INFORMED CONSENT INSTRUCTIONS – ADULT PARTICIPANTS

SOCIAL AND BEHAVIORAL RESEARCH

Effective Date: January 21, 2019

IMPORTANT: The instructions in this document are to be used in conjunction with the **ADULT INFORMED CONSENT TEMPLATE (2019)** available at https://provost.umw.edu/irb/instructions-and-forms/ For research involving **participants under age 18**, or if a **debriefing** procedure will be used, see additional forms and instructions available at the same location. (For biomedical research and/or use of existing biomedical data, consult with the IRB chair.)

Informed consent procedures are required for research involving human subjects. Appropriate consent forms must be submitted with IRB applications for both Exempt Status Review and Expedited Review.

Submit the Consent Form with your IRB application to the appropriate IRB member for your department as listed at https://provost.umw.edu/irb/board-members/ To avoid delays, ensure that the information on the Consent Form is consistent with information on the IRB application form. **Subsequent changes to the consent** form or procedures after initial IRB approval must be reviewed and approved by the IRB before they can be implemented.

Guiding Principles of Participant Consent

Participants must be informed
- before collecting data
- in a manner and using language that facilitates comprehension
- of the purpose of the study
- of what they will do to provide data for the study

Participants must
- agree voluntarily to participate without any undue influence
- be able to ask questions at any time (including after participation)
- have adequate time to read the consent form or have it read to them
- receive the researcher's contact information in a form they can keep

Obtaining Consent

- The consent form must be given in writing to participants in a form that they can keep
- In most cases, the consent form should be signed and dated by both the participant and the researcher who obtains the consent (also see the section on "Waiver of Consent" below)
- If the consent form is read aloud to potential participants, it must be read exactly as written
- An oral consent procedure, requiring a witness, may be used in circumstances where written consent is not possible or appropriate; for information on this procedure, contact the IRB chair

Editing the Consent Template

- Make appropriate changes to the form such as changing *I, me, my* to *We, us, our*, as needed throughout, and delete the italicized instructions on the form.
- Remove italicized wording
- **Organize** the information in the order shown on the template, using the headings provided.
- **Follow the instructions** below for other required changes, depending on the details of your research.

Translations

- The IRB must receive English language versions of all consent documents, as well as any translations into other languages. The researcher is responsible for obtaining accurate translations, and providing the IRB with sufficient information on the IRB Application Form to determine if the translations are accurate, such as identification and/or qualifications of the translator.
- Researchers may delay submitting the non-English translations until an IRB reviewer has determined that the English language versions are satisfactory. This determination does not, however, constitute IRB approval for the research. For additional information, go to https://www.hhs.gov/ohrp/regulations-and-policy/guidance/obtaining-and-documenting-infomed-consent-non-english-speakers/index.html

Opening Paragraph of Consent Form

- A new (2019) regulation states that the form "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."
- If appropriate, mention how prospective participants were identified, such as *I am inviting you to participate in this study because you are ...*

Details of Participant Involvement

- Include estimated **duration** of participant's participation and identify any procedures that are experimental.
- **Deception and Debriefing—**If the research procedure requires that participants not know in advance the investigative purpose of the study, or the purpose of specific interventions, and/or the types of data being collected, etc., these may be omitted from the Consent Form only if a **Debriefing Form** is provided to participants after the procedure. Otherwise a Debriefing Form is not required, but one may be used to provide additional information for participants to keep. A Debriefing Form template and instructions are available at https://provost.umw.edu/irb/instructions-and-forms/
- **Voice, Video, Digital, or Image Recordings—**Collection of adult participant data through these means must be clearly described, including whether they are made overtly or covertly. Specific permission or debriefing is needed for research that involves making any **covert recordings or images** of adult participants or their data (see "To be Completed by Participant" instructions below). If any recordings or images of participants will be used in presentations, publications, or internet archives of the research, a release form should be requested from both the child and the legally authorized representative. (See Sample Release Form at https://provost.umw.edu/irb/instructions-and-forms/.)

Privacy and Confidentiality

- Indicate the **privacy** conditions in which participants will provide data, or state that the research will not be conducted privately and describe the conditions. If the research involves a **focus group** protocol, state specifically that participants will not be interviewed privately, but while interacting with several other participants.
- **Confidential vs. Anonymous Data—**Select the wording appropriate for one of these conditions (not both). Data is only "anonymous" if no one, not even the researchers, can associate the data with the participant, either directly or indirectly.
- **Disclosure of Illegal or Prohibited Conduct—**In confidential protocols, if the researcher plans to ask subjects about their or others' **illegal activities** (e.g., underage drinking, drug use, etc.),

this must be disclosed in the Consent Form, and wording such as the following is required: *I will not reveal your identity to anyone unless required by law to do so.* UMW's Policy on Sexual and Gender-Based Harassment and Other Forms of Interpersonal Violence, states that disclosures of these types of gender-based conduct made during research that has been approved by the IRB will not trigger an investigation of the prohibited conduct.

- **Reporting the Research—**If individual subject data will be used as illustrative examples, you must assure participants that this will be done in a way that does not allow them to be identified. Occasionally, it is important to the research to identify an individual who participated, or subjects themselves may wish to have their contribution attributed to them. In such cases, it would be necessary for a participant to sign a release form indicating their willingness to be so identified.
- **Retaining Data for Future Use—**If identifiable data might be retained for an indefinite period, state that it will not be used or distributed for future studies. Or, if you think you might use confidential data for future studies or share it with other researchers after completion of the study, include the following statement of "broad consent": *After this research is complete, all participant identifiers will be removed and the data will be stored and distributed for use in future research studies without additional informed consent from participants.*

Risks and Benefits of Participation

- Include any reasonably foreseeable physical, psychological, social, political, legal, or economic **risks or discomforts** that participants might experience.
- **Minimal risk** means that the probability and magnitude of harm or discomfort anticipated in the research are not greater than those ordinarily encountered in daily life or during the performance of routine examinations or tests. (45 CFR 46.102(i)).
- If research involves **more than minimal risk**, the Consent Form should 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.
- **Unforeseeable risks:** If appropriate, include a statement that the research procedures or interventions may involve risks that are currently unforeseeable.
- If there are no direct benefits to participants, this must be stated.
- Benefits such as compensation or rewards for participating cannot be so great as to constitute **coercion or undue influence**. The IRB needs to know enough about the participant population and the context of the research in order to make reasonable judgments about how compensation might compromise the voluntariness of someone's choice to participate or the equitability of participant recruitment.
- Benefits to society or the advancement of the field should be stated in objective terms. Wording such as *You will be helping me to ...* should not be used.

Participant Rights

- The procedure for distributing Consent Forms should **actively encourage questions** from potential participants.
- If a participant's withdrawal from the study is possible after data collection begins, explain the procedure for orderly withdrawal, when it is too late to withdraw, and what will happen with any data they already provided.
- There must be no negative consequences from refusing to participate or withdrawing. If participants are students or employees under the authority of the researcher, they should be told that their decision to not participate will not negatively affect their grades, working conditions, or performance evaluations, etc.

- There must be **no exculpatory language** (i.e., wording that suggests participants waive any rights or that releases researchers or UMW from liability for negligence).
- The name and email address of the **IRB Chair** is available at https://provost.umw.edu/irb/board-members/

Contact Information

- Contact information for the primary investigator must be provided to participants in a form that they can keep. It may be provided on a Debriefing Form or Invitation to Participate instead of or in addition to including it on the Consent Form.
- If the research is being conducted by a student, contact information for the **supervising faculty** member is also required.
- If appropriate, add information about how and when the signed consent form should be returned to the researcher.
- If appropriate, contact information for participants to obtain counseling or support after participation in the research should be provided on a Debriefing Form.
- If you choose, indicate whom to contact if participants want **access to the research report** after completion of the study.

To be Completed by Participant

- If research participants are UMW students and the academic department has obtained parental permission for underage students to participate in department research, then substitute the following sentence about age: *I certify that I am at least 18 years of age or have a signed parental consent form on file with the _____ Department*.
- Specific permission is needed for research that involves making any **covert recordings or images** of adult participants or their data by explaining this in the Consent Form (or Debriefing Form) and adding the following for a separate signature:

  I understand that my participation in this research may involve audio/video/digital/photographic recording of me and/or my work:

  ___ I agree to be recorded/photographed
  ___ I do not agree to be recorded/photographed

  _____ _____
  Signature of the Participant Date

To be Completed by Researcher

- Researchers are required to sign and date the Consent Form
- Participants should be given a copy of the Consent Form or the information it contains (e.g., on a Debriefing Form). At a minimum they must have a description of the study as well as the investigator's and the IRB chair's contact information **in a form that they can keep** for future reference.
- Federal guidance prescribes that researchers keep copies of participants' consent forms in a secure location for at least three (3) years. If the researcher leaves UMW before the three years, forms should be kept by the supervising faculty member or the academic department.

Waiver of Consent

- Only the IRB can waive the requirements to obtain informed consent from participants. For research involving collection of data using **online surveys, telephone interviews**, etc., researchers may request that the IRB waive the requirement for participants' signatures when giving consent. If you expect any individuals will consent to participate but not want to sign a consent form, you may request that the IRB waive the signature requirement. For information about consent waivers, contact the IRB chair.