Goshen College Institutional Review Board Procedures

Purpose

Goshen College has established an Institutional Review Board (IRB) to review and approve research on human subjects. The purpose of this review is to meet GC's legal requirement under the Federal Office of Human Research Protection to protect individual rights to give informed consent for voluntary participation in research. The OHRP defines research as follows:

> Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.

Procedures

All GC faculty and students who propose research, and non-GC personnel who propose research on GC personnel that requires IRB review, shall complete IRB-approved researcher training and then submit their proposals to the IRB using the application template found on the IRB website. Researchers shall also notify the IRB immediately of any changes in the research that may relate to this policy following approval of the proposal. Complaints about research conducted by or with GC community members will be directed to the IRB for response.

The IRB requires all researchers submitting proposals to complete the online researcher training provided by OHRP or other IRB-approved training. The training must cover basic concepts, principles, and issues related to the protection of human research participants. When training is successfully completed, a certificate of completion should be saved (as an image or pdf file) and kept on file – proof of training is required when submitting an IRB proposal. Training must have been completed within the past three years.

Categories of Proposals and Review

The IRB may determine that research proposals fall into one of three categories as follows:

Full Board Review Research Proposals
Research projects that involve more than minimal risk to participants and/or that involve vulnerable populations require full Board review. The Board will convene within one month of receiving a proposal requiring full review to make a decision. Researcher training is required prior to submission. Proposals requiring full review may be approved for up to one year. Research beyond that date requires a request for extension.

Expedited Research Proposals
Research projects that involve no more than minimal risk to participants and do not involve vulnerable populations but do not meet the criteria for exempt research are eligible for expedited review. These projects will be reviewed by the Chair and one other Board member on a rolling basis in the order they are received. Researcher training is required prior to submission. Expedited proposals may be approved for up to one year. Research beyond that date requires a request for extension.

Exempt Research Proposals
Research projects are considered exempt if they meet the criteria outlined in the Common Rule, including research involving:

1) normal educational practices that do not impact students' opportunity to learn,
2) educational tests, surveys or interviews where data is recorded in a way that the participants cannot be identified or the information gathered is not sensitive,
3) benign behavioral interventions where data is recorded in a way that the participants cannot be identified or the information gathered is not sensitive,
4) collection or study of existing publicly available data or non-identifiable data,
5) taste and food quality evaluation,
6) storage, maintenance and use of identifiable private information obtained with a broad consent process.

The IRB chair must review a complete research application to confirm that the research is exempt. One other Board member may be asked to review the application. An exempt research project does not require further oversight by the IRB and is not limited to a specific period of time.

Proposal Process

The researcher for the proposed research is to submit an application to the IRB chair. Applications include the following elements:

1. Researcher training certificate
2. Title of research proposal
3. Name(s) and signature(s) of investigators
4. Name and signature of faculty supervisor (for student proposals)
5. Brief statement of study purpose
6. Demographics of participants
7. Description of study procedures
8. Description of procedures used to ensure anonymity or confidentiality
9. Informed Consent form (non-exempt or exempt studies) or Study Information Sheet (exempt studies only)
10. Relevant attachments, including survey instruments, interview questions, recruiting materials, research site approval for off-campus projects, permissions from other organizations, etc.

Research applications are sent directly to the IRB chair. The chair determines the status of the application (full, expedited, exempt). When a research proposal requires full Board review, the chair will convene the full IRB to review the application. Board members are to apply the ethical

guidelines and make a decision to approve or disapprove the research. Modifications may be required. A majority of the members must be present in order to take action on a proposal.

In cases requiring expedited approval, the IRB Chair will contact another member of the IRB to review the proposal together. If one or both of the reviewers do not approve the proposal, the full IRB will be convened to approve or disapprove the proposal.

The Board shall have full authority to approve or deny approval of proposed research. The Chair shall submit a formal letter via email notifying the primary contact person of the Board's decision. Notification of disapproval shall include rationale and provide opportunity for the researcher to respond in person or in writing.

Copies of all received proposals and written responses will be filed electronically and made available to the full IRB.

Except for those determined to be exempt, research proposals are normally granted approval for a one-year period, according to OHRP Federal guidelines. The IRB may also require review more often than annually if it determines that a proposal contains significant risk to participants. If research extends beyond the approved period and the research procedures have not changed, then the researcher shall request an extension by emailing the IRB Chair. If research extends beyond the approved period and the research procedures have changed, then the researcher must submit a new proposal to ensure continuing review.

Researchers must inform the Board immediately if the research deviates from the proposal or if any harm or adverse event occurs to research participants. The Board will review reports of harm to participants on a case-by-case basis and determine if significant harm has occurred. The Board has the right to discontinue a research project that is not being conducted in accordance with the approved proposal or in cases of significant harm to participants. Board notification of such to the researcher(s) will include rationale.

The Board retains on file the minutes of all meetings, as well as copies of all research proposals and correspondence.

Ethical Guidelines

The following guidelines shall be used to review research proposals:

1. Participants are protected from unnecessary physical or emotional harm, psychological distress, and undue influence; and risks are monitored during the project.
2. Potential short range benefits of the research outweigh any potential risks.
3. Informed consent or study information sheet is provided to participants in writing (see the GC application template). This includes:
    - Explanation of purposes, procedures, and timetable of the research.
    - Description of potential risks if present and means of treating these if harm could occur (i.e., list of available counseling services with contact information).
    - Description of any expected benefits.

    - Description of provision for anonymity and/or confidentiality.
    - Description of voluntary nature of participation and ability to discontinue participation if desired.
    - Names of people to contact for answers to questions.
    - If applicable, separate statement and signature line for permission to audio or video tape participants.
    - If informed consent is not to be obtained, the risk must be minimal and reasons must be justifiable (e.g., the inability to conduct the research if participants are informed of its purpose).
    - Studies involving vulnerable populations may require additional protections (e.g., parental consent for children).
4. Steps are taken to protect privacy of participants.
5. Selection of participants is equitable.

Approval by Another IRB

The Goshen College IRB is ultimately responsible for safeguarding the rights and welfare of GC students and employees involved in research as human subjects. Therefore, researchers must obtain permission from the GC IRB to conduct human subjects research on the Goshen College campus.

However, if non-exempt research spans multiple sites, the GC IRB may rely on another IRB's approval. Researchers who plan to obtain or have already obtained IRB approval from another institution must contact the GC IRB chair to determine whether separate approval from the GC IRB is necessary. Researchers will be asked to provide GC with all materials submitted to the reviewing IRB and the official notice of approval. Reliance will be documented in a written, signed agreement.

If an external IRB has determined a project to be exempt, the GC IRB cannot "rely" on this exemption. However, the GC IRB will consider the complete application documents and letter of exemption from the external IRB and, when possible, make a determination of exemption based on these documents. The GC IRB reserves the right to follow up with requests for additional information or modifications, or determine that an application must be resubmitted in the format outlined on the GC website.

Composition of the Institutional Review Board

The Board shall have a minimum of five members with varying backgrounds and expertise, according to the Common Rule. At Goshen College:

1. One member shall be a person whose primary concerns are in scientific areas, usually a faculty member from the school of Nursing & Science.
2. One member shall be a person whose primary concerns are in nonscientific areas, usually a faculty member from the school of Society & Religion.
3. One member shall be a person who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution.
4. One member shall be the director of institutional research and assessment.
5. One member shall be the vice president for academic affairs.

Persons with additional expertise may be invited to serve on the Board if needed. A member may not participate in review or decision making if they have a conflicting interest in the research project.

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