University of Wisconsin- Milwaukee
Institutional Review Board
Consent Guidance Document

A. Purpose

Based on the regulations of the Department of Health and Human Services (HHS) (45 CFR 46), the IRB is responsible for ensuring that each human subjects protocol includes an appropriate plan for *obtaining* and *documenting* that informed consent was sought from each prospective subject, or the subject's legally authorized representative, in accordance with the federal regulations. 45 CFR 46 (116) describes eight required elements of consent and six optional elements.

During the review process, the UWM IRB will review the plan for obtaining and documenting the consent of each individual participant. Improperly obtained or documented consent is a risk to the participant because they may not have a clear understanding of what they are agreeing to when signing the consent form and may not be aware of the risks of a study. Documentation of consent is important because it serves as a record that the project details, including potential risks and benefits, were explained to the participant and that they willingly agreed to participate.

B. General Information about consent

1) *Consent is a process not a form*. Consenting a participant to participate in research is an important piece of the research project. This involves more than just creating the perfect consent form, careful consideration should be given to who does the consenting, where it is done, under what circumstances it is done and how it is done.

2) *Required Elements of consent:* The Office of Human Research Protection has a list of the required and additional elements of consent. The required elements all appear in the UWM IRB consent templates but if you are creating your own consent template you will want to ensure it contains the required elements: http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.116

- 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 which are experimental;

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

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

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

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

- 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;

- 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 researchrelated injury to the subject; and

- 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.

3) *Helpful reminders for the consent process-*

- **Time to think it over**: Participants need to be given the opportunity to consider if they want to participate or not.
- **Who is recruiting/consenting and how**: steps should be taken to minimize the possibility of coercion or undue influence- see #6
- **Assessing understanding**: how will you know that participants understand what they are agreeing to do? Will you ask participants questions to assess their comprehension, will you program questions into an online consent form that they must answer correctly in order to proceed

- **Language**: Consent process should be conducted in language understandable to the potential participant-make sure there is minimal jargon and that the reading level is appropriate
- **Individual**: the consent process should be an individualized process, a group consent process is approved only for minimal risk focus groups
- **Signed copies**: participants must be given a copy of the signed consent form (If they refuse to take a copy this should be documented by the PI)

4) *Verbal Consent*- Verbal consent may be appropriate for various populations- illiterate subjects, nonEnglish speaking subjects, telephone interviews, etc… There are two different routes of implementing a verbal consent process.

- In-Person Verbal Consent: Typically used with non-English speaking subjects or illiterate subjects: Standard OHRP defined process:
- the participant must be given a written summary of the consent document and a copy of the consent form
- there must be a witness to the consent process who can sign and verify that it was conducted and that the participant gave consent
- the participant must sign the consent form, the witness must sign the consent form and the copy of the summary and the person obtaining consent must sign the summary.
- Remote Verbal Consent: Typically used with telephone interviews, or other situations where the subjects and research staff are not in the same location
- Condensed consent information provided to subject verbally
- Researcher must submit and the IRB must approve a Request to Waive Consent or waive documentation of consent

5) *Passive consent*-Passive consent is a process typically used in school-based settings where information about a study is sent home to parents with instructions on how to opt their child out of the study. Because there is no way to verify that parents ever saw the study information, in the eyes of OHRP and the UWM IRB, passive consent is equivalent to waiving the consent process all together. So, if a passive consent process is requested by the research team, a completed "Request to Waive Consent" must also be submitted with justification as to why they are requesting to waive consent.

Passive consent is likely to be approved in situations where students are not providing sensitive information or participating in interventions more than minimal risk and where the school or school district has approved of the use of passive consent.

6) *Coercion and Undue Influence*

- *Coercion* – the use of express or implied threat to intimidate a person into acting against his/her will
- *Undue Influence*- to go beyond normal or appropriate levels of influence

It is important in the consent process to account for and address areas where there is a potential for coercion, or more likely, undue influence. Below are three common examples where you should think through and in the protocol form clearly state how you will minimize undue influence during the recruitment and consent process:

- **Students**- If they are being recruited by a teacher of instructor in the classroom, the investigator should clearly address what steps they are taking so that the student feels free to decline participation
- **Children**- if they are being recruited by an authority figure the investigator should again state what steps will be taken so that the children are aware that they do not have to participate in the study.
- **Employees**- if participants are being recruited/consented in a work setting, investigators should think carefully about who does the recruiting and consenting and how it is done so that participants do not feel compelled to participate or receive the impression that it is mandatory or will affect their promotional opportunities or performance reviews. http://answers.hhs.gov/ohrp/questions/7254
- **Patients** –Whenever possible having clinicians recruit and consent their own patients should be avoided as the implicit influence of the clinician on his/her patient makes it difficult for the patient to make a voluntary decision about participation.

7) *Repeated Consent*- If a significant amount of time has passed between data collection time points and there is reason to believe the mindset of the participant may have changed (as may be the case with participants who use drugs, obtain mental health treatment or have a progressive chronic condition) or if new significant findings have emerged from the study, a participant may need to be "reconsented" or repeat the consent process at each data collection point. This repeated consent can be brief and verbal and resemble a check-in with the participant to verify they understand what the next steps are and that they are interested in continuing.

C. **Special Populations- Children**

Children are persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted (45 CFR 46.402(a)). This age varies by state, but in Wisconsin the age of majority is 18.

1) *Assent*: If it is appropriate for the age and maturity of the child, the investigator must seek and obtain assent from the child to participate in the study. This may be written and/or verbal.
2) *Parental Consent*: Consent of the parent or guardian must also be obtained unless a request to waive parental consent is approved by the IRB
    - Consent must be obtained from at least one parent guardian when the research is miminal risk or there is the possibility of direct benefit to the child
    - Consent must be obtained from both parents if the study is more than minimal risk and offers no prospect of direct benefit or if it addresses a serious problem affecting the health or welfare of children. This does not apply if one of the parents is deceased, unknown, incompetent, not reasonably available or if only one parent has legal responsibility and custody of the child
    - If a child is in foster care or a ward of the state then the consent of the person who has authority to make medical decisions for the child should be obtained. This may be the biological parent, the foster parent or the State depending on the circumstances. Contact the IRB office or legal affairs for more information.
3) *Age considerations*: If the child becomes 18 during the course of the study, they should be reconsented as OHRP has determined that parental consent/child assent is not equivalent to legally effective informed adult consent.
4) *What the regulations say*: "Assent means a child's affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent." 45 CFR 46.402 (b)
5) *Online Assent*: In studies conducting online surveys or other studies where the research team is not in the same physical location as the child, it is possible to propose and have an online assent process approved. This process can be complicated as the researcher must be able to verify that the participant is the actual person "signing" the assent form, or agreeing to participate, and also that they are doing this of their own volition. An online assent process will be approved when it is appropriate for the study procedures and when the investigator has clearly defined procedures to address these two challenges.

D. **Special Populations- Non-English Speakers**

1) The consent process and the consent document should be in a language understandable by the participant
2) Verbal consent is possible but follow these guidelines and be approved by the IRB:
    a. Witness should be fluent in both English and second language
    b. Short form document (in non-English language) should be signed by participant
    c. Summary document (in English) should be signed by person obtaining consent
    d. Both documents should be signed by witness
    e. For an example of a short form document suggested by OHRP: http://www.hhs.gov/ohrp/policy/ic-non-e.html
3) When working with non-English speaking populations, at a minimum you should explain the translation process you will use for your study documents- describe who will be doing the translation and back translation and what their qualifications are.

E. **Consent for Research Studies Conducted Online**

1) *Online surveys (no investigator-participant contact*) - the IRB has developed a consent template for use in studies involving online surveys. The investigator should be clear if the data collected will be anonymous (no identifiers including IP address) or confidential. Investigators will also need to submit a request to waive documentation of consent as physical signatures will not be collected (see section H below)
2) *Online studies not involving surveys*- these may be studies using Skype, or other online platforms to interact with and collect data from participants. Because distance is not an issue with these studies, participants and investigators may never meet in person. If the study involves risk to the participants or involved study procedures the IRB may not approve waiving documentation of consent. In this case an electronic signature process can be proposed (see IRB Guidance document on electronic signature procedures)

F. **Exculpatory Language**

Consent documents cannot include exculpatory language in which participants are told they are waiving their legal rights or releasing the institution or investigator from liability. Some examples of exculpatory language include " I waive any possibility of compensation for injuries that I may receive as a result of participation in this research" and "By agreeing to this use, you should understand that you will give up all claim to personal benefit

from commercial or other use of these biological samples" (http://www.hhs.gov/ohrp/policy/exculp.html) G. Legally Authorized Representatives

This is a person who is authorized to give consent for another person. In some cases, such as individuals with diminished decision-making capability, there is often a designated legally authorized representative. In other case there may not be. Wisconsin does not have laws specific to consenting for research studies so the default legally authorized representative is often the person who is authorized to give consent on behalf of the individual for medical treatment. For questions on who is the legally authorized representative please contact the IRB office or legal affairs office.

H. Waivers related to the consent process

In order to request waiving consent, waiving elements of consent or waiving documentation of consent a "Request to Waive Obtaining/Altering/Documenting consent" must be submitted and approved by the IRB

1) *Waiver of Consent or Elements of Consent*- in certain circumstances the IRB may approve a request to waive consent or to leave out any of the required elements of consent. There are two situations described by the federal regulations where this may be approved

a. Option 1 – evaluations of public service programs conducted by or overseen by governmental officials where it would be impractical to obtain consent from the participants b. Option 2- studies that are:

i. Minimal risk; ii. Waiver of consent would not negatively affect the rights and welfare of the subjects; iii. It is impractical to obtain consent from the participants; and iv. If appropriate, the subjects will be provided with important information after the study finishes 2) *Waiver of Documentation of Consent*-this may only be approved in two situations:

a. Option 1- studies that…

i. Are minimal risk ii. Contain activities for which consent is not normally required iii. Consent information given to participants includes all required elements of consent iv. IRB will determine if subject should receive written information

b. Option 2- used for sensitive anonymous studies

i. The only record linking subject to his/her data would be consent form ii. Main risk is breach of confidentiality iii. Each subject will be asked if they want to sign a consent form and their wishes will govern

iv. All elements of consent are provided to participant orally or written

v. IRB will determine if subject should receive written information vi. Cannot be approved for FDA-regulated studies

H. HIPAA

1) *What is HIPAA?* HIPAA refers to the Health Insurance Portability and Accountability Act and address the protection of Private Health Information (PHI). HIPAA is often referred to as the Privacy Rule

2) *How does HIPAA impact informed consent in research studies?* Investigators must obtain a participant's permission to use PHI or to waive authorization for the use of PHI before beginning the study. These documents must be submitted and reviewed by the IRB before the study begins. Often investigators wish to combined informed consent document with a HIPAA authorization agreement rather than having two separate forms. For more information and templates on forms and waiver requests please visit UWM's HIPAA website: http://uwm.edu/hipaa/overview/hipaa-overview-for-researchers/