

GOODWIN COLLEGE

Policies and Procedures

Establishment of an Institutional Review Board (IRB) for the Protection of Human Subjects in Research

INTRODUCTION: The United States Department of Health Education and Welfare established the **Institutional Review Board (IRB)** in 1974 as a way to protect research participants from harm. An IRB is responsible for proving to the federal government that the institution provides and enforces protections for human subjects who participate in research. Originally, many colleges established IRBs on their campuses as a requirement for obtaining federally funded research; now nearly all institutions require IRB review and approval of research involving human subjects regardless of the funding source.

The IRB adheres to the guidelines explained in the United States Code of Federal Regulations [Title 45 CFR, Part 36 Protection of Human Subjects](#); specifically, this applies to informed consent, minimizing risks, and the fair selection of subjects.

The IRB also adheres to accepted ethical practices and professional standards concerning the use of Human Subjects in Research including:

1. The American Nurses Association "Human Rights Guidelines for Nurses in Clinical and Other Areas of Research,"
2. The American Psychological Association's "Ethical Principles in the Conduct of Research for Human Participants",
3. The American Sociological Association's "Code of Ethics",
4. The Society of Research and Child Developments "Ethical Standards for Research with Children," and
5. The Association for Institutional Research's "Code of Ethics."

POLICY STATEMENT: Goodwin College 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 college and/or by faculty, staff or students under the auspices of the college or with college 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 publically outside the institution through presentation or publication).

- The IRB looks for written assurances that the research plan protects the rights, privacy and welfare of the human subjects involved.
- 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 data collection.***

RELATED POLICY INFORMATION: There are two levels of IRB research proposal review:

- All Goodwin College researchers (faculty, administrators, staff, or students) must: submit a research proposal application with the appropriate attachments to the Director of Institutional Research.
- 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 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 could take two to three weeks.

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 can not 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.
- Activities like 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.

IRB MEMBERSHIP AND TERMS OF SERVICE:

Members of the IRB are recommended by the Director of Institutional Research and appointed by the Vice President of Institutional Effectiveness in consultation with the Executive Vice-President/Provost and Department Chairs. There will be four instructional faculty and one professional non-faculty serving on the board. The Director of Institutional Research will serve as Chair and Facilitator. Members will serve a two-year term. [To assure continuity, two of the first appointees will serve a one year term.] Members cannot serve more than two consecutive terms. The committee will meet every other month to review and refine the process and procedures, receive reports from the chair on exempted research and to conduct full reviews. IRB Membership will be posted on the college's website.

ADMINISTRATIVE CONTACTS:

Executive Vice–President/Provost; Vice President of Institutional Effectiveness

EFFECTIVE DATE:	08/01/2010
RESPONSIBLE COLLEGE OFFICER:	Director of Institutional Research
RESPONSIBLE OFFICE:	Office of Institutional Effectiveness

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

APPENDIX B: Request for Exemption

Exempt Activities: Educational Setting

The following are the categories that qualify for exemption.

- 1) Research involving normal educational practices in established educational settings.
 - A. Both of the following must be present to be Exempt:
 - i. Established Educational Settings: The school environment or a structured school activity such as a field trip with an educational purpose.
 - ii. Normal Educational Practice: Activities in the educational setting that would be performed as part of normal classroom practices. E.g. improving academic, behavioral or social skills; individual student conferences; individualized interventions; homework issues
 - B. Addressing Consent for Exempt Research
 - i. Signed consent forms are not required for Exempt Research. However, an information sheet is required such that parents are introduced to the researcher and are aware that the study being conducted is part of a Master's thesis or Doctoral Dissertation and that the results will be shared with the school and published at the University.
 - C. Possible exceptions that may require an Expedited Review
 - i. Surveys, outside of the classroom (but not related to homework) where participants are identified (parents or child) must be expedited.
 - ii. Surveys that touch on sensitive issues, even as part of a normal curriculum, MAY be expedited
- 2) Research involving the use of educational **tests** (cognitive, diagnostic, aptitude, achievement), **unless**:
 - A. Information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; **and**
 - B. Any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

Other Exempt Categories

- 1) Survey procedures, interview procedures, or observation of public behavior, **unless**:
 - i. information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; **and**
 - ii. any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

Note: Where research includes observation of public behavior of children, there may not be any interaction or participation on the part of the researcher for this activity to qualify as exempt.

- 2) Archival research of existing data. Research records are either publicly available or all identifying information has been removed.
- 3) Subjects are appointed public officials or candidates for public office.
- 4) Evaluation of public benefit or service programs, which are conducted by or subject to the approval of federal department or agency heads.
- 5) Taste and food quality evaluation and consumer acceptance studies if the food has been found to be safe by the FDA or other food safety agency.

APPENDIX C1: Research Proposal Template

This form should be completed by the principal investigator (PI) who is proposing to conduct a study with human subjects. Forward the completed document and all applicable attachments to IRB Chair, who will contact the PI 14 days.

1. Title of Proposal:
2. Principal Investigator (PI):
3. PI Contact Information (Department, phone, email):
4. Faculty Sponsor and Contact Information (If PI is a student):
5. Other Investigators (Names, email, etc.):
6. Date of this Submission:
7. Proposed Duration of the Project (Include start and end dates):
8. Background Information and Research Questions/Hypotheses (Provide a brief rationale for the study and the main research questions):
9. Human Participants: [If this research involves the use of human subjects or data governed by other institutions, attach evidence of approval granted to you by the appropriate IRB or authority of that institution which permits your use of the subjects or data.]
 - a. Who are the participants? Does your study involve anyone under the age of 18?
 - b. How many participants do you plan to have in your study?
 - c. How will the participants be contacted or recruited?
 - d. How will the participants benefit? Will they be compensated? If so, describe:
10. Procedures: [What will you ask the participants to do? Where will your research activities be carried out (be specific)? Be sure to include all supporting documentation, i.e., data collection instruments. Be very specific about your procedures and present them in easily understandable terms.]
11. Consent: [How will the participant give consent to be in your research? Attach any consent forms.]
12. Risks & Debriefing: [If applicable, describe your plan to debrief participants. Is there deception involved in your study? What are the physical, psychological, or social risks of participating in the study? Are there any technical aspects of equipment that pose a potential hazard to participants?]
13. Privacy & Storage of Data: [Explicitly describe how you will store data to protect participants' privacy.]
14. References cited in this proposal:

**APPENDIX C2:
Informed Consent Form**

1. **INTRODUCTION:** Please read this document and ask any questions you may have before agreeing to be in the study.

Title of the Study: _____

You are invited to be a participant in a research study about [insert general statement about study].

You were selected as a possible participant because [explain how participant was identified].

The study is being conducted by [indicate College affiliation].

2. **BACKGROUND**

The purpose of this study is [explain research questions and purpose in lay language. Include some brief background information on research that has been done in the area].

3. **DURATION**

The length of time you will be involved with this study is [indicate the time that participants can be expected to be in the study].

4. **PROCEDURES**

If you agree to be in this study, we will ask you to do the following things: [Explain tasks and procedures from participant's point of view. What will he or she be expected to do? Be sure to explain how groups will be assigned (if applicable) and for survey research, indicate that not all questions have to be answered. Be sure all procedures are explained and terms defined at an eighth-grade level.]

Web-surveys: If data collection will occur through the use of a web-survey, explain how the survey will be set up so that questions can be skipped (or that participants maintain the right to not respond to certain questions by selecting an "I choose not to answer" response.

5. **RISKS/BENEFITS**

This study has the following risks: [Honestly explain risks, hazards, or discomforts, including the likelihood of any identified risks].

The benefits of participation are: [Describe any benefits to the participant or others that could be reasonably expected from the research. Describe any payment/inducement that the participant may receive].

6. **CONFIDENTIALITY**

The records of this study will be kept private. [Describe how records will be stored and who will have access to study records]. In any sort of report that is published or presentation that is given, we will not include any information that will make it possible to identify a participant.

[Web-surveys: If data collection will occur through the use of a web-survey, do not make guarantees of confidentiality or anonymity. Online transmissions do have the potential for security breaches. Researchers who

use web-surveys should explain to participants that e-mail and the Internet are not 100% secure and that all reasonable measures have been taken to protect their identity and responses (e.g., SSL encryption, which is the best security available and the same that is used by financial institutions, will be used, IP addresses will not be collected). Researchers should also encourage participants to clear the cache and browser history to protect their privacy after completing the web-survey. Finally, for web-surveys, researchers should explain to participants how the data will be stored (e.g., in a password protected database). The IRB recommends that researchers use the following statement to explain this to participants: "The researcher(s) has taken all reasonable measures to protect your identity and responses. For example, the data is SSL encrypted, it is stored on a password protected database, and IP addresses are not collected. However, e-mail and the Internet are not 100% secure, so it is also suggested that you clear the computer's cache and browser history to protect your privacy after completing the survey."

Possible text: "Please recognize that we are using a web-survey to collect this data, and have taken all reasonable measures to protect your identity and responses. For example, the data is SSL encrypted, it is stored on a password protected database, and IP addresses are not collected. These measures provide the high level of security that is used by financial institutions and it is very unlikely that your data could be accessed by anyone. However, e-mail and the Internet are not 100% secure. Therefore, we also suggest that you clear the computer's cache and browser history to protect your privacy after completing the survey."

7. VOLUNTARY NATURE OF THE STUDY

Your decision whether or not to participate will not affect your current or future relations with Goodwin College or any of its representatives. If you decide to participate in this study, you are free to withdraw from the study at any time without affecting those relationships.

[Web-surveys should be designed to allow participants to withdraw from the study at any time. Web-surveys also should be set up so that questions can be skipped (or that participants maintain the right to not respond to certain questions by selecting an "I choose not to answer" response. At the end of the survey, participants should be offered the choice to submit their responses or not. If they choose not to submit their responses, the web-survey should be set up so those responses are not saved to the server.]

8. CONTACTS AND QUESTIONS

The researcher(s) conducting this study is(are) [insert names of all investigators]. **You may ask any questions you have right now. If you have questions later, you may contact the researchers at** [include phone number of principal investigator].

If you have questions or concerns regarding this study and would like to speak with someone other than the researcher(s), you may contact Ms. Ann Clark, Executive Vice-President/Provost, Goodwin College, 1 Riverside Drive, East Hartford, CT 06118, phone 860-727-6901, e-mail aclark@goodwin.edu. Alternatively, you can contact Dr. Alan Sturtz, Chair of IRB, Goodwin College, phone 860-913-2034, e-mail asturtz@goodwin.edu.

9. COMPENSATION [This heading only needed for studies that have a risk of injury, such as physically invasive procedures.]

In the event that this research activity results in an injury, treatment will be available, including first aid, emergency treatment, and follow-up care as needed. Care for such injuries will be billed in the ordinary manner, to you or your insurance company. [Indicate any additional information regarding sponsored research and the sponsor's responsibility for compensation related to injuries.]

10. STATEMENT OF CONSENT

You will be given a copy of this form to keep for your records.

The procedures of this study have been explained to me and my questions have been addressed. The information that I provide is confidential and will be used for research purposes only. I understand that my participation is voluntary and that I may withdraw anytime without penalty. If I have any concerns about my experience in this study (e.g., that I was treated unfairly or felt unnecessarily threatened), I may contact the Chair of the Institutional Review Board or the Chair of the sponsoring department of this research regarding my concerns.

[Web-surveys: If data for low-risk studies are collected on web-surveys, implied consent often occurs electronically. In this case, it is acceptable for participants to be instructed to click on a link if they give their consent to participate in the study. State clearly that completion and return of the survey indicates consent to participate.]

Participant signature _____ Date _____

Signature of Parent/Guardian [if applicable] _____ Date _____

Name, Title and Signature of Person Obtaining Consent

_____ ***Date*** _____

APPENDIX D1: IRB Reviewer Checklist

The following are key areas that the IRB will consider for approval. It is the responsibility of the Principal Investigator to make sure they are the Application:

1. Exemption category information and justification
2. Background, objectives, description of research, and role of subjects
3. Number of subjects, records or specimens
4. Subjects are over age 18 and under age 89
5. Health information is not collected or health information is collected and a HIPAA De-Identification Certification form is attached
6. Expected duration of study and subject participation
7. Risks/benefits to the subject and to society
8. Explanation of how risks have been minimized
9. Procedures for protecting anonymity or confidentiality
10. Data security
11. Recruitment procedures
12. Gender/racial group involvement
13. Access to study population and authority to review records
14. Description of how subjects will be informed (cover letter, recruitment statement)
15. Consent/assent process and forms
16. Experience and role of investigators
17. Conflicts of Interest explained
18. Accompanying materials provided (sample survey questions, data collection sheet)
19. Do the benefits of the research outweigh the risks?

Are the following addressed in the Informed Consent Form [Appendix C2]?

1. Investigators' names and ranks
2. Explanation of purpose and justification of research
3. Description of subject's participation and duration (tasks and time)
4. Description of risks and minimization of risks
5. Explanation of how confidentiality/anonymity is protected
6. How will data be collected/recorded
7. Description of benefits to subject/society
8. Explanation of voluntary participation
9. Statement naming investigator who will answer questions and phone number, IRB contact information
10. Is the document written and in lay language and formatted for easy reading? (Translated for subjects who are non-English speakers?)

**APPENDIX D2:
IRB Review Form**

Proposal Number: _____

Title: _____

Principal Investigator: _____

Reviewer Evaluation:

Background Information and Research Questions/Hypotheses (issues around research design can also be considered)

____no modifications

____needs modification, identify issues below:

Human Participants: (number, recruitment strategies, compensation)

____no modifications

____needs modification, identify issues below:

Procedures:

____no modifications

____needs modification, identify issues below:

Consent: (consideration of waiver, issues with consent process)

____no modifications

____needs modification, identify issues below:

Debriefing: (if applicable)

____no modifications

____needs modification, identify issues below:

Privacy and Storage of Data:

____no modifications

____needs modification, identify issues below:

Risk: Check the appropriate risk category:

____The research involves no more than minimal risk to participants.

____The research involves more than minimal risk to participants.

____The risk(s) represents a minor increase over minimal risk, **or**

____The risk(s) represents more than a minor increase over minimal risk.

Benefit: Check the appropriate category:

____The research involves no prospect of direct benefit to individual participants, but is likely to yield generalizable knowledge about the participant's condition.

____The research involves the prospect of direct benefit to individual participants.

I have reviewed the proposed project in accordance with Goodwin College's IRB Policy and Procedures related to the protection of human subjects and the institutional assurance to HHS. My comments and recommendations are furnished for use in arriving at the consensus and writing the minutes.

____Full approval – no comments

____Approved subject to the modifications noted above

____Reconsideration

____Disapproval

11. Reviewer Name/Initials: _____

Date: _____

IRB Procedures Manual
[DRAFT: TO BE DISCUSSED AND DEVELOPED BY IRB]
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