The PSC Research Review Board (RRB)
Statement of Procedures

Composition

The RRB is composed of three Clinical Psychology faculty members. From among the faculty members, a RRB Chair as well as a second faculty member is appointed to the RRB by the Department Chair. Appointments are for one year, with possible reappointment for additional years. The third member is the PSC Director. The RRB Chair is responsible for informing RRB members of all submissions, meetings and decisions. If a research proposal is brought forward by a member of the RRB, then the RRB Chair will appoint a temporary replacement. The RRB Chair, the PSC Director, and the other RRB committee members each have a vote on the acceptability of a proposal. If any RRB member is away for a period of time or is unable to respond in a timely manner as described herein, the RRB Chair can appoint a temporary replacement or call a meeting of the remaining members of the committee and reach a decision on that basis. The Chair can call in a student representative to be consulted at his or her discretion, but that student would not have a vote on the RRB.

Purpose

The RRB reviews all research projects that propose the involvement of PSC clients, therapists and facilities. The purpose of this review is to ensure the appropriate procedural protections for the PSC and PSC clients and therapists. This review should include a consideration of the necessary protection of client and therapist rights. Particular emphasis should be placed on confidentiality, including the confidentiality of clinical records, written reports, questionnaires, and audio/video recordings of therapy sessions. In addition, the RRB should consider issues of participant recruitment and selection, the adequate training for research assistants, handling and storage of client information, and supervision and oversight. Finally, the RRB has the responsibility to consider any other elements of the research design that they consider relevant to the safety of clients or therapists in the clinic. The RRB is not to act as an journal submission review or grant review board and is not developed to assess the design of a study, but to check that reasonable precautions are taking place to secure client and therapist confidentiality (in relation to accepted psychotherapy research practices in the field) and that research projects are not placing excessive demands on the clinic staff that would impair client care.

Research conducted in the PSC must conform with the APA Code of Ethics, Tennessee law, and must be approved by the University IRB before beginning in the clinic.

Proposals

Any faculty member, psychology post-doctoral fellow, or graduate student can propose research projects that utilize the PSC. Students' research projects must be sponsored and supervised by a Psychology faculty member. In turn, the faculty member is responsible for the actions of their students. The RRB application is presented at the end of this document. Any adverse event that happens in relation to the ethics within a research project, as well as any breech or violation to the RRB proposal needs to be reported to the RRB Chair, PSC director, and Director of Clinical Training immediately. Reporting ethical concerns to the RRB does not negate other reporting responsibilities that investigators might have to report concerns related to their studies to granting agencies or the university IRB.

Proposals should be submitted to the PSC-RRB Chair before being submitted to the university IRB. The proposal would include the responses to the university IRB proposal questions plus an addendum (typically of 3-5 pages) addressing the questions on the PSC-RRB form. Further information can be requested by the RRB if needed.

Proposals are expected to address issues such as: whether the consent form is written in language that clients can understand, the storage of client data, and issues around the freedom of clients or therapists to decline to participate without pressure. Approvals for projects are given for a period of one-year and then a request for renewal can be submitted to the RRB Chair. Researchers should submit the Research Application for Yearly Renewal form as well as evidence of current IRB approval. The RRB Chair will make approvals of yearly renewals, in consultation with other committee members as needed.

Approved by clinical faculty 5/19/09
Approved by department faculty and chair 6/10/09

There are three levels of review that are conducted in the PSC RRB: exempted, expedited and full review. Investigators can submit their proposals to the RRB Chair who will consider which level of review is appropriate and make a decision about the level of review to be conducted. The RRB Chair will forward the proposal to the relevant RRB committee members within 3 weekdays.

1) Full reviews by the RRB committee occur when the clients from the PSC client flow are used. Full reviews require the RRB committee to review the proposal and come to a decision about ethical concerns as well as resources available.

2) Expedited reviews occur when the project does not entail the participation of clients from the PSC client flow (i.e., investigators are recruiting their own participants) but the project provides clinical services of some sort (e.g., assessment or therapy) to clients recruited from other sources. In the case of an expedited proposal, investigators need approval from the RRB Chair (or his/her designate) but not the entire committee. They still need to coordinate resources and financial issues, such as fees or staff involvement, with the PSC Director.

3) Exempted reviews occur when a project does not entail the participation of clients from the PSC client flow (i.e., investigators are recruiting their own participants) and the project does not provide clinical services. When a proposal is judged to fit the exempted category by the RRB Chair, approval from the Chair (or his/her designate) is not necessary, but the project would still need to coordinate resources and financial issues, such as fees or staff involvement, with the PSC Director. If a study is exempted, questions 5, 6 & 7 will not be relevant to that study's RRB review and the investigator can omit answering these questions when submitting a proposal that s/he thinks fits in the exempted category (although similar questions may need to be answered for the University IRB proposal). If the RRB Chair decides that a study should not be exempted, however, s/he may request answers to those questions.

Studies focused upon PSC therapists that do not involve client participants do not need to be submitted for RRB review.

Meetings

It is the responsibility of the RRB Chair to schedule RRB meetings. The initial meeting to discuss a proposal under full review must take place within an in-person meeting that the investigator(s) would be invited to attend. The purpose of the meeting is to review the proposal and, if there are any concerns, provide an opportunity for the investigator to dialogue with the committee about the research design and come to some mutual understanding about a future acceptable proposal. The RRB will have the opportunity to ask questions about the proposal and the impact of the proposal on PSC resources. If the board decides that revisions needed are trivial in form and the investigator(s) agrees, future meetings can be conducted using e-mail, instant messaging, telephone (including conference calls), or in-person meetings and the approval can be given by the RRB Chair. The Board may request input from students or others as a proposal is being considered on acceptable practices within clinical research. In addition, the RRB is encouraged to brainstorm options with researchers when changes are required and to provide researchers with specific feedback to help the researcher decide if or how to revise a proposal.

Timeliness in review of proposals is important. Reviews should be completed within one month of their submission and within six weeks if the review happens over the semester break or summer. Once the investigator has received approval from the University IRB and the RRB, they may commence data collection in the clinic.

Decisions

At the RRB meeting, the PSC Director will provide an evaluation focused on whether the research will significantly and adversely affect the clinic staff performance or resources of the clinic. If the PSC Director assesses that the expenses are too high in terms of staff or budgetary concerns to the PSC, the committee will help seek different solutions with the investigator. The RRB Chair can hold a separate meeting with the investigator and the PSC Director to seek mutually-satisfactory alternatives before the investigator returns to the RRB committee. If no acceptable solutions are found, the investigator will have to revise the proposal and seek the PSC Director's approval before the PSC RRB can approve the proposal. The RRB Chair, the PSC Director, and the other RRB committee members each have a vote on

the acceptability of a proposal. The committee will vote on the proposal and the proposal will be accepted if it has a majority vote.

The RRB Chair may appeal to the Department Chair if s/he disagrees about the decisions of the PSC Director about the impact of a proposal on PSC resources. The PSC Director similarly may appeal decisions of the RRB to the Chair. Similarly, investigators can appeal RRB or PSC Director decisions to the Department Chair.

When reviewing a proposal, the RRB is responsible for reaching a decision about whether a proposal should or should not be supported. Written notification of this decision must be sent from the RRB Chair to the researcher(s), the RRB members, the Director of Clinical Training, and Department Chair. When a decision is reached, the RRB Chair will inform the researcher of the RRB decision within the week.

The decision to support a project as having acceptable safeguards for the PSC and its clients and therapists means that the no changes need to be made to the proposal. If the RRB recommends revisions, the RRB decision should indicate that the present proposal was not supported. In such cases it would be helpful to provide written feedback to the researcher. In addition, at the end of each review, with the consent of the committee, the RRB may decide that the approval of the RRB Chair alone, following consultation with the PSC Director on any changes related to pragmatic and financial issues affecting the clinic, may be adequate for any subsequent review of revised proposals.

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PSC Research Review Board
Research Application

Individuals or groups interested in conducting research in the PSC need to be familiar with the Research guidelines described in the PSC manual. This application and accompanying University IRB application should be electronically submitted to the RRB Chair and the PSC Director.

Name _____

Phone _____ ☐ office ☐ cell ☐ home

_____ ☐ office ☐ cell ☐ home

Email address _____

Faculty advisor (if student's proposal) _____

Project title _____

Review level Proposed ☐ Exempted ☐ Expedited ☐ Full review

Attach pages that detail your response to the following questions.

1) Does this project have external funding? If so, what is the funding agency?
2) Does this project propose to recruit from the Center's existing clients participants or find participants from another source? (Please provide examples of recruitment materials in either case.)
3) What is the projected length of time needed to complete this project?
4) What roles do undergraduate and graduate research assistants play in this project? What training is provided to these research assistants to prepare them to work in a clinical environment?
5) If applicable, what procedures are used to recruit PSC clients into this study?
6) If applicable, what procedures are used to recruit PSC therapists and supervisors?
7) Are there any dangers that these procedures pose to clients and/or therapists? If so, what precautions are being taken?
8) What are the specific space, financial and time needs of this project?
9) Are support services by PSC clerical staff requested? Will the PSC phone number be given to clients? If yes, please provide details.
10) What procedures are used for safety monitoring and data transfer/storage and where will data be stored.

RRB proposal received	RRB response given	RRB approval given	IRB approval given	RRB Chair notified & final approval

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