**Form IRBF020a - MINOR REVISIONS REQUEST FORM**

**Use this form to request ONLY minor amendments to a previously approved protocol**

* Addition or removal of co-investigators who have completed appropriate training - UNLIMITED
* Correct typographical errors and omissions – UNLIMITED
* Reasonable extension or modification to the participant sample size – No restriction

1. **GENERAL INFORMATION**
   1. **Protocol Title:**
   2. **Protocol ID:**      **Expiration Date:**       **Today’s Date:**
   3. **Primary Investigator (PI) Information:**

Faculty/Staff Graduate Undergraduate Other

|  |  |  |
| --- | --- | --- |
| Name |  | |
| MTSU Email | mtsu.edu | |
| Alternative Email (if student) |  | |
| Address/Office Location |  | |
| Telephone Number |  | |
| Department/Unit and Office |  | |
| CITI training expiration date |  | Check if Training is Current |

* 1. **Faculty/Senior Investigator Information** (Skip if same as PI)

|  |  |  |
| --- | --- | --- |
| Name |  | |
| MTSU Email | @mtsu.edu | |
| Telephone Number |  | |
| Office Location & Department |  | |
| CITI training expiration date |  | Check if Training is Current |

\*The application documents MUST be emailed to [irb\_submissions@mtsu.edu](mailto:irb_submissions@mtsu.edu) by the faculty investigator. Suggested subject line to the email is “Protocol Addendum”

DO NOT CONVERT THIS APPLICATION TO PDF – There are embedded XML features

1. **TYPE OF AMENDMENTS**
   1. **Addendum request submission status:**

New request

Resubmission (explain below);

* 1. **Addendum type (select ALL that apply):**

|  |  |
| --- | --- |
| **Minor Amendments** (unlimited)  *These changes can be implemented immediately after emailing this request form and the PI/FA is not required to wait for an official notice.* | |
|  | Add co-investigators (Section3.1) |
|  | Remove co-investigators (Section 3.2) |
|  | Errors & Omissions (Section 3.3) |
|  | Participant Sample Size (Section 3.4) |
|  | OTHER non-procedural (use Section 3.5) |
| **Significant Amendments** – STOP use Form IRBF020b or the OLD ADDENDUM FORM | |

**Future Upgrades:**

* ***Use Form IRBF020b “Significant Amendments” for procedural changes and other amendments not listed in Section 2.2***
* ***Use Form IRBF020c when making both types – minor & significant – amendments simultaneousl*y**

1. **AMENDMENT PARTICULARS**
   1. **ADD Co-Investigator(s) –** Fill this section if you are requesting to add the following investigator(s) to this protocol. Simply hit enter to add more lines and keep the columns consistent for each investigator proposed to be included. .

|  |  |  |  |
| --- | --- | --- | --- |
| **#** | **FULL NAME** | **Email ID** (5-letter code for MTSU students) | **CITI ID Number** |
|  |  |  |  |

I, Click here to enter text., assure that the above mentioned individuals have completed CITI training. I understand that this protocol could be suspended if the training information provided here is inaccurate.

**Check this box** if ONLY IF have read and agree with the above statement.

*IMPORTANT INSTRUCTION:*

* *Mail this application to* [*irb\_submissions@mtsu.edu*](mailto:irb_submissions@mtsu.edu)
* *PROVISION: Addition of above mentioned investigators can be implement without having to wait for an approval notice once the applicant has* ***checked the above box*** *and emailed to* [*irb\_submissions@mtsu.edu*](mailto:irb_submissions@mtsu.edu)*. Check your sent-mail folder to ensure the request email has been sent before implementing the proposed amendments.*
* *RESTRICTION: However, the applicant(s) may be liable for IRB action if the Office of Compliance determines that the information provided here is inaccurate* 
  1. **REMOVE Current Co-investigator(s) –** Fill this section if you are requesting to remove the following investigator(s) from the protocol. Simply hit ENTER to add more lines**.**

|  |  |  |
| --- | --- | --- |
| **Name** | **Email** | **REMARKS (if any)** |
|  |  |  |

*IMPORTANT INSTRUCTIONS:*

*No further action is required by the investigators to remove the above listed investigators once the form has been emailed to* [*irb\_submissions@mtsu.edu*](mailto:irb_submissions@mtsu.edu)

* 1. **CORRECTIONS to Errors or Omissions –** Requisition to correct errors, such as spelling, grammar, and other unintentional mistakes in ANY of your document(s). Simply hit ENTER to start a new line.

|  |  |  |
| --- | --- | --- |
| **Document Type** | **Current Text** | **Proposed Correction** |
| Example 1 - Protocol Application  Example 2 – Recruitment email | In Page 3, 1st Paragraph, misspelled as “Genetics””  Opening sentence: “Dear Colleagues” | Change to “Gentiles”  Dear Recipient |
|  |  |  |

I, Click here to enter text., assure that the above mentioned corrections are unintentional mistakes and I fully understand that this protocol could be suspended if the information provided here is inaccurate.

**Check this box** ONLY if you have read and agree with the above statement

*DEFINITION*

* *Corrections of “unintentional” errors or omissions that were inadvertently introduced to any of the previously reviewed and approved documents*
* *The proposed correction(s) must not alter the methods, procedure, consent process or other assurances provided in the original protocol*
* *PROVISION: The investigators can implement the requested minor changes without having to wait for an approval notice once they agree with the following statement and email this form.*
* *RESTRICTION: However, the applicant(s) may be liable for IRB action if the Office of Compliance determines that the information provided here is inaccurate* 
  1. **EXTEND PARTICIPANT SAMPLE SIZE -** Fill this section of you are requesting to add or reduce the previously approved sample size.

1. Has the sample size extended prior to this request? Choose an item.
2. What is the current sample size?
3. What is the proposed sample size?
4. Will there be a change in the approved target population
5. Will the revision(s) lead to an alternation in the consent form? Choose an item.
6. Provide a reason for the requested sample size change (remember to include any statistical reasons):

* 1. **NON-PROCEDURAL Alterations –** Changes not listed explained within sections 3.1-3.4:

|  |  |  |
| --- | --- | --- |
| **Description** | **Current** | **Proposed Correction** |
|  |  |  |

I, Click here to enter text., assure that the above mentioned non-procedural amendments would not change the actual protocol in any way. I fully understand that this protocol could be suspended if the information provided here is inaccurate.

**Check this box** ONLY if you have read and agree with the above statement

1. **ATTACHMENTS AND ENCLOSURES**

**Select what is attached with this application:**

CITI training certificates for adding investigator(s)

Revised Application to include the proposed change in language

Revised Recruitment information

Revised consent form

Revised Surveys/questioners/interview scripts

OTHER(S), Specify:

1. **INVESTIGATOR (PI or/and FA) COMMENTS**

**Enter your note to the reviewer and other comments related to this amendment request:**

Click here to enter text.

1. **DECLARATION**

*Protocol amendments must be requested only by a faculty member. Therefore, a Faculty Sponsor must read and endorse this section if the applicant is a student*

I certify that:

1. this project is under my direct supervision
2. I have read this application thoroughly and I am fully aware of the activities to be performed under this protocol addendum

PI/Faculty Signature \_\_\_\_

Date \_\_\_\_

(Enter your name and TODAY’s date in the space provided)

* *Minor amendments listed in 3.1, 3.2 and 3.3 can be implemented immediately after submitting this form by email to* [*irb\_submissions@mtsu.edu*](mailto:irb_submissions@mtsu.edu) *and the PI is not required to wait for an action notice from the IRB. An official notice to confirm the IRB action will be sent in a timely fashion (1-2 weeks)*
* *Check your “sent” folder of your email to ensure that the request has been sent before you implement the proposed changes*
* *Amendments listed in 3.4 & 3.5 and all significant amendments will require an IRB approval before they can be* implemented