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**1 PURPOSE**

1.1 This document applies to studies that fall into Expedited or Full Board reviews.

**2 What is Informed Consent?**

2.1 Informed consent is the term given to the communication process that allows individuals to make an informed choice about participation in a research study. §46.116(a)(4) states that “The prospective subject or the legally authorized representative must be provided with the information that a reasonable person would want to have in order to make an informed decision about whether to participate, and an opportunity to discuss that information.” This process is reflected in an informed consent document that contains specific, required information about the research study. The informed consent document serves as the formal authorization by an individual of his or her agreement to participate in the proposed research.

2.2 Under §46.116(a)(5)(ii), “[i]nformed consent as a whole must present information in sufficient detail relating to the research and must be organized and presented in a way that does not merely provide lists of isolated facts, but rather facilitates the prospective subject's or legally authorized representative's understanding of the reasons why one might or might not want to participate.”

**3 OHRP guidance states the following information must be conveyed to each subject:**

3.1 A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures that are experimental;

3.2 A description of any reasonably foreseeable risks or discomforts to the subject;

3.3 A description of any benefits to the subject or to others that may reasonably be expected from the research;

3.4 A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;

3.5 A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;

3.6 For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;

3.7 An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject;


3.8 A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled; and

3.9 One of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens:

3.9.1 (i) A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative, if this might be a possibility; or

3.9.2 (ii) A statement that the subject's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

**4 Additional elements of informed consent should also be provided to each subject if relevant:**

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- 4.1 A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) that are currently unforeseeable;
- 4.2 Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's or the legally authorized representative's consent;
- 4.3 Any additional costs to the subject that may result from participation in the research;
- 4.4 The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;
- 4.5 A statement that significant new findings developed during the course of the research that may relate to the subject's willingness to continue participation will be provided to the subject;
- 4.6 The approximate number of subjects involved in the study;
- 4.7 A statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit;
- 4.8 A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions; and
- 4.9 For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).

## 5 KEY QUESTIONS

- 5.1 "The following questions may help authors of consent materials and IRBs identify the key information a prospective subject needs in order to make a well-informed choice about whether to participate:
  - 5.1.1 What are the main reasons a subject will want to join this study?
  - 5.1.2 What are the main reasons a subject will not want to join this study?
  - 5.1.3 What is the research question the study is trying to answer? Why is it relevant to the subject?
  - 5.1.4 What aspects of research participation or this particular study are likely to be unfamiliar to a prospective subject, diverge from a subject's expectations, or require special attention?
  - 5.1.5 What information about the subject is being collected as part of this research?
  - 5.1.6 What are the types of activities that subjects will do in the research?
  - 5.1.7 What impact will participating in this research have on the subject outside of the research? For example, will it reduce options for standard treatments?
  - 5.1.8 How will the subjects' experience in this study differ from treatment outside of the study?
  - 5.1.9 In what ways is this research novel?"
- 5.2 The human subjects in your project must participate willingly, having been adequately informed about the research. If the human subjects in your project are part of a vulnerable population (i.e. prisoners, cognitively impaired individuals, or minors), special protections are required. Contact the Human Research Ethics Board at 257-3282 or HREBsecretary@newpaltz.edu for more information.

## 6 ITEMS TO CONSIDER ABOUT THE INFORMED CONSENT PROCESS

- 6.1 Informed consent shall be documented by the use of a written informed consent form approved by the HREB and signed (including in an electronic format) by the subject or the subject's legally authorized representative. A written copy shall be given to the person signing the informed consent form.

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6.2 A **waiver from the requirement to obtain a signed consent form** for some or all participants may be requested in writing by the investigator to the HREB if:

- 6.2.1 The only record linking the subject and the research would be the consent document, and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or
- 6.2.2 The research presents no more than minimal risk of harm to subjects, and involves no procedures for which written consent is normally required outside of the research context; or
- 6.2.3 If the subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, that the research presents no more than minimal risk of harm to subjects and provided there is an appropriate alternative mechanism for documenting that informed consent was obtained.

6.3 A **waiver from some or all of the required elements of informed consent form** for some or all participants may be requested in writing by the investigator to the HREB if

- 6.3.1 The research involves no more than minimal risk to the subjects;
- 6.3.2 The research could not practicably be carried out without the requested waiver or alteration;
- 6.3.3 If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format;
- 6.3.4 The waiver or alteration will not adversely affect the rights and welfare of the subjects; and
- 6.3.5 Whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation.

6.4 In cases in which the documentation requirement is waived, the HREB requires that the investigator provide subjects with a written statement regarding the research.


## 7 GUIDELINES FOR PREPARING WRITTEN CONSENT

- 7.1 Please note: Except where noted, written informed consent must contain all sections described in the document.
- 7.2 The consent form should read easily (~ 8th grade level). Please note if it is intended to provide informed consent in a language other than English, please include a copy of the consent document or script in the specific language as well in English. Suggested text is included below for some required consent elements, however, the text should be revised to adequately describe your specific research project.


## 8 REQUIRED CONSENT ELEMENTS FOR ALL RESEARCH STUDIES

8.1 Summary of Key Information

- 8.1.1 "Informed consent must begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or legally authorized representative in understanding the reasons why one might or might not want to participate in the research. This part of the informed consent must be organized and presented in a way that facilitates comprehension."
- 8.1.2 Key information should include the following:
  - 8.1.2.1 The fact that consent is being sought for research and that participation is voluntary
  - 8.1.2.2 The purposes of the research, the expected duration of the prospective subject's participation, and the procedures to be followed in the research
  - 8.1.2.3 The reasonably foreseeable risks or discomforts to the prospective subject

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- 8.1.2.4 The benefits to the prospective subject or to others that may reasonably be expected from the research
- 8.1.2.5 Appropriate alternative procedures or courses of treatments, if any that might be advantageous to the prospective subject.
- 8.2 Title of the research project
  - 8.2.1 Provide title.
- 8.3 Names of the researchers
  - 8.3.1 Provide names, university affiliation, position and degrees.
- 8.4 Description of the research
  - 8.4.1 You must clearly identify your project at the beginning as research and discuss in lay terms the purpose.
- 8.5 Participants
  - 8.5.1 Describe the inclusion/exclusion criteria and state approximate number of participants.
- 8.6 Procedures: Description of participant involvement
  - 8.6.1 Discuss in lay terms what will be required of the subject during his/her participation. Include a description of the research procedures and identification of any procedures that are experimental. You must provide a reasonable estimate of the duration of each session, number of sessions, and total duration of participation across the project.
- 8.7 Risks & discomforts of participation
  - 8.7.1 Provide a detailed description, in lay terms, of the risks and discomforts of participating in the study. If applicable, provide information about other appropriate alternative procedures or courses of treatment, if any that might be advantageous to the subject. For studies that involve sensitive topics such as AIDS/HIV status, sexual behavior, illegal conduct, drug use or abuse or other potentially damaging information the risk of exposure should be identified and discussed.
  - 8.7.2 Suggested text if you do not anticipate any risks other than minimal discomfort from answering questions or surveys:
    - 8.7.2.1 “We do not anticipate any risk in your participation other than you may become uncomfortable answering some of the questions.”
- 8.8 Measures to be taken to minimize risks and discomforts (if applicable):
  - 8.8.1 Please describe in lay terms any measures taken to minimize risk and discomfort of the subject during his/her participation in the research study.
- 8.9 Expected benefits to subjects or to others:
  - 8.9.1 Provide information on the probability of direct benefits, if any. You must indicate clearly if no benefit is likely to the participant. Participant payment is not considered a benefit and should not be discussed in this section.
  - 8.9.2 Suggested text if no direct benefit is anticipated:
    - 8.9.2.1 “Although you may not receive direct benefit from your participation, others may ultimately benefit from the knowledge obtained from this research.”
- 8.10 Confidentiality of records/data
  - 8.10.1 Include a statement describing the extent to which confidentiality of records identifying the subject will be maintained. Describe the steps you are taking to preserve confidentiality and specify if participants will be identified in any reports on the research. In addition, include a description of the eventual disposal of identifiable information, tapes, questionnaires, etc.
  - 8.10.2 The researcher should specify if the research is anonymous. Anonymous means that there is no personal identifying information recorded on any research documentation,

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including consent forms and questionnaires. This includes any code that can reasonably link personal information to a specific participant.

8.10.2.1 The researcher should specify in this section when a “Certificate of Confidentiality” has been obtained and briefly explain the protections that it offers the participants.

8.10.3 Suggested Text: (if applicable)

8.10.3.1 "All information obtained in this study is strictly confidential unless disclosure is required by law. In addition, the Human Research Ethics Board, the sponsor of the study (e.g. NIH, FDA, etc.), and University or government officials responsible for monitoring this study may inspect these records."

8.11 Data Storage

8.11.1 Include a statement describing how the data will be stored.

8.12 Research Involving More than Minimal Risk (include only if applicable):

8.12.1 When more than minimal risk is anticipated you must include an explanation as to whether any compensation and/or treatments are available if injury occurs and if so, what they consist of or where further information may be obtained. This may include treatments such as referrals for counseling services, intervention services or hotline references.

8.13 Photographing or Audio/Video Recording of participants (include only if applicable):

8.13.1 Include a statement that audio and/or video-recording devices will be used, if applicable. You must state how the photos or recordings will be used, what settings context outside of study, e.g., conferences, presentations, education/classroom use, promotional materials, electronic online posting distribution. You may want to provide participants with the ability to opt in or out of any mode of utilization. This can be done through a checklist on the consent form. Caution interview participants before the interview begins to avoid mentioning the names of or identifying information about third parties. If identifying information is mentioned inadvertently, the taping should be stopped immediately, the identifying information erased, and the caution repeated before taping resumes. Please provide a separate line on the consent form for the subjects to agree to each session to be photographed or recorded.

8.13.2 Suggested Text if applicable:

8.13.2.1 "Please sign below if you are willing to have this interview recorded (**specify audio or video**). You may still participate in this study if you are not willing to have the interview recorded."

8.14 Compensation for participation in the study (include only if applicable):


8.14.1 Provide information on financial payments or reimbursement of expenses. Indicate on the consent document if full payment is given if the subject withdraws from participation in the research study.

8.15 Contact Information

8.15.1 The name, academic title, and telephone number and/or email address (as appropriate) of the investigator should appear on the consent form. If a researcher is a university student, the name and telephone number of the faculty advisor may also be provided. A copy of the consent **MUST** be provided to the participant for reference to the contact information.

8.15.2 Suggested text:

8.15.2.1 "One copy of this document will be kept together with the research records of this study. Also, you will be given a copy to keep."

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8.16 HREB Contact Information and Human Rights Statement

8.16.1 Include the following information in a separate paragraph after the principal investigator contact information.

8.16.2 Required text

8.16.2.1 For questions about your rights as a research participant, contact the State University of New York at New Paltz Human Research Ethics Board (which is a group of people who review the research to protect your rights) at 845-257-3282.

8.16.2.2 The Human Research Ethics Board of the State University of New York at New Paltz has determined that this research meets the criteria for human subjects according to Federal guidelines.

8.17 Voluntary nature of participation

8.17.1 Include a description that participation is voluntary and describe what participants are required to do if they wish to withdraw or not participate.

8.17.2 Example Text to Inform Participants of how to withdraw or not participate:

8.17.2.1 "You may choose not to answer any questions and may refuse to complete any portions of the research you do not wish to for any reason."

8.17.2.2 "If you do not wish to participate, hand in a blank questionnaire."

8.18 Withdrawal of participants and data retention

8.18.1 Investigators must also inform participants whether the investigator intends to either:

8.18.1.1 retain and analyze already collected data relating to the subject up to the time of subject withdrawal; **or**

8.18.1.2 honor a research subject's request that the investigator destroy the subject's data or that the investigator exclude the subject's data from any analysis.

8.18.2 Suggested text:

8.18.2.1 "Your participation in this project is voluntary. Even after you agree to participate in the research or sign the informed consent document, you may decide to leave the study at any time without penalty or loss of benefits to which you may otherwise have been entitled. I will retain and analyze the information you have provided up until the point you have left the study unless you request that your data be excluded from any analysis and/or destroyed."

8.18.3 **NOTE: If the exclusion or destruction of an individual's data is impracticable, this must be clearly articulated in the consent information.**

8.19 Consent of the subject

8.19.1 For those consent forms to be signed by the participants, include a line for the participants name, signature and date. (or that of a parent or guardian of minors)


8.19.2 Suggested Text for Consent Forms:

8.19.2.1 "I have read, or been informed of, the information about this study. I hereby consent to participate in the study."

**9 ADDITIONAL ELEMENTS OF CONSENT TO BE INCLUDED WHEN APPROPRIATE**

9.1 A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) that are currently unforeseeable;

9.2 Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's or the legally authorized representative's consent;

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- 9.3 Any additional costs to the subject that may result from participation in the research;
- 9.4 The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;
- 9.5 A statement that significant new findings developed during the course of the research that may relate to the subject's willingness to continue participation will be provided to the subject;
- 9.6 The approximate number of subjects involved in the study;
- 9.7 A statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit;
- 9.8 A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions; and
- 9.9 For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).

**10 REQUIREMENTS SPECIFICALLY FOR CLINICAL TRIALS**

- 10.1 All research involving clinical trials must post, to a federal website, a copy of the HREB-approved version of the consent form that was used for enrollment purposes for each clinical trial conducted or supported by a federal department or agency. §46.102(b) defines "clinical trial" to mean "a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes."

**11 REQUIREMENTS FOR BROAD CONSENT FOR THE STORAGE, MAINTENANCE, AND SECONDARY RESEARCH USE OF PRIVATE INFORMATION OR IDENTIFIABLE BIOSPECIMENS.**

- 11.1 Broad consent will provide subjects with a choice to say no to storage, maintenance, and secondary research. If an individual was asked to provide broad consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens and refused to consent, an IRB cannot waive consent for the use of identifiable private information or identifiable biospecimens.
- 11.2 46.116(b)(9) indicates that researchers must include one of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens:
  - 11.2.1 (i) A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative, if this might be a possibility; or
  - 11.2.2 (ii) A statement that the subject's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.
- 11.3 The requirements for broad consent include:
  - 11.3.1 All of the requirements for consent described above.
  - 11.3.2 A general description of the types of research that may be conducted with the identifiable private information or identifiable biospecimens. This description must include sufficient information such that a reasonable person would expect that the broad consent would permit the types of research conducted;
  - 11.3.3 A description of the identifiable private information or identifiable biospecimens that might be used in research, whether sharing of identifiable private information or identifiable biospecimens might occur, and the types of institutions or researchers that

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might conduct research with the identifiable private information or identifiable biospecimens;

- 11.3.4 A description of the period of time that the identifiable private information or identifiable biospecimens may be stored and maintained (which period of time could be indefinite), and a description of the period of time that the identifiable private information or identifiable biospecimens may be used for research purposes (which period of time could be indefinite);
- 11.3.5 Unless the subject or legally authorized representative will be provided details about specific research studies, a statement that they will not be informed of the details of any specific research studies that might be conducted using the subject's identifiable private information or identifiable biospecimens, including the purposes of the research, and that they might have chosen not to consent to some of those specific research studies;
- 11.3.6 Unless it is known that clinically relevant research results, including individual research results, will be disclosed to the subject in all circumstances, a statement that such results may not be disclosed to the subject; and
- 11.3.7 An explanation of whom to contact for answers to questions about the subject's rights and about storage and use of the subject's identifiable private information or identifiable biospecimens, and whom to contact in the event of a research-related harm.

## **12 SCREENING, RECRUITING, OR DETERMINING ELIGIBILITY**

- 12.1 The HREB may approve a research proposal in which an investigator will obtain information or biospecimens for the purpose of screening, recruiting, or determining the eligibility of prospective subjects without the informed consent of the prospective subject or the subject's legally authorized representative, if either of the following conditions are met:
  - 12.1.1 The investigator will obtain information through oral or written communication with the prospective subject or legally authorized representative, or
  - 12.1.2 The investigator will obtain identifiable private information or identifiable biospecimens by accessing records or stored identifiable biospecimens.

## **13 REFERENCES**

- 13.1 45 CFR 46 (Revised Common Rule)