Institutional Review Board for Human Subject Research

Appendix E: Sample Informed Consent Statements

These samples are provided to assist investigators in preparing effective informed consent statements that will enable subjects to make informed decisions as to whether they want to participate in the research.

These samples are not expected to fit every type of research.

These samples must be modified to fit the particular needs and situation of the research. In all cases, an appropriate heading must be included whether or not the same contact information is included in the body of the consent statement.

Investigators are not required to use these samples but all the information suggested for each sample should be included in consent statement provided to the IRB for review. In all cases, an appropriate heading must be included whether or not the same contact information is included in the body of the consent statement.

The samples provided are:

1. Passive Informed Consent for Paper-based Surveys or Questionnaires
   - Includes instructions on modifications for electronic or Internet-bases surveys or questionnaires

2. Active Informed Consent for Interviews and other Minimal Risk Studies
   - Includes instructions for use with vulnerable populations and how signatures of witnesses should be used

3. Active Informed Consent for Studies with More Than Minimal Risk
   - Includes instructions for use with vulnerable populations and how signatures of witnesses should be used

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Appendix E.1: SAMPLE Passive Informed Consent for Paper-based Surveys or Questionnaires

Instructions for Investigators:

1. Edit the Required Heading: If you are faculty, staff, or an outside investigator: delete the lines for “Faculty Sponsor” and “Course Name and Number,” and then replace “Faculty Sponsor Phone Number” with “Investigator’s Phone Number.”

2. When editing the sample text, please use (a) one tense throughout the document (either "I" or "You") for consistency and use headings as needed, (b) replace all text in brackets [such as this] with text that is appropriate for your study, (c) delete instructions that are not appropriate to your study, and (d) delete these instructions as they are not meant to be seen by subjects.

3. This sample may be converted for use online, appropriate contact information, consent information and instructions must be provided in both the recruitment email/posting and at the beginning of the survey. For example, the instructions in the recruitment email would be “If you choose to participate, click this link... or, if you do not want to participate, close and delete this email.” and the instructions in the survey would be “If you choose to participate, click continue or, if you do not want to participate, exit the survey and close your browser.”

4. The name of the research project must be on each page of the statement and each page must be numbered.

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Required Heading for Passive Consent Statements:

William Paterson University
Project Title:
Principal Investigator:
Other Investigators:
Faculty Sponsor:
Faculty Sponsor Phone Number:
Department:
Course Name and Number:
Protocol Approval Date: __________________________
IRB Contact Phone Number: 973-720-2852

SAMPLE Text for Passive Consent Statements:

This [insert survey or questionnaire] concerns [insert descriptive statement]. [If student research, insert: It is being conducted to fulfill the requirements of the above named course.] I understand that my participation is voluntary and I may stop completing the [insert survey or questionnaire] at any time and I do not have to answer any question(s) I choose not to answer.

The risks associated with my completing this [insert survey or questionnaire] are [insert the list of risks from the protocol] and I accept them. Benefits of my participation in this study are [insert description of benefits] and I accept them.

I understand that any data collected as part of this study will be stored in a safe and secure location, and that this data [will be destroyed] when this research is completed.

I understand that my identity will not be revealed in any way through my participation in this study; I will not write my name on this document and the results will not be reported in a way that will reveal individual participants.
Consent:

If I do not want to complete this [insert survey or questionnaire] I may return it uncompleted as instructed for completed surveys or I may keep it. If I do choose to participate, I will return this document by [insert return instructions].

DO NOT INCLUDE SIGNATURES. REQUESTING SIGNATURES FOR ANONYMOUS SURVEYS AND QUESTIONNAIRES WILL COLLECT IDENTIFYING INFORMATION THAT DOES NOT NEED TO BE COLLECTED.

IF MODIFYING THIS FOR USE ONLINE, THE CLOSING INSTRUCTIONS SHOULD RE-INFORCE THAT CLICKING ON THE SUBMIT BUTTON IS THE SUBJECT’S AGREEMENT TO PARTICIPATE IN THE RESEARCH.

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Appendix E.2: SAMPLE Active Informed Consent for Interviews and Other Minimal Risk Studies

Instructions for Investigators:

1. Edit the Required Heading: If you are faculty, staff, or an outside investigator: delete the lines for “Faculty Sponsor” and “Course Name and Number,” and then replace “Faculty Sponsor Phone Number” with “Investigator’s Phone Number.”

2. When editing the sample text, please use (a) one tense throughout the document (either "I" or "You") for consistency and use headings if needed, (b) replace all text in brackets [such as this] with text that is appropriate for your study, (c) delete instructions that are not appropriate to your study, and (d) delete these instructions as they are not meant to be seen by subjects.

3. For studies that require parental/guardian consent for children below the age of 12: (a) edit text to be “my child” instead of “I” or “You” as appropriate, (b) add a line for the parent/guardian to write the child’s name, and (c) in the signature area, change “Subject” to “Parent/Guardian.”

4. For studies that require parental/guardian consent for children 12 years of age and older: (a) edit text to be “my child” instead of “I” or “You” as appropriate, and (b) in the signature area, change “Witness” to “Parent/Guardian.”

5. Only include the witness signature block for research that involves a vulnerable population that requires a witness as justified in protocol for this research.

6. The name of the research project must be on each page of the statement and each page must be numbered.

It is the expectation of the IRB that the investigator will retain the signed copy of every consent statement and that every subject will receive a copy.

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Required Heading:

William Paterson University
Project Title: ________________________________
Principal Investigator: __________________________
Other Investigators: ____________________________
Faculty Sponsor: ______________________________
Faculty Sponsor Phone Number: __________________
Department: __________________________________
Course Name and Number: _______________________
Protocol Approval Date: _________________________

SAMPLE Text for Active Consent Statements:

I have been asked to participate in a research study on [insert descriptive statement]. The purpose of this study will be to determine [insert descriptive statement]. I understand that I will be asked to [insert activity(ies)]. I understand that my participation is entirely voluntary and I may end my participation in this research at any time.

Risks associated with my completing this [insert survey or questionnaire] are [insert the list of risks from the protocol] and I accept them. Benefits of my participation in this study are [insert description of benefits] and I accept them.

I understand that any data [and recordings] collected as part of this study will be stored in a safe and secure location, and that this data [will be destroyed] when this research is completed. I understand that I will be [audio-recorded...
and/or video-recorded] and that these recordings [will be destroyed] when the research is completed. I understand that I will be [photographed] and that these images [will be destroyed] when the research is completed.

I understand that, as a participant in a focus group, I will not reveal what any of the other members of the group said or did during the focus group session.

I understand that my identity will be protected at all times and that my name will not be used without my separate written permission. I understand that the results of this study will not be reported in a way that would identify individual participants.

If I have questions about this study, I may call the investigators [insert name(s)] or the other individuals listed in the heading of this document. If I have any questions or concerns about this research, my participation, the conduct of the investigators or my rights as a research subject, I may contact the Office of the Provost and Senior Vice President for Academic Affairs at 973-720-2122.

By signing this consent form, I am agreeing to participate in this research study.

Name of Subject  ____________________________  Signature of Subject  ____________________________
Date:  ____________________________

Name of Investigator  ____________________________  Signature of Investigator  ____________________________
Date:  ____________________________

Name of Witness  ____________________________  Signature of Witness  ____________________________
Date:  ____________________________

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Appendix E.3: **SAMPLE** Active Informed Consent for Studies with More Than Minimal Risk

**Instructions for Investigators:**

1. Edit the Required Heading: If you are faculty, staff, or an outside investigator: delete the lines for “Faculty Sponsor” and “Course Name and Number,” and then replace “Faculty Sponsor Phone Number” with “Investigator’s Phone Number.”

2. When editing the sample text, please use (a) one tense throughout the document (either "I" or "You") for consistency and use headings if needed, (b) replace all text in brackets [such as this] with text that is appropriate for your study, (c) delete instructions that are not appropriate to your study, and (d) delete these instructions as they are not meant to be seen by subjects.

3. For studies that require parental/guardian consent for children below the age of 12: (a) edit text to be “my child” instead of “I” or “You” as appropriate, (b) add a line for the parent/guardian to write the child’s name, and (c) in the signature area, change “Subject” to “Parent/Guardian.”

4. For studies that require parental/guardian consent for children 12 years of age and older: (a) edit text to be “my child” instead of “I” or “You” as appropriate, and (b) in the signature area, change “Witness” to “Parent/Guardian.”

5. Only include the witness signature block for research that involves a vulnerable population that requires a witness as justified in protocol for this research.

6. The name of the research project must be on each page of the statement and each page must be numbered.

It is the expectation of the IRB that the investigator will retain the signed copy of every consent statement and that every subject will receive a copy.

***************************
William Paterson University
Project Title: ____________________________________________
Principal Investigator: __________________________________
Other Investigators: _____________________________________
Faculty Sponsor: _________________________________________
Faculty Sponsor Phone Number: ___________________________
Department: ____________________________________________
Course Name and Number: ________________________________
Protocol Approval Date: _________________________________
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**INVITATION TO PARTICIPATE:** I am being asked to participate in a research study because [enter reason for subject’s selection].

**PURPOSE:** [State the purpose of the study in lay language and clearly state the nature of the research project.]

**PROCEDURES:** [The subject must be informed exactly what his/her participation will involve. This may include the length and frequency of hospitalization; types of medication; placebo administration; types and number of tests; amount of blood to be drawn (in terms a lay person can understand such as ounces, tablespoons, teaspoons); randomization; questionnaires, including the type of information to be asked; video-taping; diets; withholding of standard treatment; follow-up studies; duration of participation; etc. State if subjects will be video or audio recorded or photographed.]
RISKS: [Describe potential physical and/or psychological risks in lay language and as described in your protocol.]

BENEFITS: [Describe the direct benefits to the subject and/or to society. If there are no direct benefits to the subject, a statement reflecting this fact must be included.]

ALTERNATIVES TO PARTICIPATION: [When appropriate, describe in lay language how the subject would be treated if not otherwise engaged in a research study and any potential adverse effects from the alternatives.]

COMPENSATION: [When appropriate, describe any fees (in dollar amount) or items subject might receive (like possible raffle items) to be provided to the subject for participation, describe partial payment or no payment for early termination or bonus for completion, and describe how this compensation will be provided. If no compensation will be provided, include a statement that there will not be financial compensation for participation.]

DATA MANAGEMENT AND DISPOSITION: [Describe where informed consent statements and research data will be kept and how these items will be secured in different locations. Describe what will happen to recordings and photographs after the study is completed – the destruction of data, recordings and photographs is preferred by the WPU IRB because of the difficulty in maintaining security over prolonged periods of time.]

CONFIDENTIALITY: [There are two standard statements of confidentiality, one of which needs to be included in this section.]

For clinical trials: I understand that all information collected in this study will be kept strictly confidential, except as may be required by law. I further understand that representatives of the Sponsor, as well as the Food and Drug Administration, may review the data collected from this study and my medical records. If any publication results from this research, I will not be identified by name.

For non-clinical trial studies: I understand that all information collected in this study will be kept strictly confidential, except as may be required by law. I understand that, as a participant in a focus group, I will not reveal what any of the other members of the group said or did during the focus group session. If any publication results from this research, I will not be identified by name.

ADDITIONAL INFORMATION: [Provide a statement that any significant new findings developed during the course of the study that may relate to the subject’s willingness to continue participation will be provided to the subject. The investigator must provide the subject and the IRB with a written statement concerning any significant finding(s) that may potentially influence a subject’s decision to continue participating in the study. In this circumstance the investigator must renegotiate informed consent. If this is a long-term study, obtaining subject’s informed consent several times during the project may be required. Other concerns may include:]

For Clinical Trials involving investigational medications: I understand that there is no guarantee that I may continue receiving the medication at the end of this study.

PREGNANCY: The following statement (as is or amended as appropriate) must be included in the informed consent only if the study drug/device could effect women of child-bearing age, the unborn fetus or a women breast-feeding a child.

Due to the effect of this drug/device, there could be serious harm to unborn children (or children who are breast-feeding) and it could also jeopardize the health of the mother. In addition, it is possible that harmful side effects that are not yet known could occur to both the mother and unborn or breast-feeding child. For this reason, if I am pregnant, I will inform you and understand I will not be included in the study. If I am still capable of becoming pregnant, I will be given a pregnancy test prior to entry into the study. I also understand that I will practice a medically approved method of birth control during my participation in the study. Further, I understand that while I
am taking this drug/device I should not become pregnant, and if I do become pregnant, I must discontinue the drug/device and consider termination of the pregnancy.]

DISCLAIMER/WITHDRAWAL: [There are two standard statements of disclaimer/withdrawal, one of which needs to be included in this section.

For medical studies: I agree that my participation in this study is completely voluntary and that I may withdraw at any time without prejudicing my present or future care. I also understand that should my physician find it necessary, and/or in my best interest, he/she may withdraw me from the study.

For non-medical studies: I agree that my participation in this study is completely voluntary and that I may withdraw at any time without prejudice.]

INJURY/COMPLICATIONS: [Provide a statement that in the event of an injury resulting from the research procedures, the cost of medical treatment in excess of that covered by third party payors will be provided without cost to me by William Paterson University but additional financial compensation is not available.

For studies where an adverse effect is not separately identifiable from a patient’s disease process, provide a statement that the subject understands that complications may arise during the course of therapy either due to their disease or due to the treatment, that they have been advised that therapy for any such complications will be carried out by their doctors and costs associated with such care may be provided by third party payers but not by William Paterson University.]

SUBJECT RIGHTS, use this text: I understand that if I wish further information regarding this research, my participation, the conduct of the investigators, or my rights as a research subject, I may contact the Office of the Provost and Senior Vice President for Academic Affairs at 973-720-2122. I also understand that if I have any questions pertaining to my participation in this particular research study, I may contact the investigator by calling the telephone number(s) listed at the top of page one. I have been given the opportunity to ask questions and have had them answered to my satisfaction.

CONCLUSION: I have read and understand the consent form. I agree to participate in this research study. Upon signing below, I will receive a copy of the consent form.

Name of Subject ___________________________ Signature of Subject ___________________________
Date: ___________________________

Name of Investigator ______________________ Signature of Investigator ______________________
Date: ___________________________

Name of Witness ________________________ Signature of Witness ________________________
Date: ___________________________

NOTE: The signature of witness is only required in certain circumstances that should have been explained and justified in the protocol for this research. In general: do not include a signature block for a witness.