The process of obtaining informed consent must comply with the requirements of US Department of Health and Human Services, Office for Human Research Protections title 45 Code of Federal Regulations 46.116 (45 CFR 46.116). The documentation of informed consent must comply with 45 CFR 46.117. For further clarification of informed consent refer to UW-Stout IRB training or contact the UW-Stout IRB.

This is a sample signed consent. Copy and paste the following non-italicized text as appropriate. All sections need to be addressed unless otherwise noted. **DO NOT USE THIS DOCUMENT AS IS.**

**UW-Stout *SAMPLE* Signed Consent Form**

**for Research Involving Human Subjects**

**Consent to Participate In UW-Stout Approved Research**

|  |  |
| --- | --- |
| **Title:** *Place project title here* | **Research Sponsor:** *If appropriate, place your faculty advisor’s name and contact information here. If you are a faculty researcher, this may be removed* |
| **Investigator:**  *Place your name and contact information (phone number, office location).* |

**Description:**

*Include a description of the research you intend to perform. This description should contain enough detail that your subjects can make an intelligent, informed decision about their participation in your project. This will be similar to the section you filled out on the IRB protocol form.*

**Risks and Benefits:**

*Every situation comes with risks. The benefits also need to be explained, otherwise there is no reason for subjects to participate. While the benefits may not be to the subject directly, the general benefits need to be outlined. This will be similar to the section you filled out on the IRB protocol form.*

**Special Populations:**

*If your project requires the use of minors or other special populations, then the informed consent must reflect this. Any research involving minors must have informed consent addressed to the parent or guardian and include a signature line for them (see below). This section may be omitted if the service of any special population is not being requested.*

**Time Commitment and Payment:**

*Each subject should be provided with a general expectation of the commitment for completing the research. If they are to receive compensation for their time and effort, that should also be explicitly stated.*

**Confidentiality:**

*For the vast majority of projects, confidentiality is required by the UW-Stout IRB. Some statement must be made assuring the subjects of their confidentiality. For example,* “Your name will not be included on any documents. We do not believe that you can be identified from any of this information. This informed consent will not be kept with any of the other documents completed with this project”

**Right to Withdraw:**

*No one should ever feel obligated to participate or continue participation in a project with which they are uncomfortable. A typical right to withdraw statement would read,* “Your participation in this study is entirely voluntary. You may choose not to participate without any adverse consequences to you. Should you choose to participate and later wish to withdraw from the study, you may discontinue your participation at this time without incurring adverse consequences.”

**IRB Approval:**

*The following must be included on every informed consent*:

This study has been reviewed and approved by The University of Wisconsin-Stout's Institutional Review Board (IRB). The IRB has determined that this study meets the ethical obligations required by federal law and University policies. If you have questions or concerns regarding this study please contact the Investigator or Advisor. If you have any questions, concerns, or reports regarding your rights as a research subject, please contact the IRB Administrator.

|  |  |
| --- | --- |
| **Investigator:** *Place your name, phone number, and email address here.* | **IRB Administrator**  Elizabeth Buchanan, Research Services  152 Vocational Rehabilitation Bldg.  UW-Stout  Menomonie, WI 54751  715.232.2477  irb@uwstout.edu |
| **Advisor:** *Place your advisor’s name, phone number, and email address here.* |

**Statement of Consent:**

*This section should include the language,* “By signing this consent form you agree to participate in the project entitled, ***(INSERT PROJECT TITLE HERE)***.”

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Signature Date

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of parent or guardian Date

(If minors are involved)