KEWEENAW BAY OJIBWA COMMUNITY COLLEGE
POLICIES & PROCEDURES

Department: College-wide	**Reference:** 45 CFR 46 – Protection of Human Subjects; OHRP IRB Registration Requirements
Program: Academic or Institutional Research	**Faculty Council Approval:** October 13, 2010; June 8, 2025 (update); September 8, 2025 (update)
Subject: Institutional Review Board	**Board of Regents Approval:** June 22, 2011; September 8, 2025

1. Purpose and Authority

The Keweenaw Bay Ojibwa Community College (KBOCC) Institutional Review Board (IRB) ensures the protection of the rights, welfare, and dignity of human research participants in research.

The IRB operates under KBOCC's Federal wide Assurance (FWA) with the U.S. Department of Health and Human Services (HHS) and is registered with the Office for Human Research Protections (OHRP).

All federally funded research involving human participants must receive IRB review and approval before initiation.

The IRB has authority to approve, require modifications, disapprove, suspend, or terminate research projects.

2. Scope of Review

The IRB reviews research projects involving human participants, institutional research involving identifiable private data, classroom and service-learning projects, program evaluations involving human data, and research involving identifiable recordings.

Exempt projects, which do not involve human subjects or identifiable data, may be designated following preliminary screening.

3. Registration and Compliance

The IRB is registered with OHRP and operates under KBOCC's FWA.

The IRB will update its registration within 90 days of any changes to membership, Chairperson, institutional contact, or FWA status.

The IRB Chairperson and institutional contact will be designated and kept current.

4. IRB Membership

The IRB shall have at least five members with diverse backgrounds and expertise.

Membership will include:

- At least one member whose primary concerns are in scientific areas.
- At least one member whose primary concerns are in nonscientific areas.
- At least one unaffiliated member not employed by KBOCC and not an immediate family member of an affiliate.
- Representation of both men and women.
- At least two members who are tribal members or descendants of the Keweenaw Bay Indian Community.
- When applicable, expertise in Ojibwa culture for culturally relevant research.

Conflicts of interest must be disclosed, and affected members will recuse themselves from reviews. The IRB will elect or appoint a chairperson identified in OHRP registration. All members must complete human subjects' protection training.

5. Procedures for Submission and Review

5.1 – Submissions:

A Request for IRB Review or Exemption must be submitted to the President or the Faculty Council at least 2 weeks prior to the needed decision date. Additional time should be allowed for proposals requiring external expertise.

A brief summary is sufficient for exemption consideration and must include a justification for exemption (e.g., no human subjects, no identifiable data).

For projects requiring full IRB review, materials must be submitted at least 2 weeks before the decision date and include the following:

- Project title and summary
- Project personnel and contact information
- Description of research procedures
- Sample research materials (surveys, interview scripts, etc.)
- Procedures for anonymity, confidentiality, or acknowledgment
- Consent forms and consent/debriefing scripts (if human subjects are involved)
- Letters of permission from other institutions or agencies (if applicable)

5.2 Determinations:

The IRB will evaluate each submission to ensure that the project protects the rights and welfare of participants and meets ethical standards

Projects may receive one of the following determinations:

- **Exempt** – No IRB review required. The project does not involve human subjects or private data. Confirmation of exemption will be provided in writing.
- **Approved** – Full review completed; project may proceed as presented.
- **Conditional Approval** – Minor revisions required; project may proceed after revisions.
- **Revise and Resubmit** – Significant revisions needed; project must be re-reviewed.

- **Denied** – Project may not proceed under KBOCC auspices. A written explanation will be provided.

5.3 Appeals:

Appeals may be made to the President or Faculty Council.

5.4 Expedited Review:

In accordance with Federal code 63 FR 60364-60367 and 45 CFR 46.110, certain research projects may be eligible for an expedited review if they involve no more than minimal risk to human participants. Such research may include studies on individual or group characteristics or behavior, or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

Expedited reviews may be conducted by the IRB Chairperson or by one or more experienced IRB members designated by the Chair. The expedited reviewer(s) may approve the research or request modifications. If the reviewer does not believe the research is approvable, the proposal will be referred to the full IRB for consideration.

5.5 Continuing Review:

Research projects involving more than minimal risk are subject to continuing IRB review at intervals determined by the IRB, but no less than once per year, in accordance with 45 CFR 46.109(e). Investigators must submit a Continuing Review/Progress Report before the expiration of IRB approval. Failure to obtain renewed approval will result in the suspension of the project.

Projects qualifying for expedited review or exemption under the 2018 Common Rule may not require annual continuing review. The IRB will indicate this determination in writing at the time of initial approval.

Any unanticipated problems, adverse events, or protocol deviations must be reported to the IRB immediately, regardless of review cycle.

6. Informed Consent

Informed consent must be obtained and documented unless waived under 45 CFR 46.116. Consent forms must include purpose, procedures, risks, benefits, confidentiality protections, voluntary participation, and contact information. Additional protections apply for vulnerable populations (children, prisoners, pregnant women, decision-impaired individuals).

7. Record Keeping

The IRB will maintain membership rosters, meeting minutes, research protocols, consent documents, correspondence, and determination records.

Records will be retained for at least three years after completion of study in compliance with 45

CFR 46.115.

8. Reporting Obligations

The IRB will promptly report to OHRP, federal sponsors, and institutional leadership any serious or continuing noncompliance, suspensions, terminations, or unanticipated problems involving risk to subjects or others.

9. Training and Education

All researchers conducting human subjects research at KBOCC must complete training in research ethics and compliance (e.g., CITI Program or equivalent). IRB members will participate in ongoing training and professional development to remain current with regulatory requirements.

10. Tribal and Community Considerations

The IRB acknowledges the sovereignty of the Keweenaw Bay Indian Community and ensures that research respects cultural protocols and community priorities. Community engagement and benefit will be considered in the review process. Sensitive cultural knowledge requires additional review and safeguards.