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A Rare Opportunity: Examining the Experience of a New Institutional Review Board (IRB)

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Introduction

The process of creating an entirely new IRB or Research Ethics Committee (REC) presents many challenges. Among them, ensuring the appropriate organizational infrastructure and framework for research oversight, identifying, appointing, and training qualified board members, securing resources for staffing and operations, conducting research reviews, and interacting with a variety of stakeholders including the members of the research community. Moreover, as clinical research has become more global and complex, with clinical trials increasingly being conducted in countries outside the United States (FDA, 2017) new RECs have been established to address this international trend. It has been noted that issues of institutional support, governance, and infrastructure may be especially challenging for those responsible for establishing and sustaining RECs in low- and middle-income countries (Ateudjieu et al., 2010; Caniza et al., 2006; Denholm et al., 2017; Kass et al., 2007; Macpherson, 2001).

Notwithstanding these numerous challenges, little has been documented about the dynamics and outcomes of constituting an entirely new IRB even though the number of new IRBs registered with the U.S. Department of Health and Human Services Office of Human Research Protections (OHRP) has steadily increased from 326 in 2014 to 438 in 2017. (I. Stith Coleman, personal communication, August 8, 2018). Thus, many questions about creating a new IRB/REC and the challenges that they face remain.

The establishment of a newly-formed federal, single IRB, the National Cancer Institute (NCI) Cancer Prevention and Control (CPC) Central Institutional Review Board (CIRB),

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provided a rare opportunity to describe the experience and early outcomes of a newly constituted U.S. single IRB (sIRB). The purpose of publishing this article is twofold. First, to describe the overall dynamics, experience, challenges and early outcomes of this board in its first three years of operation, 2015 through 2017. To that end, we conduct and report a census of this board's data, collecting data elements for all studies reviewed and approved during this early phase of operation. This census data will serve as a baseline "point in time" observation against which data from this board can be compared in the future. In addition to this overall observation, a second article about this board's early experience by Rooney et al., takes a closer look at the nature and quality of the stipulations issued by this board (Rooney, Covington, Dedier & Samuel, 2019). The second purpose of this article is to add to the body of knowledge regarding the dynamics, experiences, challenges and early outcomes of constituting a new IRB.

Methods

NCI CIRB History and Structure

The NCI CIRB was established in 2001 (Christian et al., 2002), to review cancer treatment clinical trials performed through a cooperative group network of academic and community institutions. Figure 1 shows that since 2001, the NCI CIRB has expanded from one board to four boards, with the CPC CIRB being the newest (Massett et al., 2018).

Each of the four NCI CIRB boards includes the following member types: oncologists, nurses, patient advocates, statisticians, pharmacists, and ethicists. All potential members are screened for conflicts of interest and are not employed by the NCI. All four boards follow the same standard operating procedures (National Cancer Institute, CIRB, 2019). The NCI CIRB is one component of NCI's extramural human research protections program which achieved accreditation from the Association for the Accreditation of Human Research Protection Programs (AAHRPP) in 2012.

The NCI CIRB is managed by a contracted operations office with NCI oversight authority. CIRB Operations Office staff support the day-to-day functions of the NCI CIRB boards.

NCI CIRB Process

The NCI CIRB process, shown in Figure 2, begins with clinical trial protocols being designed and developed by extramural investigators, who are represented by one study chair. The study chair has overall responsibility for multisite protocols. Protocols undergo multiple levels of NCI review prior to the CIRB review. These reviews may include peer review for funding approval, concept review for scientific prioritization, and an iterative scientific review of the protocol and consent conducted by program staff and other stakeholders. Following the NCI's "approval on hold" (AOH) decision, study chairs submit their NCI CIRB application package (application form, protocol, consent) to the NCI CIRB for review. After the CIRB staff conducts an administrative review of the application package for completeness, the protocol is scheduled for initial review by the convened board at the next available monthly meeting unless the protocol qualifies for expedited review, at which point

the study is assigned to an expedited reviewer who conducts the review outside of the convened IRB.

For studies undergoing convened board review, the CIRB staff, in consultation with the appropriate NCI CIRB Chair, assigns protocol reviewers based on the reviewers' content knowledge, potential conflicts of interest, and availability. For all studies, irrespective of study design or stage (e.g., Phase 1, 2, 3), the reviewers are assigned as follows:

- Initial reviews: One scientific and one non-scientific reviewer are assigned as primary reviewers. A statistician is assigned to all initial reviews, as is the pharmacist for all studies containing an agent/drug. Statisticians and pharmacists do not generally serve as primary reviewers for other study submissions but may be asked to submit a review for any study under review in which their expertise is warranted.
- Continuing reviews and amendments: One CIRB member, with appropriate expertise and qualifications, serves as the primary reviewer for the continuing review.

All NCI CIRB board meetings are conducted virtually using a conference call and web-based board management software. Following the board member's discussion of an initial review, study chair response, or amendment, the study chair and study team joins the meeting via conference call to answer questions posed by the NCI CIRB Chair. After the study team departs the call, the board members complete their discussion, note applicable stipulations and based on the noted stipulations, if any, vote on the protocol with possible votes of: approved; approved pending modifications (APM); tabled; or disapproved. Board decisions are made by majority vote. The CIRB Operations Office sends the study chair a determination letter within 7 days after the meeting. When a protocol receives an APM or tabled determination, the study chair is asked to submit a revised protocol within 14 days of the determination letter. In general, if a protocol receives an APM determination, it is subsequently reviewed outside of a convened board meeting using expedited review procedures. Conversely, if a protocol receives a tabled determination, it is scheduled for a subsequent full-board review. Once an NCI CIRB approves the protocol, it is routed back to NCI program staff. After any final required activities are completed, the study is made available to the participating enrollment sites.

NCI CPC CIRB: Launching a New Board

The CPC CIRB is supported by four staff positions from the CIRB Operations Office, two who are solely dedicated to the CPC CIRB, a Senior Coordinator, who covers the CPC CIRB and another CIRB, and the Director of Central Operations, who oversees the management of all four boards.

The NCI CIRB expanded from 3 to 4 boards with the launch of the CPC CIRB in 2015. The CPC CIRB began with 14 members. The CPC CIRB chair had previously served as the chair of one of the NCI adult CIRBs and was familiar with the NCI's extramural research structure and the NCI CIRB. Similarly, the pharmacist and one patient advocate had previously served on one of NCI's CIRBs. Some members had local IRB experience, while

others had knowledge of either the cancer control or the cancer prevention program, or both programs. When selecting the CPC CIRB members, NCI's goal was to ensure that the members had the necessary level of experience and knowledge of such studies to ensure their ability to understand the scientific details and context of the research being reviewed. By 2017, the board expanded from 14 to 20 members. The purpose of the expansion was to add members with specialized oncology knowledge and experience (immunology, radiation oncology) and members with specific expertise in cancer care delivery research. The number of patient advocates was increased from 2 to 4 satisfy the NCI target of 25% patient advocates. Finally, a second statistician was added to share the reviewer workload.

CPC CIRB Research Portfolio.—Beginning in February 2015, the CPC CIRB became responsible for the review, approval and oversight of research funded by NCI's Division of Cancer Prevention (DCP). Whereas the scope of research for the NCI's other two adult CIRBs is generally limited to cancer treatment protocols, the CPC CIRBs portfolio of research is quite broad and includes Phase 2 and Phase 3 cancer supportive care, symptom management, screening, surveillance, and cancer care delivery protocols (referred to as "cancer control") funded by the NCI Community Oncology Research Program (NCORP) (Wade, Petrelli, & McCaskill-Stevens, 2015). DCP research subject to CPC CIRB review also includes early phase cancer prevention agent development clinical trials (referred to as "cancer prevention") funded by the Phase 0/I/II Cancer Prevention Clinical Trials Program. The NCORP and Consortia programs have different infrastructures, funding mechanisms, investigators, and scientific review processes and their clinical trials vary greatly in scope, trial design, population and sample size. The cancer control studies are generated by large, established national research networks with considerable depth of experience and resources, and cancer prevention studies are generated by academic centers belonging to a more recently constructed research consortium.

Data Collected

We conducted a census of the CPC CIRB's early activity. Data were collected for all protocols that underwent initial review by the CPC CIRB between January 1, 2015 and December 31, 2017. The data chronicled the life cycle of the protocol beginning with the CPC CIRB's receipt of the application for review, through the iterative board reviews and protocol revisions by the study chair and ending with the CIRB's approval of the protocol. The census data included information about the protocol itself (protocol number, short title); the study type (cancer control vs. cancer prevention); the board review (full board vs. expedited review; review result), the milestone dates (completed application, dates of all CIRB reviews, date determination letter sent, date revised protocol received, date of protocol approval); and number and location of stipulations (protocol, consent form, application) contained in each determination letter (Table 1). Data were analyzed for frequency, ranges and averages by year and by study type. The number of days between IRB review and the delivery of the outcome letter to the study chair and the number of days required by the study chair to submit a revised protocol were documented. Finally, stipulations were recorded by protocol, year, study type, and section (protocol, consent, or application).

Results

The first three years of CPC CIRB data were recorded in the census. Overall, from its first protocol review in 2015 until the end of 2017, the convened CPC CIRB reviewed and approved 50 protocols, which took an average of 93.24 days (range 31–251) and 2.76 reviews (range 2–4) for protocol approval. During this period, 60% of all protocols were APM and 40% were tabled on initial review. No protocols were either approved or disapproved by the CIRB at initial review. The board issued an average of 31.82 stipulations (range 9–85) per protocol.

Outcomes by Year

The board reviewed 12 protocols in Year 1, 18 protocols in Year 2, and 20 protocols in Year 3. The time-to-approval, counted as the average number of calendar days from receipt of a complete application to the board's decision to approve, was 99.0 days in Year 1, 114.94 days in Year 2, and 70.25 days in Year 3. Stipulations per protocol went from an average of 28.83 stipulations per protocol in Year 1 to 37.50 stipulations per protocol in Year 2 and back down to 28.50 in Year 3. Finally, the average number of reviews required for each protocol to receive approval (e.g., initial review and each subsequent review) was 3.08 reviews in Year 1, 2.83 reviews in Year 2, and 2.50 reviews in Year 3. (Figure 3).

Outcomes by Study Type

In addition to looking at the overall outcomes by year for the entire portfolio, the outcomes were also separated into study type, i.e., cancer control or cancer prevention. The purpose of this separation was to make the census information more informative to NCI program staff who oversee these two different programs. The outcomes are shown in Table 2.

Of the 50 initial protocol reviews, 52% were cancer control and 48% were cancer prevention protocols. At the end of three years, the cancer control portfolio had 18 protocols that received APM determinations on initial review and the cancer prevention portfolio had 12. Cancer control protocols required an average of 2.69 reviews and 90.88 days to approval and cancer prevention protocols required 2.83 reviews and 95.79 days to approval. Cancer control protocols had 26.35 stipulations per protocol and the cancer prevention protocols had 37.75 stipulations per protocol.

Stipulations

During its first three years of operations, the CPC CIRB issued 1,591 stipulations, an average of 31.82 per protocol. The actual number by protocol varied widely from nine stipulations to 85 stipulations. Most of the stipulations occurred in either the protocol or the informed consent document (Figure 4). While more stipulations were issued in cancer prevention than cancer control protocols in Years 1 and 2, the average number of stipulations for both were nearly equivalent by the third year (Figure 5).

Timeliness/Responsiveness

Once the board reviews the protocol, the required changes (stipulations) are drafted and compiled into a determination letter that is prepared by the CIRB Operations Office and sent

to the study chair. The CIRB standard operating procedure (National Cancer Institute CIRB, 2019) timeline for issuing a determination letter is seven calendar days following the board meeting. The study chair response is requested within 14 calendar days from issuance of the determination letter. Both activities contribute to the overall time required for approval.

This analysis revealed that the CIRB achieved the goal of sending the determination letters within seven calendar days for 75% of initial reviews in 2015, 28% in 2016, and 40% in 2017. Study chairs met the 14-day resubmission goal 83% of the time in 2015; 33% of the time in 2016; and 70% of the time in 2017. Since protocols that are tabled on initial review typically contain more stipulations and take longer to approve, the examination included whether it takes study chairs more time to respond to these tabled studies as compared to studies with a determination of APM. Indeed, across the 36-month period, the average number of days required by the study chair to resubmit tabled protocols was nearly double the time required to resubmit APM studies (tabled = 29.85 days; APM = 14.80 days). Given these delays, tabled studies frequently were not re-submitted in time to be scheduled for the next monthly convened meeting, hence further delaying time to approval. In 2015, 75% (3 of 4) tabled studies were reviewed the following month at the convened meeting. This rate dropped to 11.11% (1 of 9) in 2016 and increased to 28.57% (2 of 7) in 2017. Similar patterns of delay were noted across cancer control and cancer prevention. The study chair responses to studies that were APM fared better with 84.62% of responses meeting the 14-day submission in 2017.

Discussion

Creating an entirely new IRB is not a common occurrence, however, the number of new boards created every year in the United States and other countries is increasing. (I. Stith Coleman, personal communication, August 8, 2018). Thus, individuals responsible for launching and constituting entirely new IRBs could benefit from understanding what to expect. Although the experience of constituting an entirely new board is not well documented, one can imagine that a new board is influenced by a variety of factors. For instance, the history, culture, and practices of the organization in which an IRB is located may play a role in how an IRB is constituted and operated. In addition to the organizational issues, each new board is constituted with individual IRB members who bring a set of skills and experiences, a unique world view, and their own communication and decision-making styles. Taken together these organizational issues and individual IRB member factors can potentially influence the board's ability to coalesce and work together efficiently.

New Board Challenges

One can imagine that many newly constituted IRBs will face challenges in their early experience. The CPC CIRB is one such IRB. The CPC CIRB was faced with four unique challenges in their formative years. The first challenge was the use of virtual board meetings. While there are many benefits to the virtual meeting platform, some of the new CIRB members commented that it was challenging to gauge their performance without the visual feedback and other in-person cues present in a face-to-face meeting. The board members' comfort and confidence in performing their roles via the virtual platform improved over time

and was furthered by the opportunity to interact with fellow board members at an in-person Education Day.

The second challenge to the CPC CIRB was understanding the NCI's scientific review process. Unbeknownst to some of the CIRB members, before protocols come to the CIRB, the protocols have already passed multiple rounds of funding and scientific review. To ensure understanding and minimize this challenge, this topic is now addressed during new member orientation, it is reviewed at the in-person Education Day, and the topic is revisited periodically. In addition, this challenge was further mitigated by providing CIRB members with access to the records from the scientific review.

A third challenge to the CPC CIRB was the diversity of the research portfolio. Unlike the other three NCI CIRB boards whose portfolios represent similar patient populations (pediatrics) or study designs (early phase cancer treatment, large Phase 3 cancer treatment studies), the CPC CIRB reviews protocols from a diverse scientific portfolio: cancer symptom management, cancer screening, chemoprevention agent development, and cancer care delivery research. Such portfolio diversity, while commonly encountered in academic IRB settings where a single IRB may review a broad range of study types, may be more challenging to a new board, slowing the accumulation of a decision history to call upon, thus inhibiting their ability to build confidence (Klitzman, 2015) (Pritchard, 2011).

The fourth challenge to the CPC CIRB was ensuring stakeholder buy-in and engagement. There are two stakeholder groups who interact with the CPC CIRB on a regular basis: the program staff in NCI's Division of Cancer Prevention, the sponsor of the studies, and the investigators conducting the extramural research. Prior to the creation of the CPC CIRB, these multi-site protocols were reviewed by local IRBs at potentially hundreds of institutions. While DCP's program staff, research networks, and most study chairs welcomed the addition of the CPC CIRB, a period of education and adjustment was necessary for all stakeholder groups.

To facilitate this transition process for the DCP program staff, an internal CIRB Operations Team was formed. The Team, composed of DCP program staff and leadership, representatives from the CIRB Operations Office, and a regulatory consultant, met on a biweekly basis beginning before the board was launched. This meeting served as an excellent venue for education, information sharing, and addressing and resolving procedural or workflow issues. DCP program staff, who are involved in the scientific review of protocols before they come to the CIRB for review, had the opportunity to learn the IRB decision criteria and begin to 'think like an IRB member.' These efforts highlighted the importance of ensuring that study rationale, objectives, and methods were clearly and completely stated; that the NCI informed consent template was followed; and that all documents were reviewed for inconsistencies and errors prior to submission to the CIRB. The hope is that the program staff apply this knowledge in their scientific review process can work with study chairs to improve the quality of protocols before they are sent to the CIRB.

The second stakeholder group, the study chairs, also required orientation to the new process. The CIRB conducted numerous teleconferences and live presentations to the study chairs

and other investigators involved in both the cancer control and the cancer prevention research programs. Data regarding the CIRB timeliness of reviews, and the number and types of stipulations were shared with these audiences. Procedures for contacting the CIRB, for discussing reviews, and for ensuring high quality protocols were presented.

Early Board Competence

While working through these challenges, new boards must achieve certain basic competencies. These competencies include standard administrative functions, such as completing reviews in a timely manner, delivering determination letters that clearly communicate the board's intentions and their need for information, and following regulatory criteria for approval. Moreover, in the process of protecting research participants, the new IRB must also attend to the relationships and interactions with another group of stakeholders, the investigators. Complaints of lengthy IRB review processes have been raised by investigators (Stryjewski, Kalish, Silverman, & Lehmann, 2015) in the past and frustrations related to delays potentially create or increase tensions between IRBs and investigators. Indeed, investigators ranked IRB procedural justice issues, one indicator of which is timely review, as more important to them than IRB competence and other issues (Keith-Spiegel & Tabachnick, 2006).

While it goes without saying that these types of administrative measures cannot speak to the quality of the board's deliberations, their ability to systematically weigh risks and benefits, nor tell us if the board effectively improves the protection of human subjects, these administrative competency data elements should not be overlooked given that these baseline data elements provide a starting point to "check in" on a new board's performance.

Like ours, other new boards and their members likely wish to gauge their performance and are curious about how their 'time to approval' compares with other boards. Collecting the CPC CIRB census data was one of the steps undertaken to provide feedback to this new board. While the census data alone did illuminate some patterns and trends for this board, the value of the data to provide feedback to the board improves only if it can be compared against a standard or a benchmark. Unfortunately, benchmarking, while a common practice in the healthcare industry, is not easily performed among IRBs because the high-quality, well validated, and well-populated datasets necessary for benchmarking are not available in the IRB community (Vulcano, 2012).

Census Data Comparison

Given the lack of published standards or the availability of benchmarking data sets, we looked to the published literature, organizational publications, and the other 3 NCI CIRBs to put the census data into a broader context, as it relates to CPC CIRB approval time.

Published Literature.—Several authors have documented the steps involved in the lengthy process of opening a cancer clinical trial, including assessing the length of the IRB approval process. In one publication, Dilts (Dilts & Sandler, 2006) documented the process steps in a single academic center and found IRB approval times were a median of 47 days (range 1–426 days). In editorial responses to this publication, two other single institutions

reported their approval times. One academic center reported an approval time of 107 median days (range 43–150 days) for 31 phase 1 industry trials (Camacho et al., 2007). A second institution reported significant differences in IRB approval times depending on whether the study was industry sponsored (median 48 days; range 7–192 days) versus an NCI cooperative group trial (median 19 days; range 6–272 days) (Govindarajan, Young, Harless, & Hutchins, 2007). Subsequently, Dilts examined approval timelines for one of the NCI's cooperative groups and found a median time to IRB approval of 116 days (range 47–739 days) across 14 cancer clinical trials (Dilts et al., 2008). In another publication, the Ontario Cancer Research Ethics Board reported a median time of 91 days from submission to approval for 96 new protocols in 2017 (Ontario Cancer Research Ethics Board, 2018). Outside of cancer, others have evaluated IRB approval times. Hall reviewed new protocols submitted to one large urban Veterans Affairs medical center between June 1, 2009 and May 31, 2011 and found that the median days to approval for convened reviews was 131 days (range 64–296) (Hall, Hanusa, Stone, Ling, & Arnold, 2015). The University of Ibadan in Nigeria reported the average period between protocol submission and approval was 3 months in the first 8 months of 2006 (Falusi, Olopade, & Olopade, 2007). Similarly, the census data of the CPC CIRB showed a broad range of days to approval (31–251 days) and the average days to approval is not substantially different than the experience documented by some, but not all of these published studies.

Organizational Publications.—Two reports from other organizations, one a commercial entity, and the other, an accrediting organization, include approval metrics. The first, the 2010 National Benchmark Report from the National Research Network (NRN) assessed a random sample of 50 hospital, university, and government clients and reported an average of 50.6 days to approval by convened boards (NRN, 2010). The American Association for the Accreditation of Human Research Protection Programs (AAHRPP) publishes clients self-reported data from their annual reports. In 2017, the median number of days to approval for convened reviews was 30 days at hospital IRBs and 45 days at academic IRBs (AAHRPP, 2018a, 2018b).

NCI CIRB Published Literature.—Masset documented the median days for NCI CIRB approval by board in 2016 as follows: adult late-phase board, 39 days; adult early-phase board, 54 days; pediatric board, 48 days; and cancer prevention and control board, 87 days (Masset et al., 2018). Although this report counted all studies reviewed in 2016, as compared to the census data that counted all studies whose initial review was conducted in 2016, the CPC board required considerably more time than the established boards.

When comparing the CPC CIRB days to approval against the data, the CPC CIRB mean days to approval, i.e., 99 in 2015, 115 in 2016, and 70 in 2017, was similar to some, but longer than many of the time frames published for cancer clinical trials and longer than the average time frames for both hospital and academic centers in the AAHRP 2017 report. The board also took longer to approve studies than its three NCI CIRB counterparts.

A variety of issues may account for the lengthy approval times for this board—the broad diversity of the portfolio, convened meetings that are held once a month, the time required for study chairs to submit a revised protocol, and the newness of the board. However, one

trend revealed by the census data that lengthened review times was the procedures the board used for APM decisions.

CPC CIRB Trends

APM Decision Process.—During the first two years of CPC CIRB operations, the board routinely rendered APM decisions while requesting that APM studies go back to the full board for reconsideration even when expedited review procedures were appropriate. Generally, this occurred because board members wanted to review and discuss study chair responses, thereby helping to achieve board confidence. Early on, this practice allowed CIRB members to see whether a study chair understood and responded appropriately to requested changes in the stipulations, in so doing allowing the CIRB an opportunity to determine whether stipulations were worded effectively. Moreover, this practice allowed CIRB members to establish trust in the Chair's review and final approval of studies outside of convened meetings in that sharing APM designated stipulations with the convened board provided the Chair with insight into what types of stipulation responses would be deemed responsive vs. nonresponsive to noted stipulations. The Chair would use this knowledge when reviewing future studies designated with APM outside of the convened board.

While such a decision process can be considered likely and plausible with the establishment of a new board, this specific decision practice went on longer than expected. Moreover, the practice contributed to longer time-to-approval; instead of a CIRB expedited reviewer being able to issue a final IRB approval decision as soon as the reviewer receives the requested information, i.e., outside of a convened board meeting, final IRB approval could not be issued until the CIRB convened in a regular session to discuss the requested information and then approve the APM study.

Several interventions were undertaken to address this trend and to build the board's knowledge and confidence. They included a 2015 CIRB member in-service education session on IRB approval decision options; better access to appropriate reference material; and a revised IRB reviewer tool to ensure that the CIRB renders the appropriate IRB decision (APM vs. table) and processes studies accordingly.

CIRB Stipulations—Average Number of Stipulations per Protocol.—A second pattern identified in the census data was that the average number of stipulations per protocol increased from 28.83 per protocol in Year 1 to 37.50 stipulations per protocol in Year 2. One possible explanation for the increase in stipulations issued in Year 2 may be the quality of the protocols submitted. Alternatively, the increased number of stipulations could also be the result of one or more of the following phenomena, many of which are unrelated to the underlying quality of the proposed research: 1) increase in CIRB member knowledge regarding the regulations and/or underlying area of study; 2) increase in CIRB member confidence regarding the CIRB roles and responsibilities; 3) accumulation of CIRB decision history to call upon; and 4) study chairs' lack of understanding regarding a new IRB's processes and expectations.

While an increase in stipulations issued is not inherently negative, it did serve as a signal to take a close look at the stipulations issued by the board. Thus, the NCI developed the

Stipulation Analysis Review Tool (NCI StART) and used the tool to code the stipulations in the CIRB determination letters to assess whether the board was exhibiting signs of excessive scope creep or wordsmithing, two behaviors often attributed to IRBs by investigators. The process of developing the tool and the outcomes of this review are described in the companion article by Rooney, et al (Rooney, Covington, Dedier & Samuel, 2019).

CIRB Stipulations—Stipulations by Year.—During its first year of operation (2015), the CPC CIRB issued its lowest number of stipulations per study. One possible reason was that members experienced some uncertainty in their role and responsibility, such as members not knowing whether CPC CIRB had the authority to address research design or scientific issues. During its second year of operation (2016), the CPC CIRB reviewed more studies, issued more stipulations per study, took longer to compile and send determination letters, and required more time to approve submitted studies when compared to 2015. This increase could be the result of the CPC CIRB becoming more certain of its roles and responsibilities and communicating those to study chairs. During the third year of operation (2017), IRB review times became shorter, the number of stipulations issued per study decreased, and the number of days to send determination letters decreased. The lower number of stipulations and quicker turnaround times evident in 2017 may demonstrate learning over time by both CIRB members and study chairs.

Operational Processes.—A fourth pattern that emerged from the census data was that initially the CIRB Operations Office was routing all stipulations back to the board reviewers for their approval before finalizing and sending the determination letter. This required considerable time and prevented the Operations Office from consistently meeting their standard turnaround time of 7 days for sending the determination letter. The turnaround time improved in Year 3 following implementation of a new reviewer worksheet that more clearly guided the board members' review and writing of stipulations. A formal stipulation read-back during the convened meeting, a process that was implemented to ensure that all stipulations agreed to and voted on by the convened IRB were appropriately captured by the IRB staff before moving on to the next IRB order of business, eliminated the need to send the drafted stipulations back to the reviewer prior to completing the determination letter.

Best Practices

Board administrators, particularly those of boards who meet virtually via teleconference or webinar should be cognizant of the importance of feedback. The nuances of each board's culture are harder to detect in a virtual meeting environment. Employing videoconferencing technology may be of interest to new boards who meet virtually. Scheduling in-person meetings at least annually provides members the opportunity to interact and strengthen their relationships as well as engage in educational topics of interest.

Board members appreciate feedback on their performance and the performance of their board. As such, a variety of tools have been developed that a newly formed IRB might consider using to evaluate the progress of their board (Feldman & Rebholz, 2009; Keith-Spiegel & Tabachnick, 2006; Sleem et al., 2010; Adams et al., 2014). Others have documented their experiences using such tools (Hall, Hanusa, Ling, et al., 2015; Silverman

et al., 2015). While not a tool per se, Ivor Pritchard describes the dynamics of group decision making (Pritchard, 2011) that includes a discussion of how psychological characteristics may affect some outcomes of convened IRB meetings.

The census data and observations contained in this article are from one, federally-funded, single institutional review board that reviews cancer prevention and control research. Despite this limitation, this unique scenario may serve to heighten awareness among institutions that are starting entirely new boards. Each new board likely will have its own unique attributes that may promote or hinder the board's ability to coalesce and to reach efficient operations. Attending to these characteristics through observation and longitudinal data collection can allow early identification of issues or behaviors that require further examination, education, or process change.

Research Agenda

Evidence-based approaches for supporting the early experiences of IRBs would be beneficial. Both quantitative and qualitative data are needed to broadly describe the dynamics and trajectory of a new board. Board administrators, board chairs, and board members would all benefit i.e., save time and effort using proven start-up methods or a set of guideposts, as they institute new boards.

Educational Implications

The educational needs of new board members are numerous and evolve over time. Beyond learning the basics of their authority in terms of regulatory decision making, additional subject areas and educational needs may be identified during board deliberations. Rarely is sufficient time available during a convened IRB meeting to give these topics the attention they deserve. Nevertheless, specific learning goals could be assigned to a designated board meeting or special workshop with a plan to incorporate them into a learning curriculum for the board members.

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Figure 1.
National Cancer Institute's Central Institutional Review Board history and structure

Figure 2.
NCI CIRB protocol review and approval process

Figure 3.
CPC CIRB outcomes by year

Figure 4.
Average number of stipulations by section and year

Figure 5.

Average number of stipulations per protocol by study type and year

Table 1.

Data elements collected

<u>Protocol Information</u>	
•	Protocol Number
•	Short Title
•	Study type: cancer control, cancer prevention
<u>Board Review</u>	
•	Review type: full board, expedited
•	Review results: approved, approved pending modifications, tabled, disapproved
<u>Milestone dates</u>	
•	Receipt of completed CIRB application
•	Dates of all CIRB reviews
•	Date CIRB determination letter sent
•	Date study chair response received
•	Date of protocol approval
<u>Stipulations ('Stips')</u>	
•	Number of stips in protocol
•	Number of stips in consent
•	Number of stips in application

Table 2.

NCI Cancer Prevention and Control (CPC) CIRB: results of initial reviews, 2015–2017

	# Protocols Underwent Initial Full Board Review	Result of Initial Review: APM	Result of Initial Review: Tabled	Average # Days from Application to Approval	Average # Reviews for Approval	Average # Stipulations per Protocol
Cancer Control						
2015	5	3	2	114.60	3.20	18.20
2016	10	7	3	102.60	2.70	28.90
2017	11	8	3	69.45	2.45	27.73
<i>Totals/averages</i>	<i>26</i>	<i>18</i>	<i>8</i>	<i>90.88</i>	<i>2.69</i>	<i>26.35</i>
Cancer Prevention						
2015	7	5	2	87.86	3.00	36.43
2016	8	2	6	130.38	3.00	48.25
2017	9	5	4	71.22	2.56	29.44
<i>Totals/averages</i>	<i>24</i>	<i>12</i>	<i>12</i>	<i>95.79</i>	<i>2.83</i>	<i>37.75</i>