BETH-00999; No of Pages 11; 4C:

Available online at www.sciencedirect.com

ScienceDirect

Behavior Therapy xx (xxxx) xxx

Behavior Therapy

www.elsevier.com/locate/bt

Ethical and Legal Guidance for Mental Health Practitioners Who Wish to Conduct Research in a Private Practice Setting

Jacqueline B. Persons
Oakland Cognitive Behavior Therapy Center and University of California, Berkeley
Travis L. Osborne
Evidence Based Treatment Centers of Seattle
R. Trent Codd III
Cognitive-Behavioral Therapy Center of Western North Carolina, P. A.

Mental health practitioners, even when they have research training, rarely contribute to the scientific literature. One reason for this may be that they need help addressing the ethical and legal issues they encounter as they contemplate undertaking research in a clinical practice setting. To address that need, we offer several types of guidance for conducting research in a private practice setting in a way that meets high ethical and legal standards. We describe the situations in which ethical review of a research proposal by a federally registered institutional review board (IRB) is legally required, and identify alternate mechanisms that practitioners can use to obtain an ethical review when a formal IRB review is not required by law. We discuss legal and ethical requirements of conducting single-case studies in a practice setting. We provide a rationale, and free and inexpensive options, for obtaining a formal certificate of training in human subjects research. And we offer guidance for obtaining informed consent and Health Insurance Portability and Accountability Act (HIPAA) authorization from research participants. We conclude with a brief discussion of other legal and professional issues to consider when conducting research in private practice.

We thank Jeffrey Cohen and HRP Consulting Group for consultation on legal and ethical issues related to human subjects research. We thank Eric Pineda and Connie Fee for assistance with the section on human subjects training, and Rebecca Courey for assistance with the section on the Health Insurance Portability and Accountability Act (HIPAA).

Address correspondence to Jacqueline B. Persons, Ph.D., Oakland Cognitive Behavior Therapy Center, 5625 College Avenue, Suite 215, Oakland, CA, 94618; e-mail: persons@oaklandcbt.com.

Keywords: practice-based research; ethics; informed consent; HIPAA; private practice

LARGE NUMBERS OF MENTAL HEALTH PRACTITIONERS who received extensive research training as part of their graduate training choose careers in private practice. Although they may use their research training to help them consume research findings in their clinical work, these practitioners rarely use it to contribute to the scientific literature. The modal number of publications produced by clinical psychologists is zero (Norcross & Karpiak, 2012).

There are many impediments to conducting research in a clinical setting. These include (but are not limited to) difficulties finding time to carry out research, getting compensated for time spent working on research, obtaining library and journal access, developing an infrastructure to support data collection, obtaining statistical software and consultation, and obtaining help from research assistants and collaborators. Descriptions of many of these barriers, and suggested solutions to them, appear in Waltman (2018), Osborne (2018), and Persons (2018).

Another important obstacle is that little guidance is available to help clinicians address the ethical and legal issues they confront when they consider undertaking research in a clinical setting. The authors collectively have been conducting research in practice settings for decades, and have developed solutions for a range of practice-based research challenges, including those related to the ethical and legal conduct of such research (e.g., see Codd,

Persons, J. B., Osborne, T. L., & Codd, III, R. T. (2021). Ethical and legal guidance for mental health practitioners who wish to conduct research in a private practice setting. *Behavior Therapy, 51*(3), 313-323.

2018; Osborne & Luoma, 2018). We aim to share here some of the lessons we have learned. We describe mechanisms practitioners can use to obtain an ethical review of their research proposal, and legal and ethical requirements of conducting single-case studies in a clinical practice setting. We provide a rationale for, and free and inexpensive options for obtaining a certificate of training in human research. We offer guidance in obtaining informed consent and Health Insurance Portability and Accountability Act (HIPAA) authorization from research participants. We conclude with a brief description of other legal and professional issues to consider when conducting research in a private practice setting.

Obtaining an Ethical Review of the Practitioner's Research Proposal

As graduate students, we learned to verify that our research proposals met generally accepted ethical standards by obtaining a review of our proposed studies by university-based Institutional Review Boards (IRBs), which were registered with the federal government. However, as private practitioners, we often do not have easy access to an IRB. We describe here the circumstances in which a review of a research proposal by a federally registered IRB is legally required, strategies for obtaining such a review, alternative review mechanisms the clinician-researcher can use when a formal IRB review is not required, and factors to consider when selecting a review mechanism.

CIRCUMSTANCES IN WHICH REVIEW BY A FEDERALLY REGISTERED IRB IS REQUIRED

In the United States, IRBs, born out of the National Research Act of 1974, are the primary organizations that provide ethical oversight of research activity in order to protect the welfare of research participants. Federal regulations put forth by the Office for Human Research Protections (45 CFR 46, also known as the "Common Rule") require that research be reviewed and approved by a federally registered IRB when the research (a) meets the federal definition of research, (b) relies on data that meet the federal definition of data from a human subject, and (c) meets any of the four conditions described below (Health and Human Services Department [HHS], Protection of Human Subjects, 2018).

The Federal Definition of Research

The federal government defines research as "a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge" (Amdur et al., 2006). Of course, much of evidence-based clinical practice meets the definition of a *systematic investigation*, in that the clinician is systematically manipulating the treatment and collecting data to evaluate the effects of these manipulations on the client's behavior (Hayes, 1981). However, to meet the definition of research, the project must also be conducted with the *intent of contributing to generalizable knowledge.* Not all systematic investigations are intended to contribute to generalizable knowledge. Some simply involve high-quality care, some are program evaluations (which is meant to provide information to the organization collecting it but not to contribute to the larger scientific community), and some serve educational purposes (Amdur et al., 2006). To meet the federal definition of research, the project must entail both a systematic investigation and the intent to contribute to generalizable knowledge.

The Federal Definition of a Human Subject

Federal guidelines state: "*Human subject* means a living individual about whom an investigator (whether professional or student) conducting research obtains data through (1) intervention or interaction with the individual, or (2) identifiable private information" (Amdur et al., 2006). If the project does not involve human subjects, the federal regulations governing IRB review of research do not apply. Thus, analyses of data in already-existing de-identified data sets do not meet the definition of data that meet the federal definition of data from a human subject, and thus do not require a formal IRB review. Formal IRB review is not legally required unless the project meets the definition of research *and* involves human subjects as defined by the federal government.

Four Conditions Requiring Review by a Federally Registered IRB

Federal regulations put forth by the Office of Human Research Protections (OHRP) stipulate four circumstances when a review of a research proposal by a federally registered IRB is legally required (HHS Department Protection of Human Subjects, 2018). The first situation is when research is conducted or funded by a federal entity that has adopted the Common Rule (e.g., National Institute of Mental Health). Another required circumstance is when research is conducted under an entity that has elected to apply the Common Rule, regardless of whether federal funding is involved. This is commonly seen in university settings. A third situation involves research falling under the jurisdiction of federal bodies that are required to follow the Common Rule, such as the Federal Drug Administration. Finally, independent IRB review must occur in jurisdictions that require this protection for all research conducted in its jurisdiction.

Please cite this article as: J. B. Persons, T. L. Osborne and R. Trent Codd, Ethical and Legal Guidance for Mental Health Practitioners Who Wish to Conduct Research in a Private Practice ..., *Behavior Therapy*, https://doi.org/10.1016/j.beth.2020.04.012.

Most research conducted by practitioners does not fall in any of these four categories, and therefore IRB review is usually not legally required for practice-based research. Nevertheless, we recommend that investigators obtain an IRB review of their research if they can do it, as investigators are obliged to conduct research in an ethical manner, and IRBs have well-developed mechanisms for evaluating ethical research practice. Furthermore, IRB review can mitigate a researcher's legal risk in the unlikely event of an adverse event that occurs during the course of the research, for example.

Some journals and academic conferences require an IRB review even in circumstances when it is not legally required. If the journal or conference requires an IRB review when it is not legally required, the proactive and skillful clinician-investigator may be able to work with the journal or conference to educate them about the legal requirements for IRB review. We successfully negotiated a change to the IRB review requirement of the conference submission guidelines of one of our professional associations to allow investigators to submit research to the conference without a formal IRB review when this is not legally required.

STRATEGIES FOR OBTAINING A REVIEW BY A FEDERALLY REGISTERED IRB

Private practitioners by definition are not part of a large institution that maintains an IRB that the practitioner can call on for a review of his or her research. To get IRB access, the practitioner may be able to get access to a university-based IRB by collaborating with an investigator who has an academic appointment. Attending research presentations at conferences, including the Association for Behavioral and Cognitive Therapies (ABCT), can help the clinician identify academic collaborators. Similar collaborations are possible with colleagues at local hospitals, possibly affording access to their IRBs. Another potential solution is to obtain an adjunct faculty position at a local university that gives its adjunct faculty access to the university's IRB (not all do). Another strategy is to hire a private, fee-for-service IRB, although costs associated with these IRBs may be prohibitive for many private practitioners.

An additional option is to partner with other practice-based researchers to form a federally registered IRB. The execution of this solution is resource intensive, and the precise details for accomplishing this task are beyond the scope of this paper. However, we are part of a group of practitioners who did this in 2011, and we describe the process in Osborne (2018) and Osborne and Luoma (2018). Our IRB is hosted by a nonprofit organization we established to house it, meets monthly, and to date has reviewed 38 research projects that have been carried out in a variety of practice settings by our members.

ALTERNATE MECHANISMS FOR OBTAINING AN ETHICAL REVIEW OF A RESEARCH PROJECT

When an ethical review by a federally registered IRB is not legally required or easy to obtain, the investigator can conduct an informal ethical review of his/her project. We offer here some guidance for conducting an informal ethical review. As the investigator carries out this task, he or she will want to attend to the same ethical principles that guide a federally registered IRB, and we describe these first.

Ethical Principles to Attend to When Conducting an Informal Ethical Review

The fundamental ethical principles for conducting research with human participants are described in the Belmont Report, a document published by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (1979). The Belmont Report was based in part on internationally agreed-upon standards that came before it, including the Nuremberg Code and the World Medical Association Declaration of Helsinki (Amdur & Bankert, 2011). The Belmont Report describes three foundational ethical principles: respect for persons, beneficence, and justice.

Respect for persons is built upon two component standards: (a) individuals should be treated as autonomous agents; and (b) persons with diminished autonomy, such as children, prisoners, and those with limited education, should be protected. Four concepts flow out of those two standards: (a) participation in research must be voluntary, (b) participants must provide informed consent, (c) privacy and confidentiality must be protected, and (d) participants may withdraw from research at any time without penalty (Amdur & Bankert, 2011). We discuss informed consent in detail below.

The essence of the principle of *beneficence* is that the benefits of research activity should outweigh the risks. Research entailing risks that are justified by the conceivable benefits to individuals and society, and that seeks to minimize risks while maximizing benefits, are congruent with the principle of beneficence (Amdur & Bankert, 2011). Beneficence also involves the requirements that the study be well designed and likely to be successfully implemented and disseminated so it can produce useful knowledge.

Investigators can take several practical steps to assess whether their study adheres to the principle of beneficence. First, they can ask themselves, "Is the research participant being treated as I would

Please cite this article as: J. B. Persons, T. L. Osborne and R. Trent Codd, Ethical and Legal Guidance for Mental Health Practitioners Who Wish to Conduct Research in a Private Practice ..., *Behavior Therapy*, https://doi.org/10.1016/j.beth.2020.04.012

like to be treated?" If the answer to that question is "No," then the principle of beneficence requires a modification to the study procedures. Second, the investigator can work to minimize risks to research participants by carefully reviewing each of the types of risks that an IRB generally asks an investigator to consider and address, if present. These risks include legal risks; physical risks; risks arising from the use of private records, including medical or educational records; psychological risks; possible invasion of privacy of the participant or family; risks arising from the collection of personal or sensitive information in surveys or interviews; economic risks; and risks arising from the use of audio or video recording for data collection. The investigator can review this list to identify whether the research exposes participants to these or other risks, and identify strategies to minimize these risks, or at a minimum, fully inform participants about any risks. Finally, investigators can require themselves to present their research at conferences and publish it in journals so it can yield some benefit to society.

The principle of *justice* speaks to the equitable distribution of risk among those who are likely to benefit from research. Two central notions derive from this principle. First, no population should be overburdened by the risks stemming from research. Second, and perhaps less intuitive, participant categories (e.g., vulnerable populations) must not be systematically excluded from research because such exclusion may limit the generalizability of research findings to those populations (Amdur & Bankert, 2011).

Practically speaking, to follow the principle of justice, investigators will want to take care to recruit research participants from the population to which the investigators wishes the results of the study to generalize, not just a convenient sample. A particularly convenient research sample, and thus a likely overburdened research population, is undergraduate students. The investigator who wishes his or her results to generalize to populations other than undergraduate students, including to specific racial- and ethnic-minority groups, for example, will want to recruit participants from those populations.

The codes of ethics for most mental health professions are derived from the three ethical principles outlined in the Belmont Report. Accordingly, the investigator can consult his or her professional ethics code for detailed practical guidelines on following the three ethical principles described here. Section 8 of the American Psychological Association's (APA, 2017) Ethics Code, Section 5.02 of the National Association of Social Workers (NASW, 2017) code of ethics, and Section G of the American Counseling Association's (ACA, 2014) code of ethics are dedicated to ethics in research.

Conducting an Informal Ethical Review of a Research Proposal

To aid the practitioner in the process of conducting an informal ethical review of his or her research proposal, we developed a worksheet that practice-based researchers can use to keep the ethical principles listed above in mind as they design their research studies and conduct ethical reviews. The Worksheet to Guide an Ethical Review of a Research Project is available at no cost at www.oaklandcbt.com on the Research page, and readers are welcome to download it and adapt it to meet their needs. The form is annotated and guides the investigator to attend to ethical principles in the design and conduct of the research project.

To carry out the review process, the investigator can complete the worksheet and forward it to members of a review committee (i.e., three or four colleagues) that the investigator selects and who have agreed to do the investigator a professional favor. The investigator can ask these colleagues to review the write-up of the project and write a brief report in which they describe any ethical issues they identify. The investigator may wish to convene a meeting of the reviewers to discuss their input and the investigator's proposed solutions to any ethical issues the reviewers raised. Then the investigator can document the results of the review process.

To increase the chances that the investigator will obtain an unbiased review of his or her project, we recommend selecting as reviewers colleagues who are a bit removed from the investigator's practice (i.e., not business partners or relatives). The investigator can also take care to select reviewers who are licensed psychologists or other professionals who have some training in research and are familiar with the ethical principles of their discipline. Most professionals are eager to carry out their professional duties in an ethical manner. This process is not dissimilar from the sort of ethical review of treatment that occurs in clinical practice settings; when ethical dilemmas arise, we consult with colleagues we trust to advise us, and ask them to tell us their unvarnished view of the ethics of the situation—not what we want to hear.

Readers may be concerned that asking colleagues to read a description of a proposed research project, write a report outlining any ethical concerns they identify, and attend a meeting to discuss the proposed study is too burdensome for the reviewers. Certainly it is true that this task might require 3–4 hours of the reviewer's time. Although we have used this mechanism rarely, we have not had difficulty locating colleagues who were willing to participate in this

Please cite this article as: J. B. Persons, T. L. Osborne and R. Trent Codd, Ethical and Legal Guidance for Mental Health Practitioners Who Wish to Conduct Research in a Private Practice ..., *Behavior Therapy*, https://doi.org/10.1016/j.beth.2020.04.012

process. And the time commitment required is similar to that required by those of us who provide peer reviews of manuscript or conferences submissions for journals and conferences in our field or other types of service to our professions or communities.

JBP used the informal mechanism described here to obtain an ethical review of a study of the interrater reliability of cognitive-behavioral case formulations (Persons et al., 1995). She was fortunate to enlist a review committee that included a practitioner and academic who chaired the IRB at a local professional school and a former research collaborator who was a faculty member at a local university. In this study, 46 clinicians attended a training workshop on the topic of cognitive-behavioral case formulation that was provided by JBP, and then listened to audio recordings of two intake interviews she had conducted with patients who gave informed consent for their recorded session to be used for research purposes. The attendees offered their views about the problems on each patient's problem list, and listed the dysfunctional attitudes and schemas they proposed were causing and maintaining those problems. Results of the study showed that clinicians had moderate agreement on their view of patients' problems and, except for one type of belief (dysfunctional attitudes) for one client, high agreement on ratings of underlying cognitive mechanisms.

SELECTING A MECHANISM

As we described above, the practice-based researcher has several options for obtaining an ethical review of his or her research proposal. One consideration when selecting a mechanism is the complexity and riskiness of the project. If the project is a randomized controlled trial that entails providing treatment to patients, it is a good idea to obtain a formal IRB review of the project. The IRB will be skilled in evaluating this sort of complex and challenging project and helping the investigator take appropriate steps to protect the research participants as well as the investigator—for example, a randomized controlled trial may need a data safety and monitoring board, and the level of awareness required to understand that this is needed and help the investigator implement it is not likely to be available to members of an informal review committee. If the project entails very little risk, a review by the informal mechanism described above is likely to be adequate to protect the researcher and the participants.

Another consideration when selecting a mechanism is cost. If the project is self-funded, the investigator may not want to pay an independent IRB, and likely will prefer an informal review mechanism. If the project is funded by a foundation or by the federal government, the investigator can include funds to pay an independent IRB as part of the project budget.

SITUATIONS WHEN NO ETHICAL REVIEW IS REQUIRED

As we described above, no ethical review of a research proposal is legally required when the project does not meet the federal definition of research with human subjects. That means that one solution to the difficulty the practitioner confronts of obtaining an ethical review of research is to limit research activity to projects that do not meet the federal definition of research. Examples include studies based on analysis of de-identified data that do not meet the definition of human subjects. An example of such a project is a study of the relationship between outcome and dropout in naturalistic cognitive-behavior therapy by Zieve et al. (2019), which examined a de-identified data set of 1,092 patients treated in Persons's private practice and group practice over many years. Zieve and colleagues showed that although, as predicted, dropouts ended treatment with more severe symptoms than completers, dropouts and completers did not differ in their rate of symptom change during treatment. Although the project that did not require an IRB review as the database itself was totally de-identified, the investigators did obtain an IRB review of the procedures used to establish and maintain the de-identified database.

Even when ethical review is not legally required, we recommend that investigators obtain some sort of review to be certain that their project meets ethical and legal standards for conduct of the research. However, if no review process is legally required, the investigator might choose to simply review the ethical code of his or her profession, ensure that the project is consistent with those codes, and document this process. However, even if the researcher elects to proceed without any review process, obtaining informed consent for research from participants is always required, as we describe in a later section.

SINGLE-CASE STUDIES

Case reports and case series are a route for contributing to the field that is particularly and even uniquely available to the clinician, and one of the ways that clinicians most frequently contribute to the scientific literature. The issue of whether case reports are considered research is a controversial one, and IRBs address this issue in widely disparate ways. Some take the position that the study of a single case is not research (Cen et al., 2016).

Some types of reports by clinicians do not involve a systematic investigation, but simply involve a description of a case or a treatment. If the clinician

Please cite this article as: J. B. Persons, T. L. Osborne and R. Trent Codd, Ethical and Legal Guidance for Mental Health Practitioners Who Wish to Conduct Research in a Private Practice ..., *Behavior Therapy*, https://doi.org/10.1016/j.beth.2020.04.012

writes up a case without any systematic investigation or presentation of data, then this report would not seem to meet the definition of research. But if data are collected and analyzed, even via a visual inspection of a plot of the data, then the report seems to meet the definition of a systematic investigation. In fact, a carefully conducted single-case experimental design that addresses an important scientific question and is published in a peer-reviewed journal is an elegant example of a study that meets the definition of research (Kazdin, 2019).

The criterion of contributing to generalizable knowledge is sometimes challenging to apply to a case write-up. The clinician might collect data during treatment purely for clinical purposes and then, after treatment is complete, realize that the results of the treatment are of interest to the scientific community. Even if the data were not initially collected with the intent to contribute to generalizable knowledge, if the clinician later writes a report of the treatment that contributes to generalizable knowledge, then we would view this report as meeting the definition of research. If the clinician-investigator concludes that the single-case report is research, then he or she will want to obtain some sort of ethical review of the project, and, as we describe later, obtain the patient's informed consent, and, if the clinician's practice is a HIPAA-covered entity, obtain a HIPAA authorization for research.

However, a case write-up that is prepared for educational purposes is not considered research (Amdur et al., 2006)—for example, often in our field we write up case examples to illustrate the application of methods we are describing in a chapter of an edited book. The publishers of these volumes (and their lawyers) do not ask for an IRB review. Presumably this is because they do not consider the case write-up to be research, in that it is not a systematic investigation and is not intended to contribute to generalizable knowledge. Instead, these edited books are designed to serve educational purposes.

OBTAINING A CERTIFICATE OF TRAINING IN HUMAN SUBJECTS RESEARCH

We recommend that practitioners who are conducting research obtain a certificate indicating that they have completed formal training in research with human subjects, and that they ask their collaborators, staff, and research assistants to do this as well. The training provides useful information about ethical principles and research practices that the practitioner may not otherwise know. Training in research with human subjects provides information about the history of federal regulations protecting human subjects in research, the ethical principles underpinning the federal regulations guiding research in human subjects, the types of risk that arise when doing research with human subjects, and guidelines for obtaining informed consent from participants. And the certificate of completion may prove helpful from a liability standpoint in the unlikely occurrence of any complaint about the research from a participant or another adverse event. IRBs typically require that researchers update their human subjects training every 3–5 years, so we recommend that practitioners do this as well. As this time can pass quickly, we recommend you make a note in your calendar to remind you to update your training.

We describe three programs that provide human subjects training to clinicians who do not have an institution that offers such training. The Collaborative Institutional Training Initiative (CITI) Program offers several online courses in topics related to research. The course that is most relevant to the needs of the psychotherapist-researcher is named "Social-Behavioral-Educational (SBE) Basic." It currently costs $129, and for an additional fee the practitioner can purchase continuing education credits for completing the course. To access the CITI course, go to https://about.citiprogram.org/en/course/human-subjects-research-2/. The practitioner will want to register as an independent learner and will receive a certificate after completing all of the modules.

The Association of Clinical Research Professionals (ACRP), a group that supports clinical research through training, development, and certification, also offers a human subjects training course. Their course is named Ethics and Human Subjects Protection: A Comprehensive Introduction—No Contact Hours. The practitioner will not need contact hours, as these are needed for individuals who are pursuing a certification program through ACRP. The No Contact Hours course is free. To access the training, go to https://acrpnet.org/courses/ethics-human-subject-protection/ to be directed to the "Ethics and Human Subjects Protection: A Comprehensive Introduction" Web page, and go to the section titled "Pricing Without Contact Hours." After completing the course, the practitioner will need to complete the test and course evaluation to receive a certificate.

Clinicians can also obtain training and a certificate in human subjects research by completing the Protecting Human Research Participants (PHRP) online training at https://phrptraining.com/. This course is meant to serve as an alternative to the one the National Institutes of Health (NIH) previously provided but discontinued. This training currently costs $40.

Please cite this article as: J. B. Persons, T. L. Osborne and R. Trent Codd, Ethical and Legal Guidance for Mental Health Practitioners Who Wish to Conduct Research in a Private Practice ..., *Behavior Therapy*, https://doi.org/10.1016/j.beth.2020.04.012

INFORMED CONSENT FOR RESEARCH PARTICIPATION

Informed consent is the cornerstone of conducting research in an ethical manner and is an essential part of human subjects protection in all international and federal research ethics guidelines (e.g., Nuremberg Code, Declaration of Helsinki, Belmont Report). Primary components of informed consent include that the decision to participate in research is voluntary and free from coercion, relevant information about the study and potential risks are adequately described, and potential participants demonstrate comprehension of the information provided (Amdur & Bankert, 2011). Consequently, when creating policies and procedures for conducting research in a practice setting, it is critical to attend to both the informed consent process and the consent documents, as informed consent involves more than merely obtaining the participant's signature on a form. Useful guidance related to informed consent for research appears in Sections 8.02–8.05 of the APA (2017) Ethics Code and the federal guidelines (45 CFR 46.116) put forth by OHRP (HHS Department Protection of Human Subjects, 2018). Although most research conducted in private practice settings is not funded by the federal government and thus will not fall under the purview of OHRP, the guidelines delineated in the Common Rule are the gold standard for informed consent for research in the United States and therefore provide a useful guide to the clinician-researcher.

The Issue of Multiple Relationships

Clinicians who wish to involve their clients as participants in their research must attend to ethical issues pertaining to multiple roles, especially during the informed consent process. The APA (2017) Ethics Code states that multiple relationships with clients should be avoided if they "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" (Standard 3.05). Thus, if conflicts between the clinician's research and treatment roles emerge and cannot be mitigated, the treatment relationship must be prioritized over the research relationship, as clients are in a treatment setting.

Perceived coercion is a key ethical issue related to multiple roles that arises when conducting research in practice settings. Individuals seeking psychological treatment are in an inherently vulnerable position by virtue of being in distress and in need of care. To reduce risks of coercion to participate in research and to protect clients' welfare, we recommend that the clinician attend to the following issues:

- *Consider when the appropriate time is to approach clients about research participation.* Giving clients the opportunity to consider research participation at the beginning of treatment, before forming an attachment to the therapist, may reduce risk of perceived coercion and the likelihood that the patient's response to the research invitation is motivated by desires to please the therapist or concerns about harming the therapeutic relationship. Inviting clients to participate in research at the beginning of treatment can also allow clients to opt out of treatment with the therapist early on if they do not wish to be treated in a setting where research is being conducted (although we would hope that this issue was discussed as part of obtaining the client's informed consent for treatment). Conversely, clients may feel more comfortable talking with the therapist about research participation and asking in-depth questions about it after they have established trust and a working relationship, arguing for a consent process that occurs later in treatment. Moreover, conducting the consent process after some time in therapy may reduce clients' feelings of coercion to participate, as they could have worries about saying no and starting off on the wrong foot with the therapist if approached at the beginning of treatment.
- *Consider who will approach clients about research participation.* Having someone other than the treating clinician recruit clients for research participation may lower the risk that the client feels coerced to participate, because this strategy separates the research procedures from the therapy process and makes the research more of an administrative than a therapy task. For clinicians in solo practice, this arrangement may not be possible, but for those in group practice settings, administrative staff or other clinicians could serve as the point of contact for approaching clients about research participation. On the other hand, some clients may feel uneasy about research participation if their provider does not discuss it with them directly, and may feel confused as to why the process is separate from their treatment.
- *Discuss the research and review the research consent document outside of a treatment session.* Keeping discussions about research participation out of the time allotted for treatment helps prevent the research from

Please cite this article as: J. B. Persons, T. L. Osborne and R. Trent Codd, Ethical and Legal Guidance for Mental Health Practitioners Who Wish to Conduct Research in a Private Practice ..., *Behavior Therapy*, https://doi.org/10.1016/j.beth.2020.04.012

conflicting with the treatment. Instead, the clinician can set aside time to discuss the research before or after a treatment session, or at a separate time on the phone or in person.

- *Explicitly describe the relationship between treatment and research.* No ambiguity should exist about the relationship between treatment and research. The therapist should clearly explain to clients whether they have the option to receive clinical care but not participate in research. When the clinician is providing clinical services as part of a research study, this fact should be made clear before the start of treatment so clients know that they will not be able to receive treatment from the clinician unless they agree to participate in research. The consent document should include clear statements about this issue.
- *Consider how much time clients will be given to think about research participation and how often they will be asked about it.* To reduce perceived coercion, clients should be given adequate time to make a choice about research participation. However, for the same reason, the consent process should end at some point and not remain open-ended indefinitely. Clients who want more time to decide whether they want to participate in research can be given the option to be asked later in treatment if they wish. Clinicians should also be mindful of how often they ask clients about research participation. There is a balance between checking with clients to address questions and concerns, and burdening clients with repeated requests about research participation that may make them feel pressured to participate.
- *Be clear about any sources of funding for the research and any conflicts of interest for the clinician related to the research (e.g., financial stake in the development of a new treatment or treatment-related technology).* Clients should be informed of financial or other conflicts of interest that are relevant for the clinician conducting the research so the potential sources of motivation for the clinician conducting the research are clear. Transparency about such motivations are necessary for clients to make informed choices about engaging in a dual relationship with the clinician.

The Consent Document

The clinician-researcher must create a consent document that provides potential participants with the information about the research they need to make an informed choice about participating. Consent documents should be written in easy-to-understand language that is appropriate for the individual's reading and developmental level and should avoid use of technical language or jargon.

The APA (2017) Ethics Code (Standard 8.02) clearly identifies the following elements that potential research participants must be informed about if they are to provide informed consent to participate: (a) the purpose, expected duration, and procedures involved in the research; (b) the participant's right to decline to participate and to withdraw from the research; (c) the foreseeable consequences of declining or withdrawing; (d) factors that may be expected to influence the participant's willingness to participate, such as potential risks, discomfort, or adverse effects; (e) any prospective benefits of the research; (f) limits of confidentiality; (g) incentives for participation; and (h) whom to contact for questions about the research and research participants' rights. These elements are largely consistent with those described in the Common Rule (see 45 CFR 46.116). However, the federal regulations go beyond the APA Ethics Code with regard to a few issues (e.g., explicitly stating whether and how participants will be compensated or provided with treatment if injured during the course of research participation), and also include suggestions for additional information that may be appropriate to provide depending on the circumstances (e.g., situations in which the individual's participation in the study may be ended by the researcher, any financial costs the individual will incur by participating in the research, and statements about the probability of being assigned to an active treatment vs. placebo in a randomized controlled trial, among others; Bowen, 2006). Taken together, the APA Ethics Code and the Common Rule provide a "floor" and "ceiling" respectively regarding elements of a research consent document.

When conducting research with children and adolescents, the APA (2017) Ethics Code and the Common Rule both require that consent be obtained from one of the minor's parents/legal guardians and that assent also be obtained from the minor. For children, this will necessitate the creation of two written documents: a consent document for parents/legal guardians to review and sign, and an assent document for children to review and sign. Adolescents can sign the same consent document as their parents/legal guardians if the language in that form is developmentally appropriate; otherwise a separate assent form is needed. Special attention must be paid to the language used in research assent and consent forms to ensure that minors can understand what the research involves and what is being asked of them.

Please cite this article as: J. B. Persons, T. L. Osborne and R. Trent Codd, Ethical and Legal Guidance for Mental Health Practitioners Who Wish to Conduct Research in a Private Practice ..., *Behavior Therapy*, https://doi.org/10.1016/j.beth.2020.04.012

Obtaining Informed Consent

After the client agrees to consider research participation, the research team can provide the potential participant with detailed information about the study via the consent document. After reviewing the consent document, individuals should be given an opportunity to ask questions about the document and the research to help inform their decision. Additionally, best practices are for someone to ask the individual a few questions to verify that they understand the nature of the research and what will be asked of them as a research participant to ensure that they are truly giving informed consent. Individuals who do not understand the information in the consent process and/or document should not be permitted to participate in the research, as they cannot, by definition, give informed consent. When conducting research with children and adolescents, the parent or legal guardian should be approached first about research participation, because if they decline, there is no need to approach the child.

Individuals who consent to research participation will need to sign and date the consent (or assent) document, as will the clinician or other staff member overseeing the consent process. The clinician will need to store the signed research consent and assent documents in a way that maintains confidentiality (e.g., paper copies kept in a locked file cabinet, or paper copies scanned and kept electronically on a password-protected computer or server or flash drive). A copy of the consent (or assent) document should also be given to those who consent.

Many examples of informed consent documents used by various IRBs that the clinician-researcher can adapt for his or her own research purposes can easily be found online. JBP asks her patients at the end of her treatment agreement to give consent for use of data from their clinical record in research. Readers are invited to access the treatment agreement, available in the Treatment section of the Web site at www.oaklandcbt.com, and adapt it for their use.

Circumstances in which informed consent for research is not required are detailed in the APA (2017) Ethics Code (Standard 8.05) and the Common Rule (45 CFR 46.116). In general, this determination should not be made solely by the researcher. Instead, it should be made by an IRB or as part of some other ethical review process.

RESEARCH-RELATED REQUIREMENTS OF THE HIPAA

Any clinician whose practice is, or who works for an organization considered to be, a covered entity under HIPAA (many private practice settings) and who uses protected health information (PHI) in their research is legally required to comply with HIPAA regulations related to research. This is true even if the research does not fall under the purview of the federal ORHP guidelines. Additionally, it is important for clinicians conducting research to be aware of relevant state laws about research and privacy, as they preempt HIPAA when more stringent.

We describe below several key aspects of HIPAA as it relates to the conduct of research. Useful resources for understanding HIPAA (1996) requirements in more depth include the portion of the law related to research, and a free booklet written by the HHS entitled *Protecting Personal Health Information in Research: Understanding the HIPAA Privacy Rule* (available at https://privacyruleandresearch.nih.gov/pdf/hipaa_privacy_rule_booklet.pdf). Another useful resource is a chapter by Fisher and Vacanti-Shova (2012). Members of the APA can purchase this chapter online for a nominal cost at https://psycnet.apa.org/buy/2011-11699-016.

HIPAA requires that clinicians in covered entities who are conducting research that will involve creating, using, or disclosing PHI obtain signed authorization for research from participants or their legal guardians (in the case of minors or adults with diminished capacity) (Fisher & Vacanti-Shova, 2012). The scope of the research authorization should be limited to the information needed to conduct the research. The HIPAA Privacy Rule outlines the required elements of an authorization form for research, and these include:

- A description of the specific PHI to be used or disclosed;
- The names of the individual(s) who will use or make the disclosures of the PHI and to whom they will disclose this information;
- A description of the reasons for the uses or disclosures that will occur;
- An expiration date or event for the authorization, which can be a specific date, the end of the study, or never; and
- A signature of the individual providing the authorization or their legally authorized representative.

HIPAA research authorization forms must include several statements. First, the form must explain individuals' rights to revoke their authorization at any time, as well as the limits on this revocation—for example, researchers are not required to retrieve or remove PHI about a research participant that has already been used or disclosed before the participant revokes his or her authorization (i.e., data that have already been put into a research data set or used in study analyses). Second, the form must explain conditions under which

Please cite this article as: J. B. Persons, T. L. Osborne and R. Trent Codd, Ethical and Legal Guidance for Mental Health Practitioners Who Wish to Conduct Research in a Private Practice ..., *Behavior Therapy*, https://doi.org/10.1016/j.beth.2020.04.012

treatment is contingent on providing research authorization. Last, the form must inform potential research participants about risks of redisclosure of their PHI by those to whom the study team will disclose information. Sample language for authorization forms for research purposes is available from HHS at https://privacyruleandresearch.nih.gov/pdf/authorization.pdf.

The standard HIPAA authorization for research asks for authorization for use and/or disclosure of PHI for a specific study. One of us, based on HHS guidance that is posted at https://www.hhs.gov/sites/default/files/hipaa-future-research-authorization-guidance-06122018%20v2.pdf, developed a form that can be used to obtain the participant's authorization for use of PHI in a range of studies, some of which may not yet have been designed. We post that form at www.oaklandcbt.com on the Research page. Readers are welcome to download it and adapt it for their use.

It is a good idea to review the HIPAA research authorization form with clients during the informed consent process, as individuals will not be able to make an informed decision about research participation without understanding how their PHI will be used and disclosed by the investigator. HIPAA allows researchers to create separate or combined research consent documents and HIPAA authorization forms. Combining the forms allows the investigator to eliminate redundant content that appears in the two forms, and reduces the risk of individuals signing one form but not the other (which would preclude them from research participation). A drawback is that a combined form is likely to be more complex and more difficult for individuals to understand (Muhlbaier, 2006).

Clinicians working in covered entities are not required to obtain a HIPAA authorization for research purposes in several circumstances (Fisher & Vacanti-Shova, 2012). The first circumstance involves research that uses de-identified data—that is, data that do not include any of the 18 identifiers that are considered PHI in the Privacy Rule. The 18 identifiers are the following: names; dates except for year; telephone numbers; geographic data; FAX numbers; social security numbers; e-mail addresses; medical record numbers; account numbers; health plan beneficiary numbers; certificate/license numbers; vehicle identifiers and serial numbers including license plates; Web URLs; device identifiers and serial numbers; Internet protocol addresses; full-face photos and comparable images; biometric identifiers (i.e., retinal scan, fingerprints); and any unique identifying number or code. Second, HIPAA authorization for research is not needed when an IRB has granted a waiver or alteration of authorization. To do this, an IRB must find that the research meets defined criteria (including that a set of privacy measures are in place to ensure that use or disclosure of individuals' PHI), involves no more than minimal risk to their privacy, and that the research could not be practically conducted without access to the PHI and the waiver or alteration of authorization. Finally, several clearly defined research activities do not require a signed HIPAA authorization. These include activities that are considered preparatory for research, and research using the PHI of those who are deceased. When PHI is used or disclosed for research purposes without authorization, the guidelines indicate that researchers should use a minimum necessary standard (i.e., releasing the least amount of data possible while still meeting the needs of the research project), in order to maximize privacy.

OTHER LEGAL AND PROFESSIONAL CONSIDERATIONS

The practitioner's state may have laws related to research. If so, it is important to learn about these and follow them when conducting research. In addition, before undertaking a research project, we advise practitioners to send a notice in writing to their malpractice insurance company to advise them that they will be engaging in research activities and asking the insurance company to alert them right away if the insurance company is not prepared to cover this activity. One of us has done this with no pushback from the insurance company.

If the practitioner is expecting to carry out multiple research studies, we recommend that he or she develop a written set of research policies to guide research activities in his or her practice. A sample research policies document is posted at www.oaklandcbt.com on the Research page. Readers are welcome to use it or adapt it for their practice. If the practitioner relies on paid or volunteer research assistants, it is a good idea to ask them to start work by obtaining a certificate of human subjects training, and to ask them to sign a Business Associate Agreement (BAA) that calls for them to keep confidential any patient information they learn during the conduct of the research. A sample BAA is available for download at www.oaklandcbt.com on the Research page.

Conclusion

Many clinicians who work in private practice settings have the training, skills, and desire to make contributions to the scientific literature. And the overlap between the *methods* of research and high-quality clinical work (Hayes, 1981) and the *questions of interest* to researchers and clinicians (Persons, 2007) is high. To help these clinicians

Please cite this article as: J. B. Persons, T. L. Osborne and R. Trent Codd, Ethical and Legal Guidance for Mental Health Practitioners Who Wish to Conduct Research in a Private Practice ..., *Behavior Therapy*, https://doi.org/10.1016/j.beth.2020.04.012

make scientific contributions, we offer legal and ethical guidance for conducting research in private practice settings.

Conflict of Interest Statement

This article focuses on a topic I address in my consultation practice, which is a source of income for me. Trent Codd collects royalties for a book on the topic of this article that he edited. Travis Osborne reports no conflict of interest.

Uncited Reference

LeJeune and Luoma, 2015

References

Amdur, R., & Bankert, E. A. (2011). *Institutional review board: Member handbook* (3rd ed.). Jones & Bartlett. https://doi.org/10.1525/jer.2013.8.4.93

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* (pp. 101–105).(2nd ed.). Jones & Bartlett.

American Counseling Association (2014). *2014 ACA code of ethics*. https://www.counseling.org/docs/default-source/default-document-library/2014-code-of-ethics-finaladdress.pdf?sfvrsn=96b532c_2

American Psychological Association (2017). *Ethical principles of psychologists and code of conduct (2002, amended effective June 1, 2010, and January 1, 2017)*. https://www.apa.org/ethics/code/index.aspx

Bowen, A. J. (2006). The consent document. In E. A. Bankert & R. J. Amdur (Eds.), *Institutional review board: Management and function* (pp. 202–204).(2nd ed.). Jones & Bartlett.

Cen, R., Hussain, A., Pak, K. J., Mitchell, G., Nikles, J., Gaudreau, S., ... Breault, J. L. (2016). Do n-of-1 trials need IRB review? *Journal of Empirical Research on Human Research Ethics*, *11*(3), 250–255. https://doi.org/10.1177/1556264616662560

Codd III, R. T. (Ed.). (2018). *Practice-based research: A guide for clinicians*. Routledge.

Fisher, C. B., & Vacanti-Shova, K. (2012). The responsible conduct of psychological research: An overview of ethical principles, APA Ethics Code standards, and federal regulations. In S. J. Knapp M. C. Gottlieb M. M. Handelsman & L. D. VandeCreek (Eds.), *APA handbooks in psychology. APA handbook of ethics in psychology, Vol. 2. Practice, teaching, and research* (pp. 335–369). American Psychological Association. https://doi.org/10.1037/13272-016

Hayes, S.C. (1981). Single case experimental design and empirical clinical practice. *Journal of Consulting and Clinical Psychology*, *49*(2), 193–211. https://doi.org/10.1037/0022-006X.49.2.193

Health and Human Services Department Protection of Human Subjects (2018). *45 C. F. R. 46*.

Health Insurance Portability and Accountability Act of 1996 (1996, 1996). *Pub. L. No. 104-191, 110 Stat. 1936*. https://doi.org/10.4135/9781412971942.n180

Kazdin, A. E. (2019). Single-case experimental designs: Evaluating interventions in research and clinical practice. *Behaviour Research and Therapy*, *117*, 3–17. https://doi.org/10.1016/j.brat.2018.11.015

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*(6), 421–428. https://doi.org/10.1037/pro0000049

Muhlbaier, L. H. (2006). Health Insurance Portability and Accountability Act and research. In E. A. Bankert & R. J. Amdur (Eds.), *Institutional review board: Management and function* (pp. 273–277).(2nd ed.). Jones & Bartlett.

National Association of Social Workers (2017). *NASW code of ethics*. Retrieved December, 11, 2019, from https://www.socialworkers.org/About/Ethics/Code-of-Ethics/Code-of-Ethics-English

National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (1979). *Ethical principles and guidelines for the protection of human subjects of research*. http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.htm

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), 1–12. https://doi.org/10.1111/j.1468-2850.2012.01269.x

Osborne, T. L. (2018). A step-by-step guide for creating an independent institutional review board (IRB) for private practitioners. In R. T. CoddIII (Ed.), *Practice-based research: A guide for clinicians* (pp. 81–107). Routledge. https://doi.org/10.4324/9781315524610-6

Osborne, T. L., & Luoma, J. B. (2018). Overcoming a primary barrier to practice based research: Access to an institutional review board (IRB) for independent ethics review. *Psychotherapy*, *55*(3), 255–262. https://doi.org/10.1037/pst0000166

Persons, J. B. (2007). Psychotherapists collect data during routine clinical work that can contribute to knowledge about mechanisms of change in psychotherapy. *Clinical Psychology: Science and Practice*, *14*(3), 244–246. https://doi.org/10.1111/j.1468-2850.2007.00083.x

Persons, J. B. (2018). Simultaneous practice and research: A model for conducting research in private practice. In R. T. CoddIII (Ed.), *Practice-based research: A guide for clinicians* (pp. 153–169). Routledge.

Persons, J. B., Mooney, K. A., & Padesky, C. A. (1995). Interrater reliability of cognitive-behavioral case formulation. *Cognitive Therapy and Research*, *19*, 21–34.

Waltman, S. H. (2018). Research methods in practice settings. In R. T. CoddIII (Ed.), *Practice-based research: A guide for clinicians* (pp. 25–43). Routledge.

Zieve, G. G., Persons, J. B., & Yu, L. A.D. (2019). The relationship between dropout and outcome in naturalistic cognitive behavior therapy. *Behavior Therapy*, *50*(1), 189–199. https://doi.org/10.1016/j.beth.2018.05.004

RECEIVED: December 14, 2019
ACCEPTED: April 19, 2020
AVAILABLE ONLINE: XXXX

Please cite this article as: J. B. Persons, T. L. Osborne and R. Trent Codd, Ethical and Legal Guidance for Mental Health Practitioners Who Wish to Conduct Research in a Private Practice ..., *Behavior Therapy*, https://doi.org/10.1016/j.beth.2020.04.012