

1.5 INVESTIGATOR POLICY (PI AND CO-I)

This policy applies to any individual requesting to use the EVMS IRB for review of humans subject research or determinations of Not Research and Not Human Subject Research. Effective for any submission receiving final approval or determination on or after March 1, 2024.

1.5.a WHO MAY SERVE AS A PRINCIPAL INVESTIGATOR ON EVMS IRB APPLICATIONS?

- Individuals with an EVMS faculty appointment, full-time or adjunct.
- EVMS Senior Administrators may be named as PI on projects directly related to the mission and responsibilities of their offices.
- Physician and Nurse providers with CHKD or Sentara who do not have an EVMS faculty appointment.
- Other CHKD and Sentara employees regardless of whether EVMS is involved in the study.

PRINCIPAL INVESTIGATOR REQUIREMENTS
• Qualified by training and experience
• Responsible for the study design
• Experience with the proposed participant population
• Experience with the proposed procedures and methodology
• Exercises oversight and is responsible for all financial, technical, ethical, professional, and regulatory compliance aspects of the project
• Must have adequate time for study oversight, regardless of delegation of activities, to ensure the responsible conduct for the whole of the study
• Bear ultimate responsibility for the conduct of their human subjects research (HSR) studies and for the safety of all human subjects participating in such studies
• Responsible for properly training research staff in activities or procedures required for the research itself, and ensuring completion of the required CITI training, before involving individuals in the conduct of the investigation

For studies involving **EVMS trainees**, the role of Principal Investigator **must** be held by an **EVMS faculty member**. There are no exceptions.

1.5.b INDIVIDUALS INELIGIBLE TO APPLY AS PRINCIPAL INVESTIGATOR

- EVMS Medical Students.
- EVMS Health Professions students .
- EVMS Fellows and Residents.
- EVMS staff who are not Senior Administrators or who are not working on projects directly related to their office/oversight.
- Trainees in any residency, fellowship, or other program outside of EVMS.
- Undergraduate, graduate, and post-doctoral students from any institution.
- Volunteers.

While the above individuals are ineligible to serve as the Principal Investigator on an EVMS IRB application they may potentially serve as a co-investigator provided their study responsibility aligns with the assigned level of accountability.

1.5.C WHO MAY SERVE AS A CO-INVESTIGATOR ON EVMS IRB APPLICATIONS?

CO-INVESTIGATOR REQUIREMENTS
• Must have substantial intellectual contributions to the project. Individuals who are performing their job activities are not necessarily a co-investigator;
• Conduct aspects of a project that require their unique expertise*;
• Be intimately involved in the manuscript process: drafting, revising, and final approval of the version to be published; and
• Responsible for contributing to research design and study oversight, including compliance.

*For trainees, provide information within the written protocol regarding applicable coursework and hands-on experience that corresponds to their research responsibilities.

Anyone who does not meet the Principal or Co-Investigator qualifications above may serve as a Research Team Member, Study Coordinator, or other appropriate role.

Final designation of an individual's appropriate role will be determined by the reviewing IRB and must meet all requirements noted in this policy.