



# POLICY AND PROCEDURE

TITLE:	<b>Institutional Review Board (IRB) for the Protection of Human Subjects in Research</b>
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## **POLICY STATEMENT:**

Goodwin University believes all researchers have an ethical and professional responsibility to protect human subjects from harm. The Institutional Review Board will review all proposals for research conducted at the University and/or by faculty, staff or students under the auspices of the University or with University resources that involve human subjects. Characteristics that trigger IRB review include any research activity that collects data systematically, involves human subjects who are identifiable, or is collected with the intention of contributing to common knowledge (i.e., shared outside the institution through presentation or publication).

- The IRB requires written assurances that the research plan protects the rights, privacy and welfare of the human subjects involved.
- The IRB requires that all persons submitting a research proposal complete the institutional CITI training prior to submittal; the completion certificate is required at time of submittal.
- The IRB has the authority to approve, require modifications or disapprove all research activities that fall within its jurisdiction.

**IRB approval must be obtained prior to initiating any study.**

## **PROCEDURE DETAILS:**

There are two levels of IRB research proposal review:

- All Goodwin University researchers (faculty, administrators, staff, or students) must submit a research proposal application with the appropriate attachments to the IRB. In addition, it is the position of the University that **all research** that is conducted at Goodwin be reviewed by the IRB committee and the committee will determine the level of review.
- An **Expedited Review** is completed by the IRB Chair for research that involves only **minimal risk** to the subject or that may be subject to exemption (see below).
- A **Full Review** requires a convened meeting of the IRB, with a majority (75%) of the members present and voting. Full reviews are required when the research procedures involve **more than minimal risks**, collection of information regarding sensitive aspects of the subjects' behavior and any research that does not fall into categories identified as qualifying for exempt or expedited status.
- The typical full review process may require three to four weeks; or longer if revisions are requested by the IRB.

**EXEMPTION FROM REVIEW** --this determination is made by the IRB, not the researcher [SEE APPENDIX B FOR FULL DESCRIPTION]: Federal regulations dictate that a review is not needed if the research

- Uses existing data from which subjects cannot be identified
- Uses educational tests, surveys, and/or interviews or observations of public behavior unless:
  1. The subjects are identified or identifiable from the data collected
  2. Disclosure of subjects' response could place the subject at risk of criminal or civil liability or be damaging to subjects financial standing, employability or reputation.
- Includes activities such as surveys, classroom tests and questionnaires that are used for program improvement or for educational instruction are exempt from review.
  1. Most nationally normed survey research
  2. Classroom activities that teach research methodologies or simulate research activities.
  3. Activities/data collection conducted to improve the quality of teaching in a particular classroom.
  4. Activities/data collection required for quality assessment or quality improvement, including those designed for programmatic, departmental or institutional evaluation or improvement.

**PUBLISH POLICY STATEMENT (CLICK ON BOX NEXT TO OPTION-SELECT ALL THAT APPLY):**

UNIVERSITY CATALOG

STAFF HANDBOOK

FACULTY HANDBOOK

STUDENT HANDBOOK

**DEFINITIONS:**

**Benefit:** A research benefit is considered to be something of a health-related, psychosocial, or other value to an individual research subject, or something that will contribute to the acquisition of generalizable knowledge. Money or other compensation for participation in research is not considered to be a benefit, but rather compensation for research-related inconveniences.

**Human subject:** A living individual about whom an investigator (whether a professional or a student) conducting research obtains 1) data through intervention or interaction with the individual or 2) identifiable private information. - It encompasses human subjects research conducted nationally or internationally.

- It does not include routine visitor surveys if they are not research, if the results will not be distributed externally, or if they are used solely to evaluate or review a program in order to build a better program, nor does it include research on established educational practices or curricula.

**Minimal risks:** Those where the probability of harm or discomfort anticipated in the proposed research are not greater, in and of themselves, than those ordinarily experienced in daily life or during the performance of routine psychological or physical examinations or tests

**Research:** A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to knowledge or understanding about a question. It includes surveys, testing, program evaluation, interviews and focus groups. Research is collecting information (data) on people and using that data in reports presented, published or reported outside of the activity.

**Risk:** Risk is defined as the probability of physical, psychological, social or economic harm or injury as a result of participation in the study.

**EXCLUSIONS:**

Some research activity may be exempt from review, and this determination is made by the IRB, not the researcher. All research proposals must be submitted to the IRB. The following activities are generally exempt from IRB review, but must still be submitted:

- Classroom activities that teach research methodologies or simulate research activities
- Activities conducted to improve the quality of teaching in a particular classroom
- Activities required for quality assessment or quality improvement, including those designed for internal, institutional evaluation or improvement. For a complete list of exempted activities, refer to the procedure Appendix B.

**OFFICES DIRECTLY AFFECTED BY THE POLICY:**

Office of Institutional Effectiveness and Office of Provost and Dean of Faculty

**HISTORY:** Originally created March 2009; rev May 2010; approved July 26, 2010, effective August 1, 2010  
Reviewed and updated November 2015 by the University Committee on Assessment, OIE Review Spring 2016;  
reviewed May 2017, Reviewed January 2020; Updated February 2020

<b>EFFECTIVE DATE:</b>	July 26, 2010
<b>RESPONSIBLE OFFICE (ONLY ONE):</b>	Institutional Effectiveness
<b>REVIEW DATE:</b>	Annually

**APPENDIX:**

See the University website (Institutional Effectiveness page) for IRB forms.

<https://www.goodwin.edu/institutional-effectiveness/institutional-review-board>