|  |  |  |
| --- | --- | --- |
|  | **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](mailto: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 \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** |
|  |