IRB USE ONLY: Proposal #_____
Approval #_____

EXPEDITED

GOUCHER COLLEGE
INSTITUTIONAL REVIEW BOARD
PROPOSAL FOR EXPEDITED REVIEW

Please submit **one hard copy** and **one electronic copy (via email to irb@goucher.edu)** of the following documents to the IRB.

(a) IRB-EXPEDITED Form (signed and completed)
(b) Research Proposal
(c) Consent Form
(d) Recruitment materials (flyers, text of emails, etc.)
(e) Stimuli, materials, measures, interview questions, debriefing materials
(f) Certificate(s) of completion of human participants training.

When enrollment is complete, it is the researcher's responsibility to submit the signed consent forms to the IRB Contact in the Provost's Office, where they will be kept on file/archived.

Title of Study: _____

Date of Submission: _____ ___New Submission ___Revised Submission

Researcher Information

Full Name	**Student/Faculty/ Staff/Other (specify)**	**Affiliation (if not Goucher)**	**Contact information (email required; phone optional)**

Supervisor Information (if applicable, i.e., if researcher(s) is/are students)

Full Name	**Faculty/Staff/Other**	**Affiliation (if not Goucher)**	**Contact Information (email required; phone optional)**

Academic Department in which the research is being conducted: _____
Is this project part of a course[1]? ☐ yes ☐ no

If yes, which course (course ID and title)? _____

Do you intend to publish or present this research outside of Goucher College (e.g., at a professional conference or in a journal)? ☐ yes ☐ no

DATE SUBMITTED _____

Please note: The IRB makes every attempt to give initial feedback on proposals within four weeks of submission, but modifications are often required before approval can be granted. If the IRB determines that Full Board Review is necessary, the review process may be longer.

Further information, including the complete *IRB Guidelines*, can be obtained by visiting the IRB homepage—on the Goucher College website at http://www.goucher.edu/irb

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Please respond to the following questions about the proposed research or activity.

1. Briefly outline the proposed project. (This description should include 2-5 paragraphs describing the purpose and method of the proposed project. Please describe any aspects of the project that may have a bearing on risk to participants (e.g., recording interviews, handling of data with respect to confidentiality).)

2. Are subjects being selected for any specific characteristics (e.g., gender, age, ethnic origin, religion, social or economic characteristics, or disabilities)?

   ☐ yes ☐ no

   a. If yes, specify the characteristics:

   b. If yes, provide a rationale and justification for the selection process:

[1]Some projects that are conducted for a classroom assignment may not require IRB review. Please see Goucher College Policy for the Use of Human Subjects (available at www.goucher.edu/irb).

3. What are the risks to participants? ("Risk" is defined as exposure to the possibility of harm and includes psychological distress. All research involves some level of risk. In order to qualify for expedited review, the researcher(s) must demonstrate that the risk to participants is minimal, i.e., no more than would be encountered in daily life or during the performance of routine physical or psychological examinations or tests).

4. What potential benefits will justify these risks? Benefits do not include payments or other compensation (such as course credit) but rather refer to benefits to society/humanity.

5. State specifically what information the subject will receive about the investigation **and at what point in the procedure the information will be provided**. Such information may be communicated during the informed consent process and/or debriefing process.

6. State how subjects' consent will be obtained and attach the consent form to be used as well as any informative statements provided to subjects.

   (A template for an informed consent form can be found in this document.)

Reasons for Expedited Review

From the list below, state the reason you are applying for expedited review (indicate the number from the list).

A. Research activities qualify for expedited review if they involve no more than minimal risk, as defined in Question 3 above, AND are included in the categories suitable for expedited review as determined by the Department of Health and Human Services (DHHS), listed in B below. In addition, minor changes to a previously-approved research protocol may be acceptable for expedited review during the period for which approval is authorized.

B. Although the list may change from time to time, the following categories of research are currently determined by DHHS to be eligible for expedited review, as provided in Federal Register Volume 63, Number 216 (November 9, 1998):

1. Clinical studies of drugs and medical devices, only when a) the research is on drugs for which an investigational new drug application is not required, or b) the research is on medical devices for which an investigational device exemption application is not required or the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling;

2. Collections of blood samples by finger stick, heel stick, ear stick or venipuncture, under the conditions described by DHHS;

3. Prospective collection of biological specimens for research by noninvasive means (e.g. hair and nail clippings, teeth, saliva);

4. Collection of data through noninvasive procedures routinely employed in clinical practice, excluding procedures involving x-rays or microwaves (e.g. physical sensors, muscular strength testing);

5. Research involving materials (data, documents, records, or specimens) that have been collected or will be collected solely for non-research purposes (such as medical treatment or diagnosis);

6. Collection of data from voice, video, digital, or image recordings made for research purposes;

7. Research on individual or group characteristics or behavior (such as studies of perception, cognition, motivation, communication, social behavior), or research employing survey, interview, oral history, focus group, program

evaluation, human factors evaluation, or quality assurance methodologies;

8. Continuing review of research previously approved by the convened IRB, where the research is permanently closed to the enrollment of new subjects, all subjects have completed all research-related interventions and the research remains active only for long-term follow-up of subjects; or where no subjects have been enrolled and no additional risks have been identified; or where the remaining research activities are limited to data analysis;

9. Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories 2 through 8 above do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified;

Reason stated for expedited review _____ (number)

Explanation:

Research Proposal

Title of Study:

Researchers:

Supervisor:

Description/Background: *[What is this study about? What is already known about the topic? What is not known?]*

Participants: *[Who will participate in the study? How will they be recruited? How many participants do you plan to recruit?]*

Materials: *[Describe materials/stimuli/interview questions here. Attach complete materials to this proposal.]*

Procedures: *[Describe in full detail, including scripts that will be used by researchers to introduce study, debrief, etc.]*

[Not every study will use these exact headings, but use this as a model for information that should be included in the Research Proposal.]

[This form serves as a template for consent forms approved by the IRB. Explanations for the researcher are included on the template in brackets, but should not be included on the consent form presented to subjects for signature. It is the researcher's responsibility to submit original signed consent forms to the IRB Officer in the Provost's Office, and to give subjects a copy of the form for their own records.]

G O U C H E R C O L L E G E

IRB CONSENT FORM

[To be used with adult participants who can give consent. Those doing research with children, use the parent-consent and child-assent forms on the website.]

Title of Study: [Researchers please note: the title listed here may not correspond exactly to the official title used elsewhere in this proposal, if including the official title here would compromise the validity of the data collected. A less precise title may be used here.]

For questions regarding the research project, please contact:

Researcher(s): [Your name and complete contact information]
Supervisor: [name and complete contact information]

For questions regarding your rights as a research subject, please contact:

IRB Contact: Provost's Office
410-337-6044

Description

[Provide a description of the research project, including the purpose of the project explained in language accessible to a non-professional].

[Explain any tasks and procedures that the subject will be asked to undergo. The subject should

also be informed about the length of time involved in participation, the frequency of any procedures, etc. If any data collection procedures involve audio and/or video recording, and/or photography (i.e., any procedures that contain potentially identifying information and thus require additional confidentiality protections), include such information here.]

Risks

[Provide a description of the risks associated with this research project and the likelihood of these risks occurring. Risks include, but are not limited to, physical, emotional, and psychological injury. All research involves risk, and all risks must be disclosed.]

Payments

[Provide a description of any direct reimbursement to the participant, for instance, money, course credit, etc. If the subject is to receive payment, the details of this arrangement should be included here along with an explanation of when payment will be given. If there are no payments, state that fact here.]

Confidentiality

[Explain how anonymity and/or confidentiality will be assured. Describe the procedures by which any information obtained through this project, as it relates to a specific individual, will be kept private. Explain that any report published from this research will not include information that will make it possible to identify the subject (if that is the case). In addition, explain how research records will be kept secure and indicate who will have access to these records. If anyone besides the researcher will have access to the raw data, such persons must be identified.]

[If audio or video recordings are to be made, or photographs taken, explain who will have access to these items, if they will be used for educational purposes, how they will be protected (encrypted, password-protected), and when they will be destroyed.]

[Indicate exactly when (by what date) raw data will be destroyed by. Or, if raw data are to be retained, indicate when (by what date) all identifying information will be permanently removed.]

Right to Withdraw

[Explain that participation in this research project is strictly voluntary and that the subject may choose to withdraw from the study at any time. Also indicate that the subject has the right to withdraw consent and discontinue participation in the research project without prejudice.]

Voluntary Consent

[The following statement of consent must be included]

1. I have read the information above and freely volunteer to participate in this research project.
2. I understand that all aspects of this project will be carried out in the strictest of confidence and in a manner in which my rights as a human subject are protected.
3. I have been informed in advance as to what my task(s) will be and what procedures will be followed.
4. I have been given the opportunity to ask questions, and have had my questions answered to my satisfaction.
5. I am aware that I have the right to withdraw consent and discontinue participation at any time, without prejudice.
6. If I decide not to participate in this research project my performance and/or grade in any course associated with this research project will not be affected.
7. I understand that I must be at least 18 years old to participate in this project, or have a "Parental Consent Form for Research Participation" on file with the Provost's Office with my parent's or guardian's signature. I also understand that I must present a copy of this form to the researcher prior to consenting to this study.
8. My signature below may be taken as affirmation of all the above, prior to participation.

I confirm that I am at least 18 years old: ☐ yes ☐ no

For Goucher students under the age of 18: I have a form on file with the Provost's Office with parent/guardian approval that permits me to choose to consent to participate in research. I am giving a copy of this form to the researcher now.

☐ yes ☐ no

[Note to researchers doing research on children: please use parent-consent and child-assent forms on the IRB website, in place of this consent form.]

Printed Name: _____

Signature: _____

Date _____

[Please insert here any other materials required: recruitment materials, stimuli/measures/interview questions, debriefing form, certificates of completion of IRB Protection of Human Participants course, etc.]

CHECKLIST FOR COMPLETE IRB SUBMISSIONS

After printing, but before signing below, please read and initial each statement.

Initials	Criterion
	I/we understand the guidelines for choosing to submit the proposal for EXPEDITED, EXEMPT, or FULL review, and the appropriate form has been chosen.
	All fields and questions are completed accurately in the EXPEDITED/EXEMPT/FULL Review section of this IRB form.
	For EXPEDITED and EXEMPT review, the reason for choosing the review category is selected from the provided list, along with a statement further explaining the reason why my/our study qualifies for this review category.
	A complete research proposal follows the EXPEDITED/EXEMPT/FULL Review form, and contains the information requested in the model form. The information provided is sufficient for IRB members to evaluate the proposed research for ethical concerns.
	Consent form is included after the research proposal, typically based on the model form provided by the IRB. Each section of the consent form provides adequate information for participants to make an informed choice whether to participate in the study. (Write "n/a" if you are requesting that informed consent be waived for this study.)
	I/we understand that if any potential participants are Goucher College students under the age of 18, they can participate only after providing a form signed by a parent/guardian to the IRB (available on the IRB web site). This signed form must also be presented to me/us prior to signing the consent form for this study.
	I/we understand that all signed copies of the consent form must be returned to the IRB Officer in the Provost Office, to be kept on file.
	Information about recruitment materials, such as flyers or the text(s) of recruiting emails, are submitted to the IRB both electronically and in hard copy.
	Additional materials related to the proposed research, such as stimuli, materials, measures, interview questions, and debriefing questions, are submitted to the IRB both electronically and in hard copy.
	All IRB materials are completed using full sentences and are free of spelling/grammar errors. Details of the proposed research are clearly communicated.
	A certificate of completion of human participants ethics training from *each* researcher is submitted to the IRB, both electronically and in hard copy.
	All IRB materials are submitted in hard copy (to the IRB chair) and electronically to IRB@goucher.edu.
	I/we acknowledge that ordinarily an initial response from the IRB will be received within two weeks of submission, via email from IRB@goucher.edu. I/we understand that final IRB *approval* may take longer, depending on whether revisions to the IRB forms are needed and whether or not Full Board Review is necessary.

Goucher College Institutional Review Board

RESEARCHER SIGNATURE PAGE

RESEARCHER(S)' Signatures:

_____

_____

_____

SUPERVISOR Signature _____

DATE _____

For IRB Use

Action Taken:

Expedited Review approved _____ Expedited Review not approved ____

Modifications Requested: _____ Referred for Full Board Review ____

Approval #: _____

_____
Chair (or Chair's Designate), IRB

_____
DATE