

SAMPLE REVISION MEMO

TEACHERS COLLEGE INSTITUTIONAL REVIEW BOARD

To: Teachers College Institutional Review Board, IRB@tc.edu
From: Teachers College Primary Investigator First and Last Name
Contact: {Contact Information}
Protocol Title: Experiences of Participants of CBT Therapy
Regarding: Revision to study protocol and materials
Date: {January 1, 2022}
IRB Protocol #: 12-345

Thank you for your review of our IRB application (Protocol ID # 12-345).

Please see our point-by-point responses. Tracked changes documents and clean final versions have been uploaded to Mentor IRB:

1. As a research lab or center, refer to the Job Safety Assessment (JSA) conducted by Environmental Health and Safety and upload a copy as “Additional Documents.”
 - a. I uploaded a copy of our complete Job Safety Assessment in our lab COVID-19 manual, as “JSA_2022-01-1-COVID-19 Procedure Manual.” Additionally, I uploaded a copy of “Research Lab - JSA Summary.”
2. Ensure all research staff who plan to engage in-person complete the “Ethics & Safety Amid Uncertainty Training Modules.” Ask they upload it within their own PI Documentation/Mentor IRB section: <https://www.tc.columbia.edu/preparedness/campus-life-during-covid-19/research-compliance-and-safety/training-modules/>
 - a. Everyone on the IRB protocol has completed and uploaded the certificate.
3. Ensure all research staff who plan to engage in-person complete the “Health & Safety Training Modules.” Ask they upload it within their own PI Documentation/Mentor IRB section: <https://www.tc.columbia.edu/preparedness/campus-life-during-covid-19/faculty--staff--campus-access-requirements/community-health-and-safety-training/>
 - a. Everyone on the IRB protocol has completed and uploaded the certificate.
4. Upload a “safety plan” for instances when the participant may become unstable or fall during the course of in-person activities.
 - a. Safety plan specifically addressing risk of falls and actions to take in the event of an accidental fall has been uploaded under, the section, “Additional Documentation” as “Safety Plan.”
5. You state on the consent form, “This is a minimal risk study, which means the harms or discomforts that you may experience are not greater than you would ordinarily encounter in daily life while taking routine physical or psychological examinations or tests.” However, the

study includes activities that are more than minimal risk as the activities may involve the risk of pain. Please clarify.

- a. We have removed the statement about minimal risk and highlighted potential risks for participants to consider prior to taking part in the study. This change has been reflected on the “Revised Consent Form.”
6. On the consent form, include the risk of pain or discomfort during some of the in-person activities.
 - a. We have included the sentence: “There is also a risk of experiencing pain or discomfort during a physical test, a pressure similar to what you will experience while walking on a treadmill.” This is reflected on the tracked changes and clean version of the “Revised Consent Form.”
 7. Include the TC IRB protocol number (e.g., 12-345) on all recruitment materials and the consent form.
 - a. Changes made as requested and revised materials uploaded under the following documents, “Revised Consent Form,” “Study Recruitment Flyer,” “Recruitment Email.”

List the file names of the revised uploaded documents:

1. 12-345 Revised JSA_2022-01-1-COVID-19 Procedure Manual Tracked Changes
2. 12-345 Revised JSA_2022-01-1-COVID-19 Procedure Manual Clean
3. 12-345 Revised Research Lab - JSA Summary Tracked Changes
4. 12-345 Revised Research Lab - JSA Summary Clean
5. 12-345 Safety Plan
6. 12-345 Revised Consent Form_Tracked Changes
7. 12-345 Revised Consent Form_Clean
8. 12-345 Recruitment Email_Tracked Changes
9. 12-345 Recruitment Email_Clean
10. 12-345 Study Recruitment Flyer_Tracked Changes
11. 12-345 Study Recruitment Flyer_Clean

Thank you very much for your continued review of this research protocol. Please do not hesitate to contact us should you require additional information.

Sincerely,

PI First and Last Name

Title

Department

Teachers College, Columbia University

Email

Work Phone Number

Faculty Sponsor First and Last Name (*if a student protocol*)

Title

Department

Teachers College, Columbia University

Email