A. GENERAL OVERVIEW

This policy defines who is eligible to serve as a Principal Investigator (PI) for applications submitted to the Kent State University Institutional Review Board (IRB). This policy reaffirms the administrative policy regarding research involving human subjects (3-03.2) and the policy on PI eligibility for submission of proposals to external funding agencies (3-04.1 (C)(4)) as set out in the KSU Policy Register.

Investigators are responsible for the ethical conduct of human subjects research and for compliance with federal regulations, applicable state and local laws, and university policies. Investigators should also consider the applicable professional practice standards of their disciplines and other generally accepted good research practice guidelines in the development and performance of human research studies. These responsibilities are shared with investigators' research staff and the university's human subject research protection program, including the IRB.

B. DEFINITIONS

Principal Investigator (PI) – In accordance with guidance published from the Office of Human Research Protections (OHRP) the PI has overall responsibilities for studies involving human subjects.

Investigator(s) - an individual performing various tasks related to the conduct of human subjects research activities, such as obtaining informed consent from subjects, interacting with subjects, and communicating with the IRB.

C. PRINCIPAL INVESTIGATOR ELIGIBILITY, QUALIFICATIONS, AND OVERSIGHT FOR RESEARCH INVOLVING HUMAN SUBJECTS

1) For purposes of the IRB application, only one individual is designated as the PI of a human subjects research study.
2) Only faculty members and professional staff who are full-time university employees are eligible for PI status.
3) Kent State full-time employees, who may otherwise be eligible to be considered for PI status, cannot serve as a PI for a research protocol involving human subjects when they are conducting the research project as partial fulfillment of their graduate student obligations or training. When Kent State employees wish to conduct research involving human subjects as part of their graduate or undergraduate program, their faculty advisor must serve as the PI of record for IRB protocols.
4) Students conducting research for their dissertation or master's thesis research can still have primary responsibility for the intellectual content, conduct of the research, or primary authorship in publications by serving as co-investigators or key personnel on IRB applications.

5) The PI for a study must possess the appropriate scientific and/or scholarly training and expertise to assume direct responsibility for the ethical conduct of a study involving human subjects, provide technical and administrative oversight of the research, and make important study-related decisions, including:
    - Protecting the rights and preserving the safety and welfare of subjects and prospective subjects.
    - Ensuring that current laws, regulations, procedures, and guidelines are observed by all researchers/staff involved in the conduct of the project.
    - Selecting and training of individuals who may assist with the research and obtaining IRB approval for the involvement of (and any changes in) co-investigators and key personnel. Training of study personnel should ensure that staff are familiar with the research methods and objectives (as applicable), as well as study-specific information relevant to the tasks to be performed.
    - Ensuring that all research involving human subjects receives IRB review and approval before commencement of the research.
    - Ensuring that all members of the research team comply with the findings, determinations, conditions, and requirements of the IRB.
    - Ensuring that the parameters of the protocol are followed in the conduct of the study, including adhering to inclusion/exclusion criteria, number of subjects recruited, etc.
    - Ensuring that studies receive timely continued review and approval.
    - Obtaining prior IRB approval of changes to the protocol, consent forms or recruitment strategy, except where necessary to eliminate immediate apparent hazards to subjects.
    - Discontinuing all research study activities at the end of the IRB-designated approval period.
    - Reporting to the IRB promptly any unanticipated problems involving risks to subjects or others involved in the study, and any serious adverse events (SAEs) that are either unanticipated or anticipated.
6) In extenuating circumstances, an individual who is not a full-time employee may serve as the PI on an IRB application. Such cases must be approved by the chair of the department/institute or center director, or regional campus dean from which the application is submitted.