

PSC Research Review Board Protocol Review Guidelines

The following working guidelines have been formulated by the PSC RRB to provide guidance to investigators submitting a proposal to conduct research that involves PSC clients and/or therapists, **or their records**, with the goal of assisting with the preparation of proposals. By definition, clients within the PSC have specialized human subjects concerns, as they are seeking mental health services. Under the HIPAA law (which went into effect in April, 2003), any and all information regarding a client's relationship with the PSC is Protected Health Information (PHI). PSC-related research procedures need to fall within standardized HIPAA practices and guidelines to protect the privacy and confidentiality of this PHI. Some of the guidelines that are stated here reflect this concern. As well, investigators who wish to conduct research within the PSC need to be mindful that their research participants may include graduate student therapists, who are working with clients as part of their required practicum. Because student therapists are receiving training as part of their doctoral education, special concerns are raised about their involvement in research.

Relatedly, it is the supervisor who has ultimate responsibility for the treatment of the clients and training of the therapists. Supervisors, therefore, need to approve therapist and client participation and they have a right to discontinue participation of the therapist or the client (see section Right of Refusal or Withdrawal). The guidelines that are provided here reflect issues that arise under these circumstances. The RRB may raise additional concerns that are unique to your protocol that are aimed at protecting our client's HIPAA-related rights and the therapist's training needs.

All department faculty and graduate students are welcome to consider the clinic as a possible context for their research. While considering this option, researchers have the responsibility to convincingly demonstrate that research team members who interact with PSC clients or their data are trained to work with vulnerable populations and knowledgeable about client/patient rights. In addition, there needs to be appropriate supervision of any student who has direct responsibility for client interactions.

In this document, recommendations are organized topically to help investigators ensure that their research plan will provide appropriate safeguards for all participants, modeled on similar procedures required by most funding agencies for the protection of human subjects.

Training in human subjects protection

In order to ensure that all investigators who are conducting research with PSC clients and therapists are versed in the unique privacy and confidentiality issues that are involved in clinical research, we recommend the following:

1. Each faculty or graduate-level member of the research team who will have contact with client or therapist participants **or their identified data** must complete **annually** the

on–line ethics training that can be found at: <http://phrp.nihtraining.com/users/login.php>
Completion is documented via printing the final screen that indicates that all the modules have been read and mastered. A copy of this document needs to be provided to the RRB for every faculty or graduate-level member of the research team who will have contact with client or therapist participants **or their records**.

2. We recommend that each member of the research team read one of the following sources, which outlines the unique aspects of clinical research:

- Fisher, C. B. (2009). *Decoding the ethics code: A practical guide for psychologists, 2nd edition*. Thousand Oaks, CA: Sage. (ISBN: 978-1-4129-5916-2) – Chapters 1 and 7
or
- A.E. Kazdin (2003). *Research Design in Clinical Psychology*, 4th edition, Allyn and Bacon Publishers. (ISBN: 0-205-33292-7) – Chapters 16 and 17

3. In addition, each member of the research team needs to have read the current APA Ethics Code. The reference for this is: *American Psychologist*, 57, 1060-1073, December, 2003 **(also available at <http://www.apa.org>)**.

Recruitment

- ✓ Be explicit about who will approach the client about participation, to guard against an awkward interaction with someone known in another academic, professional or social role (e.g., “Would you be interested in talking to Jane Doe about participating in a research project being held in the clinic?”).
- ✓ Note that recruitment should be conducted by graduate students or faculty, rather than undergraduate research assistants, given the large number of undergraduate students, staff and faculty who seek services in the clinic as clients.

Right of refusal or withdrawal

The consent form should:

- ✓ Specify that clinical supervisors have the prerogative of preventing participation of a therapist in a research protocol if doing so is inconsistent with the therapist’s training needs. When therapists consent to participate, their consent forms should be countersigned by the supervisor of the case.
- ✓ Make explicit that student therapists have the right to decline participation or withdraw from the study at any time, as do clients, without prejudice or coercion.
- ✓ Make clear that clinical supervisors can discontinue the participation of either a client or a therapist, based on the clinical needs of the client or training needs of the therapist; specify that if participation is terminated by the clinical supervisor, the client or therapist is still entitled to compensation (if any was offered); and explain how a client or therapist will be informed that a clinical supervisor has stopped their participation.

Consent forms

- ✓ Specify whether client materials (e.g., questionnaires, case notes, audio or video recordings) will be removed from the PSC, and if so, the procedures for ensuring their safe handling and confidentiality, noting that this procedure supersedes typical PSC recordkeeping procedures described in intake material.
- ✓ Indicate the purposes for which these materials will be used and the duration for which they will be held (e.g., “anonymous audio recordings of sessions will be coded by trained graduate students for verbal behaviors of the therapist, and then destroyed. No identifiable records associated with your case will be retained beyond 12 months of collection”).

Restrictions on the involvement of undergraduate research assistants

- ✓ Undergraduate RAs are only allowed access to de-identified data, in view of the unacceptably high probability of dual relationships with clinic clients (e.g., as fellow students or instructors in past, current or future classes or in broader social networks at the university).
- ✓ Note that some data (such as audio and video recordings) cannot be effectively de-identified, and so should not be accessed by undergraduate RAs for any purpose (e.g., coding or transcription).

Safety management plan

- ✓ Specify to whom adverse events (e.g., client or therapist complaints or withdrawal from the study) will be reported. This should include simultaneous notification of the RRB, PSC Director, clinical supervisor for the therapist/case, and the faculty sponsor of the research project within 24 hours of the occurrence of the event. Reporting should occur in writing but not via email, as email is not a private form of communication (does not comply with HIPAA guidelines).
- ✓ Submit a brief annual report, within one year of initiating the study, which reports the number and character of dropouts and other adverse events (by condition), as well as the number of participants completing the study.

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Amended and approved by clinical and school faculty 7-23-2009.