

SAMPLE MODIFICATION MEMO

TEACHERS COLLEGE INSTITUTIONAL REVIEW BOARD

To: Teachers College Institutional Review Board, IRB@tc.edu
From: Teachers College Student, Ph.D., Faculty Sponsor, Ph.D.
Contact: {Contact Information}
Protocol Title: Experiences of Participants of CBT Therapy
Regarding: Modification to study protocol and materials
Date: {January 1, 2022}
IRB Protocol #: 12-345

Thank you for your continued review of our “Experiences of Participants of CBT Therapy” study protocol (Protocol ID #12-345). We are submitting a modification for changes to the study protocol and materials. Below we describe each change and list the study materials that have been updated to reflect these changes. The changes do not alter the risk level of the study for the reasons described below.

Please note that all documents that end with “CLEAN” in their file names are revised documents and are accompanied by a track change version (which is indicated by “Tracked Changes” in their file names).

The researcher(s) for this project would like to make the following changes to this protocol:

1. Modification to expand geographic location for recruitment
2. Modification to mental health resources
3. Modification to study inclusion criteria related to CBT therapy
4. Modification to phone screen language
5. Modification to protocol
6. Modification to consent form

Below is a detailed summary of the requested changes:

1. **Modification to expand geographic location for recruitment.** We have expanded the geographic location through which we will recruit participants. We were previously recruiting participants who reside in the city of Los Angeles, but will now include participants with residency in the states of California, Nevada, and Oregon. This change has been reflected in the Recruitment Form 12345 CLEAN.docx and IRB Protocol 12345 CLEAN.docx.
2. **Modification to mental health resources.** We have modified our list of mental health resources of CBT Therapy to feature those that are suitable for participants residing in any of the states in which we are recruiting. Previously, our resources were Los Angeles based (in line with our original recruitment location). This change has been reflected in the Measures 12345 CLEAN.docx, Mental Health Resource List 12345 CLEAN.pdf, IRB

Protocol 12345 CLEAN.docx, and Safety Protocol 12345 CLEAN.docx.

3. **Modification to study inclusion criteria related to CBT Therapy.** We have modified our CBT Therapy inclusion criteria such that participants must have had 3 months of active CBT Therapy within the past three years to be eligible to participate. This was previously set to 1 month in the past two years. This will not affect participants who are currently enrolled and will only affect enrollment after this modification is approved. This change does not alter the risk level of the study. This change has been reflected in IRB Protocol 12345 CLEAN.docx and Inclusion Criteria 12345 CLEAN.docx.
4. **Modification to phone screen script language.** We have modified the language in our phone screen script asking participants about CBT Therapy. Previously, we asked participants “Have you ever had CBT Therapy?” and will now ask participants “Have you ever participated in CBT Therapy?”, in addition to follow-up questions asking them to identify when and how long they participated in CBT Therapy. This change has been reflected in the Phone Script 12345 CLEAN.docx.
5. **Modification to protocol.** We have modified the language in our protocol to clarify that participants must use a tablet (e.g. iPad or Microsoft Surface) or a computer to participate in the baseline and follow-up Zoom sessions. This is in line with language that is already in our phone screen script. This change has been reflected in the IRB Protocol 12345 CLEAN.docx
6. **Modification to consent forms.** We have modified the language in our consent forms to clarify that we will take measures to avoid actively linking the participants’ names to their study responses (unless exceptions to the confidentiality policy apply). This change has been reflected in the Consent Form 123456 CLEAN.docx.

Uploaded Revised Modification Documents

1. IRB Protocol 12345 CLEAN.docx
2. IRB Protocol 12345 Tracked Changes.docx
3. Consent Form 123456 CLEAN.docx
4. Consent Form 123456 Tracked Changes.docx
5. Inclusion Criteria 12345 CLEAN.docx
6. Inclusion Criteria 12345 Tracked Changes.docx
7. Phone Script 12345 CLEAN.docx
8. Phone Script 12345 Tracked Changes.docx
9. Mental Health Resource List 12345 CLEAN.pdf
10. Mental Health Resource List 12345 Tracked Changes.pdf
11. Measures 12345 CLEAN.docx
12. Measures 12345 Tracked Changes.docx
13. Safety Protocol 12345 CLEAN.docx
14. Safety Protocol 12345 Tracked Changes.docx

15. Recruitment Form 12345 CLEAN.docx
16. Recruitment Form 12345 Tracked Changes.docx

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 Signature

Title

Department

Teachers College, Columbia University

Email

Work Phone Number

Faculty Sponsor Signature

Title

Department

Teachers College, Columbia University

Address

Work Phone Number