Brief Summary of Investigator Responsibilities Related to the Protection of Human Subjects for Exempt Research

All University of Wisconsin-Madison faculty, staff, students, and agents of the institution are required to submit for Institutional Review Board (IRB) review any research project involving human subjects. Human subjects research includes a wide range of activities, including clinical trials, the collection or use of specimens obtained from human subjects, survey and interview research, research involving medical records, and the creation of databases for research purposes. By campus policy, human subjects research that may qualify for exemption from IRB review must nonetheless be submitted to an IRB for a determination regarding the appropriateness of an exemption.

Some of the responsibilities that researchers assume when conducting exempt research involving human subjects include, but are not limited to, the following:

- **Complying with the principles of the Belmont Report and Institutional Policy.** Exempt human participants research cannot begin until an IRB has notified the study team in writing that the research qualifies as exempt. Following a UW-Madison IRB’s determination that a study is exempt, study teams must conduct the study in a manner that maintains the ethical standards under which the IRB made the exempt determination. In addition, the University of Wisconsin’s Federalwide Assurance with the U.S. Department of Health and Human Services, Office for Human Research Protections states that all human subjects research activities will be guided by the ethical principles outlined in the Belmont Report and the Common Rule. Investigators should become familiar with these principles and regulations to ensure that their research complies with such principles and regulations. Failure to comply with these principles can place both subjects and the institution at risk.

- **Completing required human subjects protection training.** The University of Wisconsin requires all key personnel on a human subjects protocol to complete the online Human Subjects Protection Training Module (https://my.gradsch.wisc.edu/citi/index.php) and any relevant HIPAA Privacy Rule training. It is the responsibility of the principal investigator to ensure that all key personnel on a protocol have completed required training related to research involving human subjects.

- **Complying with the campus Conflict of Interest Policy.** Investigators are required to file an Outside Activities Disclosure prior to the submission of a protocol to an IRB for review and keeping these disclosures current. Additionally, investigators must comply with the campus Conflict of Interest policies related to human subjects research.

- **Providing adequate training to and oversight of study personnel.** Although principal investigators may delegate research responsibilities to others, they retain ultimate responsibility for the conduct of those to whom they delegate research responsibilities. Investigators are responsible for certifying that key personnel have received adequate training to ensure they are aware of the regulations governing human subjects research.

- **Obtaining informed consent, when required as a condition of exemption.** If a consent and process was accepted as part of the IRB’s exemption determination, the study team is expected to conduct a consent process appropriate to the research.

- **Obtaining permission for the use and disclosure of protected health information in compliance with the HIPAA Privacy Rule.** As of April 14, 2003, all researchers who are part of the University of Wisconsin Health Care Component (HCC) or collaborating with someone within the HCC and who are using or disclosing protected health information (PHI) must obtain written permission (i.e., an authorization) from patients for the use of the PHI or obtain a waiver of authorization from an IRB regardless of whether the human subjects research is determined to qualify for exemption.

- **Obtaining IRB sign off on substantive changes of protocol to ensure the category(ies) of exemption continues to be appropriate.** Submitting substantive changes to the study to the IRB for review in order to confirm the exemption status. Changes that are likely substantive include, but are not limited to, those that:
  - Increase the risk to participants or change the risk:benefit ratio of the study
  - Could affect a participant’s willingness to participate in the study
  - Add study procedures or study components not covered by the Exemption Category (listed above) determined for this study, such as revisions to subject identification and recruitment procedures
  - Alter the study population
  - Add tools or instruments that are not largely similar to those already reviewed by the IRB
- Modify how study data or biospecimens are transmitted or stored
- Involve the collection of additional data or biospecimens from subjects, especially information that could be sensitive
- Allow sharing subject data or biospecimens with collaborators not previously identified
- Update the Principal Investigator
- Update the study sponsor
- Add a non-UW site
- Add a new source of data or biospecimens
- Alter the financial conflicts of interest relevant to the study
- Alter the meaning of applicable consent document(s) or change the nature of subject participation

Contact the ED/SBS IRB Office if you are unsure whether your changes are substantive and require submission to the IRB for review.

- **Reporting unanticipated problems and complaints related to the research that cannot be resolved by the study team to the IRB.** Federal regulations and institutional policies require that investigators report to the IRB any unanticipated problems that pose risks to subjects or others or complaints from study participants or others that the study team cannot resolved. These should be reported to the IRB in accordance with the campus unanticipated problems policy.

- **Submitting a final report to the IRB.** When the research is completed, investigators are expected to submit a *Study Closure Report*. After five years, exempt studies may be administratively closed by the IRB, unless the study team indicates that the study is ongoing.