



Institutional Review Board - Human Research Protection Procedure

Persons wishing to conduct human research at Polk State College must first submit an Institutional Review board (IRB) Research Protocol Submission Form for approval. After approval has been received, investigators must comply with the Investigator Responsibilities listed below and with all Polk State College policies and procedures (as well as with all applicable federal, state, and local laws regarding the protection of human subjects in research).

Investigator Responsibilities

1. Obtain IRB approval prior to involving any human subjects (including their data) in research studies. (Only the IRB may determine if research is exempt from federal regulations; investigators may not make the final determination of exemption.)
2. Ensure that only qualified personnel conduct the study according to the approved protocol, in compliance with each individual's scope of practice.
3. Ensure the rights and welfare of each research participant. The participant's rights and welfare must take precedence over the goals and requirements of the research.
4. Implement no changes in the approved protocol or Participant Informed Consent Form without prior IRB approval, except in an emergency, if necessary to safeguard the well-being of human subjects.
5. Ensure that anyone obtaining informed consent has read the protocol and has sufficient knowledge of all information provided in the informed consent document.
6. Obtain legally-effective informed consent from human participants or their legally responsible representative before any research-related screening or intervention commences, using only the currently-approved Participant Informed Consent Form.
7. Provide each participant enrolled in the study a copy of the IRB-approved informed consent document at the time of the consent, unless the IRB has specifically waived this requirement.
8. Unless specified otherwise, retain all signed informed consents and other research-related documents (including but not limited to paperwork submitted to and approved by the IRB) throughout the study and for an additional three years after the study is completed/closed with the IRB.
9. Promptly report any injuries or unanticipated problems to the IRB in writing within five (5) working days of occurrence or discovery of occurrence.
10. Report progress of approved research to the IRB in the manner prescribed by the IRB.

11. Ensure that the American Psychological Association's (APA) ethics code and record keeping guidelines are applied, and that the respective federal and state guidelines are followed.
12. If unavailable to conduct or direct this research personally for a period exceeding fourteen (14) calendar days (as when on sabbatical, leave, or vacation), notify the IRB Chair in writing in advance of the absence, indicating arrangements made for a co-principal investigator to assume research-related responsibilities in the principal investigator's absence.
13. Internal Investigators only: In the event that employment with Polk State College is discontinued, complete one of the following with each approved/active protocol prior to the last day of employment: (1) transfer the study to a new principal investigator, or (2) close the project. These changes must be sent in writing to the IRB Chair. This notification must be submitted at least two (2) weeks prior to the end of employment.
14. Exemption from Polk State College IRB review does not exempt the principal investigator or co-principal investigator from compliance with all applicable institutional, federal, state, and local rules, regulations, policies, and procedures.

Because Polk State College does not typically conduct medical research, this list of responsibilities does not include any references to medical or health-related research activities. Such research projects require special IRB review because they are subject to additional requirements above and beyond those addressed in the standard Polk State College IRB process. Therefore, investigators must contact the IRB Chair to seek approval for protocols related to medical research.

If you have any remaining questions about Polk State College's IRB process, contact the IRB chair at mclark@polk.edu.