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| **IRB#** | **STUDY00021455** |
| **Date** | **11/14/2022** |

Dear Rick:

The Institutional Review Board (IRB) has reviewed the application, protocol, and supporting materials. It has been determined that clarifications and/or revisions are needed. Please access your study documents in CATS to make the changes that are outlined below.

**Please see the IRB Study Submission Guide located in the CATS Help Center (‘Guides’ tab) for instructions on using track changes to revise applicable documents and how to upload revised documents in CATS.**

**NOTE:** Please ensure REVISED documents are uploaded as a replacement to the previous document **OR** there will be two of the same document in the CATS. This can be accomplished by clicking the “Update” button beside the name of the document [or the “Upload Revision” button on the “Study Team Member” page]. **DO NOT DELETE THE PREVIOUS DOCUMENT.** The submission will be returned to fix duplicate documents in CATS. The Human Research Protection Program (HRPP) does not have the ability to make changes to and re-upload documents in CATS.

1. **Training Requirements for Researchers:**
   1. **Human Subject Training:** All personnel listed on your IRB submission must complete the required Human Subjects Research training before the proposal can be approved by the Institutional Review Board (IRB).  Information on training requirements is located in the Investigator Manual (HRP-103) in CATS IRB Help Center. For instructions on how to access the CITI program training please visit <https://www.research.psu.edu/education/citi>. The following individuals need to complete the Human Subjects Research training:
2. **Briana Ezray (Expired 09/25/2022)**
3. **Please make the following changes to your CATS submission:**
   1. Basic Information:
      1. Question #8: Please see the requested revisions to the protocol outlined below.
   2. Local Site Documents:
      1. Question #1: FYI: This study qualifies for review at the exempt level, which means that the informed consent form and/or recruitment materials that were uploaded for review will not be finalized or approved. To ensure that you have all the required elements of consent in your consent form, you may wish to utilize “HRP-584 - HRPP Consent Guidance for Exempt Research” for this study. This form may be found in the Library under the “Templates” tab in CATS and does NOT need to be uploaded for review.
      2. Question #3: Please upload the survey document to this section of the submission as a data collection tool.
4. **Please revise the protocol document [HRP-591 - Protocol for Human Subject Research.docx(20221111)] as follows:**
   1. **Please ensure ‘tracked changes’ is enabled PRIOR to making any revisions to the document.**
   2. **Before making any additional changes to the protocol, please accept all of the previous changes made to the document.**
   3. Page 1 – Please update the “Version Date” to reflect the date of resubmission.
   4. Item #2.2: Were these projects reviewed and approved by the IRB? If they were reviewed and approved by the PSU IRB, please provide the CATS Study ID.
   5. Item #4.1: Please provide a response to this item.
   6. Item #4.2: Please remove the information provided underneath the gray box, as the template says not to type/write directly underneath the gray instruction box.
   7. Item #5.2.1: How will subjects indicate their consent to participation?
   8. Item #6.2.1.1: Per the instructions in the gray box, if the section is not applicable, remove the statement in italics and indicate as not applicable.
   9. Item #6.3: Per the instructions in the gray box, if the section is not applicable, remove the statement in italics and indicate as not applicable.
   10. Item #7.2: Please provide a response to this item.
   11. Item #8.1: What is the maximum number of subjects to be enrolled?
   12. Item #22.1: Because it was indicated in 22.4 that there will be a study code with linking list, check the box for “Study code number with linking list”.

* 1. Section 22.2: Please provide a response to subparts 22.2.1, 22.2.2, and 22.2.3 or indicate as not applicable.
  2. Please upload the revised protocol for review on the “Basic Information” page.

**In order to facilitate the review process, please complete these requested revisions by December 14, 2022.** Please note that **every 15 days** the CATS IRB system will automatically send an e-mail notification for a submission when clarifications have been requested. **If no response or follow-up has been received by this 30-day deadline, your submission will be considered inactive.** While the Human Research Protection Program (HRPP) may grant requests for extensions to your revisions, it is ultimately your responsibility to contact us if additional time is needed to complete your changes.

Please do not hesitate to contact me if you have questions via one of the following:

* “Add Comment” function in the CATS submission
* Email or phone
* Schedule a meeting via [Bookings](https://outlook.office365.com/owa/calendar/BookingswithHRPPAnalyst@PennStateOffice365.onmicrosoft.com/bookings/)

Thank you,

Brittany Wickham, MS | IRB Analyst IV

Human Research Protection Program (HRPP) | The Pennsylvania State University

Email: [bmw71@psu.edu](mailto:bmw71@psu.edu)

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