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DISCUSSION AND REVIEW PAPER

Establishing Consumer Protections for Research in Human Service Agencies

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Abstract

Conducting research in practice settings is the primary mechanism for establishing a strong foundation of evidence for clinical decision making. In behavior analysis, this type of research frequently originates from university-based systems that have established institutional review boards. Independent human service agencies that want to contribute applied research to the literature base that is clinically meaningful and conducted in an ethical fashion must establish a research review committee (RRC). The purpose of this article is to provide information and guidance for establishing and maintaining the activity of an RRC in a human service setting.

Keywords Consumer protection · Human service agencies · Institutional review board · Research

Cooper, Heron, and Heward (2007) describe four interrelated domains of science and practice in behavior analysis: (a) behaviorism (i.e., theory, philosophy), (b) experimental analysis of behavior (i.e., basic research), (c) applied behavior analysis (i.e., applied research), and (d) the professional practice of behavior analysis. Practicing behavior analysts are likely to achieve a higher quality of services for their clients when the intersection of these first three domains informs their everyday activities. First, practitioners should implement programming that is informed by theory, concepts, and principles (i.e., behaviorism, experimental analysis). Second, programming should include procedures that have been experimentally validated for their beneficial effects on socially significant behavior (e.g., applied behavior analysis). Third, practitioners should systematically evaluate their own services to determine if their programs are producing meaningful change for the individual client or if modifications in programming are warranted (Barlow, Hayes, & Nelson, 1984). Kazdin (2011) provides a treatment research and evaluation framework that emphasizes the importance of using single-subject research designs as tools to answer both clinical *and* scientific questions.

In the field of psychology, a mature and well-established profession, the scientist–practitioner model was developed at the Boulder Conference in 1949 as a mechanism to produce integration between research and practice (Baker & Benjamin, 2000). Training on the scientist–practitioner model has long been required as a part of graduate-level coursework in clinical psychology (American Psychological Association, 2013); however, the requirement has fallen short in supporting the day-to-day integration of research into clinical practice (LeJeune & Luoma, 2015). The field of behavior analysis, a much younger but rapidly growing independent discipline, might find itself in similar straits if there is not a fluid interchange between the science of behavior analysis and the professional practice of the discipline. The Behavior Analyst Certification Board (BACB) has reported an increase of 110% per year in certificants over the last 5 years (Carr & Nosik, 2017). This growth presents risk if new practitioners are disconnected from the science of the discipline in their everyday practice. However, the growth presents opportunities to contribute to the evidence base for our field if we further develop and evaluate mechanisms to facilitate the integration of research in practice settings.

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The interchange between the scientific domains and the practice of the profession should be bidirectional, such that practice questions guide our scientific inquiry and scientific evidence guides our treatment approaches in clinical settings (Hayes, Barlow, & Nelson-Grey, 1999; Stricker & Trierweiler, 1995). The use of scientific methods in behavior–analytic service provision is a means to answer our clinical questions, improve the quality and effectiveness of treatment for our clients, and contribute to the literature base that helps other practitioners make clinical decisions. Love, Carr, LeBlanc, and Kisamore (2013) conducted a preliminary evaluation of a training model as a mechanism for creating the capacity to conduct scientifically sound research in an early and intensive behavioral intervention setting. The authors used a modified behavioral skills training approach to teach staff with varying educational backgrounds how to conduct single-case design research. Participants were able to learn and apply several important research skills, and several published studies resulted from the training effort (e.g., Charania et al., 2010; Gunby, Carr, & LeBlanc, 2010; Marchese, Carr, LeBlanc, Rosati, & Conroy, 2012). The authors identified several critical components to establishing a research culture and capability within a human service organization. In addition to providing a supportive executive leadership team and effective training on research methods, they addressed the need for an infrastructure to protect the rights and safety of research participants (Love et al., 2013).

There have been several events, beginning with the Nuremberg trials in 1945, during which mistreatment of human subjects highlighted a serious need for a way to protect research participants from harm (Byerly, 2009). The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research issued a landmark report—the Belmont Report—that has guided human subjects' protections for decades. The Belmont Report (1979) described three critically important principles of human protections in research: (a) respect for persons, (b) beneficence, and (c) justice (U.S. Department of Health and Human Services Office of Human Research Protections [USDHHOHRP], 2016a). Based on the principles identified in the Belmont Report, in 1991, the U.S. Department of Health and Human Services codified regulations for human subjects research that is sponsored or funded by any U.S. federal agency. This regulation is known as the Common Rule (Protection of Human Subjects, 2009). These regulations include specific requirements for institutional review board (IRB) oversight.

In addition to the aforementioned U.S. federal regulations, professionals must adhere to requirements outlined in the code of ethics for their profession. The BACB's *Professional and Ethical Code of Conduct for Behavior Analysts* (hereafter "the Compliance Code") specifies in Section 9.02 (Characteristics of Responsible Research) that "behavior analysts conduct research only after approval by an independent, formal research review board. Any research conducted with vulnerable populations requires the approval of a research review committee" (BACB, 2015, p. 18). The Compliance Code uses the term *research review committee*, which is not specific to university settings (i.e., IRB), to allow for any organization that is not affiliated with a university to establish a review committee for its research purposes. The Compliance Code also includes definitions for *research review committee* and *research* (BACB, 2015, p. 24). These protections exist because of the long and documented history of unprotected participants being taken advantage of in the absence of any oversight (e.g., Helsinki Accords, Tuskegee Syphilis Study).

Participant protection in research is even more important for behavior analysts who conduct research in human service settings because of contingencies that could lead a clinician to behave in ways that are not fully controlled by client goals. When a clinician is conducting research with a client–participant, a dual relationship necessarily exists (i.e., clinician and researcher). A behavior analyst functioning in both roles is at risk of losing sight of his or her clinical priorities without fully understanding the controlling variables in operation. Reinforcement contingencies that have the potential to exert some degree of control over the researcher's behavior include professional recognition, incentives, career advancement, and publication or presentation opportunities, among others.

The Compliance Code (http://bacb.com/ethics-code), Section 9.02 (Characteristics of Responsible Research), specifies that it is the responsibility of the clinician to prioritize the welfare of the client at these times:

> Behavior analysts conducting applied research conjointly with provision of clinical or human services must comply with requirements for both intervention and research involvement by client-participants. When research and clinical needs conflict, behavior analysts prioritize the welfare of the client. (BACB, 2015, p. 18)

Clients and their families may feel indebted to a capable provider, making them more likely to consent even if they have concerns (Fouka & Mantzorou, 2011). They may also fear negative effects on the quality of their services if they do not consent to participation. The context in which research might occur needs to be clearly explained as a part of the consent process so the client understands the potential risks and actively consents to research participation with a full understanding that there will be no impact on services if he or she declines the opportunity.

The behavior–analytic literature does include research conducted in clinical settings, but it is often affiliated in some way with a university-based system that has an established IRB (e.g., Kennedy Krieger Institute, Munroe Myer Institute, New England Center for Children, Marcus Autism Center). It is important for independent human service agencies

without university affiliations to have a means to conduct clinically meaningful applied research in an ethical and responsible fashion. A human service organization that wants to contribute to the scientific literature base needs to take steps to prepare, including establishing a research culture (e.g., research director with protected time, value for research in the culture), training staff in the design and execution of protocols, and creating an infrastructure to ensure participant protections (i.e., a research review committee [RRC]). The purpose of this article is to provide information and guidance for establishing and maintaining the activity of an RRC in a human service setting.

Defining Qualifications for Research

There are several general guidelines used to determine what should be considered research. The Compliance Code (BACB, 2015) includes a glossary that defines *research* based on the purpose of the data as

> any data-based activity designed to generate generalizable knowledge for the discipline, often through professional presentations or publications. The use of an experimental design does not by itself constitute research. Professional presentation or publication of already collected data are exempt from elements in section 9.0 (Behavior Analysts and Research) that pertain to prospective research activities (e.g., 9.02a). However, all remaining relevant elements from section 9.0 apply (e.g., 9.01 Conforming with Laws and Regulations; 9.03 Informed Consent relating to use of client data). (p. 28)

This is an important distinction that is intended to provide additional guidance for practitioners who decide to make archival data public in some form (e.g., presentations, publications). Similarly, the Common Rule defines research as "a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge"; further, such an investigation is considered to be human subjects research if it involves "a living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information" (USDHHOHRP, 2016b). Thus, in both the Compliance Code and the Common Rule, data collection on humans is considered research if it is designed to contribute to "generalizable knowledge." This may be a somewhat vague criterion given that the generalizability of data exists on a continuum; however, as implied in the Compliance Code, a common interpretation is that data are intended to contribute to generalized knowledge if they are shared through publication or public presentation in such a way that they may influence the behavior of others in the discipline practically or theoretically. Thus, if systematic data collection activity is designed specifically with the possibility in mind that it may produce information that warrants public sharing, it constitutes research (see Cassarett, Karlawish, & Sugarman, 2000, for a discussion of what constitutes research).

Kazdin (2011) distinguishes between treatment research and treatment evaluation. In conducting treatment research, the participant is selected based on two criteria: scientific needs and importance to a specific research question. Treatment evaluation includes all of the same systematic requirements (e.g., systematic data collection, possible publication, clearly specified procedures), but the evaluation is based on the needs of the client and is not intended to fill a knowledge gap beyond the identification of an effective treatment for that particular client. An important question to be asked regarding treatment evaluation in practice settings is whether and when such an evaluation might be considered research that requires prospective review by an RRC. As specified in the Compliance Code, practitioners who carefully and scientifically evaluate their everyday clinical work, including the use of reliable measurement and an experimental design, are not necessarily conducting research. If such a careful treatment evaluation is conducted exclusively for the benefit of the client and the data are never shared outside of the organization, then clearly it does not constitute research.

However, some everyday treatment evaluations are retrospectively found to yield information that is worth sharing with the broader behavior–analytic community. The existence of this possibility does not mean that all careful treatment evaluations must be submitted to the RRC review ahead of time, as this might delay treatment against the best interests of the client. The Compliance Code recognizes that data that have already been collected in the process of conducting clinical activities may be shared without having undergone prior research review, as long as they conform to laws and regulations and client-informed consent has been obtained for data sharing (even if the data are presented without identifiable information). In other words, conducting a treatment evaluation for the client's benefit without prior research review does not necessarily preclude later sharing of the data. However, it is prudent to have an RRC review prior to presentation of the data to ensure that all client privacy protections have been maintained and that appropriate client-informed consent has been obtained. This level of review is typically referred to as *expedited*. Some level of review of every shared project facilitates identification of drift in defining translational or extraordinary procedures as standard treatment.

In addition, some treatment evaluations require prior review by an RRC. The determining factor for whether the evaluation crosses the border into research is that the

evaluation is "designed to generate generalizable knowledge" (BACB, 2015, p. 24). A client's treatment evaluation should be considered designed for this purpose if one or more of the following conditions exist: (a) The evaluation is known to address a gap that exists in the published literature, including a need to replicate a previously reported finding; (b) the rigor of the evaluation exceeds that of normal clinical practice in the organization because of the possibility of future public sharing (e.g., more rigorous assessment of interobserver agreement and treatment integrity than is collected for other client data); or (c) the evaluation includes potentially countertherapeutic elements in order to enhance experimental control (e.g., lengthy withdrawal or withholding of treatment). In addition, a treatment evaluation should be considered research if a plan is made to evaluate a particular treatment with the next client who presents with a particular problem; in this case, there is a clear intention to learn something from the evaluation beyond how to solve a particular client's problem. An important first step to establishing an RRC in a human service organization is for the organization to define its scope by considering which data collection activities should be reviewed prospectively for the client's protection versus retrospectively but prior to presentation.

RRC Purpose and Composition

A guiding principle for the purpose of an RRC can be derived from the Hippocratic Oath: "Do no harm." The U.S. federal guidelines define the purpose of an RRC to be "to assure, both in advance and by periodic review, that appropriate steps are taken to protect the rights and welfare of humans participating as subjects in research" (USDHHOHRP, 2016b). The Compliance Code defines the RRC as

> a group of professionals whose stated purpose is to review research proposals to ensure the ethical treatment of human research participants. This board might be an official entity of a government or university (e.g., Institutional Review Board, Human Research Committee), a standing committee within a service agency, or an independent organization created for this purpose. (BACB, 2015, p. 24)

The Compliance Code is synthesized with U.S. federal requirements to ensure that required measures are taken in the oversight of research conducted by behavior analysts. Three broad areas of compliance for RRCs derived from the U.S. federal regulations include committee composition, committee training, and operational procedures (Protection of Human Subjects, 2009).

Committee Composition The U.S. federal requirements for the composition of an RRC include professional competence to review all aspects of the research activities (i.e., organization policies, applicable law, and professional ethical standards), a minimum of five members who have specific functions (i.e., nonscientist, nonaffiliated, and scientist), and diversity (i.e., gender, profession) that promotes complete review of the research activities typically conducted by the organization (Protection of Human Subjects, 2009). Depending on the organizations' volume of research and the resources available, a research committee may serve one or more organizations. At a minimum, the membership of the committee should include at least one representative from the organization(s), a nonscientist, a nonaffiliated member, and a scientist. Although each of these roles is required to be filled, it is acceptable for one person to serve the function of multiple roles (e.g., nonaffiliated and nonscientific). The committee member, function, U.S. federal regulation, and recommendations for recruiting each of these are briefly described in the following and are provided in additional detail in Table 1.

A challenge to composing the committee is often selecting representatives who are nonaffiliated and nonscientific, often called community or consumer representatives (Klitzman, 2012). The function of these members is to provide the perspective of an average citizen regarding the research project and to represent an unbiased (i.e., the member has no financial ties to the project, does not make scientific contributions to the project, and is not affiliated with the consumer or organization) review. These representatives may have some inherent conflicts of interest, especially in smaller communities, because they hear about clients they may know personally. These members are often difficult to maintain on a committee (Klitzman, 2012). However, members can be paid or alternatively recruited through self-selection. Local human resources professionals or human rights committee members who have an interest in participating in similar activities are more likely to value the purpose of the committee and additionally provide relevant expertise to research review. The scientific member is often an organization representative or professional associated with a local university training program. The function of the scientific member is to provide the expertise of someone who has demonstrated experience in the type of research that is likely to be conducted through the organization(s). It is important to consider the type of research that will be conducted by the organization and ensure that this representative reflects experience that aligns with those research goals. Identification of an appropriate scientific member can begin through local university training programs, authors of recent scholarly publications that align with the research goals of the organization, or personal contacts of the behavior analysts who work within the organization(s). The RRC has the option of recruiting an additional review

Table 1 Research review committee member, function, U.S. regulation, and recruitment tips

Member	Function	U.S. regulation	Recruitment
Nonscientific	Voices concerns about potential research subjects and provides a broader community perspective	Protection of Human Subjects (2009): "at least one member whose primary concerns are in nonscientific areas"	Human resources representative, local human rights committee representative
Nonaffiliated	Unbiased to organization's financial concerns and represents a community perspective	Protection of Human Subjects (2009): "at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution"	Can be a local scientist (e.g., physician) or retired professional (e.g., schoolteacher, administrator) who will not have a conflict of interest
Scientist	Provides expertise on experimental design for research that aligns with that of the organization	Protection of Human Subjects (2009): "at least one member whose primary concerns are in scientific areas"	Local university training program faculty members, relevant research authors aligned with organization's activity
Competent experts	Supports projects that require additional expertise outside of that represented by the committee	Protection of Human Subjects (2009): "individuals with competence in special areas to assist in the review of issues which require expertise beyond or in addition to that available on the IRB"	Researchers who have recently published in the relevant area

IRB Institutional review board

member when additional expertise is necessary to adequately review a research project. These individuals may attend the committee meeting and present their recommendations to the committee but will not have a vote on the application. After determining the membership of the RRC, it can be useful to identify members who have experience in policy development to assist with the writing and planning of the operational procedures.

An additional consideration for the composition of the RRC is any conflicts of interest. Federal regulations specify that "no IRB may have a member participate in the IRB's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB" (Protection of Human Subjects, 2009). This is important to consider, particularly for the chairperson of the RRC if his or her involvement might result in delays in the review process. Although it is not uncommon for a researcher to serve as the RRC chairperson for human service organizations, especially given the limited resources (e.g., lack of funds, lack of qualified individuals), in some cases this should be a consideration. In either case, the RRC should define what constitutes a conflict of interest for the RRC chairperson, members, or alternates and identify the process for recusal and documentation procedures that reflect that the conflicted member did not have a vote toward quorum.

Committee Operational Procedures

The scope and content of RRC written procedures will vary based on differences in the type of research, organization policies and administrative practices, and local and state law. Written procedures should be established, documented, and made available to researchers and committee members prior to beginning review committee operations. If a project is considered human subjects research according to the RRC written procedures, it will require review by the RRC. The procedures described in this section are specifically relevant to human service organizations that conduct behavior–analytic research in a clinical setting; these include committee training, review type, application submission instructions, informed consent, approval criteria and timeline, protocol changes, risks and protections, incentives, and audit and record retention. Each of these items is described briefly in the following sections based on the Common Rule (Protection of Human Subjects, 2009). These items are also provided in Table 2 as part of an RRC checklist.

Training It is necessary to provide basic training on human subject protection for each RRC member. A presentation that goes through the critical components can be used to facilitate such training. The Collaborative Institutional Training Initiative offers online training that complies with the National Institutes of Health policy (https://www.citiprogram.org/). Alternatively, an organization could develop its own training that covers the same material.

The U.S. federal regulations specify that the committee must be able to determine the acceptability of proposed research in accordance with the organization's commitments and policies and applicable local law (Protection of Human Subjects, 2009). Relevant local laws can vary between states and include, but are not limited to, laws that pertain to the age at which an individual is considered an adult instead of a minor ("age of majority"), guardianship, and who can legally consent on behalf of another. A means for accomplishing this would be having a member who can provide this expertise

Table 2 Research review committee component checklist

Item description	Completion checklist
1. Committee is appropriately composed (i.e., nonaffiliated, nonscientist, scientist, organization representative, and at least five members)	Nonaffiliated member
	Scientist
	Nonscientist
	Organization representative
	Consumer or community representative
	Other
2. Training	Functions, processes, and procedures of a review committee
	Organization specific
	Local state law
3. Written procedures or information developed for each item	Review types
	Exempt
	Expedited
	Full
	Submission instructions
	Informed consent process
	Approval timeline and criteria
	Protocol changes
	Audit and record retention

from the organization or conducting organization-specific training that includes information on applicable local law for the members of the committee as a whole.

Review Types The written RRC procedures should include specification of the level of review required for different types of projects, which may be modeled after those described in the federal regulations. According to the Common Rule, some research with human subjects requires full committee review by a convened RRC, some research can undergo expedited review by one or more members of the RRC, and some research is exempt from RRC review. An RRC should have a process in place to determine into which of these three categories a research protocol falls. Importantly, a determination that a protocol is exempt from review should not be made by the investigator, who may have a conflict of interest, but by the RRC or its designee. Thus, a description of all proposed human subjects research projects should be submitted to the RRC, even when the investigators believe that the research may be exempt. A common procedure is for the RRC chair or a designee of the chair to screen an incoming protocol and to issue an exemption determination if applicable. Generally, research may be considered exempt if it meets the criteria described in the Common Rule (Protection of Human Subjects, 2009). Three categories of exemptions may be most relevant to research conducted in practice settings. First, a study may be considered exempt if it is conducted in "established or commonly accepted educational settings" and involves "normal educational practices" (Protection of Human Subjects, 2009), commonly understood to mean that the intervention and data collection would occur identically if the research were not being conducted. This exemption may apply, for example, to certain types of research conducted in special education classrooms. Second, archival research involving de-identified records is generally exempt as long as all of the records are already in existence at the time the research project is initiated. This exemption might apply, for example, if a research project involved analyzing data from all functional analyses conducted within the organization in the last 10 years after all identifying information has been removed from the records. Third, research involving the use of "educational tests (e.g., cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior" (Protection of Human Subjects, 2009) may be exempt when all data are recorded anonymously or when the data can be linked to individual subjects but there is no risk of harm to the subject (e.g., criminal or civil liability or damage to financial standing, employability, or reputation) if the data were to be disclosed outside of the research (Connelly, 2014). This last category of exemptions, however, applies only to adult subjects. In other words, research with children that involves educational tests, surveys, interviews, or public observation cannot be exempt and must undergo expedited or full committee review. Recent changes to the Common Rule, most of which are scheduled to take effect on January 19, 2018, slightly expand the criteria for exempt research; most relevant for research in clinical settings will be an exemption for storing and using identifiable private information for secondary research provided that broad consent has previously been obtained for such use. The RRC chair or designee can always decide to subject a protocol to RRC review instead of granting an exemption, even when it uses a methodology that may meet the exemption criteria.

If a protocol is not exempt from review, the RRC chair typically determines (in consultation with other RRC members or outside experts if need be) whether the protocol qualifies for expedited review or requires full committee review. Expedited review can be carried out by the RRC chair alone or by one or more RRC members designated by the chair. The term *expedited* does not necessarily mean that the review will occur more quickly, although in practice it may result in a faster turnaround. Through the expedited review procedure, the RRC chair or designee can approve the protocol without or following revisions. In order for a protocol to be disapproved, however, it must be referred to full RRC review. In order to determine that a new protocol is eligible for expedited review, two conditions must be met according to the Common Rule: (a) The research must present no more than minimal risk to the subjects and (b) it must involve only procedures included in the Department of Health and Human Services list of

expedited categories (Protection of Human Subjects: Categories of Research That May Be Reviewed by the Institutional Review Board [IRB] Through an Expedited Review Procedure, 1998). Most pertinent to behavioral researchers are Categories 6 ("Collection of data from voice, digital, or image recordings made for research purposes," p. 60366) and 7 ("Research on individual or group characteristics or behavior … or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies," p. 60366). A behavioral research study that falls into these categories can be considered expeditable if and only if it also poses no more than minimal risk to subjects. Minimal risk is defined as that which does not exceed risks "ordinarily encountered in daily life or during routine physical or psychological examinations or tests" (Protection of Human Subjects, 2009). Risk assessment, according to this criterion, always carries some degree of subjectivity, and if the level of risk seems open to interpretation, the protocol goes to full committee review. In addition, an RRC may decide to use more stringent criteria for expedited review in terms of the types of minimal risk protocols that can be expedited.

A full committee review occurs when a nonexempt protocol does not meet criteria for expedited review or when the RRC chair prefers input from the full committee as part of the review. The committee is provided with the application far enough in advance of the meeting that its members are able to completely review the materials and then discuss the information at a convened meeting of the review committee where a majority of the members are in attendance, including a nonscientific member (Protection of Human Subjects, 2009). In the event that a member has a conflict of interest, he or she may recuse himself or herself from the review. If at any time the RRC needs expertise in a particular area, it may solicit additional review from one or more experts who are not members of the RRC; these experts may be invited to attend the RRC meeting but cannot vote on the approval of the application. The review committee will vote to approve, disapprove, or require modifications for each research application. Written notification will be provided to the researcher, at which time the research protocol can begin if it is approved; otherwise, the researcher will respond to requests for modifications to the application. Final approval should specify the committee's determination of risk level (minimal or greater than minimal). When the RRC approves a protocol with minimal risk, the approval motion should also specify whether future review of modifications or continuing review of that protocol can occur via the expedited route or must be performed by the convened RRC. If risk is greater than minimal, review of modifications and continuing review must be performed by the convened RRC.

Vulnerable Populations The federal regulations establish special protections for certain vulnerable populations, including pregnant women, fetuses, neonates, prisoners, and children. Special protections for children probably have the greatest relevance to research in behavior analysis practice settings. Requirements for parent permission and child assent (Protection of Human Subjects, 2009) apply to all nonexempt research with children, and additional protections apply to research that carries greater than minimal risk. Although other populations are not afforded special protections by the regulations, RRC review of participant protections should always consider the specific vulnerabilities of the participant population. For example, particular caution may be warranted in research with adults with disabilities, older adults with dementia, and other populations whose ability to provide informed consent may be compromised.

Application Submission Instructions A process description and a list of required materials for submission are helpful to ensure that RRC members have all of the information needed to make an appropriate decision regarding the approval of the research protocol. The instructions should be sufficiently detailed such that any committee member, in any functional role on the committee, will be able to understand the application and the risks to participant protections. Some standard inclusions in the Submission Instructions section are research procedures, subject inclusion and exclusion criteria, subject recruitment procedures, informed consent process and procedure, and procedures for protecting confidentiality. Investigators should also submit copies of consent or parent permission documents.

Informed Consent Informed consent is key to the protection of human subjects in research, and the procedures vary depending on the population of participants being recruited. For example, there are specific considerations for the recruitment and establishment of assent for children along with permission from an appropriate guardian. The RRC reviews information that will be exchanged with the participant before, during, and after participation in the research. The RRC also reviews the consent procedure that is described for communicating the information (e.g., delivery, method of attaining consent). The presentation of the informed consent must describe the protocol in a way that allows the potential participant to make an informed, voluntary decision and ask questions or express concerns about the research. There are a number of considerations for the RRC in reviewing informed consent, including ensuring adequate time for participants to make a decision, eliminating any potential for coercion, explaining the voluntary nature of participation, and providing continued check-ins throughout the study to ensure the participants' continued willingness to participate, among others (USDHHOHRP, 2016f). For example, incentives are often used for

participation in research, but excessive use of incentives can be considered a form of coercion (Polit & Beck, 2014).

When a participant signs the consent form, he or she has agreed to participate in the research; however, the participant can withdraw consent at any time without penalty. In a case where the participant is a child and cannot consent, there must be a process for obtaining permission from a parent or guardian, and there are often assent procedures to determine the child's willingness to participate. The consent, permission, and assent requirements will vary depending on the amount of risk associated with participation. The required elements of the consent form (or permission form, in the case of parent or guardian permission) include purpose, procedures, risk, benefit, alternatives, confidentiality, compensations, contact information, and statement of voluntariness of participation (Protection of Human Subjects, 2009). The RRC must also ensure that the consent form is written in nontechnical language, accurately represents the research protocol, includes all critical information, and minimizes the potential for coercion. In addition to ensuring the quality of the form, the RRC must ensure that the process for obtaining consent is sufficiently described (i.e., who, when, where, and how the informed consent will be obtained). The RRC may alter the requirements (e.g., removal of several elements in the process) for informed consent when the research involves minimal risks to participants and the waiver of such elements will not adversely affect the participants in any way. One such example includes if the provision of exhaustive information prior to beginning the research would affect the scientific benefit of the research by altering participants' performance during the research.

Approval Timeline and Criteria There are several criteria that must be met for the approval of a research study; these criteria must be met for both initial and continuing review and should be the framework for the RRC's evaluation of research and decision-making procedures (Protection of Human Subjects, 2009). These criteria are as follows:

1. Participant risks are minimized by using procedures consistent with sound research design and if appropriate using treatment approaches already being implemented based on best practice.
2. Risks to participants are reasonable in relation to anticipated benefits and the importance of the knowledge that may reasonably be expected to result.
3. Selection of participants is unbiased.
4. Informed consent will be obtained from each participant or his or her legally authorized representative and it will be documented properly.
5. Appropriate safeguards are included to protect participants from coercion or undue influence (e.g., overly generous incentives, dual relationships).
6. When the research involves vulnerable populations (e.g., children, individuals with disabilities, students), the research also meets those requirements.

In conducting continued review of the research, the RRC will assume that the previously approved protocol has met the aforementioned criteria and will evaluate any new information at that time (USDHHOHRP, 2016c). There are four primary considerations during continuing review of the research protocol:

1. Risk assessment and monitoring (e.g., any new information that would alter the IRB's previous conclusion that risks to participants are minimized).
2. Adequacy of the process for obtaining informed consent (e.g., review a sample of the investigators' informed consent document to ensure that the approved version is being used).
3. Researcher issues (e.g., complaints, changes in employment status).
4. Research progress (e.g., participant enrollments and withdrawals).

All multiyear protocols are subject to RRC review on at least an annual basis, but an RRC can require more frequent review based on risk assessment. The RRC will identify a plan for continuing review of the research, which may include requiring the researcher to complete a progress report.

Protocol Changes Any changes to the protocol, informed consent, recruitment materials, or any other material or documents must be reviewed by the RRC and approved before the changes are implemented. Once a research protocol is approved, proposed changes (e.g., additional data collection, altered procedures) should be submitted to the chair of the RRC so that he or she can determine whether the change is minor enough to be handled through an expedited process or major enough to warrant full committee review. In addition to protocol changes initiated by the researcher, if any unanticipated problems involving risks to subjects or others occur while conducting the research, they must be reported to the RRC chair to determine the best course of action for approving them, temporarily suspending data collection, or terminating the project completely, depending on the severity of the problem. The phrase *unanticipated problems* is not defined, but there are criteria for researchers to determine what types of events might fall into this category. For example, there are unplanned outcomes to conducting research that do not present risks to subjects or others and would not qualify as unplanned, unanticipated problems; however, the loss of data from an unsecure laptop holding sensitive identifiable data is something that would qualify within this reporting category (USDHHOHRP, 2016d). In addition to unanticipated

problems, an RRC might consider requiring investigators to report adverse events related to risks that were identified in the protocol. For example, a protocol might identify physical injury as a possible risk in a functional analysis of self-injurious behavior and describe extensive precautions to prevent it. If injury occurs despite these precautions, it does not qualify as unanticipated but is nevertheless an adverse event that an RRC may wish to monitor.

Audit and Record Retention The RRC must maintain records of all research applications reviewed, detailed meeting minutes, documentation of risks and approval periods, and documentation of any findings of the committee related to approval of research involving children. The RRC records should be kept "for at least 3 years, and records relating to the research which is conducted [should] be retained for at least 3 years after completion of the research" (Protection of Human Subjects, 2009).

Recommendations and Resources for Establishing an RRC

Those who are interested in conducting research within applied practice settings first need to determine whether they should establish or join a collaborative RRC. If the agency is not closely affiliated with or part of a university system or medical school that provides oversight of projects, some source of oversight is needed. If the organization has multiple skilled and productive researchers who are knowledgeable about ethics, it is feasible to establish an RRC within the organization and recruit external members. If the organization does not have researchers with publication records, it may be beneficial to establish a collaborative effort for oversight. A collaborative effort might involve multiple agencies collaborating to have their research reviewed by a joint committee. The local state or regional behavior analysis association (e.g., California Association for Behavior Analysis, Florida Association for Behavior Analysis) might be a place to start to determine if others are interested in a collaborative effort or to determine if a collaborative committee already exists. It may also be reasonable to recruit an experienced researcher to consult on the conceptualization and design of the research project as well as training of the team to execute protocols with reasonable consistency to increase the probability of future dissemination of the research efforts (Love et al., 2013). The first author has consulted with multiple organizations to establish research infrastructure and publish applied findings (Gunby et al., 2010; Love et al., 2013; Marchese et al., 2012). A local university or the state behavior analysis association may be a good place to identify such a collaborator.

If establishing the committee proves to be the right option, the following recommendations are offered for establishing, running, and participating in the committee.

The first recommendations pertain to establishing the committee. First, identify the individual who will serve as the chair of the committee. This person should have sufficient influence in the organization to prevent research efforts that might cause others harm. In addition, this person should have the interpersonal and organization skills to run a multidisciplinary committee effectively. Second, establish the basic policies and procedures for review based on the relevant aforementioned section. It may be useful to establish a mission statement related to your research efforts to serve as a guide for the committee that you will soon recruit. Third, recruit the additional members of the committee with both internal members and external members who can fulfill the various roles described in the relevant aforementioned section. If you have established a relationship with an experienced research collaborator, that person may be able to share his or her experience and knowledge about other review systems and external members. The new committee members will need to be trained on basic research ethics, the research mission of the organization, and the established policies and procedures for the committee. They should also be given a sample of a research review application. This training session might include review of a previously published study by one of the committee members to illustrate the application of the policies and procedures and the type of information that is typically revealed (e.g., pseudonyms, aggregated data with aggregated demographics) in journals. The training may also need to include a review of the logic of single-subject research design for committee members who are less familiar with this type of experimental design.

The next recommendations pertain to the conduct of the activities of the committee. Fourth, the chair should clearly and repeatedly announce the establishment of the committee and its purpose throughout the organization. Those interested in conducting a study may need assistance and feedback from the chair in the preparation of the application before the application is distributed to the full committee. Fifth, the chair should establish a meeting schedule for the committee to review projects. If few projects are submitted, the committee may only meet twice a year, but two meetings should be the minimum number of meetings per year so that the committee conducts review of ongoing projects and has an opportunity to discuss any needed revisions to policies and procedures. It may be useful to establish the review meetings a month or two prior to conference deadlines to allow for expedited review of projects that are evaluations of ongoing clinical activities that might be presented as posters. The applications for new projects should generally be distributed 1 to 2 weeks before the committee meeting to allow all members adequate time to carefully review the materials and prepare questions.

Sixth, after each meeting, the chair or the responsible delegate should conduct all appropriate correspondence (e.g., letter of approval, requests for revisions prior to approval, indication of next date of ongoing review), creating permanent and detailed records of the activities of the committee. Seventh, the chair or responsible delegate should periodically conduct a review of some of the projects to ensure that the appropriate consents have been completed and that storage of all materials is consistent with the approved project and the Health Insurance Portability and Accountability Act (HIPAA).

The last set of recommendations pertains to the actions of the individuals who are serving on the committee as members (rather than the chair). The members of the committee should only agree to serve on the committee if they are certain that they can fulfill their commitment to remain educated about research ethics and the type of research being conducted within the review system. Those who commit but determine that they are unable to regularly prepare for and attend meetings should step down from the committee if the barriers to participation are likely to persist. The committee members should generally focus on the risks and protection of the participants rather than the research methodology unless they have particular expertise in research similar to that being conducted under the oversight of the committee. It is often tempting to revise projects based on personal preferences for specific research methodologies or experimental questions. However, if the project is not flawed at a level that will render it ineffectual for garnering new knowledge, the RRC should remain focused on oversight of ethics and human participant protections rather than specific content of the project.

Several resources exist to assist the RRC chair and other committee members with the development of operational procedures and with the day-to-day operations of the committee. The website of the OHRP (www.hhs.gov/ohrp) contains the full text of the applicable regulations along with several guidance documents that have been issued by the OHRP and pertain to the recommended interpretation of language contained in the regulations. Also available on the OHRP website are helpful decision charts that can be used to help determine whether a particular project meets the criteria for human research and to help determine whether a protocol is exempt or requires expedited or full board review. Public Responsibility in Medicine and Research is an organization that provides many kinds of training opportunities to research administrators and members of review committees, including annual conferences, online courses, and webinars. The organization also provides a variety of resources on its website (www.primr.org). Membership in this organization, which could be beneficial to an RRC chair, provides access to additional online resources as well as access to the online IRB Forum, which provides an opportunity to connect with other committee chairs and administrative personnel, ask questions, and participate in discussion.

Conclusion

The primary purposes of this article are to help practitioners ensure consumer protections in their research and to provide a resource for the behavior–analytic community for integrating research into practice settings. Whether the research generated in applied settings is published or not, the scientist–practitioner is much better equipped to deliver the most effective treatment when experimental control is used to determine effectiveness. Practitioners have participants, new research questions to ask that are directly relevant to their work, and the ability to replicate already-existing research. This article could serve as a springboard for organizations to consider contributing to the growing evidence base for clinical decision making through research. Further, this research might inspire further ethics coursework specific to consumer protection in behavior–analytic graduate training programs, supervised experience that incorporates training on this information, and conference workshops on ethics that specifically focus on research in practice settings.

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Compliance with Ethical Standards

Conflicts of Interest The authors declare no conflicts of interest regarding this article. In addition, human or animal participants were not used for this research, so informed consent was not necessary. The content of this article does not represent an official position of the Behavior Analyst Certification Board.

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