Institutional Review Board Proposal Transmittal Form

This form is initiated by the Principal Investigator (PI) proposing to conduct research with human subjects. **The PI should complete all items on the following pages.** Please allow two weeks for the review of your proposal and letter providing the results of the review.

The completed proposal may be forwarded via surface mail or electronic mail (confirmation receipt required for either method) to:

Chair Institutional Review Board Goodwin University
One Riverside Drive East
Hartford, CT 06118
MQuinlan@goodwin.edu

Proposals that concern research conducted with human subjects must be submitted to the Goodwin University Institutional Review Board for review and approval. Student proposals that have not been approved and signed by a faculty advisor, department chair or appropriate committee will not be reviewed by the Goodwin University Institutional Review Board. Employee proposals that have not been reviewed and signed by a department head and senior administrator will not be reviewed by the Goodwin University Institutional Review Board.

Project Title:

Principal Investigator:
Institution:
Mailing Address:
City, State, Zip:
Contact Phone Number:
Department:

Status: ___ faculty ____staff ___ student _____ other
Joint Research with another institution: ____Yes ___ No

Students	Employees
Faculty Program Advisor:	Department Head:
Office Number: _____	Office Number:
Contact Telephone :_____	Contact Telephone:

1. If your research involves the use of human subjects or data governed by other institutions, ***attach evidence of approval granted to you by the Institutional Review Board (IRB) or Human Subjects Committee (HSC) of those institutions***, which permits your use of the subjects or data.

2. If your research involves the use of human subjects or data governed by other institutions that **do not** have an IRB or HSC,
   attach evidence of approval granted to you by those institutions**,** which permits your use of the subjects or data.

3. If your **research involves any of the following** populations, a **full IRB review is required**. Please check all that apply:
    - Subjects younger than 18 years of age YES__NO___
    - Prisoners YES__NO_____
    - Pregnant women YES__NO_____
    - Mentally disabled persons YES__NO_____
    - Economically disadvantaged persons YES__NO_____
    - Educationally disadvantaged persons YES__NO_____

I attest that all information provided in this Proposal Transmittal Form is true:

Signature of Principal Investigator_____Date:

Printed/Typed Name: _____

To be completed by Research Advisor or Institutional Officer approving research project:
I attest that I have reviewed this proposal and approve the content. To the best of my knowledge, the content is accurate, the study is methodologically sound, and the proposal conforms to all ethical requirements for human subjects research.

Signature of Research Advisor/Institutional Officer: _____

Title:_____

Printed/Typed Name_____Date: _____

Please select the type of review for which you believe you qualify:

____Exempt Review:
For proposals found to be exempt from full IRB review. (Proposals must still be submitted to the Institutional Review Board). Research activities will involve human subjects in one or more of the following: (i) research conducted in commonly accepted educational settings, involving normal educational practices (research on regular or special education instructional strategies or on the effectiveness of instructional techniques, curricula or classroom management methods); (ii) research involving the use of educational tests (cognitive, diagnostic, aptitude or achievement), if information obtained is recorded in such a manner that subjects cannot be identified, directly or indirectly; (iii) research involving surveyor interview procedures (except if all of the following exist: responses are recorded in a manner that subjects can be identified directly or indirectly; subject's responses, if known outside the research, could place the subject at risk of criminal or civil liability or be damaging to subject's financial standing or employability; and the research deals with sensitive aspects of the subject's own behavior); (iv) research involving observation of public behavior (except if all the following exist: observations are recorded in a manner that subjects can be identified, directly or indirectly; observations recorded about the individual could place the subject at risk; and the research deals with sensitive aspects of the subject's own behavior); or (v) research involves the collection or study of existing data, documents, records or specimens if these sources are publicly available, or if recorded by the investigator in a manner that subjects cannot be identified, directly or indirectly.

____Expedited Review:
For proposals where there may be no more than minimal risk to the human subject, and the proposed activities are among the following: (i) collection of hair and nail clippings in a non-disfiguring manner; (ii) collection of excreta and external secretions including sweat or saliva; (iii) recording of data from subjects 18 years of age or older using non-invasive procedures routinely employed in clinical practice (this includes physical sensors applied to the body surface or at a distance, and do not involve input of matter or significant amounts of energy into the subject, or an invasion of the subject's privacy. It also includes procedures such as weighing, testing sensory acuity, electrocardiography or electroencephalography); (iv) collection of blood samples; (v) collection of dental plaque; (vi) voice recordings; (vii) moderate exercise by healthy volunteers; (viii) the study of existing data, documents, records or specimens; (ix) research on individual or group behavior or individual characteristics (including perception, cognition, game theory, or test development); or research on drugs or devices for which investigational new drug exemption or device exemption is not required.

____Full Committee Review:
All cases where a proposal fails to qualify for either the exempt or expedited category.

Proposal Narrative:
Please observe the posted page limits. Failure to provide requested information could delay IRB consideration and/or decision

Project Description:
Describe the purpose of the research proposed.

Rationale:
Describe the rationale for the study

Description of Activities Involving Human Subjects or Data Governed by Other Institutions:
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 the authority of that institution which permits your use of the subjects or data.

Study Research

Questions:

Study Design:
Briefly describe the design of the study, e.g., case study, mixed methods, survey research, etc.

Study Sample:
Briefly describe the sample to be used in your study, including the approximate number of subjects.

Participant Recruitment:
Describe how you will recruit participation in your study, the duration and execution timeline.

Summary of Recruitment Timeline and Strategies

Timeline
Week One
Week Two
Week Three

Description of Procedures:
Describe how you will implement the survey or describe how you will conduct subject interviews, etc.

Time Commitment:
Describe the time commitment required of the participants.

Voluntary Participation:
Describe the participation requirements.

Benefits of Participation:
Describe the benefits of participation.

Risks of Participation:
Describe any risks of participation. Risks of participation in this study should not be greater, considering probability and magnitude, than those ordinarily encountered in life, e.g., school related stress. Therefore, the informed consent form contains the following statement “If you are experiencing stress or need help: students should contact the Therapist here at the University [860-727- 2072]. Faculty and staff should contact the Director of Human Resources [860-913-2070]. This is a small campus and these services are readily accessible to students."

Confidentiality of Participants: *Explain how confidentiality wi**ll** be ensured*. Please include all that apply:

- The confidentiality of participants will be maintained throughout this study.
- No personally identifying information will be collected.
- Materials (e.g., paper-pencil survey) will not be coded in any identifiable way.
- All of the study participants and the school will be assigned pseudonyms.
- All data will be reported in aggregate. Individual responses will not be reported.
- All digital files will be saved in a secure computer and paper files will be stored in a locked file cabinet in the researcher’s office. Each file is accessible only to the researcher and their advisor.
- The data collected from this investigation will be kept for a period of five years, to allow for data verification and confirmation of results and analysis (American Psychological Association, 2010, p. 12). After five years, all data and analysis (digital and paper) will be destroyed.

I* hereby *certify that the human subjects review process is being completed as required by the Goodwin University Institutional Review Board.

_____ _____

Signature of Principal Investigator Submission Date

SAMPLE INFORMED CONSENT FORM

[PLEASE MODIFY THIS FORM TO MEET SPECIFIC RESEARCH NEEDS AND SUBMIT A COPY TO THE IRB]

Briefly describe purpose of the study in terms the research population will be able to understand.

- Participation is **voluntary. You must be at least 18 years old.**
- You may **withdraw from this study at any time** without hurting your relationship with the sponsoring institution or your school.
- It is estimated that the **survey** will take about **XX minutes** to finish.
- You may be compensated for completing and returning the **survey**.
- Submitting a completed survey implies permission to use your information in our study.
- If you want to take part in an interview**, sign the form** and we will schedule a time to meet.
- The interview will last about **XX minutes;** you may be compensated for participating in the interview.
- There are no apparent risks involved in participating in this study.
- When I write about you, I will give you a fictitious name.
- Your survey and interview responses will be kept in confidence.
- All survey responses, audiotapes, and the interview transcript will be stored in a locked file cabinet. They will be destroyed five years from completion of the study.

The following two items MUST be included on your Informed Consent Form:

- If you are experiencing stress or need help: students should contact the Therapist here at the University [860-727- 2072]. Faculty and staff should contact the Director of Human Resources [860-913-2070].

- If you have any questions about your rights as a research subject, please contact the Chair of the Goodwin University Institutional Review Board at 860-727-6740. The IRB is a group of people that reviews research studies and protects the rights of people involved in the project.

Thank you for volunteering to participate in this study!

If you have any questions about this study, you may contact me or my faculty advisor at the

phone numbers below:

Researcher Contact:_____Faculty Advisor Contact_____

Signature of Research Participant:_____ Date: _____

Please keep a copy of this page for your records.

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 children) 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 C:
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 addressed appropriately in 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?

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 D
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: ___needs modification, identify issues below:

____no modifications

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

____no modifications

Debriefing: (if applicable) ___needs modification, identify issues below:

____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 University's IRB Policy and Procedures related to the protection of human subjects. 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

Reviewer Signature:_____Date:_____

Print Name: _____