|  |  |  |
| --- | --- | --- |
|  | **METHODIST UNIVERSITY INSTITUTIONAL REVIEW BOARD** **REQUEST for MODIFICATION** |  |

For Information or help completing this form, contact: **The Institutional Review Board**

**Phone:** 910-480-8494 **E-Mail:** irb@methodist.edu **Web Address:** http://www.methodist.edu/irb

*In MS Word, click in the white boxes and type your text; double-click checkboxes to check/uncheck.*

**• Federal regulations require IRB approval before implementing proposed changes.**

**• Change means any change, in content or form, to the protocol, consent form, or any supportive materials (such as the Investigator’s Brochure, questionnaires, surveys, advertisements, etc.). See Item 4 for more examples.**

**• Hand written forms will not be accepted.**

|  |  |
| --- | --- |
| **1. Today’s Date** |       |

|  |
| --- |
| **2. Principal Investigator (PI)** |
|  **Principal Inves. (title):** |       | **Faculty PI (if PI is a student):** |       |
|  **Department:** |       | **Department:** |       |
|  **Phone:** |       | **Phone:**  |       |
|  **MU E-mail:** |       | **MU E-mail:** |       |
| **Contact person who should receive copies of IRB** **correspondence (Optional)** |
|  **Name:** |       | **Department Head:** |       |
|  **Phone:** |       |  |  |
|  **MU E-mail:**        |  |

|  |
| --- |
| **3. MU IRB Protocol Identification**  |
|  **3.a. Protocol Number** |       |
|  **3.b. Project Title**  |       |
|  **3.c. Current Status of Protocol—For active studies, check ONE box at left; provide numbers and dates where applicable** |
| [ ]   | **Study has not yet begun; no data has been entered collected** |  |
| [ ] [ ]   | **In progress If YES, number entered** **Adverse events since last review****Data analysis only** | **Approval Dates:** | From      To  |
| [ ]   | **Funding Agency and Grant Number:**       **MU Funding Information:** |
| [ ]   | **List any other institutions and/or IRBs associated with this project:** |

|  |
| --- |
| **4. Types of Change** |
| **Mark all that apply, and describe the changes in item 5** |
| [ ]  | **Change Key Personnel**Attach CITI forms for new personnel. |
| [ ]  | **Additional Sites or Change in Sites, including MU classrooms, etc.** Attach permission forms for new sites. |
| [ ]   | **Change in methods for data storage/protection or location of data/consent documents** |
| [ ]   | **Change in project purpose or project questions** |
| [ ]  | **Change in population or recruitment** Attach new or revised recruitment materials as needed; both highlighted version & clean copy for IRB approval stamp |
| [ ]  | **Change in study procedures** Attach new or revised consent documents as needed; both highlighted version & clean copy for IRB approval stamp |
| [ ]   | **Change in data collection instruments/forms (surveys, data collection forms)**Attach new forms as needed; both highlighted version & clean copy for IRB approval stamp |
| [ ]   | **Other** (BUAs, DUAs, etc.) Indicate the type of change in the space below, and provide details in Item 5.c. or 5.d. as applicable.Include a copy of all affected documents, with revisions highlighted as applicable. |
|        |

|  |
| --- |
| **5. Description and Rationale** |
|  |
| **5.a. For each item marked in Question #4 describe the requested changes to your research protocol, with an  explanation and/or rationale for each.** Additional pages may be attached if needed to provide a complete response. |
|        |
| **5.b. Briefly list** (numbered or bulleted) **the activities that have occurred up to this point, particularly those that involved participants.**  |
|        |
| **5.c. Does the change affect participants, such as procedures, risks, costs, benefits, etc.**  |
|        |
| **5.d. Identify any changes in the safeguards or precautions that will be used to minimize described risks.** |
|        |
| **5.e. Attach a copy of all “stamped” IRB-approved documents currently used. (information letters, consents, flyers, etc.** |
|        |
| **5.f. Attach a copy of all revised documents (high-lighted revised version and clean revised version for the IRB approval stamp).** |
|        |
| **6. Signatures****Principal Investigator \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_****Faculty Advisor PI, if applicable \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** |
|  |