Research Policies at the Oakland Cognitive Behavior Therapy Center

This document describes research policies at the Oakland Cognitive Behavior Therapy Center, a private practice in Oakland, CA, described hereafter as "the Oakland CBT Center."

Oversight of Research Activities at Oakland CBT Center

The person responsible for maintaining and adhering to these research policies at the Oakland CBT Center is the Director, Jacqueline B. Persons, hereafter referred to in this document as the Director of Research.

Relationship of Research to the Oakland CBT Center's Mission

Inviting our patients, consultees, students, or trainees to participate in research involves a dual relationship. It is our policy that the therapist's or consultant's, or supervisor's clinical and training responsibilities and missions always take priority over the research goals. Patients, consultees, students, and trainees at our organization are invited to participate in research but are not required to do so as a condition of receiving care or consultation or training at our organization. (We use the word "participant" in this document to refer to all of those types of research participants.)

If the research proves to conflict with the clinical or training goals, the researcher will discuss the issue with the participant and arrive at a solution to the conflict that is acceptable to the participant. The researcher will always consider the option of resolving the conflict by discontinuing the research with that participant. If the conflict is not quickly and easily resolved, the researcher will follow the procedures outlined below in the section titled Security Breaches, Protocol Violations, and Other Adverse Events.

Training in Research Involving Human Subjects

All professional and administrative staff engaged in research activities at the Oakland CBT Center, including management or analysis of data derived from these activities, will complete a course on protecting human research participants and obtain a Certificate of Course Completion. This training will be obtained through the National Institute of Health or the Collaborative Institutional Training Initiative, or a comparable organization meeting federal standards for protecting human research participants. Each individual engaged in research activities will renew his/her certification every five years at minimum and will provide a certificate of completion to the Oakland CBT Center's Director of Research. Everyone at the Oakland CBT Center who is engaged in research will complete the required training before engaging in any research activities.

Ethical Review of Proposed Research

All research projects involving the collection or analysis of data obtained at our organization must undergo some type of review to assure that the project is legal and ethical unless the project relies on data from a de-identified Data Repository that has itself been subject to an ethical review (see the section below titled Policies Governing a Data Repository). The Principal Investigator for each project will present his or her project to the Oakland CBT Center's Director of Research and/or any other individuals the Director of Research designates, who will make a decision about the type of review needed for the project.

Options for the type of review include: a formal Institutional Review Board review that meets Department of Health and Human Services (DHHS) standards; a review by a body of professionals convened for that purpose; a formal consultation from an expert in IRB issues; an informal consultation from a colleague or group of colleagues.

The level of review selected will be commensurate with the nature of the project. Factors to consider include: risk of harm, especially risk of loss of confidentiality by the participants, which is always a main concern; number of collaborators from outside organizations; ratio of benefits to costs of the research; burdensomeness of the research to the participants; concerns about coercion of participants; or other factors. Regardless of the type of review conducted, the review must be documented to show that relevant legal and ethical issues have been addressed.

Informed Consent

Individuals providing research data to the Oakland CBT Center must always provide their explicit informed consent to participate in research. Informed consent procedures must include an "opt-out" option.

Consent may be obtained and documented via a formal written or online consent document that that meets DHHS standards. Other methods of obtaining and documenting consent may include: signed and initialed agreement to a statement in the Oakland CBT Center's agreement for provision of treatment or consultation; a statement in an employee's employment agreement. The Director of the Center must approve the informed consent mechanism used, ensuring that the degree of explicit and detailed consent and process used for consent (e.g., online, phone discussion, face-to-face meeting) is commensurate with the level of risk posed by the research. Whenever there is uncertainty about the rigor and intensity of the informed consent process, the Director will seek consultation with an Institutional Review Board and/or other knowledgeable professionals.

When a prospective research participant is under the age of 18, informed consent will be obtained from a parent or legal guardian, and to guard against coercion, assent procedures will be used.

<u>Audit of Consent Documents</u>

After the data are analyzed and before the study is presented or submitted for publication, the PI or someone that s/he designates will audit the consent documents to be certain that every participant included in the data set has provided consent for the research using the consent procedure agreed upon for that project.

State Law

The Oakland CBT Center will follow laws in the State of California pertaining to conducting research with human participants.

American Psychological Association (APA) Ethics Codes

The Oakland CBT Center follows the APA ethics codes, which provide guidelines for research, confidentiality, dual relationships, and other relevant issues, including with regard to sharing authorship and credit for the research.

For example, principle 3.05 of the 2002 ethics code states, "A psychologist refrains from entering into a multiple relationship if the multiple relationship could reasonably be expected to impair the psychologist's objectivity, competence, or effectiveness in performing his or her functions as a psychologist, or otherwise risks exploitation or harm to the person with whom the professional relationship exists. Multiple relationships that would not reasonably be expected to cause impairment or risk exploitation or harm are not unethical."

Malpractice Insurance Provider

Upon annual renewal of its malpractice insurance, the Director of Research will inform its malpractice insurance carrier that the Oakland CBT Center conducts research involving human subjects.

Unpaid Research Assistants

The Oakland CBT Center may use unpaid/volunteer research assistants (RAs) to assist with research tasks. We will take care to provide them with a useful training experience and not exploit their efforts. Like others engaged in research at Oakland CBT Center, we will ensure that all RAs know how to handle sensitive data with care, maintain confidentiality of the data, use secure procedures for handling and storing the data, and conduct research in an ethical way. We mentor our RAs in the development of research skills to help them move forward professionally.

All unpaid/volunteer RAs sign a Business Associate Agreement before they begin their work at the Oakland CBT Center unless the Director of Research deems that this is not necessary given the nature of the research.

Costs of Research

The Oakland CBT Center will only engage in research that it is able and willing to support financially, either through its own funds or through grants and contracts with outside organizations. Funding agreements are established between the Director of Research before commencing with the research. When the research involves a direct cost to the organization to conduct the research, Oakland CBT Center researchers will seek approval for the research from the Director of Research before committing the organization to do the research.

Collaboration

If Oakland CBT Center conducts research with collaborators that involves data collected from our patients, clients, trainees, or students, no identifying information about our research participants will be provided to the collaborators. We will ask collaborators with whom we share data collected from our patients, clients, trainees or students to sign a written agreement that includes the certification that the collaborator will make no attempt to re-identify the data and will not share the data with anyone.

Prior to inviting a new collaborator to work with us on data that were collected as part of work with other collaborators, we will obtain permission from the original collaborators.

Security of Research Data

We agree to adhere to the following minimal standards to store and handle our research data in a secure way that protects the data and protects participants' privacy. As standards and technology are constantly changing, we will seek ongoing consultation to ensure our standards and processes are up to date.

- Protected Health Information (PHI) and Personally Identifiable Information (PII) are removed from the data or are replaced. For example, the participant's name is replaced with a unique research identification number or code ("ID Codes");
- Names and social security numbers are not incorporated into or used for ID codes;
- Face sheets containing PII or PHI are removed from completed survey instruments;
- Access to master code lists or key codes is limited to the Director of Research, the Project's Principal Investigator, and/or other designees approved by the Director of Research or the project's Principal Investigator.
- Master lists are stored separately from the data and destroyed as soon as reasonably possible (and as indicated in approved IRB protocols).
- Contact lists, recruitment records, or other research documents that contain PII or PHI are destroyed when no longer required for the research.
- Files containing data are not transferred to collaborators (or anyone) via e-mail; instead we will use a secure web-storage service or other means of communication (i.e., telephone).
- Research data/specimens are stored securely in locked cabinets and rooms.
- Electronic data are stored in password-protected computers or files.

- When data are gathered and/or are stored in cloud-based storage locations, the sites meet minimal standards HIPAA standards for security.
- Files containing electronic data are closed when computers are left unattended.
- Consent and HIPAA authorization forms are stored securely in locked cabinets and rooms (or electronically on HIPAA-secure server systems), separately from the research data.
- If using SurveyMonkey or a similar survey tool, the program is set to not collect IP addresses of research participants.

Security Breaches, Protocol Violations, and Other Adverse Events

If a security breach or protocol violation or similar event occurs (e.g., confidential information is shared with someone who should not have access to it; data are lost; etc.), the project's Principal Investigator (PI) will share information about the situation with the Director of Research and others who are responsible for the research (e.g., other collaborators, HIPAA security officer, IRB chair). Unless otherwise specified by the specific research's protocol or the IRB of record, the PI in collaboration with the Director of Research will determine how best to respond to the situation. They will seek out consultation as needed from qualified persons.

Immediate measures to prevent further or potential harm (e.g., securing a database found to be vulnerable) will be taken in collaboration with the Director of Research.

Policies Governing 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 is pulled from the clinical record only when the patient provides written informed consent.

The Center has established a retrospective data repository of data that is named the Persons SFBACCT Archival Database. The data repository is a de-identified database of clinical data stored in an excel document. No linking code are included in the data repository that connects the data in the repository to the identity of the participants who provided the data. The Persons SFBACCT Archival Database was collected when Dr. Persons was in solo private practice and later, a partner at the San Francisco Bay Area Center for Cognitive Therapy. The database consists of data from 1092 outpatients who gave written permission for data from their clinical record that does not identify them to be used in research. The procedures used to establish and maintain the data repository were reviewed and approved by the Behavioral Health Research Collective on 1-16-2019. The procedures used to maintain the data repository will be reviewed annually by the BHRC.

Research studies based on a data repository that has itself been reviewed by the BHRC do not require additional ethical review. However, the principal investigator of projects based on the

Data Repository will inform all of the partners at the Oakland CBT Center about these projects early in the project so as to give the partners an opportunity to give input into the project.

The Oakland CBT Center may elect to establish a second data repository. If it does so, it will follow the procedures for establishing and maintaining a data repository that were adopted by the Behavioral Health Research Collective and that are described in the IRB form for establishing and maintaining a data repository.

A Description of the Data Repository is appended to the Center's Evaluation and Treatment Agreement.