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." These policies were last revised on 5-8-18.

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 a review to assure that the project is legal and ethical. 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 consent document that that meets DHHS standards. Other methods of obtaining and documenting consent may include: a statement in the Oakland CBT Center's agreement for provision of treatment or consultation; a statement in an employee's employment agreement; or a statement in the "Terms of Use" document provided as part of a behavioral health software system. The Director of Research is required to 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 of Research 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. 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 <<Short Title>> 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

The Oakland CBT Center may elect to establish a data repository. The data repository is a de-identified database of clinical data. No linking code will be included in the data repository that connects the data in the repository to the identity of the participants who provided the data. Thus, this type of repository contains data that do not meet the definition of human subject. As such, the data repository may be considered a non-human subjects (NHS) repository. Often a data repository consolidates data from a variety of clinical sources. The reason for this is that if, for example, a solo clinician-investigator creates a de-identified database of data from his/her own patients, even if the identifying information is removed and no linking code is available, the investigator may still be able to identify some of the cases and thus the database is not truly de-identified. If the proper consent is obtained, data repositories allow for gathering and storing data for use in future research endeavors that may not be known by Oakland CBT Center researchers at the time the data are gathered. Research conducted using de-identified data does not typically require IRB review and approval. However, the policies and procedures used to establish, maintain, and monitor the functioning of the data repository are subject to IRB approval.

<u>Informed Consent</u>

Human participants must provide consent to have their data entered into the data repository. Consent may occur in writing or electronically. The consent document will provide potential

participants with information about how data in the repository will be used, the types of studies that could be conducted using the data, who may access the data, and how the data will be de-identified. The consent document may provide potential participants a range of options (e.g., the option to participate in all possible studies, or just some involving a particular topic). In some instances, receipt of or involvement in certain services may be contingent on the participant's willingness to have his/her data de-identified and entered into the data repository. Individuals must have the option to opt out. The consent document must indicate that the data cannot be withdrawn from the data repository once it is placed there.

Consent may be obtained in a written document that is part of the treatment agreement that patients review and sign at the onset of therapy, obtained electronically as part of a standard consent procedure, and/or included in terms of use for a particular technology-based service. Consent documents will be written at a reading level accessible to most consumers.

Placing Data into the Repository

No data will be placed into the data repository until an IRB reviews the procedures that describe how the repository will be administered. These are detailed below.

Data may be moved from the clinical record into the data repository by each participant's clinician/trainer/employer or another member of the research team as approved by the Director of Research. The data will be placed into a database where it will be removed of all identifying information. The de-identified data will be placed in a secure storage medium that meets HIPAA standards.

The Oakland CBT Center may use the safe harbor method to de-identify PHI where all identifiers noted in the HIPAA Privacy Rule are deleted (45 CFR § _164.514(b)(2)). Oakland CBT Center may use a statistically valid method to de-identify the PHI as described in the HIPAA Privacy Rule (45 CFR § _164.514(b)(1).

At a minimum, the following identifying information will be removed from the clinical data in order to create the de-identified database: name, address, birthdate, social security number, and any other information that uniquely identifies the participants.

Withdrawing Data from the Repository

Permission to remove data from the data repository is granted to a principal investigator at the Oakland CBT Center by the Director of Research. The Director of Research may ask the principal investigator to provide:

- The purpose of the research and why the de-identified data are needed and/or
- The scientific justification for the study, and/or
- A summary of initial analyses the principal investigator seeks to conduct based on explicitly stated hypotheses.

- Once approved, the Principal Investigator is free to conduct his/her analysis and write up the study for publication and conference presentation, etc., following the usual ethical standards for research.

Access to and Use of De-Identified Data in the Data Repository

The Oakland CBT Center participates in data sharing practices. Informed by the National Institute of Health's Data Sharing Policy and Implementation Guidelines, the Oakland CBT Center will share its de-identified data with other researchers who have a clearly defined research objective and whose research has undergone a review process that meets standards described above in the section titled Ethical Review of Proposed Research.

Researchers who request use of Oakland CBT Center's de-identified data must provide a proposal to Oakland CBT Center's Director of Research for consideration and approval. The proposal must include the following components:

- The purpose of the research, including the rationale for use of de-identified data.
- The scientific justification for the study.
- A summary of initial analyses the Principal Investigator seeks to conduct based on explicitly stated hypotheses.
- Documentation that researcher has completed an IRB training course in the protection of human subjects research participants in the past five years through NIH, the Collaborative Institutional Training Initiative, or a comparable organization.
- Letter from Institutional Review Board Chair or Department Chair that indicates awareness of the research and that attests that the researcher is in good standing with his/her academic or scientific community.
- Documentation of Professional Liability Insurance that clearly states research activities are covered.
- A signed statement indicating that the Principal Investigator intends to use the de-identified data to promote the greatest societal good and share broadly his/her findings with the larger scientific and treatment community in the form of publications and presentations about his/her findings if significant.

Oversight of the Repository

The Director of Research at Oakland CBT Center has oversight of and is fully responsible for the data repository. From time to time, the Director of Research may task another Oakland CBT Center scientist with oversight of the data repository. If the responsible person no longer wishes to maintain oversight of the repository, the Director of Research or Oakland CBT Center's Chief Executive Officer will select another person at Oakland CBT Center to oversee the repository.

The Director of Research at Oakland CBT Center will obtain ongoing oversight of the data repository from the Behavioral Health Research Collaborative (BHRC) or another institutional

review board to assure that policies and procedures for the data repository are being followed, particularly when data are extracted.

The Oakland CBT Center will write a yearly report to the institutional review board that oversees the repository that describes how many participants' data were placed in the repository, how many participants had data withdrawn and for what purposes, how the data were stored, the consent document participants signed, security measures used to protect the data, and methods for protecting participants' privacy.

Compliance with HIPAA Privacy Rule

Participants must give permission for use of healthcare information for secondary purposes. This will occur via the written consent form we have developed for the data repository.

Per the recommendation of HIPAA consultant Mr. Chris Apgar, we agree to use the safe harbor method to de-identify the data, with exceptions documented below. More information about the safe harbor method can be found at:

http://www.hhs.gov/hipaa/for-professionals/privacy/special-topics/de-identification/index.html. The safe harbor method aims to eliminate all identifiers that make up PHI. The following chart identifies potential identifiers to be removed:

(2)(i) The following identifiers of the individual or of relatives, employers, or household members of the individual, are removed:
(A) Names
(B) All geographic subdivisions smaller than a state, including street address, city, county, precinct, ZIP code, and their equivalent geocodes, except for the initial three digits of the ZIP code if, according to the current publicly available data from the Bureau of the Census: (1) The geographic unit formed by combining all ZIP codes with the same three initial digits contains more than 20,000 people; and (2) The initial three digits of a ZIP code for all such geographic units containing 20,000 or fewer people is changed to 000
(C) All elements of dates (except year) for dates that are directly related to an individual, including birth date, admission date, discharge date, death date, and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older.

(D) Telephone numbers	(L) Vehicle identifiers and serial numbers, including license plate numbers
(E) Fax numbers	(M) Device identifiers and serial numbers
(F) Email addresses	(N) Web Universal Resource Locators (URLs)
(G) Social security numbers	(O) Internet Protocol (IP) addresses
(H) Medical record numbers	(P) Biometric identifiers, including finger and voice prints
(I) Health plan beneficiary numbers	(Q) Full-face photographs and any comparable images
(J) Account numbers	(R) Any other unique identifying number, characteristic, or code, except as permitted by paragraph (c) of this section [Paragraph (c) is presented below in the section "Re-identification"]; and
(K) Certificate/license numbers	
(ii) The covered entity does not have actual knowledge that the information could be used alone or in combination with other information to identify an individual who is a subject of the information.	

No Re-Identification of the Data

Modern technology enables the re-identification of data. It is the policy of the Oakland CBT Center that no attempts will be made to re-identify data. Such actions by anyone at our organization are strictly prohibited. The Oakland CBT Center reserves the right to report such actions, if they are discovered, to the principal investigator's institutional review board of record and/or to his/her licensing board. We will ask our research collaborators to agree that they will not attempt to re-identify any de-identified data that we share with them.

Terminating a Repository

When the Oakland CBT Center is dissolved, or when the data in the repository are being transferred to another repository, or the repository is no longer needed, the repository should be terminated. At the next IRB review of the administration of the repository, the Oakland CBT

Center will report on the procedures used to terminate the repository in a way that protects the security of the data.