UNMUTE/NYU Culturally Affirming Racial Equity (CARE) Study

Research Informed Consent Form — THERAPIST

PID _____

Title of Study:	Unmute's Culturally Affirming Racial Equity (CARE) framework: A Novel Approach to Strengthen the Therapeutic Alliance and Reduce Treatment Disparities with Racial/Ethnic Minority Patients Study #: IRB-FY2024-9189
Trials registration number	ClinicalTrials.gov Identifier: NCT06625502
Principal Investigators:	Dr. Doris F. Chang NYU Silver School of Social Work 1 Washington Square North Rm 206 New York, NY 10003 Colleen Leung Unmute Enterprises, Inc. 65 Breakwater Drive Chelsea, MA 02150
Emergency Contact:	Dr. Doris F. Chang (212) 998-5889 dfchang@nyu.edu
Funder	National Institutes of Mental Health

1. SUMMARY OF THE RESEARCH STUDY

You are invited to participate in a research study to learn more about how to improve mental health services for treatment-seeking Asian Americans. The Principal Investigators are Doris F. Chang, PhD (New York University) and Colleen Leung (Unmute). Dr. Chang is also a co-founder, equity holder, and the Chief Clinical Officer of Unmute. As part of the study, you will receive training and biweekly group supervision in Unmute's Culturally Affirming Racial Equity (CARE) framework, which emphasizes therapist-patient collaboration and culturally-informed assessment to center the patient's experience. The goal is to improve the cultural fit of treatment for diverse populations, even when the therapist may not share the same cultural background as the patient.

This study is focusing on training non-Asian clinicians to cultivate the cross-racial/cultural therapeutic alliance and conduct culturally-affirming assessment and treatment to English-speaking Asian Americans seeking short-term psychotherapy.

If you agree to be in this study as one of our study clinicians, you will be asked to do the following:

1. Complete brief periodic surveys, including (<5 min) post-session surveys and termination surveys (<10 min) about your experiences of working with each patient, and surveys (~10 min) about your relevant training and background, supervision, and the study overall.
2. Participate in a semi-structured individual debriefing interview conducted through Zoom to share feedback about your experiences of the program to improve the approach.
3. Additionally, as your clinical sessions will be recorded for quality assurance purposes, you may also consent to allow your session videorecordings to be retained for future research. Otherwise, we will delete the recordings 6 months after the study ends.

Your participation in these activities should take approximately 9 months.

The risks associated with this study are minor. One risk is that it may be difficult or uncomfortable to reflect on and answer questions about your work with patients, including the quality of the therapeutic relationship, and how you handle relational ruptures that may arise. There is a potential risk of loss of confidentiality; however, we have procedures in place to protect your confidentiality, as we will explain.

The benefits which may reasonably be expected to result from your participation in this study are that you may experience improvement in your therapy skills as a result of reflecting on your clinical practice with Asian American patients. Your participation may inform the development of more culturally-responsive services for Asian Americans and other racial and ethnic minority groups.

Participation in this study is voluntary. You may refuse to participate or withdraw at any time without penalty. Your decision to withdraw from the study will not affect your eligibility to receive compensation for completed work as outlined below. Please read the rest of this consent form for more information about the study. Please ask any questions you have about the study or about this form before deciding to participate. If you decide to take part in this study, we will note your consent for our records. We will give you a copy of this form for you to keep.

2. PURPOSE OF THE STUDY

The purpose of the Unmute CARE Study is to test an approach to improving the cultural fit of treatment for diverse patients, even when the therapist does not share the same cultural background as the patient. The study examines how patients respond to the treatment approach

and whether it improves the patient's experience and the effectiveness of short-term psychotherapy.

3. ELIGIBILITY TO PARTICIPATE

All participants hired as interventionists for the Unmute study are eligible to be a research participant if they are willing to complete periodic brief assessments (surveys, interview) about their experiences of training and service delivery.

4. DESCRIPTION OF STUDY PROCEDURES

If you agree to participate in this study, you will be asked to complete various assessments to evaluate activities. Please note that the data that you provide through these various activities (surveys, group supervision, debriefing interviews, etc.) will be linked to each other, on the individual level, using your unique participant ID number:

A. Training Evaluation Survey

After you complete the training, we will ask you to complete a short survey to rate what you think about the treatment approach, your satisfaction with the training; and how confident you feel about implementing the approach with Asian American patients.

B. Post-Session Questionnaires

After each session, you will be sent a link to complete a very short (2-3 minute) survey about the session you just conducted. You will be asked to rate the session on several characteristics and identify any issues or challenges that arose in your work with the patient. The information you provide will be confidential and not shared with your patient.

D. Other Periodic Assessments

From time to time, you will also be asked to complete additional brief assessments including a Termination Survey (5-7 min) at the end of each patient's treatment to rate each patient's progress, symptom distress and functional impairment, and any issues that arose in the therapy relationship.

At the end of the study, you will be asked to complete a final Feedback Survey and participate in a 30-minute interview with study staff (over Zoom) to reflect on your study experience and share any feedback you have. We will ask if we can audiorecord this interview for research purposes. However, this is optional and you can do the interview even if you do not want it recorded.

5. RISKS OR DISCOMFORTS

One risk associated with this study is that it may be difficult or uncomfortable to reflect on and answer questions about your work with patients, including the quality of the therapeutic relationship, and how you handle relational ruptures that may arise.

Another possible risk is loss of confidentiality. The study will do everything possible to protect your confidentiality. Confidentiality of your research records will be strictly maintained by the research team. Every participant will receive a participant identification number (PID). The PID will be used instead of your name on all surveys, videorecordings, and materials. Activities will take place through a secure online survey platform or over Zoom, a web-based video conferencing and web conferencing service that employs industry-grade encryption and other measures to ensure data confidentiality.

The study may involve other risks that are unknown at this time.

6. BENEFITS

This study may help us learn how to improve the quality of mental health services for Asian Americans, by exploring how therapists can effectively collaborate with patients on a course of treatment tailored to their needs and cultural contexts, and to address any issues that may arise due to cultural differences.

You may experience personal benefits from participating in the study. You may experience improvement in your therapy skills and increase your effectiveness in working with Asian American patients.

There may be benefits to others as well. This study may help us learn about the various factors that can improve treatment effectiveness for Asian Americans, even if their therapist does not share their cultural background. Your participation may inform the development of more culturally-responsive services for Asian Americans and other racial and ethnic minority groups as well.

But, you may or may not get any direct benefit from being in the study.

7. COMPENSATION

You will receive compensation of up to $550 for completing assessments throughout the study period. Payments will be made in the form of an e-gift card (www.tangocard.com), which will be disbursed as a single lump sum at the end of the study. E-gift cards may be redeemed online at 100+ popular retailers. You will receive compensation for completing the following activities:

- **$40 for completing the Post Training Survey** at the end of orientation
- **$5 per completed Post-Session Questionnaire (PSQ)** after each therapy session, for a maximum of $75 per patient for up to 15 sessions
- **$20 for each Patient Termination Survey**, for a maximum of $100 for up to 5 patients
- **$35 for participating in a 30-minute debriefing interview** at the end of the study

If you receive more than $600 from NYU in a calendar year, then NYU will issue a 1099 for tax purposes and report the information to the IRS, in which case you may need to pay taxes on it. Because your compensation as a research participant will be over $250, we will collect personally identifying information from you for tax purposes, e.g., name, address, social security number on your W9). However, this information will be kept only for this purpose and not connected to any data that you provide as part of this study.

8. VOLUNTARY PARTICIPATION

Participating in this study is completely voluntary. You may choose not to take part in the study or to stop participating at any time, for any reason, without penalty or negative consequences. However, you will only be compensated for the activities you engage in.

You may be withdrawn from the study if you are no longer serving as a study therapist.

If you leave the study or are withdrawn from the study or are otherwise unable to continue providing treatment to your study patients, we may reassign your patients to another study therapist to ensure continuity of care. You may still be eligible to complete some of the surveys and optional interview, however. You will only be compensated for the activities you engage in.

9. PRIVACY AND DATA CONFIDENTIALITY

NYU and Unmute are committed to protecting the privacy and confidentiality of the information you provide to us. Confidentiality of your data, including survey data and video/audio recordings, will be strictly maintained, and shared only with your provider and supervision team, and research staff to ensure quality of care. In the case of activities involving others (for example, your group supervision sessions with the other study clinicians), your responses will be kept confidential by the research team, but we cannot guarantee that others in the group will do the same.

As mentioned, your participant identification number (PID) will be used instead of your name on all surveys, recordings, and materials to protect your identity. Activities will take place through a secure online survey platform or over Zoom. Data will be stored on password-protected computers and a cloud-based back-up system. In written reports, data will only be reported in the aggregate.

The information you provide to us will be used by the research team and others involved in the study to conduct and oversee the study. At the end of the study, you will have an opportunity to consent to allow your video and/or audio recordings to be retained for research and/or training purposes. Recordings will be retained only if the patient also provides consent. Otherwise, the recordings will be destroyed six months after the completion of the study.

Survey data, video and audio files, and transcripts (if applicable) will be kept on a computer that is password protected and also backed up to a password-protected cloud-based storage system. Only study personnel will have access to the files. Please note that information not containing identifiers may be used in future research, shared with other researchers, or placed in a data repository without your additional consent.

If there is anything about the study or your participation that is unclear or that you do not understand, if you have questions or wish to report a research-related problem, you may contact Dr. Doris F. Chang at (212) 998-5889, dfchang@nyu.edu, 1 Washington Square North, Room 206, New York, NY 10003.

For questions about your rights as a research participant, you may contact the University Committee on Activities Involving Human Subjects (UCAIHS), New York University, 665 Broadway, Suite 804, New York, New York, 10012, at ask.humansubjects@nyu.edu or (212) 998-4808. Please reference the study IRB-FY2024-9189 when contacting the IRB (UCAIHS).

10. Certificate of Confidentiality

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. Researchers with this Certificate will not disclose or use information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, even if there is a court subpoena.

Exceptions include:

- A federal, state, or local law requires disclosure, such as information about suspicion of child abuse or neglect, or suspicion of harm to yourself or others.

- Your explicit approval for the researchers to release your name and/or personally identifiable information.

11. Clinicaltrials.gov

A description of this clinical trial will be available on https://www.clinicaltrials.gov/, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

When you sign this form, you are agreeing to take part in this research study as described to you. This means that you have read the consent form, your questions have been answered, and you have decided to volunteer.

You will receive a copy of this consent document to keep.

Do you agree to participate in this research study?

_____	_____	_____
Name of Participant (Print)	Signature of Participant	Date

_____	_____	_____

Name of Person Obtaining Consent (Print)	Signature of Person Obtaining Consent	Date

I agree to have my sessions videorecorded for supervision and quality assurance purposes.

_____ Yes _____ No

Initials Initials

I agree to allow my session video and/or audiorecordings to be retained for future research and training. (You can say no and continue in the study)

Video _____ Yes _____ No Audio only _____ Yes _____ No

Initials Initials Initials Initials

I agree to be contacted for future research. (You can say no and continue in the study)

_____ Yes _____ No

Initials Initials