to federal guidelines, informed consent forms must be created for each research project. There is no "standard" form; every researcher must create an informed consent form specific to the study.

The Roger Williams University HSRB stipulates that the following information must be included in every informed consent. For research involving special populations (minors, prisoners), see the addendum to this section.

• Title of Project:

• Principal Investigator(s)

• Other Investigators:

• Purpose of the Study: Provide a brief summary of the purpose of the study. This should be written in terms that the layperson would understand. Include the number of participants that will be involved in the study.

• Procedures to be Followed: Indicate all procedures that will require the participants' involvement and what is required of them. Be specific. This includes the use of any audio, or audio/visual or other technological equipment that will be used.

• Time Duration of the Procedures and Study: Explain how much of the participant's time will be required to complete his/her participation in this research (e.g. minutes, hours, days). Also include the period of time during which this participation will occur (e.g. over 1 month, during the course of 1 year.

• Statement of Confidentiality: Explain the extent to which participants' records and data will be held confidential. An appropriate sample statement: Your participation in this research is confidential. Only the investigator and his/her assistants will have access to your identity and to information that can be associated with you. In the event of publication, pseudonyms will be used.

• Right to Ask Questions: This statement should explain whom to contact for answers to pertinent questions about the research. In the case of student research, the sponsoring faculty should be listed here with email, telephone, and university address.

• Compensation: Explain any additional costs that may result from participation including travel expenses. Also include any compensation that will be provided to participants including a stipend or extra credit in a course.

• Voluntary Participation/ Risks: In a final statement, explain that participation in the study is voluntary and that a participant can withdraw at any time. If applicable, explain any conditions under which the participant's involvement may be terminated by the

investigator without regard to the participant's consent. In addition, describe any reasonably foreseeable risks or discomforts to the participant.

• Signatures:
Write a one-line statement that ensures the participant is signing under his/her own consent. A suitable statement may include:

This is to certify that I consent to or give permission for my participation as a volunteer in this research study. I have read this form and understand the content. (In the case of parental permission, change language to read: my child's participation).

_____ _____
Participant's signature Date

Write a one-line statement that ensures that you explained the study to the participant. A suitable statement may include:

This is to certify that I have defined and explained this research study to the participant named above.

_____ ____