

# IRB Expedited Form

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# INSTITUTIONAL REVIEW BOARD PROPOSAL FOR EXPEDITED REVIEW

Please submit the following **via email attachment to the** [**IRB Coordinator**](mailto:irb@goucher.edu)**.** Information and instructions can be found on the [Goucher IRB site](https://www.goucher.edu/policies/institutional-review-board/). If this is a resubmission to respond to IRB feedback, *please use track changes for revisions*.

1. *IRB Expedited Form* (current document, which includes prompts for all of the following)
2. Research Proposal
3. Consent Form
4. Additional materials (e.g., recruitment and research materials)
5. Research materials (e.g., stimuli, survey or interview questions, measures, debriefing)
6. Certificate(s) of completion of human subjects ethics training through CITI for “Social and Behavioral Science Investigators” (information and link on [Goucher IRB site](https://www.goucher.edu/policies/institutional-review-board/))
7. Submission checklist with researcher initials

**Title of Study:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Date of Submission**: \_\_\_\_\_\_\_\_\_\_\_ **New Submission Revised Submission** *(use track changes)*

**Researcher Information**

|  |  |  |  |
| --- | --- | --- | --- |
| **Full Name** | **Role (Student/ Faculty/ Staff/Other)** | **Affiliation (if not Goucher)** | **Contact Information (email required; phone optional)** |
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**Supervisor Information (if applicable, i.e., if researchers are students)**

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

**Academic Department** in which the research is being conducted: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

If this project is part of a course, list course ID and title[[1]](#footnote-2): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Do you intend to publish or present this research outside of Goucher College?** (e.g., at a professional conference or in a journal, a published Senior or Master’s Thesis) yes no

*[Optional: Provide details about your plans for sharing this work.]*

*Note: The IRB makes every attempt to give feedback on proposals* ***within two weeks*** *of submission, but modifications are often required before approval can be granted. Be sure to submit requested modifications using Track Changes to expedite the approval process. If the IRB determines that Full Board Review is necessary, the review process may be longer.*

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

1. **Briefly** **outline the proposed project.** (This description should include 2-4 paragraphs describing the purpose and method of the proposed project. Typically this is an abbreviated version of the research proposal below that summarizes the overall purpose and design, highlighting aspects of the project that may have a bearing on the IRB’s evaluation of risk and potential benefits to participants, for example, recording interviews, confidentiality of data, sensitive topics, potential for harm.)
2. **Are subjects being selected for any specific demographic characteristics?** (e.g., gender, age, ethnic origin, religion, social or economic characteristics, or disabilities) yes no

***If yes*, specify the characteristics and provide a rationale/justification for the selection process.** (To qualify for *EXPEDITED* review, the research must not include individuals from vulnerable populations, e.g., minors under age 18, those with history of alcohol or drug abuse or other mental illness, victims/survivors of abuse and trauma, the homeless, those who are suicidal, undocumented immigrants, refugees, incarcerated people, and ex-convicts.)

1. **What are the risks to participants?** (“Risk” is defined as exposure to the possibility of harm and includes potential psychological distress. All research involves some level of risk. To qualify for *EXPEDITED* review, researcher(s) must demonstrate the risk to participants is *minimal*, i.e., no more than would be encountered in daily life or during performance of routine physical or psychological examinations or tests.)
2. **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.)
3. **State specifically what information the subjects 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.)
4. **State how subjects’ consent will be obtained. As relevant, 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. Note that subjects should be offered a copy of the consent form.)

**Reason for Expedited Review**

The list below contains the most commonly used categories for research appropriate for Expedited IRB review. Select the reason for Expedited review (from [OHRP 45 CFR 46.110](https://www.hhs.gov/ohrp/regulations-and-policy/guidance/categories-of-research-expedited-review-procedure-1998/index.html#footnote1), 1998) and explain below.

1. 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.
2. 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 Vol 63, No 216 (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;

* 1. 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;
  2. 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.

*Content created by Office for Human Research Protections (OHRP)*

**Reason for *EXPEDITED REVIEW* (letter/number): \_\_\_\_\_**

**Explanation:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Research Proposal**

*Note: This is a model for information that should be included in the Research Proposal. Not every study will use these exact headings. You may replace this model with your own proposal, or you may submit the proposal as a separate document. The most important elements are the research question/goal and rationale, who will participate in the study, the method and materials used during the study, and the procedure to carry out the study, with a focus on elements of human subjects protections such as consent and data confidentiality.*

**Title:**

**Researcher(s):**

**Supervisor(s):**

**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 and methodology, including any stimuli/survey items/interview questions here. Attach complete materials to this proposal (e.g., complete interview questions or the content of an online survey).*

**Procedure:** *Describe the steps in the research, including elements of consent and procedures relating to confidentiality and, more generally, human subjects protections. Include any scripts that will be used by researchers, the content of the debrief, etc.*



**INSTITUTIONAL REVIEW BOARD**

###### IRB CONSENT FORM

*[Note: Below is a template for consent forms approved by the IRB. This is for adult participants who can give consent. For those doing research with children, use the templates for Parent Consent and Child Assent Forms on the IRB web site. Explanations for the researcher are included on the template in brackets/italics, but these should be removed (including this note) from the consent form before submitting to the IRB. It is the research supervisor’s responsibility to retain completed consent forms for a period of at least three years and to offer subjects a copy of the form in hard and/or electronic copy.]*

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**Title of Study:** *[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 (i.e., would reveal too much about the study’s purpose or predictions). A less precise title can/should 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, contact the Provost Office via [irb@goucher.edu](mailto:irb@goucher.edu).

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#### 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 occurring. Risks include, but are not limited to, physical, emotional, and psychological injury. All research involves risk, though you might describe a low-risk study as having “minimal risk.” All risks must be disclosed.]*

#### Payments

*[Provide a description of any direct reimbursement to the participant, for instance, money, prize raffle, 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 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 statements regarding 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.

1. I have been informed in advance as to what my task(s) will be and what procedures will be followed.
2. I have been given the opportunity to ask questions and have had my questions answered

to my satisfaction.

1. I am aware that I have the right to withdraw consent and discontinue participation at any time, without prejudice.
2. 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.
3. I understand that I must be at least 18 years old to participate in this project. If I am under the age of 18, I have a “Parental Consent Form for Research Participation” with parent/guardian’s signature submitted via DocuSign (contact [irb@goucher.edu](mailto:irb@goucher.edu) for details). I understand that researcher(s) need to check this form before continuing with my participation in the study.
4. 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: My parent/guardian has approved my choice to consent to participate in research, via DocuSign. Researchers can obtain proof of this approval via [irb@goucher.edu](mailto:irb@goucher.edu).

yes  no

Printed Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_

*[For online surveys, the above may be an e-signature with full name instead of printed name/signature/date. For anonymous surveys, replace the above section with, for example, “By clicking the link to continue the survey, you are consenting to participate.”]*

**Additional Materials**

*Insert below any other materials required, which may include recruitment materials, study materials such as stimuli/measures/survey/interview questions, script, debriefing form, etc..]*

**CITI Human Subjects Ethics Training Certificate(s)**

*Insert below a Certificate of Completion of CITI Program for Social & Behavioral Research Investigators for every researcher listed above. Find information and login link on the* [*IRB web site*](https://www.goucher.edu/policies/institutional-review-board/)*.*

**CHECKLIST FOR COMPLETE IRB SUBMISSIONS**

The lead research or supervisor must read and electronically initial each statement before submitting.

|  |  |
| --- | --- |
| **Initial** | **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. See FAQ on the [Goucher IRB web site](https://www.goucher.edu/policies/institutional-review-board/additional-resources-for-irb-members-and-researchers/vulnerable-populations) for more information. |
|  | 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 the study qualifies for this review category. |
|  | A complete research proposal is included, 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. |
|  | As relevant, a 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. |
|  | I/we understand that if any potential participants are Goucher College students under the age of 18, they can participate only if they have a parent/guardian complete the Parental Consent DocuSign. Contact the [IRB Coordinator](mailto:irb@goucher.edu) to confirm before they participate. |
|  | I/we understand that hard copy and/or electronically signed copies of the consent form must be retained by the research supervisor for a period of at least three (3) years. |
|  | Additional materials related to the research, such as recruitment materials, stimuli, measures, interview questions, and debriefing questions, are submitted as part of this form. |
|  | All IRB materials are completed using full sentences and are free of spelling/grammar errors. Details of the proposed research are clearly communicated. |
|  | A CITI certificate of completion of human participants ethics training from *each* researcher is submitted electronically. This/these can be pasted above or submitted as a separate email attachment(s). |
|  | All IRB materials are submitted electronically to the [IRB Coordinator](mailto: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 the [IRB Coordinator](mailto: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 a higher level of review is necessary. |

**Goucher College Institutional Review Board**

**RESEARCHER SIGNATURE PAGE**

***\*Leave this page blank until sent to you via DocuSign for final approval.\****

**RESEARCHER(S)’ Signatures:**

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**SUPERVISOR** **Signature:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**DATE:** \_\_\_\_\_\_\_\_\_\_\_\_\_

## *For IRB Use*

Action Taken:

Expedited Review Approved (1 year)  Expedited Review Not Approved

Modifications Requested  Referred for Full Board Review

Approval # and Expiration Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

IRB Chair (or Chair’s Designate)

\_\_\_\_\_\_\_\_\_\_

DATE

1. Some projects that are conducted for a classroom assignment may not require IRB review. Please see FAQs and *Goucher College Policy for the Use of Human Subjects* (available at <http://www.goucher.edu/irb>). [↑](#footnote-ref-2)