

## **Aquinas College Institutional Review Policy for Research Involving Human Subjects**

Aquinas College supports the use of research to advance knowledge. When this research includes the use of human subjects, consistent with Federal Regulations and the Belmont Report, researchers must take efforts to protect their subjects. To ensure that this occurs, the faculty and administration of the College have developed this policy and established an Institutional Review Board (IRB) to review all research completed under the auspices of Aquinas College that involves human participants.

### **Research that Requires IRB Approval:**

Pursuant to the Code of Federal Regulations Title 45, Part 46: Protection of Human Subjects, the activities that require IRB approval include:

- Research that involves human subjects.
  - Research is defined as "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge"<sup>1</sup>"
  - Human subject "means a living individual about whom an investigator (whether professional or student) conducting research obtains (1) Data through intervention or interaction with the individual, or (2) Identifiable private information."<sup>2</sup>"
- Activities undertaken for educational purposes with the likelihood that data or new knowledge will be presented beyond the educational setting such as a community, or professional meeting or poster session; included in a professional publication (print or on-line); shared with representatives of a community or other off-campus organization; or used in funding proposals or similar documents.

Activities that do not require IRB approval include:

- Research involving evaluation of normal education practices (pursuant to Section 46.101 of the Code of Federal Regulations Title 45, Part 46, Subpart A, paragraph (b). This includes regular College or faculty evaluations of teaching strategies and course content, including those used for assessment purposes.
- Research utilizing existing data that is either publicly available or cannot be linked, either directly or through identifiers, to individual subjects.
- Activities undertaken for educational purposes that will not be presented or published, defined in the federal regulation as "Research conducted in established or commonly accepted educational settings, involving normal educational practices"<sup>3</sup>".

### **Institutional Review Board Membership:**

Members of the Institutional Review Board are appointed by the Provost following recommendation by Department Chairs. Membership is for a term of two years, with the terms staggered.

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<sup>1</sup> Section 46.102 of the Code of Federal Regulations Title 45, Part 46

<sup>2</sup> ibid

<sup>3</sup> Section 46.101 of the Code of Federal Regulations Title 45, Part 46

Consistent with Section 47.107 of the Code of Federal Regulations Title 45, Part 46, membership of the IRB shall include:

- Two faculty members representing two separate departments within the Social Sciences.
- One faculty member representing the Natural Sciences.
- One faculty member representing the Arts and Humanities.
- One community member not affiliated with Aquinas College and not part of the immediate family of a person affiliated with Aquinas College. This individual shall have expertise to adequately review research activities that come before the IRB.
- The IRB must include both female and male members.
- An IRB member with a vested interest in a proposed project is disqualified from participating in the decision.
- The IRB may invite individuals with competence in special areas to advise the Board, but these individuals do not serve as voting members of the IRB.
- The IRB will elect a Chair at their first meeting of each academic year. Unless otherwise arranged, the Chair is elected for a period of 12 months. The Chair must be an Aquinas College faculty member.

The IRB will use documents provided by The Office for Human Research Protections and the U.S. Department of Health and Human Services to determine if an activity is exempt from IRB review, and interpret federal regulations related to research involving the use of human subjects.

**The Process for Institutional Review of Research Involving the Use of Human Subjects:**

Student, faculty, and staff research protocols that require IRB approval will be provided to the Institutional Review Board (IRB) in the *Application for Institutional Review of Research Involving Human Subjects*. This application should be prepared by the Principal Investigator, and IRB review and approval must be received **before any data collection begins**.

The completed *Application for Institutional Review of Research Involving Human Subjects* and supporting documents should be submitted to the Provost's Office where it will be forwarded to the Institutional Review Board for consideration at their next meeting. Generally, applications submitted during the academic year (Fall and Spring semesters) will be reviewed within two weeks. Applications submitted during breaks and over the summer may take a longer period of time for review.

For the IRB to render a decision regarding an application, four of the five Board members must be in attendance at the meeting. Approval of an application requires a unanimous decision of the IRB. An absent IRB member may submit written comments to the Board to be considered by those present, but will not have a vote on the application.

In the case of applications for protocols that include subjects under the age of 18 or those who may be considered compromised vulnerable subjects, unanimous approval must include all five IRB members

Following review of the application, the IRB will arrive at one of the following decisions:

- Approval without modification

- Approval with modification
- Application remains pending until additional information is provided by the Principal Investigator
- Application is denied

The Chair of the IRB will notify the Principal Investigator and the Provost's Office of the IRB decision regarding each application. In the event that modification is required; additional information is required; or the application is denied, the Chair will notify the Principal Investigator in writing of the changes needed, information requested, or reason for denial.

Pursuant to the Code of Federal Regulations Title 45, Part 46.115, all IRB applications, correspondence, and minutes of all meetings will be kept in the Provost's Office and retained for at least three years, and records pertaining to research will be retained for three years following completion of the research.

Approval of a research project is for the duration of 12 months from the date of IRB approval. IRB approval must be renewed at the end of the 12 month period for the research to remain in compliance with the College policy. Renewal is submitted using the *Application for Institutional Review of Research Involving Human Subjects*.

**The Process for Expedited Institutional Review of Research Involving the Use of Human Subjects:** Section 46.110 of the Code of Federal Regulations Title 45, Part 46: Protection of Human Subjects allows for expedited review of research involving the use of human subjects that involves no more than minimal risk, or has minor changes to research that was approved less than one year previous. The Aquinas College IRB may develop procedures pursuant to this section of the federal regulation.

**Researchers Not Affiliated with Aquinas College:**

If a researcher is not affiliated with Aquinas College, but wants to use College resources for research purposes or collect data from Aquinas College students, faculty, or staff members, the following information must be submitted to the IRB for review and approval before data collection begins:

- A letter to the IRB that details:
  - researcher's institutional affiliation and position
  - researcher's education and training
  - purpose of the proposed project
  - reasons for collecting data at Aquinas College
- A copy of the approved application for institutional review of research involving human subjects from the researcher's home institution.