Only certain persons may be designated as the Principal Investigator (PI) on a human subject research study. These include Michigan State University (MSU) regular faculty, emeritus faculty, and fixed term faculty employees with rank of assistant professor or higher. Students, staff, and individuals holding other appointment titles, such as research associate, specialist, post-doctoral fellow, visiting, adjunct, or clinical faculty, may be designated on the MSU Institutional Review Board (IRB) application as an additional investigator, but not as the PI. Exceptions to this general requirement are outlined in the “Exceptions” section below. In the case of graduate student research for theses or dissertations, the student’s major advisor or another faculty member should be designated on the MSU IRB application as the PI and the graduate student as an additional investigator.

When an individual accepts the role of PI on a human research study, s/he accepts the responsibility for the proper execution of the research and is accountable for the conduct and oversight of the study. The IRB does not have a specific limit on the number of research studies for which an individual may accept the role of PI since there are many factors to consider in addition to the number. However, an individual should not accept the role of PI unless s/he has the time, effort, and ability to maintain adequate oversight over the conduct of the study. This oversight includes, but is not limited to, protecting the rights and welfare of research subjects, overseeing the conduct of personnel, complying with relevant standards and policies, and maintaining adequate resources to fulfill these commitments. See HRPP Manual 4-6 “Responsibilities of Investigators.” The PI is responsible for assessing his/her overall workload and resources and determining whether s/he has the needed time, effort, and ability to appropriately oversee the study. The IRB, on a case-by-case basis, may assess the number of open studies in which an individual is the PI. Assessments should include, but not be limited to, information about studies with active enrollment (e.g. number of research staff, local subject enrollment, complexity of the research studies, risk level, number of studies), the PI’s role on other human research studies, and time commitment to other university activities.

Exceptions
Only under special circumstances and with approval may an MSU individual (e.g., director, specialist) who is not MSU regular faculty, emeritus faculty, or fixed term faculty employee with a rank of assistant professor or higher serve as the PI on a human subject research study. In these special circumstances, the individual may
become a “waived PI” with the IRB if the request is approved. Requests for waived PI status should be sent to the IRB.

Waived PI status may be granted with the recommendation from the dean and chair (or director) of the faculty member, pursuant to the following conditions that the individual must meet:

1. Have the necessary experience and independence to be approved to serve as the PI.
2. Submit a current curriculum vitae.
3. Obtain a written recommendation from the department chair or academic director as appropriate, and the dean.

Once the Institutional Official (IO) or designee (e.g. IRB chair) has granted waived PI status, the PI does not need to reapply for each research study.

When MSU is the primary awardee and a non-MSU performance site is conducting the majority of the human subject research, in very limited situations when advance arrangements have been made and approved, a non-MSU individual may be the PI on the MSU IRB application. These requests are reviewed and approved by the IO or their designee. The designation of a non-MSU individual as a PI shall be limited to the particular research study.

No individual who requests or has obtained waived PI status may serve as the PI on the study if the research is to satisfy their master's thesis or Ph.D. dissertation requirement.