IRB Modification Form

This form is used to request an amendment or modification to a previously reviewed and approved IRB protocol. Questions can be directed to the IRB Office at irb@umary.edu or 701-355-8037.

\* Required

General Information

1. Primary Contact Name: \*

2. Primary Contact Email: \*

3. Primary Contact Phone:

4. IRB Protocol Number: \*

5. Project Title: \*

6. Is this project being funded by an external funding agency? \*

 [ ]  No

[ ]  Yes

7. If yes, what agency? \*

8. Is this project: \*

[ ]  Student project

[ ]  Faculty/Staff project

[ ]  External Project

Project Oversight - Student Projects

Please enter your project advisor/research committee chair's name and email below. (S)he will be required to review and approve your modification request before IRB reviews it.

9. Project Advisor (Full name & credentials.) \*

10. Project Advisor Email \*

Current Status of Project

11. What is the current status of this project? \*

[ ]  Project currently in progress

[ ]  Project not yet started. No subjects enrolled.

[ ]  Other:

Proposed Modifications

Modifications include, but are not limited to, changes in: investigators or research team members, purpose/scope of research, recruitment procedures, compensation, subject population, data collection procedures, surveys or other data forms.

12. Described the proposed modification(s). \*

13. Explain the justification for these modifications. \*

14. Will the modification(s) require a change to any appendices (Informed Consent, Survey, Recruitment Materials, etc?) \*

[ ]  Yes

[ ]  No

15. If yes, attach modified documents. Max 10 files; 10 MB each. \*

 Upload file(s)

File number limit: 10 Single file size limit: 10MB Allowed file types: Word,Excel,PPT,PDF,Image,Video,Audio

16. Will the modification involve a change in research personnel? \*

[ ]  Yes

[ ]  No

Changes to Project Investigators

Please list all the project personnel who will be added or removed. Skip if answered “no” above.

17. Are you adding new personnel to this project? \*

[ ]  Yes

[ ]  No

18. List the names of all the personnel you would like to add here. \*

19. List the email(s) for the new personnel. If multiple, please separate each email with a semicolon. \*

20. I confirm that the new personnel uploaded their CITI Training Certificate to the IRB Canvas site. I understand that they must do so prior to this modification request being reviewed. \*

[ ]  Yes

21. Are you removing personnel from this project? \*

[ ]  Yes

[ ]  No

Personnel to Remove

Skip if “no” to above question.

22. List the names of all the personnel you would like to remove here. \*

23. List the email(s) for the removed personnel. If multiple, please separate each email with a semicolon. \*

Risks

24. Will the modification(s) increase any risks or present any new risks (physical, emotional, or psychological)?

[ ]  Yes

[ ]  No

25. If yes, provide a detailed explanation and how you will minimize the risks to participants. \*