**Institutional Review Board**

Amendment Form

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| INSTRUCTIONS | | | | |
| * Use this form for amending an existing IRB approved protocol. Examples of changes include:   1. research personnel,   2. consent form(s), recruiting materials   3. survey instruments, interview questions,   4. study procedures, compensation, or duration of participation. * Add rows as needed. * Indicate all changes by modifying the Protocol Form and any other applicable study documents using track changes, or highlights, as a means to distinguish between previously approved information and current requested changes. **Documents submitted without distinguishing between “new” vs “old” content will be returned to the PI and/or instructed to do so.** * For exempt protocols, contact the IRB at [orc@mu.edu](mailto:orc@mu.edu) with “Exempt Amendment for HR-####” as the subject line. Include IRB HR#, study title, and an explanation of the requested change(s) in the message. | | | | |
| **1. PI Name:** | |  | | |
| **2. Faculty Advisor if PI is student:** | |  | | |
| **3. E-mail:** | |  | | |
| **4. Department:** | |  | | |
| **5. Protocol Number:** | |  | | |
| **6. Study Title:** | |  | | |
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| **7a. Provide a detailed list of each change. Changes may include: study activities, number of participants, study sites, questionnaires, recruitment materials, consent forms, research personnel, etc.** | | | **7b. Provide a detailed justification for each change:** |
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| **8a. Does any change materially increase risk, materially decrease benefit, or materially decrease scientific merit? Place an “X” below.** | | | **8b. Provide an explanation if “Yes”:** |
| **Yes [ ]** | **No [ ]** | |  |
| **9a. Does any change need to be communicated to currently enrolled subjects? Place an “X” below.** | | | **9b. If, “Yes”, describe how change will be communicated (e.g., re-consent, next visit, letter, etc.) will take place:** |
| **Yes [ ]** | **No [ ]** | |  |
| **HELPFUL TIPS** | | | |
| * Changes may indirectly affect other documents. For example:   1. Changes to research personnel or number of research participants may affect the contact information of the consent or recruitment materials.   2. Adding or subtracting survey instruments or study activities may affect the risks and duration of the consent.   3. Changes to study activities may affect the risks section of the consent and Protocol Form. * Changes to PI, Faculty Advisor, or other key-personnel must detail their role and first and last name in **7b**. * To minimize future amendment submissions, non-key personnel roles such as student or graduate student “research assistant” do not require those individuals to be named in **7b**. * A change in PI or faculty advisor may require completion of human subjects training. See IRB Training for more information. | | | |
| **SUBMISSION INSTRUCTIONS** | | | |
| * Indicate all changes by modifying the Protocol Form and any other relevant attachments that have changed because of the amendment using track changes, or highlights, as a means to distinguish between previously approved information and current requested changes. **Documents submitted without distinguishing between “new” vs “old” content will be returned to the PI and/or instructed to do so.** * E-mail this completed form and any other relevant attachments that have changed because of the amendment to [orc@mu.edu](mailto:orc@mu.edu) with the following subject line:   1. **Amendment Submission for [first and last name of PI], HR-[XXXX]**   2. In the body of e-mail, include the title of the study and an itemized list of attachments.   3. Explain if changes are identified by highlights or “Track Changes”   4. The email address of the sender must be the Principal Investigator’s Marquette email.   5. If the PI is a **student**, the faculty advisor **must** be cc’d. * Once submitted, the ORC will e-mail back a response of receipt. If you do not receive an e-mail confirmation of submission within 3-5 days of submission, please contact the ORC by phone (414) 288-7570 or email ([orc@mu.edu](mailto:orc@mu.edu)) to verify receipt. | | | |