

Requirements for Obtaining Letters of Cooperation/Approval from Collaborating Institutions

Background

Research with human subjects often involves collecting data from persons through their affiliation with an institution (e.g., students/staff in schools or universities, patients/staff in medical clinics, employees in a workplace, etc.). Obtaining approval or permission prior to conducting research with individuals within the institution helps establish or maintain collegial relationships between ISU researchers and these institutions. It may also be required by the collaborating institution's policies. Evidence of permission is required during the IRB review process when deemed necessary to ensure protection of human research participants. This document outlines requirements for obtaining letters of cooperation/approval from outside institutions in which ISU research is conducted.

Guidance

Investigators are responsible for ensuring that adequate permission is obtained from each institution in which research will occur, *in accordance with that institution's policies and procedures*. Normally, this requires identifying the individual or entity with sufficient authority to grant permission for research to take place in the institution. Investigators should also be aware that IRB approval means that the research plans meet the requirements of federal regulations and ISU policies governing human subjects research. *IRB approval at ISU in no way implies or guarantees that permission from other institutions will be granted.*

Investigators are expected to maintain documentation of permission in their files. Documentation of permission will be required during IRB review in the following cases:

- **Research conducted in prisons:** Documentation of permission from prison officials must be included with submitted IRB applications. The approval/permission documentation should address the requirements outlined in the IRB's guidance on [Research Involving Prisoners](#).
- Any other situations when the IRB determines that obtaining permission is necessary to ensure that regulatory criteria for approval (per 45 CFR 46.111) are met (e.g., that risks are sufficiently minimized, informed consent is obtained without coercion or undue influence, adequate safeguards are in place for vulnerable populations, etc.).

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