Informed Consent Form

Trial Name: Optimizing Provider Training in Eating Disorders (OPTED)

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UNIVERSITY OF CALIFORNIA, SAN FRANCISCO (UCSF)
CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Training in Family-Based Treatment for Restrictive Eating Disorders

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Introduction

This is a research study at UCSF that is examining different ways of training mental health providers in family-based treatment (FBT) for restrictive eating disorders, specifically those working with Medicaid-insured youth. The study researchers, led by Erin Accurso, PhD, from the UCSF Department of Psychiatry and Behavioral Sciences, will explain this study to you.

Research studies include only people who choose to take part. Please take your time to make your decision about participating and discuss your decision with your family or friends if you wish. If you have any questions, you may ask the researchers.

The first part of this consent form gives you a summary of this study. We will give you more details about the study later in this form. The study team will also explain the study to you and answer any questions you have.

Purpose of the Study

The purpose of this study is to compare the effectiveness of two training methods—a traditional two-day training and a self-paced web-based training, with the ultimate goal of improving cost-effective training models and care for clinicians who treat youth insured by Medicaid. This research is being funded by the National Institutes of Health.

You are being asked to take part in this study because you are a mental health provider who treats Medicaid-insured youth and have expressed interest in receiving training in FBT. Providers who are not yet licensed will need to have a clinical supervisor who agrees to take legal responsibility for any cases treated with FBT, or are also invited to participate in the study.

Detailed Information about the Study

Study Procedures

If you choose to participate in the research study, you will be asked to complete questionnaires pre-training, at the completion of training, 6 months, and 12 months post-training. After completing initial questionnaires, your clinic/agency will randomized to web-based training (≈67% likelihood) or two-day live training (≈33% likelihood) in family-based treatment. All participants who enroll in the study will be provided training at no cost. Following training, up to 36

participants will be provided expert group consultation, based on their training condition, for up to a year at no cost. If more than 36 participants express interest in group consultation, access will be prioritized based on geographic location, language capacity, and/or access to a training case. Clinicians who are unable to access group consultation through this study can still access consultation outside of the research study. Participants who treat at least one case (and up to 4 cases) using a family-based treatment approach will also be asked to provide retrospective de-identified demographic and clinical data on cases treated, including weights, total scores on questionnaires, and self-report of your implementation via online Qualtrics survey.

What side effects or risks can I expect from being in the study?

Participation in this study may involve some added risks or discomforts, including the following:

- Potential for loss of confidentiality. Research records will be kept confidential to the extent allowed by law. Data will not be released without your consent. All data will be labeled with a study ID. If this research is published, your name and other personal information will not be included.
- Because this is a research study, some of the risks are currently unforeseeable.

Possible Benefits

You will receive training in the assessment of eating disorders and in family-based treatment for anorexia nervosa and other restrictive eating disorders, with the possibility of expert group consultation in family-based treatment for up to 12 months post-training, all at no cost.

Your Other Options

You are free to choose not to participate in the study; this will not affect your ability to seek training in family-based treatment elsewhere.

How many people will take part in this study?

We hope to enroll up to 120 mental health providers. Up to 36 of providers who complete the training and express interest will be offered access to expert group consultation.

What will happen if I take part in this research study?

If you agree to be in the study, you can expect the following:

- You will be asked to complete questionnaires on your attitudes toward evidence-based treatment and FBT, knowledge about FBT, and provider-rated treatment acceptability.
- You will participate in your assigned training, either web-based or two-day live training.
    - We will be collecting data on your participation and progression through your assigned training modality (web-based or two-day live training).

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- You will participate in your assigned training, either web-based or two-day live training.
    - We will be collecting data on your participation and progression through your assigned training modality (web-based or two-day live training).
- A limited number of participants will be able to receive weekly group consultation if interested in implementing FBT in their practice. While receiving consultation is a potential benefit to a limited number of participants for participating in the study, we will be collecting data throughout the consultation process, such as treatment fidelity.
- You will be asked to complete a self-report measure of fidelity to FBT components (FBT-TTS) every month in which you have an active case in treatment, as well as provide de-identified clinical data collected by you in the treatment of your case(s).
    - De-identified clinical data includes: demographics and clinical/diagnostic data, including height, weight, treatment goal weight, and total scores for clinical measures (e.g., ED-15-Y, ED-15-P, and Parent versus Eating Disorders)

Where will the study take place?

Both training models will be conducted virtually due to the COVID-19 pandemic. The two-day training will be conducted via zoom. Web-based training will be paced across six to eight weeks. Group consultation for both training groups will be offered via zoom for up to one year—weekly for the first 6 months and twice monthly for the next 6 months.

How long will I be in the study?

Your participation will be approximately two years, provided you are seeing a case in FBT. Total length of participation is not to exceed two years.

Can I stop being in the study?

Yes. You can decide to stop at any time. Just tell the study researcher or staff person right away if you wish to stop being in the study. Also, the study researcher may stop you from taking part in this study if you do not follow the study rules or if the study is stopped.

What about confidentiality?

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or suit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena. There are some important things that you need to know. The Certificate DOES NOT stop reporting that

federal, state or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate CANNOT BE USED to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate DOES NOT stop disclosures required by the federal Food and Drug Administration (FDA). The Certificate also DOES NOT prevent your information from being used for other research if allowed by federal regulations.

Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other persons not connected with the research. The Certificate of Confidentiality does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information

How will my information be used?

Researchers will use your information to conduct this study. Information gathered during this research study will only be used for this study and will not be shared with other researchers. Authorized representatives from the following organizations may review your research data for the purpose of monitoring or managing the conduct of this study:

- Representatives of the University of California
- Representatives of the National Institutes of Health
- 3C Institute

What are the costs of taking part in this study?

There are no costs associated with participation in this study.

Will I be paid for taking part in this study?

In acknowledgement of your time and effort in participating, you may receive up to $75 in gift cards for completing surveys at post-training ($25), 6 months ($25), and 12 months ($25). Should you start treatment for a client with a restrictive eating disorder, you may receive an additional $5 per client, per timepoint for de-identified clinical data provided at 6 and 12 months.

What are my rights if I take part in this study?

Taking part in this study is your choice. If you decide to take part in this study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you in any way.

What happens if I am injured because I took part in this study?

It is important that you tell your study doctor, Erin Accurso, PhD, if you feel that you have been

injured because of taking part in this study. You can tell the doctor in person or call her at 415-476-5139.

Treatment and Compensation for Injury: If you are injured as a result of being in this study, the University of California will provide necessary medical treatment. The costs of the treatment may be billed to you or your insurer just like any other medical costs, or covered by the University of California or the study sponsor [NIH], depending on a number of factors. The University and the study sponsor do not normally provide any other form of compensation for injury. For further information about this, you may call the office of the Institutional Review Board at 415- 476-1814.

Who can answer my questions about the study?

You can talk to the researcher(s) about any questions, concerns, or complaints you have about this study, including calling Erin Accurso, PhD, at 415-476-5139. If you wish to ask questions about the study or your rights as a research participant to someone other than the researchers or if you wish to voice any problems or concerns you may have about the study, please call the Institutional Review Board at 415-476-1814.

CONSENT

PARTICIPATION IN RESEARCH IS VOLUNTARY. You have the right to decline to be in this study, or to withdraw from it at any point without penalty or loss of benefits to which you are otherwise entitled. You will be given a copy of this consent form to keep.

If you wish to participate in this study, you should sign below.

_____
Name of Participant

_____ _____
Signature of Participant Date

_____ _____
Signature of Person Obtaining Consent Date

DISCLOSURE OF PARTICPATION IS VOLUNTARY. Leadership has indicated that it may be helpful to know the names of individuals in their county who have enrolled in training, but your participation in this study is confidential. **To maintain standard confidentiality for your participation in this study, leave this section blank.** Should you like for our team to disclose your participation in this training (and therefore this study) to your designated county representative (**Alameda**: Jennifer Ling; **Contra Costa**: Floris Mendoza; **Marin**: Brian Robinson; **San Francisco**: Karen Mu; **San Mateo**: Marta Perez; **Solano**: Robin Zywiciel), please initial below.

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_____ **Yes**, I would like the research team to share my name with my county representative.