Office of Human Subjects Research Institutional Review Boards

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Date: August 23, 2021

APPLICATION ACKNOWLEDGEMENT

Review Type: Exempt

Principal Investigator: Tracy Vannorsdall IRB00292955

Title: Personal Experiences of COVID-19

Committee Chair: Richard Moore

IRB Committee: IRB-3

Date of acknowledgement: August 10, 2021

Date of expiration: August 10, 2024

The JHM IRB has determined that the above-referenced new application qualifies as exempt research under the DHHS regulations.

If there are changes in this project that may affect this determination, you should consult with the JHM IRB before making those changes.

45 CFR 46.104(d)(2)(ii) - Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) where any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation;

To keep the JHM IRB application current we are assigning an Expiration Date as noted above. Prior to the expiration date, you will receive an email notification indicating that some action is required. If the Board has determined that a Continuing Review or Progress Report is required, you will need to submit Continuing Review or Progress Report prior to the expiration date. If the Board has determined that No Progress Report is required, you may run the administrative extend approval function.

IRB review included the following:

The enrollment of the non-English speaking participants. If you are using a short form consent, follow the JHM IRB Guidance on Obtaining and Documenting Informed Consent of Subjects Who Do Not Speak English.

The Board determined that there is no requirement for continuing review or progress report for this application.

This project has been assigned a 3-year expiration date. You will receive an email notification prior to the expiration date, allowing you to extend this project by completing an 'Extend Approval' activity.

Expiration Date: The expiration date for this research is listed above. If a continuing review application is required for this research and the approval lapses, the research must stop and you must submit a request to the IRB to determine whether it is in the best interests of individual participants to continue with protocol-related procedures.

Continuing Review/Progress Report: Continuing Review/Progress Report Applications should be submitted at least 6 weeks prior to the study expiration date.

If a progress report is required, failure to submit a progress report in the time period requested will result in your inability to submit any further study actions other than a progress report until your progress report is submitted and acknowledged.

If a Continuing Review application is required, failure to allow sufficient time for review may result in a lapse of approval. If the Continuing Review Application is not submitted prior to the expiration date, your study will be terminated and a New Application must be submitted to reinitiate the research.

Unanticipated Problems: All unanticipated problems must be submitted using a Protocol Event Report.

If this research has a commercial sponsor, the research may not start until the sponsor and JHU have signed a contract.

Study documents:

Recruitment Materials:

Recruitment-7.1.2021 v3.docx

Additional Supplemental Study Documents:

Survey Questionnaire_7.1.2021 v2.docx

Protocol:

eformE_8.4.21 v3_Clean.docx IRB Information for Qualtrics.pdf Protocol-8.4.2021.docx

Johns Hopkins Study Team Members:

None

The Johns Hopkins Institutions operate under multiple Federal-Wide Assurances: The Johns Hopkins University School of Medicine - FWA00005752, Johns Hopkins Health System and Johns Hopkins Hospital - FWA00006087