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## Librarians and the Institutional Review Board (IRB): Relationships Matter

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## Librarians and the Institutional Review Board (IRB): Relationships Matter

### Abstract

Libraries and librarians have a variety of relationships with Institutional Review Boards (IRBs). These relationships differ by the institution type, engagement level with the IRB, and the type of library within which a librarian works. What roles, then, might a librarian fill with regard to an institution's IRB? This article provides a short history and an overview of the purpose of the IRB, and proposes three possible roles for librarians: that of the lead investigator in their own research, that of a reviewer for the IRB, and that of an ex-officio member or research liaison serving as an information consultant to the IRB. The role of lead investigator is the most common role for librarians on the IRB, while ex-officio and/or librarian consultant memberships on IRBs are less frequently found relationships. However, seeking a closer relationship with the IRB is logical and would be suitable for librarians in and beyond academic librarianship. Librarians with full IRB appointments seem to be the least common role and may require closer ties with the research operations of an institution and higher qualifications than an ex-officio or consultant position. Each possible relationship comes with its own set of advantages and disadvantages. These are explored in this article.

### Keywords

Institutional Review Boards; IRBs; Research; Active research; Human subjects research; Faculty engagement; Campus engagement; Collaboration

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### Abstract

Libraries and librarians have a variety of relationships with Institutional Review Boards (IRBs). These relationships differ by the institution type, engagement level with the IRB, and the type of library within which a librarian works. What roles, then, might a librarian fill with regard to an institution's IRB? This article provides a short history and an overview of the purpose of the IRB, and proposes three possible roles for librarians: that of the lead investigator in their own research, that of a reviewer for the IRB, and that of an ex-officio member or research liaison serving as an information consultant to the IRB. The role of lead investigator is the most common role for librarians on the IRB, while ex-officio and/or librarian consultant memberships on IRBs are less frequently found relationships. However, seeking a closer relationship with the IRB is logical and would be suitable for librarians in and beyond academic librarianship. Librarians with full IRB appointments seem to be the least common role and may require closer ties with the research operations of an institution and higher qualifications than an ex-officio or consultant position. Each possible relationship comes with its own set of advantages and disadvantages. These are explored in this article.

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### Introduction

Libraries and librarians are an integral part of every academic institution. Libraries exist to serve all members of the community and generally do not focus on one specific discipline or group. Librarians stand outside academic departmental silos yet exist inside the ivory tower. This holistic perspective provides a unique vantage point, one which is usually broader than any one discipline or department. They meet the information needs of all stakeholders, playing both a supportive and a teaching role in academe. As Stephanie Bangert suggests, "Libraries contribute to learning in many ways: by the intelligent collection and arrangement of resources, through the teaching of how knowledge is organized, and in the creation of environments which foster reading, inquiry, and critical thinking."<sup>1</sup> Institutional Review Boards (IRBs) are also an integral part every institution where researchers conduct research using human participants. The IRB may also be known as the Research Ethics Committee, or something similar.

At some institutions, the IRB may be housed in the library or have a librarian serving formally or informally on the IRB.

Librarians as information professionals have much to offer researchers. Moreover, as researchers themselves, librarians can identify areas in which libraries excel in supporting student success on campus and point out areas for partnership with teaching faculty, bridging the divide between the classroom and the research process. However, as librarians are well aware, the status and recognition of librarians as equal contributors within academe is patchy at best. Lack of recognition may be due to the lack of any one clear definition concerning the status of librarians across all institutions. University librarians can be either tenure track or non-tenure track faculty, but they may also be considered as professional staff more closely aligned with administration than with teaching faculty. At medical schools, hospitals, law libraries and other specialized institutions, their status can become even more nebulous. There is a perception in the



professional literature – and by librarians themselves – that other stakeholders believe the role of the librarian is limited to that of an information provider, a conduit to resources, or even as a gatekeeper. A restricted view such as this denies users and librarians the chance to realize their capacity to build new knowledge, especially in the research arena.<sup>2</sup> Each institution has unique challenges, perspectives, and research needs. Yet a review of the literature indicates that, despite the fact many librarians have subject specializations with advanced degrees and advanced research skills, they seem to be underutilized by other researchers conducting literature reviews in preparation of an institutional review board (IRB) application.

Librarians also do not appear to be either frequent participants on or contributors to the IRB itself. Between 2004 and 2014, there were ten articles listed in EBSCO Academic Search Complete and Library, Information Science & Technology Abstracts with Full Text discussing the role of the librarian and the IRB.<sup>3</sup> A further review of the literature using those same databases to locate articles discussing librarians and their interactions with IRBs for their own research projects, or an introduction and overview of the IRB process for conducting research was more productive. The search returned thirty-nine results using the search terms *librar\* AND IRB*. There were far fewer articles discussing librarians as members of the Institutional Review Board or that examined the librarian as an affiliated participant in the literature review process.

### History and Purpose of the IRB

The IRB and its role in providing oversight for proposed research using human subjects developed over time in response to several notorious research projects where researchers showed a blatant disregard of the rights of human subjects. The names are familiar even today, many years after the abuses occurred: Nuremberg; Tuskegee; and Willowbrook. These abuses of human subjects outraged the public and added urgency to the need for protection and oversight of any such research using human subjects, even for pre-and post- instruction testing and for survey research and focus groups, these being some

of the most common types of research conducted by librarians.

The Nuremberg trials (1945-1949) included one of particular note, *U.S.A. vs. Karl Brandt, et al. (1946-1947) a.k.a., the "Doctors' Trial,"* that highlighted the atrocities carried out by Nazi physicians on innocent victims which eventually resulted in the Nuremberg Code. The infamous syphilis study conducted by the United States Public Health Department from 1932-1972 at Tuskegee University involved the socioeconomically disadvantaged, predominantly illiterate, male minority participants who were "were deprived of penicillin even after it was proven to be an effective treatment for syphilis." The Willowbrook Study deliberately infected children at a New York State mental institution with Hepatitis.<sup>4</sup>

The Nuremberg Code was developed in an attempt to address such atrocities, and served as the foundation for international standards of ethics on the treatment of human subjects.<sup>5</sup> The Nuremberg Code was further clarified to distinguish therapeutic from non-therapeutic research through the Declaration of Helsinki (1964), which was first adopted by the World Medical Association General Assembly in 1964. It contains "ethical principles for medical research involving human subjects, including research on identifiable human material and data."<sup>6</sup> This was followed by the Belmont Report (1979), "a statement of basic ethical principles and guidelines that should assist in resolving the ethical problems that surround the conduct of research with human subjects."<sup>7</sup> It serves as a guiding document for the protection of human subjects, and provides three general "prescriptive judgments" to "guide the investigators or the reviewers of research in their work" representing the ethical principles of beneficence, justice, and respect for persons.<sup>8</sup> It describes the boundaries between practice and research, basic ethical principles, and applications of the general principles. Training is now required of every researcher intending to use human subjects, for any research commonly using Collaborative Institutional Training Initiative, (CITI) certification, or the National Institutes of Health (NIH) training, both of which are available online.



Connecting the necessity and applicability of the IRB to social and behavioral sciences can be confusing given that IRB regulations were largely developed for the medical sciences and to mitigate the risk of physical harm to individuals. But when considering research ethics and the potential for harm to participants, *Zimbardo's Stanford Prison Experiment*, *Humphrey's Tearoom Trade study*, and *Milgram's electric shock obedience experiments* come to mind. Research ethics violations here range from researcher identity misrepresentation and participant privacy abuses to participant rights of withdrawal from the study, from participant deception to potentially harmful psychological stress among those enrolled in the study, from selection bias to the breakdown of the researcher-as-neutral-observer role. The function of IRBs with regard to social science research, then, echoes the responsibilities an IRB undertakes for medical research — namely, the protection of human subjects. And, while there are existing arguments for modified ethical regulation within social sciences (and humanities) research, such as *Dingwall (2008)* and the frustrations noted in *De Vries & Forsberg (2002)*, as stated by *Heimer and Petty*, “compliance, though expensive, is still less costly than being prevented from doing a study or than having research shut down midstream.”<sup>9, 10</sup>

### United States: Federal Law and Codes

In the United States, IRBs are governed federal regulations, which are enforced by the U.S. Department of Health and Human Services Office for Human Research Protections (OHRP). The Office for Human Research Protections “provides clarification and guidance, develops educational programs and materials, maintains regulatory oversight, and provides advice on ethical and regulatory issues in biomedical and behavioral research.”<sup>11</sup>

Key Laws and Codes include:

1974: A “series of highly publicized abuses in research led to the enactment of the 1974 National Research Act (Public Law 93-348), which created the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research.”<sup>12</sup>

and

1981: Legal standards for protection of human subjects in research were enacted by the U.S. federal government through *45 CFR 46*.<sup>13</sup>

All institutions engaged in research covered by the above legal standards must either register with the U.S. department of Health and Human services or designate an already registered IRB operated by another institution, after establishing a written agreement with that institution in accordance with and for the purposes expressed in Title 45 CFR Part 46.<sup>14</sup>

Keeping informed about the history, purpose, policies and procedures of the Institutional Review Board can enable librarians to understand better and support the information search process and literature review research of student, faculty, and administrative researchers at their institution. For example, *Smale [2010]* notes that there may be a lack of confidence in search skills among researchers and/or a lack of awareness of the extent of library resources available to researchers, and how the librarian can support the research process.<sup>15</sup> This would be a natural fit for a librarian and support an argument for a variety of librarian IRB participation avenues. Additionally, as librarians become more engaged in institutional research activities, establishing a foundational knowledge regarding the history and laws surrounding human subjects, as well as their own institution's policies and procedures, benefits the institution and broadens the librarian's role within their organization. This role may vary from institution to institution and may have strong, direct connections or more loosely aligned connections within the institution. These three roles are now considered.

### Librarian as Researcher

The first role under discussion is that of the primary investigator (PI) or co-investigator (co-PI). Librarians have many opportunities for action research. Conducting a review of the literature, digging into data, reflecting on our profession and how it is changing are natural avenues of exploration. Many librarians are interested in pursuing their own research — user studies, surveys, human-computer interactions, health information seeking, usability studies, and so



forth, that may involve members of their community. Any time research uses human subjects (whether or not the subjects are physicians, patients, staff, students, faculty, administrators, other librarians, or community members, etc.), it is critical to obtain approval by an Institutional Review Board (IRB).

The *Glossary of Education Reform* defines action research within the field of education as “a wide variety of evaluative, investigative, and analytical research methods designed to diagnose problems or weaknesses – whether organizational, academic, or instructional – and help educators develop practical solutions to address them quickly and efficiently.”<sup>16</sup> Additionally, action research is often synonymous with “cycle of action” or “cycle of inquiry.”<sup>17</sup> Given the cyclical statistical reporting patterns, tallying, and assessments that occur within academic libraries, whether working as nine- or twelve-month employees, librarians frequently engage in what would be considered action research.

As libraries continue internal and external funding justifications and strategically position themselves within institutional planning activities, the orientation of action research with problem identification, data collection, plan implementation, and evaluative efforts allows librarians to be not only actively engaged within their organization but also to turn that engagement into research-based scholarship. Farrell emphasizes the capacity of the often informal ways librarians reflect upon their services, programs, and collections to help “overcome the natural barriers to publication” and establish a “systematic approach for balancing competing workplace demands.”<sup>18</sup> The latter may apply most directly to the requirements set up for tenure-track librarians, but there is no shortage of non-tenure track librarians engaged in research and publication. Furthermore, Horowitz’s master’s paper (UNC-Chapel Hill) finds through descriptive analysis that, while non-faculty librarians may publish less frequently, their efforts are cited just as often as the publications of faculty status librarians.<sup>19</sup> The value of actionable research continues to increase for librarians in all facets of librarianship, and the value of IRB assessment for that research should increase as well – even if it is simply to confirm that the re-

search effort is exempt from the rigors of IRB approval and to document the need to use collected data for the purposes of research and publication. Even if the IRB’s role is only to confirm exempt status, it is important to gain institutional permission.

When developing a research question and methodology, it is strongly recommended that some time is taken to review the institution’s IRB website and policy concerning the use of human subjects. It is the lead or co-investigator’s obligation to recognize the importance of obtaining approval for research involving human subjects, and to become familiarized with the policies and procedures of the institution. One should not begin collecting any data until after one has applied for and received approval from the IRB as failing to do so could potentially place researchers in legal jeopardy. An IRB application will fall into one of three review categories: exempt, expedited or full – these are discussed in detail in the section below, “Librarians as full-fledged members of the IRB.” Being aware of and following institutional policies regarding research and data collection is critical. Most institutions have their own policies and regulations available for researchers online.

As an example, the University of Northern Colorado’s policy concerning human subjects states:

“3-8-104 Human Subjects. It is the policy of the University that all research and research-related activities, in which humans are used as subjects, shall be subject to review under current Public Health Service regulations by an Institutional Review Board (IRB). The involvement of human subjects in research covered by this policy shall be prohibited until the IRB has reviewed and approved the research protocol.”<sup>20</sup>

Every investigator who conducts research involving human subjects has both the legal and ethical obligation to:

- Obtain IRB approval before conducting any research involving human subjects.
- Fully inform potential participants of the research goals, procedures, risks and benefits of the research.
- Fully inform potential participants of their right to refuse to participate in the research

or to withdraw from it at any time after they consent.

- Protect populations that necessitate special consideration, e.g., children, disabled individuals, prisoners, homeless and others.
- Protect individual's confidentiality and privacy both during the data collection phase and after the research is completed.
- Consider the professional standards for research within the discipline.

When developing a research application for the IRB, bear in mind the whole process can take longer than one might anticipate. Allow at least two or three months of lead time rather than optimistically believing a completed and approved IRB application can be achieved in a week or two. The application should undergo careful review, especially as sections may require additional information or authorizations. The more detailed and complete the application is when submitted, the more likely it will be approved without additional revisions and resubmissions.

### **Librarians as Ex Officio IRB Members and IRB Consultants**

According to the U.S. Department of Health & Human Services, an institutional review board must include no less than five members, and those members should have diverse backgrounds suiting the institution and its research activities.<sup>21</sup> Among other requirements, the board must also have "at least one member whose primary concerns are in scientific areas and at least one whose primary concerns are in nonscientific areas," and at least one "unaffiliated" member.<sup>22</sup> Nonscientists serving on IRBs are members "whose training, background, and occupation would incline them to view research activities from a standpoint outside of any biomedical or behavioral scientific discipline."<sup>23</sup> Unaffiliated members may often be referred to as community members; they are non-institutional, nonscientific, and "uniquely positioned on the IRB to put people first, unhampered by personal ambition, scientific bias, interdepartmental rivalry, or the profit motive."<sup>24</sup> Klitzman found that distinctions between community members and nonscientific and/or non-affiliated members are not always made.<sup>25</sup> This

grey area can create a problem of definitions for IRB member roles such that fulfilling the intention of IRB regulations can become difficult.<sup>26</sup> Klitzman puts forth the question: "Will someone who is not a scientist by training but who works at a research organization be able to contribute the perspective of a nonscientist?"<sup>27</sup> Thus, IRB membership is not merely a matter of quantity but also of a critical need to have the roster filled by those who are best able to contribute from the point of their defined role so that the populations and principles addressed in IRB work are not ignored or glossed over by those designated to protect them.

Feedback received by Klitzman indicated understanding of the value of choosing the right individuals for ex-officio, community, nonscientist, and unaffiliated IRB memberships. One respondent noted:

"[...] we've had a law professor for a number of years...he's interested in people's ability to understand consent forms, and he's been a very strong advocate for making things clear. That's very nice. We have a woman with a master's in counseling. She's also a very good layperson. We've had some Reverends, which has been very good because they've been able to talk about these studies at their churches on Sunday: 'They're doing good stuff if you've got diabetes or hypertension.' So they've been able to help promote the science, too, and actually help recruit subjects."<sup>28</sup>

While Klitzman's article is published in the journal, *Academic Medicine*, the salient traits indicated are not exclusive to medical research environments or IRBs, namely critical assessment of consent forms; fluency in ethical subject recruitment; communication skills; empathy; patience; trustworthiness; strong understanding of confidentiality; advocacy work; and more.

With those characteristics in mind, the potential for librarians becoming involved on IRBs as members – as opposed to engaging with IRBs only as researchers – may be more evident. However, the setting in which a librarian operates (academic and nonacademic; medical-only academic and non-medical-only academic), their position classification and requirements (staff,

professional/administrative, tenured faculty, tenure-track faculty, non-tenure-track faculty, and others), and whether or not they are institutionally affiliated, may determine whether librarians fit more or less well into the “community” or “unaffiliated” category of IRB membership.

If a librarian has an institutional affiliation, e.g. employed as faculty or staff, the librarian really cannot serve in the role of community member on their institution’s Institutional Review Board. However, there are other avenues for participation that should be considered not only by librarians interested in the work of these important groups, but also by institutional administrators and IRB offices and governance. For example, SUNY-Potsdam’s IRB features a voting-member librarian, as does Jacksonville State University.<sup>29, 30</sup> Fort Lewis College’s IRB includes a librarian in a non-scientific voting-member spot.<sup>31</sup>

Indiana State University IRB has a librarian serving as an alternate member of their IRB, a role that is detailed within their Policies and Procedures and which is permitted by the FDA, so long as the role is explicitly defined within such a document and does not permit ad hoc substitutions of IRB members (but only formal alternates).<sup>32</sup> Indiana State’s IRB alternates serve three-year terms, just like the other IRB members, and includes the provision that, should an IRB member take a sabbatical or other form of leave, an alternate may become an IRB member in their stead. East Carolina University’s roster of IRB members includes a librarian among the alternates as well, and states that “alternates may vote only in the absence of their pre-designated members.”<sup>33</sup> Other clever options include East Carolina University’s “Research and Statistics Consultant” with the Office of Faculty Excellence (though the role is not played by a librarian, their office is housed within Joyner Library), and Columbia University’s librarian seat on their Standing Committee on the Conduct of Research.<sup>34, 35</sup>

Librarian involvement on an IRB can result from volunteer opportunities or appointments, but they may also arise due to tragedy and subsequent reorganization, as in the case of the East

Virginia Medical School (EVMS). Events in 2001 caused EVMS to reconsider the roles and needs of their IRB after the death of a subject at Johns Hopkins University (JHU) was found to be at least in part resulting from a less-than-complete literature review.<sup>36</sup> Resources prior to 1966 would have indicated to researchers the adverse effects subjects could experience and, ultimately, would have prevented the death of a healthy individual. Robinson and Gehle cite EVMS librarians’ interest in a “more proactive role” in the research activities of their institution prior to the headline-making oversight at JHU but felt that, after that investigation concluded, they had an opportunity to change the positioning of the library and its librarians with the work of their IRB. A new role was created: IRB Librarian.<sup>37</sup>

While this decision unfolded at a medical school, Institutional Review Boards without ties to medical schools could still experience a death within their study and thus could consider taking the same actions as EVMS. If the concept of an IRB Librarian can be examined as an extension of the role of community or ex-officio members, then the same advantages would apply – the IRB receives another member who should operate without personal ambition, scientific bias, interdepartmental rivalry, or the profit motive. But EVMS found additional benefits from using an IRB Librarian – perks more specific to the skillset, and the mindset, of librarians:

- A built-in resource for additional literature reviews requested from IRB members, particularly in the case of controversial topics or research areas for which the IRB does not have a member-expert;<sup>38</sup>
- A better understanding of the research pursuits of the institution and its constituents (approved or not);<sup>39</sup>
- A way to request additional information on a particular aspect of a consent form (e.g., side effects) or other aspect of the study (e.g., safety), and other specific information discovery needs (e.g., definitions, study sponsors, etc.);<sup>40</sup>
- An on-board expert in information retrieval to find answers to reference questions during meetings (e.g., via e-reference books)



and arrange for interlibrary loan of requested relevant literature.<sup>41</sup>

With all the benefits to participating on the IRB, one might conclude that IRBs should always have a librarian in some capacity. But if an institution or a library is considering approaching their IRB about a librarian spot in their membership, further advantages and disadvantages to the library, and the librarian, must also be considered.

EVMS discovered that the IRB librarian's role must be concretely established and acknowledge the "high-risk nature" of medical research.<sup>42</sup> Whether medical or otherwise, research using human subjects can be at of risk legal action as well, and developing scaffolding of support for the IRB librarian proved useful at EVMS. Just as health professionals have others in their field to whom they can turn, so must an IRB librarian. Furthermore, if serving in a consultant capacity, there must also be a "back up" IRB librarian in case the librarian officially serving is unavailable.<sup>43</sup> While important for providing "uninterrupted information service," this then requires the back-up librarian also to have Human Subjects Protection training.<sup>44</sup> One could ask, what if both librarians are unavailable? Should all librarians, then, undergo IRB training so that the entire library staff of librarians feels prepared to serve adequately? More wide-spread IRB training for librarians would assist in succession practices for the ex officio and consultant roles, but the extent of the number of individuals employed in the library and who should be trained in human subjects research protections at any given time is variable at best.

As mentioned above, human subjects research can result in litigation and the possibility exists of an IRB being sued. One should take this into consideration before becoming an IRB member. Also, the support network which could provide additional training and mentoring for an IRB librarian may not be available at smaller institutions. A librarian serving in *any* capacity on an IRB must have confidence in their listening, critical thinking, and questioning skills enough to be assertive, as well, so that as IRB discussions progress and proposals are assessed, the librarian can identify and vocalize "learning issues"

and train new members in their role.<sup>44</sup> Reflection regarding the librarian's role on the IRB and within the library should aid in structuring, solidifying, and improving the work of librarians and enhance institutional understanding of the positive outcomes the relationship can bring.

The professional gains of IRB membership include the increased familiarity with the interests of their colleagues and their institution leading to better acquisitions, collection development, and internal trainings.<sup>45</sup> The librarian's increased visibility among the campus community, particularly among researchers and administration, shows engagement in a "high profile service [...] in support of research that helps minimize risks to the institution."<sup>46</sup> Raising the library's organizational profile with that involvement in mind may also have some small advantage (as EVMS discovered) when it comes to library budget conversations with administration.<sup>47</sup>

While non-voting and/or ex-officio roles could indeed become popular ways to bring librarians into the work of the IRB, lack of a vote has its pros and cons. The website rosters for many IRBs within higher education list names and IRB terms only – rather than including departmental affiliations and, for those that do include school level affiliations, there's always the possibility that the Library is considered among or under, say, a school of Arts and Sciences, or a leader in library administration may have a title which doesn't indicate attachment to the library (e.g., Dean of Libraries vs. VP for Academic Affairs). For all of these reasons, IRB rosters with only minimal information about their members can muddle the ability to discover librarian presence, and the nature of their presence, on IRBs – particularly when they aren't voting members.

But they can be voting members. Institutions can have a librarian as a voting member within the IRB (and to actually list their contact information and campus role on the roster), as long as the requirements are met. Understanding such a position for a librarian, and its responsibilities, requires understanding of the functions of voting IRB members as a whole, the interpersonal dynamics of the IRB members, as well as the types of research most commonly brought

before that particular IRB. If the research interests and need for support don't align well with the expertise of the librarian, it may be better to offer a supporting role, rather than propose full membership.

### **Librarians as Full-fledged Members of the IRB**

If an institution has an Institutional Review Board, librarians are a logical choice to be included as a member of the IRB, as long as they themselves are interested in research and have a proven record of research and publication. If a librarian has not completed and published any research, then this committee would not be an appropriate service commitment, although they could offer to serve as an ancillary arm of the IRB, such as conducting risk assessment literature reviews for the IRB on an as-needed basis or assisting patrons with the information search process for their own research through consultations and workshops. While one does not need to be a member of the IRB to assist with a literature review, offering to help in this capacity can help establish a stronger tie between the library and the IRB. As such, an official liaison role could be established, rather than a full IRB membership.

To be considered for membership on the IRB, a librarian should have a track record of successfully completed research with at least a few publications in peer reviewed journals. The interested librarian should be able to provide cogent reasons as to why they wish to be part of the IRB and documentation supporting their qualifications. The first reaction from the Chair of the IRB may be one of surprise; librarians are quite frequently not viewed as researchers. An updated resume or CV, details regarding any advanced degrees and research completed, and other relevant qualifications should be made available to the Chair. A librarian's ability to discuss their understanding of the IRB process as it pertains to the institution, and how they see their potential role within the IRB will also be important. It is vital for a librarian making such a pitch such have a thorough understanding of the IRB's role and that they have gone through the application process for their own research at least once at that institution before approaching the Chair of the IRB.

For the IRB, members are expected to attend scheduled meetings, participate in developing policies and procedures as needed, review research proposals, and provide feedback concerning other applications to other reviewers as needed, depending on the level of review required. Each IRB usually has set processes for receiving all applications, and for sending them out to the appropriate reviewer(s). It is wise to become familiar with the institution's IRB website in order to gain an understanding of the current policies, processes and procedures. It is advised to review previously approved IRB applications with a colleague currently serving on the IRB and discuss the most common reasons for resubmissions and revisions. Training for IRB members is usually provided, and will need to be completed. Avail yourself of all training offered and ask questions about any particular internal policies the IRB may have that one might not be aware of as a new member.

In the review process, an IRB member may be one of several reviewers expected to provide feedback to a lead reviewer for some applications, or may be the lead reviewer. As lead reviewer, the IRB member will be tasked with collecting feedback from other reviewers in a timely manner before making the final decision. In the case of an expedited review for research deemed to have minimal risk to participants, a single IRB member may be the only reviewer.

IRB members need the ability to review an IRB proposal carefully and determine whether it was filled out completely and comprehensively enough to make a determination based on the information provided in the application and the supporting documentation. Members are expected to assess the risk to the participants and to admit when they are out of their depth as reviewers. This is not always as clear cut as it seems; sometimes there are clues that the researcher left important information out of the application. This may be as simple as the file name listing more than one researcher when the application itself only lists one researcher. Sometimes the consent form does not align with the stated methodology. Sometimes the approval letter from a participating institution appears to be signed by someone other than the person who would normally be expected to provide

permission. Sifting through the information and making the right determination is a detail oriented task involving more than simple fact-checking.

The level of review is determined by the level of risk as indicated by the applicant's responses to the questions in the application. There are three levels of review:

1. Exempt

- a. If there is little to no risk to participants, other than that which would occur normally in everyday life.
- b. One reviewer usually makes this determination after carefully reviewing the application and supporting documentation. Examples might include surveys and archival data.

2. Expedited

- a. One reviewer is usually assigned as a lead reviewer. If there are minors involved or potential risk to vulnerable populations, more than one reviewer may be assigned.
- b. This review will usually take longer to review than one that is considered exempt.
- c. With more than one reviewer, there may be a difference of opinion on one or more aspects of the application. If there are differences of opinion, the lead reviewer makes the final determination.

3. Full

- a. The application is considered to have a higher than normal level of risk to the participants.
- b. The IRB will meet as a group to determine the appropriate course of action.

In conducting the review of proposed research, the IRB is required to follow federal regulations as stated in 45 CFR 46.109-112.<sup>48</sup> Suspension or termination of IRB approval is outlined in 45 CFR 46.113.<sup>49</sup>

## Conclusion

For a librarian having an interest in research and assessment involving research, becoming familiar with IRB functions, policies, and members at your institution is worth the time and effort. At the very least, going through an Institutional Review Board when planning assessment, or other research efforts, will enable a librarian to publish their results with a sense of security. The advantages of understanding and having an interest in the work of an IRB can also facilitate additional means of engagement, such as serving as an alternate, ex-officio, or consultant to the IRB, or even serving in a voting capacity. A number of doors may be open for librarians to foster a closer engagement with their institution's IRB given the roles discussed in this article. Opportunities include both participation on an IRB and supporting researchers engaged in the processes of the IRB.

- Research shows that IRBs *could* have less staff-per-application, but the drawback is larger per-person workloads. This is less than ideal. A librarian with research experience could help mitigate this overburden in work.<sup>50</sup>
- There may be some concern about whether the right expertise can be found outside of the institution. A local public library librarian with the appropriate interest level and willingness to volunteer could serve as a useful community member for large and small institutions alike.<sup>51</sup> This might require some networking with a public librarian having some research experience or ethics training, but it would be definitely worth exploring this option.
- Perhaps a librarian focused on assessment, on undergraduate and/or graduate research, or on scholarly communications could be considered. A library director or library dean could explore the possibility of an IRB appointment with those in charge of the Board, and whether or not an appointment could be voting or non-voting.
- An institution may not consider the library to be discipline-focused or class librarians as non-faculty. This can present challenges for librarians seeking an IRB appointment. Administrative level conversations within

the institution may be needed to establish the nature and level of service librarians could provide an IRB. This might involve enlarging the understanding of the librarians' role in research generally and in the specific institution.

- Arguing from librarian participation on an IRB becomes much more effective with if librarians have the appropriate credentials. Professional development opportunities abound, free or fee-based. Options of both varieties could be gathered and presented to a library supervisor, director or dean. Such options may include the Collaborative Institutional Training Initiative (CITI) at the University of Miami as part of Human Subjects Research (HSR) trainings.<sup>52</sup> If an institution is already involved with CITI, sponsoring the training tends to be easier. Alternatively, another option would be exploring massively open online courses (MOOCs), such as the class "Guinea Pigs, Heroes & Desperate Patients: The History & Ethics of Human Research" offered by Johns Hopkins on Coursera.<sup>53</sup> Librarians could also take advantage of tuition benefits, internally, in-state, or otherwise, to enhance their credentials for research-based appointments. There may be attractive courses available in the social sciences, on scientific research methods, human subjects research, survey methods, and so forth.
- Many libraries subscribe to Springshare's LibGuides or similar products, or librarians create their own webpages related to research. Students who need to go through the IRB (often undergraduate seniors or graduate students) could benefit greatly by such resources that help guide a researcher through the IRB process. This could also provide reasons to (1) talk to the IRB in consultation and even add them as an editor to the page, (2) bring the library into closer engagement with the IRB under the "supporting students" umbrella, and (3) provide a means of self-taught professional development on how IRBs work – with or without institutionally-backed professional development opportunities.
- Many libraries are identifying and rebranding the value libraries offer their communities and exploring innovative outreach op-

tions and library infrastructure enhancements. Library and institutional administrators could mount an argument that the Institutional Review Board, or an equivalent board or unit of the institution be housed in the library building itself. Such is the case at Belmont University in Nashville, TN. This could be an advantageous and appropriately symbolic move regardless of whether librarians are brought into the IRB membership.

- If giving office space to IRB is not an option for whatever reason, the option exists for librarians to work with the IRB to create a workshop on the need, role and functions of the Board. Perhaps by marketing such a workshop to new and seasoned faculty alike, to graduate students and to researchers supported by the institution, a new and engaged audience can be found that can become invested in the work and resources of the library, and new partnerships and collaborations can be forged.

Regardless of the role a library or its librarians develop with the IRB, soliciting feedback on the relationship remains an important step. Whether teaching workshops or voting on proposals, or conducting research on behalf of the IRB, or submitting proposals of one's own, librarians have many reasons to seek and improve engagement and collaboration with the IRB.

### Endnotes

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