

Overcoming a Primary Barrier to Practice-Based Research:
Access to an Institutional Review Board for Independent Ethics Review

Travis L. Osborne, Ph.D.¹

Jason B. Luoma, Ph.D.²

¹ Evidence Based Treatment Centers of Seattle, 1200 5th Avenue, Suite 800, Seattle, WA 98101

² Portland Psychotherapy Clinic, Research, & Training Center, 3700 N Williams Ave, Portland, OR 97227

Please direct correspondence to: Travis L. Osborne, Ph.D.

Address: Evidence Based Treatment Centers of Seattle
1200 5th Ave., Suite 800, Seattle, WA 98101

Phone: 206-374-0109

Fax: 206-374-0108

E-mail: tosborne@ebtseattle.com

Author Note

We would like to thank and acknowledge the following individuals for their significant contributions to the BHRC IRB: Jennifer Sayrs, Linda Dimeff, Andrew White, Jennifer Tininenko, Polina Eidelman, Julie Wilchins, Paul Gauthier, Kathryn Patricelli, and Krystal Visser. Additionally, we thank the following individuals and organizations for their consultation related to forming and running the BHRC IRB: Susan Publicover, Paul Ahern, hrp Consulting Group, and Apgar and Associates. Finally, we would like to thank Jaqueline Persons, Kelly Koerner, and R. Trent Codd for their feedback on earlier drafts of this manuscript.

Citation

Osborne, T., & Luoma, J.B. (in press). Overcoming a Primary Barrier to Practice-Based Research: Access to Independent Ethics Review. *Psychotherapy*.

© 2018, American Psychological Association. This paper is not the copy of record and may not exactly replicate the final, authoritative version of the article. Please do not copy or cite without authors permission. The final article will be available, upon publication, via its DOI.

Abstract

Practice-based research is an important means of bridging the gap between the science and practice of psychotherapy. Unfortunately, numerous barriers exist for clinicians who want to conduct research in practice settings. One specific barrier that has received minimal attention in the literature – lack of access to institutional review board (IRB) oversight for independent ethics review – can impede the ability to carry out and disseminate research projects. This paper identifies reasons that practice-based researchers may want to seek IRB review even when not required, reviews the pros and cons of a range of strategies that some practice-based researchers have used to try and address lack of access to an IRB, as well as describes a novel solution for this problem: the creation of the Behavioral Health Research Collective (BHRC) IRB, a non-profit IRB whose mission is to provide ethical oversight to practice-based researchers. The authors describe their experiences of developing and running the BHRC IRB, with the intent of providing a model for other professionals to create similar mechanisms for supporting practice-based research.

Keywords: Practice-based research, IRB, ethics review

Overcoming a Primary Barrier to Practice-Based Research:

Access to an Institutional Review Board (IRB) for Independent Ethics Review

Early in the history of the field of psychology, the scientist-practitioner model emerged as a means to train psychologists who could both *apply* the products of science and also *produce* scientific research (Lampropoulos et al., 2002). Despite the dominance of the scientist-practitioner model in doctoral-level training programs (Chan, Lee, & Hargreaves, 2008), most psychologists choose either a research-focused career path largely divorced from clinical practice or a clinically-focused career path in which they rarely engage in research (Goldfried & Wolfe, 1996). The result is that most researchers work in isolation from the practice of psychotherapy and most psychotherapists have little regular contact with research (Goldfried et al., 2015; Teachman et al., 2012).

Arguably, this is not an optimal state for the field or the dissemination of evidence-based psychotherapy. The advancement of clinical psychological science requires a two-way dialogue with practitioners who can provide their contextually-situated knowledge of the day-to-day practice of clinical intervention within systems of care (Vivian et al., 2012). Practice-based research refers to the kind of research conducted in naturalistic care settings that has the potential to foster a bi-directional interaction between research and practice. This type of research is typically conducted by, or in conjunction with, practitioners working in clinical as opposed to academic settings. Case studies, controlled single-case designs, psychotherapy process studies, and effectiveness studies are all examples of common types of practice-based research methodologies. Proponents of practice-based research argue that it is of great value to psychotherapists, policy-makers, and other researchers (Barkham, Hardy, & Mellor-Clark, 2010; Castonguay & Muran, 2016).

As the most common employment setting for clinical psychologists remains individual and group practice (41% of those sampled by Norcross & Karpiak, 2012), these settings are primary targets for the development of practice-based research capacity. Unfortunately, research shows that the modal number of publications for clinical psychologists is zero and that few publish more than a handful of papers during their careers (Norcross, Karpiak, & Santoro, 2005). The result is that most research is being conducted by a relatively small handful of psychologists in academic settings and that the research abilities of many psychologists are being underutilized.

Although one of the main barriers to practice-based research is the reality that many practicing psychologists do not wish to conduct research, for those who do, various means of building capacity for such research have been proposed, including changes in training (Hershenberg, Drabick, & Vivian, 2012), the development of practice research networks (Borkovec, Echemendia, Ragusea, & Ruiz, 2001), researcher-led collaborations between groups of practitioners (Koerner & Castonguay, 2015), changes in the conduct of research to make it more applicable to clinical settings (Kazdin, 2008), and more widespread use of outcome monitoring and data collection to better evaluate routine psychotherapy practice (Boswell, Kraus, Miller, & Lambert, 2015). Other authors have described a range of challenges that exist for clinicians who wish to conduct practice-based research, as well as strategies to address these challenges (Koerner & Castonguay, 2015; LeJeune & Luoma, 2015; Osborne, 2018b). A primary goal of this paper is to examine a common barrier to building research capacity in practice-based research settings in the United States that has received little attention in the literature - lack of access to ethical review of research, typically in the form of a federally-registered institutional review board (IRB). Another goal is to review the pros and cons of common solutions to lack of ethical review of practice-based research and describe our solution to this problem – the

formation of the Behavioral Health Research Collective (BHRC), a nonprofit entity that hosts our federally-registered IRB. BHRC is currently comprised of eight evidence-based behavioral health care organizations located in six states (CA, NC, NY, OH, OR, and WA) that vary widely in size (three to 35 clinical providers). All of the organizations are privately owned, are not affiliated with academic institutions, share a commitment to the scientist-practitioner model, and are currently engaging in practice-based research or plan to.

We begin with a discussion of why IRB review of practice-based research can be important, even when not technically required. We then discuss how BHRC member organizations dealt with access to ethical review before the BHRC IRB was formed. Finally, we describe the formation of the IRB, experiences to date, and lessons learned in running the IRB. As there does not currently appear to be any published research examining lack of IRB access as a barrier to practice-based research, we conducted a survey of BHRC member organizations about this issue and describe the responses to this survey when relevant.

Lack of Access to Ethical Review as a Barrier to Practice-Based Research

It is a common misconception among psychologists that research cannot be conducted with human subjects in the United States without independent ethics review by an IRB. After consultation with numerous expert consultants and attorneys, as well as reviewing the federal regulations regarding IRBs (HHS Protection of Human Subjects, 2009), we confirmed that review by an IRB is only required by the federal government under certain circumstances. The federal regulations specify when entities are required to follow the “Common Rule,”¹ which is

¹ The Common Rule will be updated in 2018; researchers will need to familiarize themselves with these changes in order to stay compliant with federal regulations (Riley & Akbar, 2017).

the rule of ethics for all government-funded human subjects research in the United States. Generally, human subjects research must be reviewed by an IRB when that research: (1) is conducted or supported/funded by a federal entity that has adopted the Common Rule, (2) is conducted under the auspices of an entity, such as a university, that has elected to apply the Common Rule to all research, regardless of the source of support, (3) falls under the jurisdiction of other federal entities that must follow the Common Rule, such as the Food and Drug Administration or public schools under the jurisdiction of the Department of Education, or (4) is in jurisdictions that require human research protections for all research conducted within its jurisdiction (e.g., some states have applicable regulations or require the application of federal regulations). Outside of these situations, it is typically not legally required that a researcher in the United States obtain review from an IRB to conduct research with human subjects (although researchers should always check to ensure whether state or local laws exist that may apply to conducting research).

Most researchers in practice-based settings, such as independent or group practices that do not receive federal funding for research and are not located in jurisdictions that require specific forms of review, do not fall under the purview of the Common Rule and, therefore, do not necessarily need to obtain IRB review to conduct research. While there are ways to conduct human subjects research in an ethical and legal manner without IRB oversight, below we outline a number of reasons why a practice-based researcher might consider having their research reviewed by an IRB, even if not required.

A first reason to consider obtaining IRB review, even if not legally necessary, is that the regulations and practices that have emerged over the decades to guide the conduct of IRBs do much to ensure that research is conducted ethically and that the rights of human subjects are

protected. Procedures for IRB review are well established and provide excellent guidance and an established means of ensuring that research is ethical. IRBs can also help researchers be aware of local or state laws that may regulate the conduct of their research. Although other routes to assuring the ethical and legal practice of research are possible, IRBs are the most well-tested and well-accepted procedure for doing so in the United States. Surprisingly, there do not appear to be any published studies examining the effectiveness of IRB oversight with regard to the identification and resolution of ethical concerns (Grady, 2010). Our survey of BHRC member organizations indicated that of the organizations who have had studies reviewed by the BHRC IRB, all but one reported that the review process led to the identification of ethical issues they had not previously detected. This feedback from our members is consistent with the observations of the BHRC IRB Chair (the first author), who estimates that reviewers have identified ethical concerns that were overlooked by investigators in over 90% of the study protocols reviewed to date (with many being minor but still important to address). Taken together, these data show that the IRB appears to have functioned to provide helpful ethical oversight, at least for this sample.

Another reason to obtain review by an IRB is to manage potential legal liability. IRBs, investigators, hosting institutions, and IRB members have all been subject to lawsuits based on perceived research misconduct (Icenogle, 2003). Consequently, practice-based researchers and their host institutions should take steps to protect themselves from legal liability, with IRB review being a primary mechanism for such liability protection. Because IRB review is so widespread in the United States, it has become the *de facto* legal standard for determining whether a research project meets ethical standards to protect human subjects. Thus, obtaining IRB review for human subjects research is likely to be an important protective factor against legal liability in the case of a lawsuit. All but one BHRC member organization expressed some

level of concern about conducting research without the liability protection of IRB review, with half of the organizations indicating that they would be extremely unlikely to conduct research in their settings without this level of protection.

Finally, publication in peer review journals may be hampered without IRB access, thereby limiting the ability of practice-based researchers to disseminate their findings. To quantify the extent of this barrier, we conducted a survey of the ethical review requirements of 25 of the top 30 journals in clinical psychology, based on citation impact (two of the 30 journals only publish review papers and three did not respond to our inquiries). All 25 journals stated that studies must comply with relevant ethical guidelines (e.g., APA or the Helsinki Declaration). In addition, 40% (n=10) explicitly stated that independent review from a research ethics committee is required for submission and publication. The other 60% (n=15) either did not explicitly require research ethics committee approval or implied that there could be exceptions to such oversight. These data indicate that at least 40% of the journals sampled are likely to reject any human subjects research that has not been reviewed by an IRB. Other journals may also require IRB review, as suggested by a published recommendation by the Committee on Publication Ethics (Committee on Publication Ethics, 2014), wherein review of a study by an IRB prior to publication by a journal was strongly recommended, even though the data under consideration were later found by an IRB to be exempt from needing review. This published case suggests that at least some of the 60% of journals we surveyed that did not explicitly state a requirement for independent ethics review may be reluctant to publish data without such review. In aggregate, this information indicates that not having access to an IRB is an impediment to dissemination of research findings. Survey responses from BHRC member organizations were consistent with these data: half of the member organizations were moderately or extremely concerned about

being able to publish research findings without IRB review prior to the formation of the BHRC IRB and several other organizations reported at least some concern about this issue as well.

In sum, though IRB review is probably not required to conduct research in many practice-based research settings (as most of these settings do not fall under the purview of the Common Rule), lack of IRB access was identified by our member organization as an important barrier to carrying out and disseminating research for all of the reasons described above. Based on these factors, obtaining access to IRB services can be very important for the success of practice-based research programs.

Methods Used by BHRC Members to Overcome Barriers to Access Ethics Review

BHRC member organizations tried a range of solutions for accessing independent ethics review prior to the formation of the BHRC IRB. The benefits and limitations of each strategy are described below.

Obtain a Faculty Appointment

Several BHRC member organizations were able to gain university-based IRB access via members of their staff who had adjunct faculty appointments. Common reasons for these appointments included serving as supervisors for graduate students in psychology or teaching a class within a local psychology department. An advantage of this solution was that it provided IRB access to organizations that might not otherwise have such access. However, this solution also came with limitations for several of our members, including an excessively long review time due to the IRB's lack of familiarity with practice-based research, as well as several IRBs revoking previously granted access. Several other members were told that their adjunct appointments did not allow IRB access from the outset. These experiences highlight that adjunct faculty appointments may not afford IRB access at some institutions. It is also possible that some

practice-based researchers could obtain IRB access through obtaining a part-time faculty appointment that has more associated rights than an adjunct appointment.

Collaborate

A second strategy that some of our member organizations attempted was to only participate in projects for which the principal investigator or a graduate student was part of an institution with an established IRB. Although this provided IRB access that otherwise was not available, it did have some drawbacks, namely, being limited to the research topics that were of primary interest to the collaborating faculty or graduate student and not being able to develop independent lines of research. Our experiences suggests that collaborating with university-based researchers can be fruitful in some cases, but that this strategy can limit the independence of practice-based researchers.

Pay for IRB Services

Several private companies exist that provide fee-for-service IRB review. One BHRC member organization obtained federal grant funding for research prior to the development of the BHRC IRB and was therefore required to obtain review from a federally-registered IRB. This organization hired a private IRB and paid the required submission fees, which amounted to several thousand dollars for the initial review and several hundred dollars for every subsequent modification. Another organization worked out a potential agreement to have protocols reviewed by a local university IRB, but the fees were cost prohibitive. Based on our experience, the fees charged to contract outside organizations offering IRB review amount to thousands of dollars per study and, therefore, may lie outside the budgets of many practice-based researchers. Indeed, half of BHRC member organizations indicated that prior to the formation of the BHRC IRB, costs associated with private IRBs were a major impediment to conducting research in their

settings and only two organizations indicated that they would definitely conduct research if they had to pay for private IRB services. Additionally, commercial fee-for-service IRBs typically provide reviews for more biologically and medically oriented research and may have less expertise in providing appropriate and cogent review for the more behaviorally and psychologically oriented studies that are often the focal point of practice-based research.

Proceed Without an IRB

An additional option is to proceed with conducting research without formal IRB oversight. One BHRC member conducted research in this fashion after inserting language into their treatment consent document asking clients' permission to use their de-identified data for research purposes. This individual also consulted with an ethics expert and, as a result of that consultation, put together an informal committee of colleagues to provide some level of ethical review and legal protection in the event of a lawsuit. For minimal risk research, another option could be for practice-based researchers to consider relevant ethical standards and principles (e.g., American Psychological Association Ethics Code) that apply to their research, obtain appropriate ethics consultation from knowledgeable colleagues, and verify that federal regulations and local and state laws do not apply to one's research. A further option could include restricting research to secondary data analyses of existing de-identified data sets, as analysis of de-identified datasets does not meet the federal definition of research with human subjects, and thereby IRB review is not required (Amdur, Speers, & Bankert, 2006). However, this strategy limits the kind of research in which the independent researcher can take part.

All of these approaches have the downsides inherent in not having IRB oversight, such as the potential for increased liability, restricted dissemination opportunities, and the need to invest time in developing one's own means of assuring the ethical conduct of research. Of the eight

BHRC member organizations, only two stated that they would definitely conduct research if they did not have access to the BHRC IRB.

Creating the Behavioral Health Research Collective (BHRC) IRB

As a result of the obstacles with access to ethical review described above, seven behavioral healthcare organizations² with a commitment to furthering practice-based research formed a nonprofit organization that could host a federally-registered IRB (an eighth organization joined BHRC a few years after it was founded). We hoped that collaborating in this manner would lead to a range of benefits for member organizations, including: (1) minimizing barriers to dissemination; (2) allowing practice-based researchers to be primary investigators; (3) providing ethical guidance and legal protection; (4) avoiding high costs charged by fee-for-service IRBs by reviewing each other's applications on a largely volunteer basis; and (5) providing relevant, expert, and useful reviews, as all participating organizations were involved in behavioral healthcare. Additionally, we hoped that we might be able to disseminate our IRB model to others as a way to help remove a barrier to practice-based research. This paper represents one of our first attempts to share the model we have created.

The process of developing of a cost-effective, independent IRB to provide ethical review of practice-based research protocols began in 2008 and resulted in the formation of a federally-

² The founding members and organizations of the BHRC IRB include:
Evidence Based Treatment Centers of Seattle (EBTCS), Seattle, WA
Portland Psychotherapy Clinic, Research, & Training Center, Portland, OR
Oakland Cognitive Behavior Therapy Center, Oakland, CA
Evidence-Based Practice Institute (EBPI), Seattle, WA
Cognitive-Behavioral Therapy Center of Western North Carolina, PA, Asheville, NC
The Center for Cognitive and Behavioral Therapy of Greater Columbus, Inc., Columbus, OH
Center for Cognitive and Dialectical Behavior Therapy, New York, NY

registered IRB in 2011. Below we provide an overview of the key components of this process, as well as discuss the primary obstacles we faced along the way and our efforts to address these.

Decision About Who Should Host the IRB

In order for an IRB to be federally recognized it has to register with the Office of Human Research Protections (OHRP), part of the U. S. Department of Health and Human Services (HHS) and identify the organization to which the IRB is affiliated. In our case, we had to decide whether one of the organizations involved in creating the IRB would host the IRB, or whether we would create a separate entity to host the IRB. We chose to create a separate nonprofit entity to host the IRB because: (1) no single organization would have to take on a disproportionate amount of liability associated with hosting the IRB; (2) having a separate entity host the IRB provided some additional liability and legal protection for each of the member organizations; (3) creating a separate entity was more in line with the collective spirit of the project; and (4) this model would allow for the possibility of flexible membership over time if desired (i.e., organizations could leave or join without having to change which entity hosts the IRB).

The decision to form a nonprofit organization, specifically, to host the IRB was consistent with a core goal of the project - to create a low-cost mechanism for ethical review to address an important barrier (i.e., cost) to access. Thus, we were intentional from the outset in designing a model that would be not-for-profit and this had important implications for the financial structure of the organization and the IRB (see below). However, this decision did entail significant work, including legal consultation, legal documents (i.e., articles of incorporation, bylaws), creation of a board of directors, and setting up a business (e.g., incorporation with the state, obtaining a federal tax ID number, setting up a bank account).

Liability Protection

Although the risks of lawsuits are fairly low for IRBs (Hoffman & Berg, 2005; Resnik, 2004), agreeing to provide ethical oversight to research involving human subjects is not completely without risk. One of the most significant challenges associated with creating the IRB was deciding whether to obtain liability insurance and if so, identifying what type(s) coverage would be most appropriate, as well as carriers for this coverage. These decisions were not trivial, as insurance premiums are one of the largest operating expenses for the IRB. After considerable discussion, our group elected to obtain liability insurance for the nonprofit organization hosting the IRB as we determined that the additional layer of protection was worth the associated fees. We opted for a liability policy (but not a Director's and Officer's policy) and found an insurance company that was willing to underwrite the policy (Sprague Israel Giles, Inc.). This latter step proved to be challenging as insurance companies were generally unfamiliar with insuring IRBs and most of the IRBs we spoke to about this were hosted by large institutions (i.e., universities) and the IRBs' activities were covered under their broader insurance policies. During the six years that the IRB has been up and running, no complaints or legal action have been made against the IRB. Despite the limited risk, there is peace of mind with having this liability protection and the costs are fairly nominal when shared among the group of organizations.

It is important to note that had our group decided to have one of the member organization host the IRB, it might have been possible to have that organization's insurance policy cover the workings of the IRB and thereby limit costs. Thus, it is useful to keep in mind that decisions about how to structure an IRB can impact this issue. Individual malpractice insurance policies held by each IRB board member (as all are licensed mental health providers) may also provide additional liability protection, though this would need to be verified by each IRB member.

Professional Consultation

We have sought consultation from various professionals over time to assist us in both creating and running the IRB. In all cases, this consultation has proven to be highly valuable in terms of saving us considerable time and energy, as well as helping to ensure that we both understand and follow important standards and regulations. This consultation has been both paid and unpaid and although paid consultations have at times been costly, the benefits have always been worthwhile. Over the years we have consulted with individual IRB board members, professional IRB administrators, a lawyer specializing in IRB-related law, staff at OHRP, a professional IRB consultant, security consultants, Health Insurance Portability Accountability Act (HIPAA) consultants, accountants, and a lawyer specializing in nonprofit organizations. Topics of our consultations have included: nonprofit accounting, risk management, regulations around the forming of an IRB, IRB Standard Operating Procedures (SOP), exempt and expedited review processes, guidelines for setting up data repositories, and HIPAA regulations. We highly recommend that others interested in creating an IRB seek appropriate professional consultation.

Financial Structure

Our goal of developing a low-cost IRB had key implications for the financial structure of the IRB. To start, this decision meant that to contain costs, individual IRB board members/reviewers would not be able to be paid for their time spent working on study reviews or attending IRB meetings. As a group we opted to view this work as volunteer professional service, akin to providing reviews of manuscripts for peer-reviewed journals or serving on committees for professional associations. This decision created significant cost savings for the IRB, however, there were several expenses that were unavoidable and needed to be factored into the budget. To begin, there was considerable writing and editing involved in creating the first

draft of SOPs and the group paid for a postdoctoral fellow to assist with this work. One substantial ongoing cost has been the pay for a part-time administrative coordinator who works as an independent contractor supporting the IRB and the IRB Chair in key administrative tasks, such as creating forms, taking minutes at meetings, helping to organize and store electronic submission files, and maintaining the IRB meeting calendar. There is also an annual cost for the liability insurance premium for the nonprofit hosting the IRB. Other miscellaneous expenses include paying legal and IRB consultants for assistance with key issues, paying for IRB-related trainings for the IRB Chair, and yearly taxes.

We divided costs into two main categories – standard operating expenses (i.e., taxes, administrative pay, training fees) and one-time or larger expenses (i.e., start-up fees associated with creating the organization, consultation fees, and insurance premiums). As a general rule we opted to have member organizations split the latter costs evenly and to set our fees for new and renewal IRB applications at a level that would allow the IRB to cover its standard operating expenses. There was also an agreement that whenever collected fees exceeded standard operating costs they could be applied to other expenses. This led to setting initial fees that were very affordable (\$225 for new applications; \$50 for renewing applications; no fees for study modifications) and represented a marked cost savings over hiring a private fee-for-service IRB.

Scope of Work

The decision to run the IRB as a nonprofit and to rely mostly on volunteer labor required careful thought about the scope of the work that the IRB is willing to take on. Our goal was to create a mechanism for ethical review of practice-based research that is sustainable over time. Therefore, preventing burnout among our reviewers is essential and this can only be accomplished if the workload needed to run the IRB is reasonable. From the outset we agreed

that the IRB would only review research that was primarily behavioral health in nature, as that is the area of expertise held by all of the IRB board members. Additionally, we agreed to limit the number of organizations that are part of the collective, as well as to only review applications from member organizations, in order to cap the total amount of work that would be needed from the IRB.

We have also made some practical choices about how the IRB operates to limit the burden on reviewers. For example, we decided that the IRB would only meet once per month and that a maximum of two protocols would be reviewed at the same meeting. We have recently implemented exempt and expedited review processes for studies involving minimal risk to reduce the burden on reviewers (as they do not require review by the full IRB).

Selecting and Training IRB Members

After the IRB was formed, we identified and trained individuals to fill the various roles that were needed, including primary IRB members, alternate IRB members, and a Chair. Federal regulations require that IRBs have a minimum of five primary members, with at least one being a scientist, at least one being a nonscientist, and at least one not affiliated with the institution hosting the IRB (and who can also serve as either scientist or nonscientist member; HHS Protection of Human Subjects, 2009). Due to the collective nature of our IRB structure, we agreed that a maximum of one person from each member organization would serve as a primary (scientist) member on the IRB at any given time in order to distribute the workload. We also agreed that these individuals would be senior research staff within member organizations. Because BHRC has more member organizations (eight) than the minimum number of required IRB members (five), it was agreed that individuals from a subset of member organizations would serve as primary IRB members on the board at first and others would serve as alternate members

and rotate into primary member positions over time. We recruited a nonscientist member who was also not affiliated with any of the member institutions (which met two membership requirements with a single individual) and who was interested in volunteering time to this effort. This person's professional background is in law which was a very useful perspective to have represented on the board. This individual was the only reviewer who was not employed by a BHRC member organization. An employee of one of the founding member organizations who was central to the creation of the IRB volunteered to serve at the IRB Chair (the first author). Given the substantial learning curve associated with this position, this individual agreed to hold this position for several years in order to provide continuity on the board.

Although all of the initial scientist members on the board had experience with conducting research, disseminating research findings, and reviewing manuscripts for peer-reviewed journals, none had ever served on an IRB. Thus, we developed a training protocol for IRB members to provide what we felt was the necessary level of information needed to competently provide ethical review and oversight of research protocols. There is no national standard for training of IRB members and IRBs vary widely with regard to what they require of members in terms of training. Our group settled on the following requirements for training: (1) completion of a widely recognized online human subjects training, such as those offered by the National Institutes of Health (NIH) and Collaborative Institutional Training Initiative (CITI); (2) review of the Belmont Report; (3) review of a published handbook for IRB professionals (Amdur & Bankert, 2011); and (4) review of the IRB's SOPs.

In addition to this training protocol, we also sought out other sources of information and training for IRB professionals. Two resources have been particularly helpful. First, OHRP conducts trainings around the country on an ongoing basis and BHRC pays for expenses

associated with the Chair attending. Second, our organization also pays for one of our IRB reviewers to be a member of Public Responsibility in Medicine and Research (PRIM&R), a professional organization for research and IRB professionals. PRIM&R has numerous online resources for IRB professionals and also sponsors annual conferences where additional training on the research oversight can be obtained. Finally, in order to reduce the IRB's legal liability and ensure that IRB members stay up-to-date about changes in regulations, we have followed recommendations that IRBs engage in ongoing education of IRB members (Icenogle, 2013).

Developing Standard Operating Procedures (SOPs) and Forms

Before the IRB began accepting protocols for review, we developed a set of documents to guide our work, including a comprehensive set of SOPs, as well as relevant forms for protocol submissions and oversight. This part of the start-up process was one of the most time consuming. We began by reviewing examples of SOPs and forms from several other IRBs (as most of these are publicly available on IRB websites) and selecting examples that were most closely related to our structure and type of work. We then drafted documents using these examples as a guide. A postdoctoral fellow from one of the member organizations was contracted by the BHRC to assist with creating the SOPs. Our administrative coordinator helped create forms for various IRB functions (e.g., initial submissions, annual status reports, study modification forms, protocol deviation reports). Once the SOPs and forms were drafted, IRB members volunteered their time to review and revise these documents. The entire process took about nine months, highlighting a challenge of trying to find the time to do this work while also doing clinical work. We continue to revise our SOPs and forms as needed in response to feedback from study investigators and IRB members, changes in federal regulations, and learning more efficient ways to operate.

Conducting IRB Reviews

The start-up time for our IRB – the time between our first discussions about creating an IRB and being ready to accept our first application for review – was three and one half years. Once we began accepting applications, we made a series of decisions that were designed to help ensure that IRB members learned as much as possible about this process in order to provide a high quality of ethical oversight. First, although there are different types of ethical review that IRBs can offer depending on the level of risk involved in research (i.e., exempt, expedited, full board review), our group decided that for an initial period of time, all protocols, regardless of risk level, would go through full board review. This decision was made so that as a group we could all become familiar and comfortable with the review process, as well as learn more about common ethical dilemmas that emerged in the protocols being reviewed. Research studies involving minimal risk that can undergo exempt review do not need to be reviewed or discussed by the entire IRB. Although this provides a more streamlined process of review for low-risk projects, it also would have prevented valuable discussions and learning among our IRB members. As a group we learned a lot in our first several years of conducting reviews because all IRB members were part of discussions about each of the projects we reviewed. This also helped us to establish reliable parameters for review, greater agreement between reviewers, and policies for our IRB in response to the common ethical themes with which we had to grapple.

Second, although many IRBs operate in such a way that a few members do the bulk of the work of reviewing a protocol prior to the IRB meeting (often referred to as a primary reviewer system), our group decided that all members would participate in this process in a meaningful way by providing written feedback on the protocol prior to a meeting. Again, although this created more work in the short-term, it facilitated and accelerated our collective

learning. This approach made for rich discussions of ethical issues because all IRB members were well informed about the protocols being review, having examined them in detail.

Our group has recently established processes for exempt and expedited reviews of minimal risk studies. This is helping to decrease the workload on IRB members (as well as study investigators) and will hopefully help extend the longevity of the IRB. However, our group only made the switch to adopting these practices after we felt that we had sufficient confidence in our collective skills and knowledge base to ensure ethical review of research.

In addition to initial review of research protocols, the IRB also provides ongoing oversight and review of approved studies on a yearly basis (as is typical for IRBs, unless studies are exempt and do not require such ongoing review). This helps to ensure that studies are carried out in ways that are consistent with their initial protocol and that any ethical or other problems that emerge during the course of the study are addressed appropriately by study investigators.

As our member organizations are spread out geographically throughout the United States, all IRB meetings are conducted virtually via teleconference. Additionally, all IRB applications are submitted electronically via email and all documents are stored electronically using web-based file storage tools (e.g., box.com).

Progress to Date

As of this writing our IRB has been reviewing research studies for six years and we have reviewed 28 protocols, all of which were submitted by investigators working outside traditional research settings. Applications have been submitted from six of our eight member organizations, with the number of applications submitted from individual organizations ranging from one to eight. Of the 28 protocols reviewed thus far, 23 have been full board reviews, one has been expedited review, and four have been exempt reviews. To date, at least 16 conference

presentations, three published papers, and two papers under review for publication have been generated from these projects (many of the studies are still ongoing and are not yet in the dissemination phase). Some of these studies would have been conducted without the creation of our IRB, as they were federally funded and thus, the study investigators would have had to seek IRB review from a private IRB company. However, as half of BHRC member organizations indicated that they would be very unlikely to conduct research without the legal protection of an IRB and given all of the barriers these organizations previously faced with trying to access IRB review, it is clear that many of these projects would not have been conducted without access to the BHRC IRB. Moreover, we have collectively saved BHRC member organizations tens of thousands of dollars in fees as compared to if they had submitted applications to fee-for-service IRBs, which for most of these organizations would have been the only other option given their challenges with accessing university-based IRBs. As previously mentioned, the BHRC IRB charges \$225 for an initial review, \$50 for annual review, and no fees for study modifications. In contrast, the 2017 fees for one private IRB company previously used by one of our member organizations included a *minimum* fee of nearly \$2,500 for initial review, over \$1,000 for annual review, and between nearly \$300 to \$700 for study modifications.

Although the non-profit, largely volunteer model of the BHRC IRB does save member organizations considerable money, there are some financial costs associated with running the IRB, as well as costs in terms of volunteer time/labor. The financial costs for operating the IRB can be separated into those for start-up and those for ongoing operating expenses. Start-up costs for the IRB were between \$3,500 and \$4,000. Annual operating costs to run the IRB averaged nearly \$3,000 each of the last several years. Expenses have decreased over time as our liability insurance policy premium has decreased. Primary expenses, aside from this premium, include

pay for the administrative coordinator, business license fees, the PRIM&R membership, taxes, and consultant fees. As already mentioned, the annual insurance premium is split evenly between member organizations and the remaining costs are generally covered by collected IRB fees.

In terms of volunteer labor, this too can be divided into start-up labor and labor associated with ongoing running of the IRB. We estimate that the core group of individuals who were most involved in creating the IRB collectively volunteered approximately 500 hours over several years to assist with the start-up. This time included meetings, learning about IRBs and the process of forming and registering an IRB, talking with consultants, identifying models of IRB SOPs and forms, assisting with creating and editing these documents, and completing the IRB's required reviewer training (see above). In terms of the number of hours that IRB members have volunteered since the IRB was formed, based on survey results and other records, we estimate that our reviewers have collectively donated around 1,500 hours of time over the last six years. This includes time spent attending IRB meetings, reviewing initial study applications, reviewing annual renewals and study modifications, and time spent engaging in continuing education and training activities related to IRB regulations and functions.

Based on all of the information presented here, we believe that thus far the BHRC IRB has proven to be a viable mechanism for our member organizations to obtain low-cost ethical review and oversight for behavioral health research in applied settings. It has been exciting to help develop one mechanism for bridging the gap between research and practice settings and facilitate the inclusion of ideas, participants, and data from real-world settings that are so under-represented in the literature.

It has become clear that our IRB will have to continue to limit the scope of our work in order to remain viable, meaning we are unlikely to have the capacity to add member

organizations in any substantive way over time. This is unfortunately at odds with one of our values, which is increased access to this type of ethical review for those conducting practice-based research. One way we are hoping to address this limitation is to train others to do what we have done. This paper is a primary step toward this goal, in addition to several presentations at professional conferences (Osborne, 2011; 2014) and a chapter in an edited book, which provides a much more detailed “how-to” guide for creating an IRB (Osborne, 2018a).

Limitations and Conclusions

Several limitations of the model described here are worth noting. First, none of the members of BHRC IRB are solo practitioners and thus, it is unclear whether this model would be as helpful or relevant for solo practitioners who wish to conduct practice-based research. Although we see no reason why such a model would not be a workable solution for these individuals, this has yet to be tested. Second, the practitioners who formed the BHRC IRB had several objectives when creating the IRB that may not be representative of all those who wish to engage in practice-based research. For instance, a few of the organizations already had, or wished to pursue, federal funding for research. As a result, it was necessary for them to have access to a federally-registered IRB to conduct this research. Other organizations were concerned about limitations around disseminating research findings that can occur when IRB review is lacking. Finally, most of the organizations were concerned about legal liability associated with conducting research without ethical oversight by an IRB. The development of the BHRC IRB addressed each of these concerns and thus, was a good fit for the organizations involved. However, such a model may not be appropriate for those who do not share these concerns as IRB review would not be legally required for many practitioners interested in conducting research.

Practice-based researchers are uniquely suited to tackle challenges related to developing new psychological treatments, as well as improving and disseminating existing treatments, with significant potential benefits to both the field and the public. There are many psychotherapists in practice with excellent research training and skills who would like to contribute to the advancement of clinical science and who also have the skills to build and run an IRB to support this kind of work. Our hope is that over time, other IRBs similar to ours will be developed to help address this important barrier to building research capacity among practicing clinicians.

References

- Amdur, R. J. & Bankert, E. A. (2011). *Institutional review board: Member handbook, Third Edition*. Boston: Jones and Bartlett.
- Amdur, R. J., Speers, M., & Bankert, E. (2006). Identifying intent: Is this project research? In E. A. Bankert & R. J. Amdur (Eds.), *Institutional review board: Management and function, Second Edition* (pp. 101-105). Boston: Jones and Bartlett.
- Barkham, M., Hardy, G. E., & Mellor-Clark, J. (Eds.). (2010). *Developing and delivering practice-based evidence: A guide for the psychological therapies*. West Sussex: Wiley-Blackwell.
- Borkovec, T. D., Echemendia, R. J., Ragusea, S. A., & Ruiz, M. (2001). The Pennsylvania Practice Research Network and future possibilities for clinically meaningful and scientifically rigorous psychotherapy effectiveness research. *Clinical Psychology: Science and Practice*, 8, 155-167.
- Boswell, J. F., Kraus, D. R., Miller, S. D., & Lambert, M. J. (2015). Implementing routine outcome monitoring in clinical practice: Benefits, challenges, and solutions. *Psychotherapy Research*, 25, 6-19.
- Castonguay, L. G. & Muran, J. C. (Eds.). (2016). *Practice-oriented research in psychotherapy: Building partnerships between clinicians and researchers*. New York: Routledge.
- Chang, K., Lee, I. L., & Ann Hargreaves, T. (2008). Scientist versus practitioner – An abridged meta-analysis of the changing role of psychologists. *Counseling Psychology Quarterly*, 21, 267-291.

Committee on Publication Ethics (2014). *Institutional review board approval required?*

Retrieved from <https://publicationethics.org/case/institutional-review-board-approval-required>.

Goldfried, M. R., Newman, M. G., Castonguay, L. G., Fuertes, J. N., Magnavita, J. J., Sobell, L. C., and Wolf, A. W. (2015). Closing the gap between practice and research: The two-way bridge initiative. *Psychotherapy Bulletin, 50*, 5-7.

Goldfried, M. R. & Wolfe, B. E. (1996). Psychotherapy practice and research: Repairing a strained relationship. *American Psychologist, 51*, 1007-1016.

Grady, C. (2010). Do IRBs protect human research participants? *JAMA: Journal of the American Medical Association, 304*, 1122-1123.

Hershenberg, R., Drabick, D. A., & Vivian, D. (2012). An opportunity to bridge the gap between clinical research and clinical practice: Implications for clinical training. *Psychotherapy, 49*, 123-134.

HHS Protection of Human Subjects, 45 C.F.R. 46 (2009).

Hoffman, S. & Berg, J. W. (2005). The suitability of IRB liability. *University of Pittsburg Law Review, 67*, 365-428.

Icenogle, D. L. (2003). IRBs, conflict and liability: Will we see IRBs in court? Or is it when? *Clinical Medicine & Research, 1*, 63-68.

Kazdin, A. E. (2008). Evidence-based treatment and practice: new opportunities to bridge clinical research and practice, enhance the knowledge base, and improve patient care. *American Psychologist, 63*, 146-159.

Koerner, K. & Castonguay, L. G. (2015). Practice-oriented research: What it takes to do collaborative research in private practice. *Psychotherapy Research, 25*, 67-83.

- Lampropoulos, G. K., Goldfried, M. R., Castonguay, L. G., Lambert, M. J., Stiles, W. B., & Nestoros, J. N. (2002). What kind of research can we realistically expect from the practitioner? *Journal of Clinical Psychology, 58*, 1241-1264.
- LeJeune, J. T. & Luoma, J. B. (2015). The integrated scientist-practitioner: A new model for combining research and clinical practice in fee-for-service settings. *Professional Psychology: Research and Practice, 46*, 421-428.
- Norcross, J. C. & Karpiak, C. P. (2012). Clinical psychologists in the 2010s: 50 years of the APA division of clinical psychology. *Clinical Psychology: Science and Practice, 19*, 1-12.
- Norcross, J. C., Karpiak, C. P., & Santoro, S. O. (2005). Clinical psychologists across the years: The division of clinical psychology from 1960 to 2003. *Journal of Clinical Psychology, 61*, 1467-1483.
- Osborne, T. L. (2014, November). Overcoming obstacles to access to ethical review for practice-based research. In J. B. Persons (Chair), *Overcoming obstacles to doing research in a private practice setting*. Clinical Roundtable conducted at the Association for Behavior and Cognitive Therapies Annual Convention, Philadelphia, PA.
- Osborne, T. L. (2011, November). Development of an institutional review board (IRB) for practice-based research. In J. B. Persons (Chair), *Practice-based research: How to conduct meaningful research in clinical practice*. Symposium conducted at the Association for Behavior and Cognitive Therapies Annual Convention, Toronto, Canada.
- Osborne, T. L. (2018a). A step-by-step guide for creating an independent institutional review board (IRB) for private practitioners. In R. T. Codd (Ed.), *Practice-based research: A guide for clinicians*. New York: Routledge.

- Osborne, T. L. (2018b). Research in private practice settings. In R. T. Codd (Ed.), *Practice-based research: A guide for clinicians*. New York: Routledge.
- Resnik, D. B. (2004). Liability for institutional review boards. *Journal of Legal Medicine*, 25, 131-184.
- Riley, W. T. & Akbar, F. (2017). Revision to the common rule: Implications for behavioral and social science research. *Association for Psychological Science Observer*, 30, 17-18.
- Teachman, B. A., Drabick, D. A., Hershenberg, R., Vivian, D., Wolfe, B. E., & Goldfried, M. R. (2012). Bridging the gap between clinical research and clinical practice: Introduction to the special section. *Psychotherapy*, 49, 97-100.
- Vivian, D., Hershenberg, R., Teachman, B. A., Drabick, D. A., Goldfried, M. R., & Wolfe, B. (2012). A translational model of research-practice integration. *Psychotherapy*, 49, 143-151.