The descriptions provided below are intended to indicate the kinds of responsibilities of the Human Research Liaison office staff. The descriptions shall not be construed as declaring what the specific duties and responsibilities of any particular person or position shall be. It is not intended to limit or in any way modify the right of any supervisor to assign, direct, and control the work of employees under his or her supervision. The use of a particular expression or illustration describing duties shall not be held to exclude other duties not mentioned that are of similar kind or level of difficulty. The descriptions are not intended to limit or displace applicable Michigan State University Human Resources policies and procedures for employment.

The manager of the Human Research Liaison office shall:

1. Manage daily operations of the Human Research Liaison office to assure that human research studies are conducted in a manner that is in compliance with regulatory requirements, policies, and procedures for human subject research.

2. Supervise the human research liaison staff.

3. Develop a flexible monitoring plan and work with the Human Research Protection Program (HRPP) to set site visit priorities.

4. Oversee coordination of site visits of human research liaisons to human research investigator labs, offices, and facilities.

5. Review written reports generated by human research liaison staff.

6. Provide status reports to the HRPP and identify areas that may require education or corrective action across multiple departments or units.

7. Participate in site visits as needed, including conducting site visits to human research labs, reviewing compliance with approved human research protocols, interviewing researchers involved with human research procedures, inspections of facilities for compliance, reviewing standard operating procedures (SOP), and training researchers.
8. Coordinate monitoring efforts of Institutional Review Board (IRB) activities to assure compliance with regulatory requirements, policies, and procedures for human subject research.

9. Review internal monitoring findings of the HRPP and the IRB and provide recommendations for corrective actions to the HRPP and IRB as appropriate.

10. Serve as a resource for researchers regarding regulatory requirements and university policies and procedures for conducting human research.

11. Prepare and present reports to the HRPP director regarding recent activities.

12. Coordinate oversight activities related to clinical research including U.S. Food and Drug Administration (FDA) regulations and requirements for investigational uses of new drugs and devices.

13. Interact and communicate with MSU units also involved in human research compliance areas such as the Office of Sponsored Programs, Pharmacy, etc.

14. Perform other projects or tasks as assigned.

The human research liaisons shall:

1. Conduct site visits to investigator labs, offices, and facilities where human research is conducted, review compliance with approved human research protocols, interview researchers involved with human research, inspect facilities for compliance, and review SOP's, regulatory binders, study related materials, and training records.

2. Generate written reports with results of site review and identify strengths and deficiencies or deviations from federal regulations, university policy, or Good Clinical Practice.

3. Review approved protocols to assess information prior to site visit. Compile and collate data from each site into reports and supply a copy of reports to HRPP and / or IRB as appropriate.

4. Assist researchers in developing corrective measures after discussion with HRPP and the IRB, as appropriate.

5. Conduct follow-up site visits to verify implementation of corrective measures.

6. Perform internal monitoring of the HRPP and IRB to assure compliance with the federal regulations, state laws, university requirements, and accreditation standards for human research.
7. Serve as a resource for researchers regarding regulatory requirements and university policies and procedures for conducting human research.

8. Perform oversight activities related to clinical research including FDA regulations and requirements for investigational uses of new drugs and devices.

9. Train or provide training resources to researchers on human research regulations, policies, and procedures.

10. Advise HRPP and the IRB as appropriate of unresolved discrepancies/non-compliance related to protocol procedures and documentation.

11. Participate in noncompliance investigations as requested.

12. Perform other projects or tasks as assigned.