

University of Wisconsin - Madison

Collaborating Investigator Responsibilities Summary

(For use in non-federally funded multisite research projects. Provide copy of summary to each non-UW- Madison collaborator listed on your protocol, as per [IRB Reliance Policy.](#))

UW-Madison strongly encourages non-UW-Madison investigators collaborating on UW-Madison human subjects protocols to review the Belmont Report, the Common Rule, the UW-Madison's Federalwide Assurance (FWA) and the corresponding Terms of Assurance, and well as UW-Madison's institutional policies for the protection of human subjects.

Those documents are available at the websites listed herein:

- (a) The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research (<http://www.hhs.gov/ohrp/policy/belmont.html>),
- (b) The Common Rule (<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html>),
- (c) UW-Madison's Federalwide Assurance (FWA) (<https://kb.wisc.edu/gsadminkb/page.php?id=34048>) and the applicable Terms of the FWA (<http://www.hhs.gov/ohrp/assurances/assurances/filasurt.html>), and
- (d) The relevant UW-Madison institutional policies for the protection of human subjects (<https://kb.wisc.edu/gsadminkb/page.php?id=34101>).

UW-Madison requires that collaborating investigators comply with the standards and requirements stipulated in the above documents and to protect the rights and welfare of human subjects involved in research. Additionally, UW-Madison requires that collaborating investigators:

- (1) Comply with all other applicable federal, international, state, and local laws, regulations, and policies that may provide additional protection for human subjects participating in research conducted under this agreement.
- (2) Abide by all determinations of the UW-Madison Institutional Review Board (IRB) that reviews and approves the research project and accept the final authority and decisions of the IRB, including but not limited to directives to terminate participation in designated research activities.
- (3) Complete any educational training required by UW-Madison and/or the IRB prior to initiating research in collaboration with UW-Madison employees.
- (4) Report promptly to the IRB any proposed changes in the research and obtain IRB approval before initiating any changes in the research, except where necessary to eliminate apparent immediate hazards to subjects.
- (5) Report immediately to the IRB any unanticipated problems involving risks to subjects or others in the research.
- (6) When responsible for enrolling subjects, obtain, document, and maintain records of informed consent for each such subject or each subject's legally authorized representative to the extent required under the Common Rule and as stipulated by the IRB.
- (7) Cooperate with the IRB in its responsibility for initial and continuing review of research, record keeping, reporting, and certification of the research by providing all information requested by the IRB in a timely fashion.
- (8) Obtain IRB approval before enrolling subjects in research.