

## Institutional Review Board: Ally Not Adversary

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**ABSTRACT.** Institutional Review Boards (IRBs) were developed in response to a historically demonstrated need for ethical guidance and accountability in research with human subjects. The inhumane and unethical treatment of prisoners of war and underrepresented populations in the pre-IRB era are the antithesis of today's national and international acts, codes, and declarations. Over the last five decades of IRB-reviewed research, several concerns about the IRB process have been raised. In this editorial, we review common concerns regarding the scope and functioning of IRBs. We also review the updated federal Common Rule, effective January 2018, and discuss how some of the reviewed concerns will be addressed in the update. Lastly, we end with recommendations for collaborating with IRBs. These recommendations are not tips on how to circumvent the review process but rather reflective and action-oriented steps to engage the IRBs, which are allies, collaborators, and expert consultants in the research enterprise.

**I**nstitutional Review Boards (IRBs) were established in the United States with the passage of the National Research Act of 1974. The National Research Act led to the creation of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (NCPHSBBR). The Commission was charged with identifying the basic ethical principles to be upheld when researchers conduct biomedical and behavioral research involving human subjects. In addition, the commission was tasked with the development of guidelines to carry out research in accordance with these basic ethical principles. The basic ethical principles are outlined in a document known as the Belmont Report (NCPHSBBR, 1979). The Belmont Report advances three principles—respect for persons, beneficence, and justice—that should guide researchers in the preparation and execution of their research projects. The observable manifestations of these principles are seen in current-day practices for obtaining informed consent, providing a thoughtful and thorough risk-benefit assessment, and providing a rationale for the selection of research participants.

In the 1970s, the National Research Act was ground-breaking and provided a much-needed response to chronic and abusive behavior on the part of government-sponsored researchers. However, some might argue that the United States was slow to enact these policies. The Nuremberg Code (Germany) was released in 1947 after the end of World War II. In 1964, the World Medical Association adopted the Declaration of Helsinki. The United States waited another 10 years before enacting comprehensive federal legislation. In the ensuing five decades, IRBs have been working to protect the rights of human participants in research activities across the nation. Unfortunately, IRBs are often perceived as barriers to research and cumbersome foes in the quest for research productivity.

The purpose of this editorial is to provide an alternative framework for understanding IRBs. The authors of this article are all scholars who also officially participate in the IRB. This places us in a unique position to bridge the gap between researchers and IRBs. In this editorial, we advance the notion that IRBs serve as close colleagues in the research enterprise, providing methodological and

SUMMER 2017

PSI CHI  
JOURNAL OF  
PSYCHOLOGICAL  
RESEARCH

ethical support, and doing so in a timely manner and free of charge. IRBs were founded to preserve and promote human rights, and to protect individuals from harm while volunteering their time and talents to advance scientific knowledge. Yet their functioning has been criticized; we provide guidance on which of these criticisms are well-founded and which may have strong ties to the human rights foundation. We make recommendations on best practices in collaborating with local IRBs so as to establish and/or maintain a strong collaborative relationship with this “ally not adversary.”

### The Evolution of the Protection of Fundamental Human Rights

The existence of IRBs is due directly to human rights violations under the guise of research and perpetrated by professionals using the tools and methods of research. Modern-day IRBs were established by the National Research Act of 1974. However, there is evidence of ethical oversight for federally funded research in the United States as early as 1966 (Ghooi, 2014).

The Tuskegee Syphilis Study (1932–1972) by the United States Public Health Service is credited with being the catalyst that led to the National Research Act, yet there had been ample violations of basic human rights in the name of research prior to Tuskegee. Accounts of atrocities in the United States are documented in various accounts (Skloot, 2010; Washington, 2008). Internationally, during World War II, experiments on altitude, freezing, sterilization, and immunizations, among others, were carried out using brutal and unnecessary methods. Findings were either later replicated with greater validity while using humane methods or the research had already been carried out with animals and provided valid results (Moe, 1984). The abuses during the war led to the Nuremberg Military Tribunals in 1946–47 (Nuremberg Military Tribunals, 1949). Shortly after the tribunals, the Universal Declaration of Human Rights (1948) was published.

The public record of the Nuremberg Military Tribunals (1949) included 10 basic principles for researchers to follow during experimentation, namely, (a) voluntary consent is “absolutely essential,” (b) results of research must be for the greater good of society and the knowledge not attainable through other means, (c) medical experiments should be based on prior research with animals, (d) the research should seek to avoid physical and mental suffering as well as injury, (e) experiments

are not justified that may cause death or disability, (f) risks should not exceed benefits, (g) facilities should be prepared so as to protect human participants, (h) research should be carried out only by qualified persons, (i) participants may stop participation at any time, and (j) researchers use their judgment and are prepared to terminate the experiment when injury, disability, or death is likely to occur.

These basic principles are fundamental to other codes of ethics for researchers. For example, the Declaration of Helsinki, initially adopted in 1964 by the World Medical Association (WMA, 2013) General Assembly, covers all of these points either explicitly or implicitly and adds important details that are clearly tied to present-day IRB protocol structures. For example, the Declaration of Helsinki covers compensation of participants, vulnerable participants, formal protocols and review boards, adverse events, privacy and confidentiality, consequences for participants for choosing to withdraw from research, provisions for what occurs if participants are harmed, ongoing safety and monitoring, and appropriate dissemination of results (WMA, 2013).

The Declaration is unique from the Nuremberg codes in its international scope and clear articulation of expectations for researchers at a global scale. Specifically, the Declaration notes that protocols must take into account laws, regulations, norms, and standards, of the country in which the research is carried out. The Declaration of Helsinki also reaches beyond humans to specify that the environment must be protected from harm in the course of medical research.

The Belmont Report (NCPHSBBR, 1979) adds an important dimension to the consideration of human participants in research by explicitly adding behavioral research to the scope of attention for the federal regulations. The Belmont Report is a statement of policy of the Department of Health and Human Services. It specifies three principles that must be examined in making decisions regarding the ethicality of human subjects research: (a) beneficence, (b) respect for persons, and (c) justice.

An important contribution of the Belmont Report was to provide a clear, operational definition of research:

“Research” designates an activity designed to test a hypothesis, permit conclusions to be drawn, and thereby to develop or

SUMMER 2017

PSI CHI  
JOURNAL OF  
PSYCHOLOGICAL  
RESEARCH

contribute to generalizable knowledge (expressed, for example, in theories, principles, and statements of relationships). Research is usually described in a formal protocol that sets forth an objective and a set of procedures designed to reach that objective. (United States Department of Health and Human Services [USDHHS], 2009, para. 6)

The specific laws that were developed to address the guidance of the Belmont Report are codified in 45 C.F.R. 46 (USDHHS, 2009). The law follows, and extends, the Belmont Report definition of research:

Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities. (USDHHS, 2009, 45 C.F.R. 46.102(d))

These laws further specify the definition of *human subject* as “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” (45 C.F.R. 46.102(f)).

In sum, the current protections for human participants in research evolved from clear violations to fundamental human rights in the United States and abroad. Lawyers, judges, scholars, ethicists, and many others around the world convened to consider how to move forward. The varied yet converging guidelines from around the world suggest there are core human values that must be prioritized and put into practice in research.

### Modern Day IRBs

Modern day IRBs function as independent bodies for research review and oversight. Many IRBs are affiliated with universities, medical centers, and research centers. However, they are not under the direct oversight of those institutions but rather are affiliated. This independence is critical to avoid conflicts of interest with institutional demands. A conflict of interest resulting from the interests of those within an institution can arise, for example,

when a granting agency requires IRB approval prior to releasing funds for research. Institutions are often interested in receiving these funds, and there may be temptation to provide rote approvals in order to secure funds. This is why many institutions do not set their IRB leadership up to report to the individual overseeing sponsored funding for the institution. These conflicts of interest were foreseen in the Declaration of Helsinki (WMA, 2013). The declaration clearly states that research must be reviewed by an ethics committee that “must be transparent in its functioning, must be independent of the researcher, the sponsor, and any other undue influence” (para. 23).

A growing number of independent IRBs provide human research review and oversight to researchers who are not affiliated with any institution (USDHHS, 1998). Thousands of IRBs are registered with USDHHS nationally and internationally. A full list of IRBs can be found online (<http://ohrp.cit.nih.gov/search/search.aspx>).

### Types of Reviews

IRBs are tasked with making the determination for whether or not a protocol review is required and, if so, which level of review a protocol should receive. An IRB may decline to review a protocol when the proposed project does not meet the definition of research articulated above, and/or its activities do not pertain to humans. If a protocol presents human subjects research, then it may be reviewed under one of three main categories: (a) exempt, (b) expedited, and (c) full board. An IRB determines that research is exempt from IRB review when, generally, it involves research on common instructional practices, anonymous surveys or interviews, passive observation of public behavior without collection of identifiers, and retrospective record reviews, or secondary data analyses without recorded identifiers. Readers are encouraged to consult 45 C.F.R. 46.101 for a detailed list of exemptions.

Initial expedited reviews must present no more than minimal risk to human participants in research and must also fall in one of six categories (Office of Human Research Protections [OHRP], 2016). These categories include limited clinical studies involving drugs and medical devices, collection of blood samples, noninvasive collection of blood specimens, noninvasive collection of data routinely collected in clinical practice, research involving materials that were collected for nonresearch purposes (e.g., records, specimens), and

some audio or video recordings. The final category for expedited consideration is where much sociobehavioral research falls, specifically:

Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (OHRP, 2016, para. 7)

Finally, full board reviews are conducted for research considered to carry some increase over minimal risk, or which are not described in the allowable expedite categories. The federal regulations define minimal risk as: “The probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests” (45 C.F.R. 46.102i). The determination of what constitutes an increase over minimal risk is a judgment that is evaluated by the IRB. Once a study has been determined to surpass minimal risk, it is forwarded to the full IRB for review and discussion/determination at the next convened meeting. Some characteristics of research automatically lead to full board review; for example, studies involving vulnerable populations such as prisoners. Although not automatic, studies that involve the collection of sensitive data that could lead to reporting (e.g., child abuse), that use deception, or are carried out in international settings without a clear local authority to oversee the research activities, may receive full board review.

### **Composition of the Board**

IRBs are required by federal regulation to have a minimum of five members (45 C.F.R. 46.107) who are qualified to review research, have varied expertise, and provide demographic diversity. Each IRB must have at least one scientific member, one nonscientific member, and at least one community member. IRBs vary in size, number, and relative composition of members. At our institution, there is only one IRB, which has 11 members, most of whom are scientific scholars. We have one community member and one prisoner advocate. Composition of IRBs varies outside of the United States as do the regulations for such composition.

For example, in India, IRB chairs cannot belong to the same institution with which the IRB is affiliated (Ghooi, 2014)

### **Researcher Training**

In the summer of 2000, the National Institutes of Health (NIH, 2000) released a notification of the requirement for researchers to be formally trained in human subjects research protections. It is now commonplace for institutions to have this requirement for researchers, thus nonfederally funded researchers are often held to the same standard. Since then, certification programs have been developed and are in common use such as the Collaborative IRB Training Initiative known as CITI and NIH’s Protecting Human Research Participants course. However, some institutions use their own home-grown training. The federal regulation does not specify a program for training or even a set frequency for the renewal of certifications.

### **Accreditation**

IRBs function independently. The freedom from institutional oversight in decision-making protects against conflicts of interest. However, the independence also begs the question “who oversees the IRB?” Accreditation is an option for IRBs who want an independent assessment of their functioning and ongoing plan for improvement. The major accrediting body for IRBs in the United States is the Association for the Accreditation of Human Research Protection Programs (AAHRPP). To date, there are 229 IRBs accredited by AAHRPP.

### **Criticisms of IRBs**

A wide variety of criticisms exist regarding the IRB. Some are more basic concerns of efficiency and timeliness. Other concerns focus on data-driven concerns such as inconsistencies in function and judgments. Yet others express frustrations with IRBs’ overreach or intrusive practices.

### **Efficiency and Timelines**

Delays in feedback or approval can occur even on exempt protocols when IRBs become overwhelmed with reviews (Dziak et al., 2005). When protocols require full board review, this can further lengthen the research process, which may pose challenges for graduate students or junior tenure-track faculty who are working on tight timelines and for whom research productivity is tied to formal evaluations that can have significant outcomes on progress or employment. These issues are real and quite

SUMMER 2017

PSI CHI  
JOURNAL OF  
PSYCHOLOGICAL  
RESEARCH

varied. Our own IRB maintains careful records of turnaround times and provides annual updates to various stakeholders. Additionally, accreditation oversight provides a good mechanism for monitoring response times and creating plans for setting goals and reaching adequate response times. Unfortunately, many IRBs are not yet participating in the voluntary accreditation process.

### Disparate Judgments

When researchers develop their studies and an IRB reviews them, both parties are conducting a risk-benefit assessment. One concern researchers have expressed is the disproportionate weight given to immediate risks and benefits compared to long-term benefits (Ceci & Bruck, 2009; Saxton et al., 2015). Others highlight the difference between individual autonomy and protection and communitarian ethics (Malone, Yerger, McGruder, & Froelicher, 2006). The criticism is similar for both accounts: IRBs focus too much of their concern on what is right in front of them and fail to recognize the importance of the greater good (i.e., individual participants and immediate risks or benefits to the individual versus eventual benefit for the community). In any work requiring judgment, there will be variability in outcomes for decisions. Some of this should be expected by researchers and not necessarily catalogued as problematic or dysfunctional. Research could be carried out to examine the kinds of protocols, methods, or other research conditions that lead to the greatest variability in decisional outcomes. We suspect that some of the variability is also due to the differences in composition of IRB members. For example, on a board where there are more community and/or nonscientific members, there may be systematic differences in outcomes when compared to a board that has mostly scientific members. Future research may also gather information about the relationship between board composition and different outcomes.

### Inconsistent Practices

IRBs are critiqued for the inevitable diversity of structures, practices, and outcomes of IRBs across the country. Critics point out that conclusions drawn are often inconsistent both across reviewers and across IRBs. For example, Dziak et al. (2005) submitted the same protocol to 15 different IRBs across the country and, while all protocols were eventually approved, the type of review, form of notification and recruitment, and time to approval varied. Some have complained that different

protocols submitted to the same IRB may be inconsistently reviewed because of conflicts of interest (Keith-Spiegel & Koocher, 2005).

Recommendations for how the IRB can address criticisms have been offered, some of which are already being addressed with new regulations. Specific recommendations include better recruitment and training of staff and faculty members, educating researchers, improving turnaround times, nonbiased reviews, and proscience sensitivity (Fiske, 2009; Keith-Spiegel, Koocher, & Tabachnick, 2006). Keith-Spiegel and Koocher (2005) pointed out that, if researchers feel that they are not receiving fair reviews, they may begin to submit dishonest protocols that will be more easily approved. Researchers may begin to describe their studies inaccurately, omit important information, or forego the IRB process altogether (Keith-Spiegel & Koocher, 2005).

For example, a professor may ask students to participate in a classroom activity under the guise of an evaluation related to the course (e.g., a comparison of students' exam performance when they do or do not use a study guide), but intend from the outset to contribute generalizable knowledge (e.g., evident by a stated intention and/or by the use of randomization to guide/no guide conditions). The professor may justify bypassing the IRB because "the semester will be over before IRB approves the project" or "it's not really research." Ironically, a professor *using* her students to advance her research agenda may be highly problematic because (a) her activities constitute research that requires oversight and (b) her position as professor of the course places students in a heightened position to be coerced into participation. In addition, (c) there is a conflict of interest that could threaten the integrity of the findings. There could be an additional problem (d) related to the professor having access to FERPA-protected information without student consent.

### Scope of Practice

Some critics claim mission creep is occurring when IRBs take issue with and/or responsibility for aspects of research studies that are outside of their bounds (e.g., research methodology, university policies; Fiske, 2009; Malone et al., 2006). These disagreements may be simply differences in judgment. For example, a researcher may consider that the use of an idiosyncratic Spanish translation of a survey is appropriate to answer her research questions. An IRB member with expertise in working

with Latina/o populations may note that the reliability and validity of the instrument has not been established, and that poorly conceived research methods and tools may threaten the enactment of the principles of respect for persons and justice. Other IRB members may feel comfortable trusting the researcher's expertise to carry out the work, claiming that the knowledge gained may benefit the marginalized community. Both perspectives may be correct. The work of the committee is to arrive at a sufficient consensus to make a determination. Future research could examine archival data from IRBs on various determinations to help arrive at a consensus of mission creep and examine its prevalence.

In addition, the scope of practice of the IRBs is often questioned. For example, the federal regulations characterize research as both generalizable and systematic. Some researchers have questioned the need for review of qualitative or social science research claiming that it is not systematic and/or intended to be generalizable. Additional criticism notes that the historical context centers on human rights concerns in biomedical research (Ceci & Bruck, 2009) and thus should not apply to behavioral research. Yet other researchers have outlined challenges in providing an a priori systematic account for board review as is the case in qualitative methods that require the flexibility to adapt to findings as they are occurring. These are reasonable observations that suggest that an examination of procedures may be warranted. In our experience, some qualitative researchers have questioned the need for IRB oversight. When offered the option to discuss whether their activities are intended to be research, there has consistently been an adamant and decisive "yes" response. Thus, where researchers intend to do research and agree basic human rights are worthy of protection, it seems logical to turn attention to the suitability of existing procedures to meet the needs of the researcher population. Revisions based on recommendations from qualitative experts, for example, could provide a wonderful base from which to create a meaningful process and materials for qualitative research.

In essence, some of the main criticisms are warranted. There are existing systems that may help address some of the valid criticisms (e.g., accreditation). There are also opportunities to create better and more relevant systems for researchers who find that the current IRB doesn't "fit" for them. Finally, we believe much data are needed to better

understand which challenges are tied to research (e.g., quality of the proposals submitted) and which are tied to the IRB process (e.g., differential prioritization of human subjects protections). New regulations on the horizon also will address some of these issues in the near future. We turn our attention to them.

### **New Regulations**

The long-awaited updates to the federal Common Rule (effective beginning January 2018) have been designed to alleviate some of the aforementioned concerns. For example, many updates throughout the new Common Rule were "designed to more thoroughly address the broader types of research ... such as behavioral and social science research." (USDHHS, 2017, para. 5). This includes the expansion of exemption categories, which will undoubtedly result in more qualitative and social science work being reviewed as exempt, rather than expedited. Social, educational, and behavioral researchers in particular should see a decrease in the turnaround time on their protocols as a result of the shift in allowable exemptions. We expect that biomedical and clinical investigators will see decreased turnaround times as a result of the lighter load on IRB members who typically work as volunteers, but who are responsible in many cases for conducting the expedited reviews.

Another piece of the new regulations that should lighten the burden of IRB review is the elimination of annual (or more frequent) continuation review for most studies. The updated Common Rule provides for the elimination of annual continuation review for studies reviewed via the expedited procedure that pose minimal risk. The elimination of this responsibility should free up the time of IRB staff to allow initial reviews of protocols to move along at a more expedient rate.

Inconsistent practices between institutions and IRBs is another issue that the updated Common Rule seeks to address. Although the rest of the Common Rule will be effective in January 2018, beginning in 2019, all studies funded by the agencies adopting the Common Rule will require single-IRB review. The single-IRB review means that one IRB will be the responsible entity for oversight of research at multiple sites. The NIH plan to adopt this requirement in September of 2017, and it is expected that many IRBs will come into compliance along with NIH's adoption of the requirement. The requirement that a study be reviewed by a single IRB, with some exceptions, should ensure more

SUMMER 2017

PSI CHI  
JOURNAL OF  
PSYCHOLOGICAL  
RESEARCH

consistent timelines and reviews between members of cooperative research projects. Although doing this effectively may be a burden on IRBs, we expect that the benefits of single-IRB review will accrue to the research teams and, hopefully, to their participants.

### **Collaborating With IRBs**

We offer our recommendations based on our knowledge of the research integrity literature, our own experiences collaborating with colleagues broadly and in research activities specifically, and as members of the IRB in different roles (Chair, Graduate Assistant, Director, Prisoner Advocate). These are not intended to imply to any potential problems with a local IRB reside solely outside of the IRB, nor that solutions are only found outside of the IRB. Rather, we share some pointers for common points of miscommunication that we have experienced.

### **Do Some Homework**

We recommend approaching the human protections activities with the same rigor with which researchers engage the preparation of a manuscript: consult original sources and seek data. There are many points of misinformation that often are the result of hearsay, conflicting experiences at other institutions, or even differential practices across departments/units within the same institution. Researchers would benefit from reviewing original documents that provide a historical perspective and current expectations: 45 C.F.R. 46, the Belmont Report, and your IRB's Standard Operating Procedures. Along with these, we recommend having handy the code of ethics of your professional association, the regulations of the researcher's institution, and regulations of any funding agencies. On the data end, researchers could ask for annual reports documenting key outcomes such as speed of determinations to verify whether their experience signals a chronic problem or a unique situation.

### **Check Your Mindset**

When collaborating with colleagues, we recommend that researchers prepare their mindset. For example, researchers may want to assume expertise and expect collegiality from the IRB staff and members. Many research administrators are highly trained in the regulatory and ethical landscape surrounding human subjects research. When researchers receive requested changes or clarifications that

are confusing or seem unnecessary, we recommend picking up the phone and asking for clarification from a staff person at the IRB. Also, remember that, while the electronic protocol systems many institutions use can seem terse or even punishing, the people behind that system are often trying to make a point as quickly as possible for your ease. Language or guidance that may appear "short" may have a well-developed rationale that, if carefully explicated, would create more burden or clutter in the protocol review system.

We also recommend assuming good will on the part of the IRB. In our experience, a small but vocal subset of researchers respond to queries for further information or clarification with defensiveness, as if being summarily charged with unethical conduct. We are often surprised by these responses. IRB staff and board members are tasked with protecting human participants in research. This is by definition, a prevention activity. Obtaining clarification or requesting further materials serve to *verify* that protections are in place. If researchers assume that IRBs are collaborators in the research enterprise, then these requests can be seen as prompts rather than as admonitions. We cannot assume that all IRB staff and board members have good intentions or helpful motivations. We do know our own motivations and intentions, and we have experienced the difference when working with colleagues who assume good will and those who do not.

### **Use Existing Resources**

Using the structure of the IRB protocol template when developing a research project can serve as an excellent outline for the method section of a future manuscript. Having an empty IRB protocol handy as researchers build their proposal can ensure that all human protections issues are addressed at the outset of a study. In our experience, it is not unusual for a student to engage in research that has to be approved by a committee. When the IRB then detects a potential threat to the protection of human participants such as insufficient justification for sample size, we find that students and their primary advisors respond with frustration. They might have secured money or arrived at a committee consensus for sample size, but the decision was not based on a scientific process (e.g., calculation of power using statistical software). Checking IRB protocols ahead of time can save time and hassle, and also ensure a more scientifically rigorous process from the outset. In our experience, an additional benefit may be that this thoroughness

provides an excellent spring board for publication.

Another important resource that is often overlooked is the members of the IRB. Many departments with active human subjects research portfolios have faculty sitting on the IRB. If researchers do not feel comfortable approaching an IRB staff person with questions or concerns about the human research review process, students or faculty can check in directly with an IRB member! Additionally, researchers who have less experience with protocol submission can request recommendations for securing a peer-mentor who is not on the board.

### Consider Timelines

Preferably well in advance of submitting a protocol, researchers become familiar and prepare for a future protocol submission. New researchers forget that they have to complete formal training in human protections, and seasoned researchers forget to check deadlines for their recertifications. This training can take a substantial amount of time. In addition, the frequency of IRB meetings and the volume and type of submissions varies tremendously across institutions. Check with your IRB office to see expected turn-around times and add a little buffer in case of snow days, natural disasters, or other unanticipated events. If your institutional IRB is accredited, you can likely check existing reports for timeliness. Also remember that asking an IRB to speed up a process is often tantamount to “skipping” your colleagues in line. There are circumstances where it is appropriate (e.g., just in time reviews for NSF or NIH funding), but nothing beats advance planning.

### Remember History

When researchers are frustrated about turn-around times or lengthy forms that may delay research start times, we recommend taking a moment to consider the historical context that gave rise to IRBs. We invite the reader to consider how you might feel about the current oversight if you, or a loved one, had been a participant in any of the many egregious experiments that led to regulatory bodies. Lengthy forms may be dismissed as tedious. Or they may be considered a great support to ensure a thorough review of the research activities. We recommend researchers shift perspectives to productive stances that facilitate communication and understanding.

### Conclusion

Absent clear data to the contrary, there is no need

to characterize IRBs as foes in the research enterprise. Researchers work daily to advance science, increase discipline-specific understanding, and use the data for the betterment of society. IRBs are tasked with supporting those activities while overseeing the protection of human participants in research. History has given compelling examples for the need for oversight in research. Researchers and IRB staff/members (who sometimes share both identities), are working different pieces of the same common goal to “do good.” We do not believe that researchers or IRB staff/members operate with a desire to harm or vex anyone. Rather than see each other in opposition, we encourage asking the question: how do we communicate effectively to reach our common goal to move science forward without doing harm? We hope that we have provided some useful ideas.

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SUMMER 2017

PSI CHI  
JOURNAL OF  
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RESEARCH



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