

DATA REPOSITORY: If you agreed to participate in research, Dr. Persons is additionally asking your broad consent permission to add data from your clinical record to the Oakland CBT Data Repository. This database differs from the research database described above in that no participant ID code is maintained. *The data repository database will not include your name, address, or any other information that could identify you.* The data repository database will be used for scientific research about the nature and causes of anxiety, depression, and other psychological difficulties; about the processes of change during treatment; and about the quality of our assessment tools, in order to improve our understanding of psychological difficulties and to improve our treatment of those difficulties. More information about the data repository is provided in the attached document titled Description of the Oakland Cognitive Behavior Therapy Center Data Repository.

You do not have to give permission for your data to be included in the Data Repository unless you want to. Declining to give permission will not affect your treatment with Dr. Persons in any way. If you agree to give permission to provide data for the Data Repository, you may withdraw permission by letting Dr. Persons know in writing. At that point, no further data from your clinical record will be added to the database. However, because the data are completely de-identified, it will not be possible to remove your data from the data repository once they are placed there.

Please initial below to give consent to add data from your clinical record to the Oakland CBT Data Repository. If you do not initial below, Dr. Persons understands that she does not have your permission to enter material from your clinical record into the Oakland CBT Data Repository.

_____(initial)

I have read and understood this agreement and the attached Patient Bill of Rights and Data Repository Description, and I have had my questions answered to my satisfaction. I accept, understand, and agree to abide by the contents and terms of this agreement and consent to participate in evaluation and/or treatment.

Name of patient: _____

Date: _____

Description of the Oakland Cognitive Behavior Therapy Center Data Repository

REPOSITORY GUARDIAN: Jacqueline B. Persons, Ph.D., Director
Oakland Cognitive Behavior Therapy Center
5625 College Avenue, Suite 215, Oakland, CA 94618
510-662-8405; persons@oaklandcbt.com

WHAT IS A DATA REPOSITORY?

A data repository is a de-identified database of data culled from patient clinical records that is stored in an excel document (or similar). The database does not include any information that would uniquely identify any patient, and the data are pulled from the clinical record only when the patient provides written informed consent.

PURPOSE

The purpose of this data repository is to support research that helps us improve our understanding and treatment of psychological difficulties. Typical research topics include: the relationships among various symptoms of anxiety and depression, how learning skills in therapy relates to symptom change, patterns of change in symptoms during therapy, the relationship between session frequency and treatment outcome, and the quality of our assessment tools. As the field develops, we may identify additional hypotheses that we want to study with the data in the data repository.

WHAT DATA WILL BE COLLECTED?

Your therapist will collect information from your clinical record that does not identify you, including your age, gender, and other demographics, your diagnosis, your personal and treatment history, your symptoms, number of sessions of therapy, and information from questionnaires you completed.

HOW WILL DATA BE COLLECTED?

To transfer data from your clinical record to the repository, your therapist will remove identifying information from the data and transfer the anonymous data into a research database.

WHAT WILL HAPPEN TO THE DATA?

The data repository will be stored on a password-protected computer in the office of the Repository Guardian (Jacqueline B. Persons). Backups of the data repository will be stored in secure web-based locations, and on password-protected thumb drives or computers to protect against loss of the data. The data will be stored indefinitely. The data repository will be accessible to your therapist, other researchers at the Oakland CBT Center, and other researchers who follow the policies and procedures established by the Repository Guardian and the Institutional Review Board of the Behavioral Health Research Collective. To increase the contribution that your data can make to science, the data repository may be shared with other investigators via a secure web-based approved third-party data repository that manages access to data to qualified

researchers through a documented process.

PRIVACY & CONFIDENTIALITY PROTECTIONS

To protect your privacy, the data in the data repository do not include any information that will identify you.

RISKS AND DISCOMFORTS

Although your therapist and the Repository Guardian will make every effort to protect your identity, there is an extremely small risk of loss of confidentiality. In the highly unlikely event that the data in the repository should become linked to your identity and distributed to an outsider, sensitive information about you and your therapy could become available to an insurer, employer, relative, or someone else.

BENEFITS

You will not receive any direct benefit from participating in this research repository. Your participation will support research that contributes to advances in scientific knowledge. You can access research reports based on the data from the repository at www.oaklandcbt.com/Research. Because the data you provide will not affect your treatment, if you agree to provide data for research, you will not be informed about the results of research based on your data or about subsequent studies of similar topics.

COSTS

You will not be paid for providing data for the data repository. There will be no cost to you for contributing to the data repository.

PARTICIPANT RIGHTS

You have a right to refuse to provide data for the repository. **No information about you will be placed in the data repository unless you initial the DATA REPOSITORY section of the Evaluation and Treatment Agreement.** You can also withdraw from participation by notifying your therapist in writing that you wish to withdraw from participating in the data repository. However, if you withdraw your participation once your data have been entered into the repository, there will be no way to remove your data from the repository, as your data are not linked to your name or any other identifying information. However, if you withdraw, no new information will be added from your record to the repository. If you refuse to participate or later withdraw your permission to provide data for the repository, you will not suffer any penalty or loss of benefits to which you are otherwise entitled or give up any legal rights. Your treatment at the Oakland CBT Center will not be affected if you decline to participate in the repository.

OVERSIGHT

Policies and procedures that govern this data repository were approved by the Behavioral Health

Research Collective Institutional Review Board, chaired by Travis L. Osborne, Ph.D., 1200 Fifth Avenue, Suite 800, Seattle, WA 98101 (206) 374-0109. Email: collectiveirb@gmail.com. The BHRC IRB is registered with the federal Office of Human Research Protections (OHRP). The BHRC reviews the procedures of this data repository on an annual basis to evaluate its compliance with BHRC standards, OHRP standards, HIPAA regulations, and other applicable standards.

If you have questions, concerns, or complaints about the data repository, you may contact the guardian of the repository (listed at the beginning of this document) or Travis Osborne, Ph.D., Chair of the BHRC IRB (contact information in the preceding paragraph) that oversees the data repository.