

Investigators can include physicians, scientists, nurses, administrative staff, teachers, and students, among others. Some research projects are conducted by more than one investigator, and usually one investigator is designated the “principal investigator” (PI) with overall responsibilities for the project. In every human subject research project, investigators have certain responsibilities regarding the ethical treatment of human subjects. (45 CFR 46)

Investigator (Food and Drug Administration (FDA)) – The FDA defines investigator as an individual who actually conducts a clinical investigation, i.e., under whose immediate direction the test article is administered or dispensed to, or used involving, a subject, or, in the event of an investigation conducted by a team of individuals, is the responsible leader of that team. (21 CFR 50.3 (d))

POLICY:

1. In accordance with *Corporate SOP: Principal Investigator Eligibility (RS.GN.160)*, individuals who meet the eligibility requirements described may be identified as Principal Investigator on MCW human subject research projects.
 - a. Residents and fellows may not serve as PI on projects. They may be co-Investigators collaborating with an eligible MCW PI.
 - b. Individuals with the rank of Visiting Professor, Visiting Associate Professor and Visiting Assistant Professor are not eligible to serve in the PI role, nor are Volunteer (unpaid) Faculty, postdocs, or graduate students.
2. **Eligibility Requirements to be Principal Investigator for human subject research:**
 - a. **Faculty** – Individuals with the faculty rank of Professor, Associate Professor, Assistant Professor and Instructor who are employed by MCW Full-Time or with Full Professional Effort are eligible to serve as PI for human subject research projects.
 - i. Individuals with the rank of Emeritus professor who were previously employed by MCW with the faculty rank of Professor, Associate Professor, Assistant Professor and Instructor will remain eligible.
 - b. **CTSI Consortium** - Individuals with the rank of MCW Adjunct Professor, MCW

- i. Individuals in this category must be a physician, hold a medical appointment at Froedtert West Bend Hospital, and receive designation

REFERENCES:

45 CFR 46

21 CFR 50.3 (d)

SUPPORTING DOCUMENTS:

MCW Corporate SOP: Principal Investigator Eligibility (RS.GN.160)

IRB SOP: Reliance Agreements for Multi-Site Projects

IRB SOP: Human Subject Research Protections Training Requirements

Effective Date:

07/01/2023