**Protocol Change Form**

**Institutional Review Board Human Subjects Research**

**Northwest Missouri State University**

**Instructions:**

IRB approval is only granted to a project in the state that it was submitted and reviewed by the Northwest IRB. If any changes to protocol or procedures are made following IRB approval, the principal investigator must submit this document outlining all changes made to the procedures, materials, modalities, and data collection strategies of the project. **Data cannot be collected using changed protocols until IRB approval of the protocol change has been obtained.**

Once this form is submitted, it will be reviewed at same level at which the initial IRB application was reviewed. When a decision is reached, the chair of the Northwest IRB will contact you through email notifying you of approval to continue with the new protocol or requesting changes to the protocol. Note that some protocol changes may require your project to undergo an entirely new review if the protocol leads to higher subject risk or if your project no longer fits under the exempt or expedited category it was originally approved under.

To submit your protocol change, answer all questions below and attach both the old and new versions of any documents or materials that have been changed. Protocol changes should be submitted to the Northwest IRB through email (IRBNWMS@nwmissouri.edu).

**1. Project IRB Approval Code:** Click or tap here to enter text.

**2. Current Date:** Click or tap to enter a date.

**3. Project Title:** Click or tap here to enter text.

**4. Principal Investigator(s):**

 PI 1

 Name: Click or tap here to enter text. Email: Click or tap here to enter text.

 PI 2

 Name: Click or tap here to enter text. Email: Click or tap here to enter text.

 PI 3

 Name: Click or tap here to enter text. Email: Click or tap here to enter text.

**5. What is the current status of your project?** Choose an item.

 If you chose “Other”, explain the status of your project in the space below:

 Click or tap here to enter text.

**6. Explain all aspects of your project that need to be changed or amended. Your explanation should have enough detail that the reviewer could reasonably reconstruct your project from the answer you provide.**

Click or tap here to enter text.

**7. Explain why each proposed protocol change is necessary.**

Click or tap here to enter text.

**8. Attachments**

 Along with this form, your protocol change submission should also include:

 - Original informed consent statement

 - Updated informed consent statement (if changes affect the consent document)

 - Original and updated versions of any materials that were affected by the protocol change

 - Original and updated list of PI(s), faculty advisor(s), and other researchers (if changes were made to the PIs/advisors/researchers involved in the study)

 - Any new documents that were added to the project as part of the protocol change

 - A link to online materials/surveys (if the protocol change is for a change from in-person to online data collection)

**9. Signatures**

As with the original IRB application, protocol change forms must be signed and dated by the principal investigator as well as the faculty advisor (if applicable).

I affirm that all materials submitted are accurate and represent the documents as they will be used in this project, and that the statements I have made herein are truthful to the best of my knowledge.

Principal Investigator Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_

Faculty Advisor Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_

(if applicable)

All materials should be submitted electronically to the Northwest IRB email address (IRBNWMS@nwmissouri.edu). Any necessary supplementary documents should be included as attachments to your electronic submission.