Any individual who is involved in conducting a human subject research study that is under the jurisdiction of the Michigan State University (MSU) Human Research Protection Program (HRPP) is responsible for carrying out sound ethical research consistent with research plans approved by an Institutional Review Board (IRB), following MSU policies and procedures, and complying with all applicable laws and regulations.

These responsibilities extend to individuals (e.g., all investigators, research staff, employees, students) engaged in conducting human subject research. The responsibilities listed below summarize the requirements detailed in other sections of the HRPP Manual and federal regulations.

These responsibilities include, but are not limited to:

1. Obtain required training on human subject research prior to commencing any research activities that involve human subjects or their identifiable private data. See HRPP Manual 11-1-A “Education: Investigators and Research Staff.”

2. Disclose financial conflicts of interest. See HRPP Manual 10-1 “Conflict of Interest.”

3. Obtain IRB approval or an exempt determination before involving human subjects in research. This is generally a responsibility of the Principal Investigator (PI). See “PI Responsibilities” section below. However, it applies to all individuals, including graduate students conducting human subject research for their thesis, dissertation, or medical education requirement. See HRPP Manual 9-2 “Noncompliance.”

4. Use recruitment processes that are fair and equitable. See HRPP Manual 6-5 “Selection of Subjects and Recruitment.”

5. Obtain and document informed consent of subjects or subjects’ legally authorized representatives prior to the subjects’ participation in the research, unless these requirements have been waived by the IRB. See HRPP Manual 6-4-A “Informed Consent: Documentation of Informed Consent.”
6. Monitor research subjects for potential harm and take steps to minimize or mitigate those harms when possible. See HRPP Manual 6-7 “Data and Safety Monitoring” and 9-1 “Unanticipated Problems Involving Risks to Subjects or Others.”

Report any activities or circumstances that affect the rights and/or welfare of research subjects, including subject complaints or questions, directly to the IRB or to the PI. See HRPP Manual 4-8 “Reporting Policy.”

7. Report suspected or confirmed non-compliance to the IRB. Mechanisms for reporting include written notice (207 Olds Hall, East Lansing, MI 48824), electronic notice (irb@msu.edu), or by phone (517-355-2180). See HRPP Manual 4-8 “Reporting Policy.”

8. Maintain, manage, and retain research data and records relating to the research as required by applicable policies and regulations. See HRPP Manual 4-7 “Record Keeping” and MSU guidelines on “Research Data: Management, Control, and Access.”

9. Contact the IRB if there are any questions about whether an activity involves human subject research. See HRPP Manual 4-1 “Determination of Human Subject Research.”

**Principal (Responsible) Investigator Responsibilities:**
PIs have additional responsibilities for the oversight and conduct of human subject research studies, including hiring qualified staff, ensuring that the staff have current training on ethical human subject research and applicable rules, following the IRB-approved research study, promptly reporting any non-compliance and unanticipated problems, maintaining IRB approval throughout the duration of the research, and being involved in or maintaining oversight of the recruitment, consent, and research procedures. See HRPP Manual 4-9 “Principal Investigator” for who can be a PI on human research study.

Specific responsibilities of PIs include, but are not limited to:

1. Ensure that individuals conducting human subject research (e.g. research staff) receives appropriate training prior to contact with research subjects or their identifiable private information. See HRPP Manual 11-1-A “Education: Investigators and Research Staff.”

2. Maintain adequate and appropriate oversight over the conduct of the research study. Co-investigators and other members of the research team must adhere to appropriate policies and ethical standards related to the protection of human subjects. The PI is held responsible for the conduct of the research personnel (e.g. co-investigator, investigators, research staff).
3. Use sound scientific study design in the research protocol and obtain peer review of the research study as appropriate, e.g., thesis committee review, sponsor peer review, academic unit review. See HRPP Manual 6-2-A “Minimization of Risks: Sound Research Design.”

4. Use research designs that protect human subjects' privacy and confidentiality of their information appropriately. See HRPP Manual 6-6 “Privacy, Confidentiality, and Anonymity.”

5. Ensure that adequate resources are available to protect human subjects during the proposed research. See HRPP Manual 6-2-B “Minimization of Risks: Adequate Resources.”

6. Obtain IRB approval or an exempt determination before involving human subjects in research.
   a. Submit an application to the MSU IRB and obtain IRB approval of any planned activity that meets the definition of research involving a human subject (DHHS regulations 45 CFR 46), or the definition of clinical investigation involving a human subject (FDA regulations 21 CFR 50 and 56). See HRPP Manual 4-3 “Determination of Human Subject Research.”
   c. Submit an application to the MSU IRB for a determination of any human subject research that may be exempt. See HRPP Manual 8-1 “Exemptions.”

7. Report any of the following to the MSU IRB (see HRPP Manual 4-8 “Reporting Policy”):
   a. Any unanticipated problems involving risks to subjects or others. See HRPP Manual 9-1 “Unanticipated Problems Involving Risks to Subjects or Others.”
   b. Any potential or confirmed non-compliance with the regulations or the requirements or determinations of the IRB. See HRPP Manual 9-2 “Noncompliance.”
   c. Emergency use of investigational drugs or devices. See HRPP Manual 7-3 “Emergency Use of Investigational Drugs and Devices.”
   d. Premature completion of the study, completion of the study, or closure of the research. See HRPP Manual 8-9 “Closure.”
e. Any modifications, information, or unexpected or adverse events that would increase the risk or change the status of a study determined exempt by the IRB. See HRPP Manual 8-1 “Exemptions.”

f. Any subject complaints, including exempt studies. See HRPP Manual 9-4 “Subject Complaints.”

g. Any other circumstance that affects the rights and/or welfare of research subjects.

8. Obtain prior approval from the IRB for any modifications of the previously approved non-exempt research, including modifications to the informed consent process and document, except those necessary to eliminate apparent immediate hazards to subjects. See HRPP Manual 8-6 “Revisions to an Approved Research Study.”

9. Submit an application for renewed approval to the IRB for non-exempt research (i.e., progress reports, data safety or monitoring reports, activities, events, and/or information) as requested and in sufficient time to allow for IRB review prior to the expiration date of current approval. See HRPP Manual 8-7 “Renewed Approval.”

10. Keep records relating to the research as required by MSU and applicable regulations after completion of the research study, for a minimum of three to six years depending on funding agency and type of record. This requirement also applies to research records for student research conducted under the supervision of the PI. See HRPP Manual 4-7 “Record Keeping” and MSU guidelines on “Research Data: Management, Control, and Access.”