

# IRB Continuing Review or Protocol Modification Form

#

# INSTITUTIONAL REVIEW BOARD REQUEST FOR

# CONTINUING REVIEW OR PROTOCOL MODIFICATION

*[Use this form if your project has been approved by the IRB and (a) you wish to continue it beyond the expiration date of the initial approval, and/or (b) you wish to make changes to the current protocol, including the addition or removal of researchers.]*

Please submit the following **via email attachment to the** **IRB Coordinator****.** Information and instructions can be found on the [Goucher IRB site](https://www.goucher.edu/policies/institutional-review-board/).

1. *IRB Continuing Review or Protocol Modification* *Form* (this document, which includes prompts for all of the following)
2. Any documents you wish to change (consent form, measures, materials, procedures) – include “tracked changes” and clean (changes-accepted) versions
3. Certificate(s) of completion of human subjects ethics training through CITI for “Social and Behavioral Science Investigators” for anyone added (information and link on [Goucher IRB site](https://www.goucher.edu/policies/institutional-review-board/))

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

**Primary Researcher Name(s):** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Original IRB Approval #:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ **Date of Original IRB Approval:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Date this form is being filed:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

*Note: We make every effort to give an initial response within two weeks of receiving your proposal; revisions may be requested before approval is granted. You may not continue data collection beyond the expiration of your original approval without obtaining approval for a continuation of the study (unless doing so would cause harm to participants, in which case special permission may be granted).*

**Names of Co-Investigators including Students:** *[Check “Add” for investigators new to the project, and “Remove” for investigators who were involved in the past year, but whose involvement with the research has ended. Check neither if the investigator is continuing with the project.]*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Full Name** | **Role (Student/ Faculty/Staff/Other)**  | **Affiliation** **(if not Goucher)** | **Add\*** | **Remove** | **Contact information** **(email required; phone optional)** |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |

\*For newly added investigator(s), submit CITI certificate(s) of completion.

1. **Number of individuals who have participated as research subjects to date:** \_\_\_\_\_\_\_\_\_\_\_\_
2. **During the course of the study, did any problems arise involving issues of human subjects protection (i.e., unanticipated adverse events, threats to anonymity, or breaches of confidentiality)?** [ ] yes [ ] no

 *If yes, please explain:*

1. **Did the procedures for the project differ in any substantial way from the procedures described in the approved proposal?** [ ] yes [ ] no

*If yes, please explain.*

1. **Do you intend to make any changes to the approved procedure?** [ ] yes [ ] no

*If yes, please explain. If changes in questionnaires or consent forms are planned, please append the relevant documents, including a tracked-changes and a clean version.*

|  |
| --- |
| 1. **Summarize the conclusions obtained so far (ideally in one paragraph or less).**
 |

**Goucher College Institutional Review Board**

**RESEARCHER SIGNATURE PAGE**

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

**Signature of Supervisor (or of faculty/staff researcher):** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Date:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Signatures of those added to the study:**

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

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

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

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

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

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

## *For IRB Use*

Action Taken:

Continuing Review Approved [ ]  Continuing Review Not Approved [ ]

Modifications Requested [ ]  Referred for Expedited or Full Board Review [ ]

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

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

IRB Chair (or Chair’s Designate)

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

DATE