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The Institutional Review Board and Library Research:

Memoirs of a Multi-site Project

Abstract: Although many librarians perform research involving online surveys, assessments, focus groups, observations, and structured interviews, we sometimes fail to realize that these studies may constitute "human subjects research", and require approval of our organization's Institutional Review Board (IRB).   These boards exist to ensure that human subject research is carried out in an ethical fashion. While such research is governed by the principles of respect for persons, beneficence, and justice, most academic institutions have some degree of local control over their IRB requirements. The need for exempt, expedited or full review can vary among institutions, as can the requirements for signed consent, anonymity, sound and computer recording, destruction and retention of records, etc. Some institutions have an IRB-02, which covers behavioral and non-medical research, while others have only one IRB, requiring librarians and gene therapists alike to complete the same application process. The requirements can be confusing enough when confined to one institution; they become astronomically more complicated in multi-site studies.

This paper describes my negotiation through the IRB process at 18 separate institutions in support of two multi-site studies related to researchers' use of online bioinformatics resources and perceptions of library-based bioinformatics support services. The term "human subjects research" will be defined and a brief introduction to

the need for institutional review and informed consent will be presented.   Differences between exempt, expedited, and full reviews, IRB-01 and IRB-02, benefits and compensation, and anonymity and confidentiality will be delineated. IRB processes at my study sites will be compared, and some useful tips in dealing with the IRB approval process will be noted.

Introduction

This saga begins with my decision to write two research grants while on sabbatical from the University of Florida during 2006-2007. For several years I had been interested in how researchers use the online resources that are available from the National Center for Biotechnology Information (NCBI), what researchers and librarians think about library-based bioinformatics services and programs, and how such services and programs come into being at various institutions. However, there never seemed to be enough time to begin such projects, at least not until sabbatical year.

When the opportunity arose, I was able to secure funding from the Medical Library Association for two separate projects. The Lindberg Fellowship provided $25,000 to learn about how and how well researchers use NCBI resources, as well as the particular search paths that they take, while the Kronick Traveling Fellowship of $2000 would allow me to visit at least three medical libraries to learn how they implemented library-based bioinformatics support services. Because data collection for these research projects would rely on structured interviews, focus groups, observation, and online assessments, I knew that I would have to run them through the University of Florida's Institutional Review Board.

The University of Florida's Health Science Center Libraries have a long research history and have extensive experience writing UF IRB protocols, and we are currently

involved in a multi-center project led by a university located out of state. However, this would be my first time as the lead for a multi-center study (actually two such studies), and I would soon learn that working with UF IRB was the least of my worries. I knew that IRB approval (or exemption) would need to be formally negotiated at each of the institutions in which I planned to do my studies. What I did not know was that there are a number of areas in the IRB process in which institutions have some leeway for interpretation, and that these institutional differences could either make my life very simple, or complicate matters far beyond expectations.

Why Need IRB Approval for a Library-based Study?

The history of human subjects research is rife with abuse, from those elucidated by the Nuremberg Trials after World War II, to the well-known case of Tuskegee Syphilis Experiment.   The Nuremberg Code (1946) was one of the first efforts to define and regulate ethical medical research, and emphasized the importance of voluntary and informed participation by research subjects.   Additional foundation for ethical research comes from the Belmont Report (1979), which incorporates three fundamental elements: respect, beneficence, and justice.   The informed consent process relies on respect as defined by the Belmont Report – individuals are autonomous agents, and those with diminished autonomy should be protected.   Beneficence relates to the ideas of doing no harm, or providing greater benefit than harm. Finally, justice refers to the system of choosing research subjects - the fairness involved in who benefits from research, and who bears the potential risks and hardships. No particular population should gain all the benefits at the exclusion of others, and no one population should

bear all the burden of the research enterprise. For a brief history of human subjects protection, see The Institutional Review Board Guidebook.

It may be difficult to see how these aspects relate to library-based research, as we generally think of questionnaires, focus groups, observation and the like as being completely innocuous. In most instances this is probably the case. But it is the job of an the Institutional Review Board to ensure as much. Because the Code of Federal Regulations defines research as "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge", it is likely that much of library research is subject to the code. The code goes on to indicate that human subject research includes research on 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." Again, this covers most of the research that libraries would typically perform in terms of observation, focus groups, interviews, and assessment; it certainly covers the two research projects that I had proposed. So, it was on to IRB at UF.

The IRB-02 Process at the University of Florida

Over the years the IRB process at UF has been greatly simplified for librarian researchers with the creation of IRB-02 (behavioral/non-medical IRB). My first real research project at UF had involved surveying students in a genetics classroom to determine their perceptions about library-based bioinformatics instruction. For that project, I was required to apply for IRB approval through the only one that existed on campus, IRB-01 – the same IRB with which medical and science researchers must

contend. The IRB-02 process for my new studies contrasted greatly with IRB-01 – my IRB-02 application form was less than two pages in length (in contrast to 18 pages of forms for IRB-01), and did not require any training in research ethics.   Unlike IRB-01s, it was not necessary for me to provide evidence of scientific review of the study, statistical justification for sample size, or development of an emergency plan.   While I was hopeful that I would be granted an "exemption", rather than "expedited" or a "full" review, I did not need to choose between various forms to complete. Once I prepared the generic proposal, the IRB-02 office decided to which category of approval the project belonged.

The criteria for determining whether a project should be exempt from review or undergo expedited or full board review are similar across institutions, although sites may have differing interpretations of these criteria. Exemptions are based on the Code of Federal Regulations, and include research studies such as "evaluation of "normal educational practices", instructional techniques or classroom management methods", "educational tests, surveys, interviews or observations of public behavior", and "collection or study of existing data, documents, records, pathological or diagnostic specimens, if these sources are publicly available or if the information is recorded by the researcher in such a manner that participants cannot be identified."   Although the CFR lists these as possible grounds for exemption, each institution's IRB has some leeway in terms of how these categories are "interpreted".   Surprisingly (at least, to me!), the UF IRB-02 determined that my research projects did NOT meet these criteria.   Instead, the IRB-02 determined that the projects should undergo expedited review, in other words, formal review by one member of the board. Expedited review can be granted if the project consists of "Research that involves no more than minimal risk ... " and also falls

into specific categories; at UF the most common reason for expedited review is that the research is "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" ([UF IRB-02 website; Types of Protocol Review](#)). Therefore, expedited review best fit my projects as proposed.   Full board review at UF is reserved for "protocols that may involve more than minimal risk to research participants, or involve vulnerable populations of participants"; these are reviewed at the monthly meeting of the fully convened board.

In any case, the writing of the proposal was relatively simple and straightforward, and in less than two weeks I had received provisional approval for both projects. In order to gain final approval, I needed to revise aspects of the consent forms and our IRB-02 officer was very helpful in suggesting appropriate revisions.   The changes dealt primarily with the manner in which I used terminology; specific terms must be used in very specific ways (See [UF IRB-02 website](#)).   Such terms as "confidential" ("When names or other identifiers may be given to the researcher by the research participant and/or data could be traced back to that participant; but, the Principal Investigator has implemented a means of protecting the privacy of that individual"), "anonymous" (Names or identifiers are not given to the researcher by the research participant. Data are recorded in such a manner that responses cannot be traced back to the individual participant"), "compensation" (form of payment for participation, in money or other tangible item), and "benefits" (gained by the simple act of participating in the research; for example, learning more about library-based

bioinformatics support services) all have very specific meaning in the IRB world and must be used accordingly on consent forms.   (One additional (and somewhat amusing) issue concerning the incentives provided for participants will be discussed later in this paper.) Within two weeks of initial submission, I received final approval through expedited review. Seemingly, life was beautiful! It was now time to wander into the world of multi-institutional IRB submission.

My Year with IRB

During my year of research, I was hoping to visit up to 20 institutions and expected to have to negotiate IRB with all of them. My very first site followed the SLA Annual Conference in 2007, so as I write this paper I am coming up to my one year anniversary. I am happy to report that I have visited 13 libraries outside the state of Florida, and have visits planned (if not yet scheduled) for the others. The IRB experiences at these institutions have been varied, and mostly positive in nature. Given the fact that I would like to keep my IRB experiences at each site anonymous, and because my beloved Tampa Bay Rays are in first place this late in the season for the first time in history, I have decided to code my institutions with baseball terminology (from the hitter's perspective.) Therefore, my experiences will be lumped into the following categories (from most positive to least positive): "Grand Slam", "Home Run", "Ground-rule Double", "Shut Out" and "No Hitter".

A number of the institutions that I dealt with could be considered **"Grand Slam" Universities.** Grand Slam U's made my life incredibly easy. These are the institutions that decided because my project had been approved by University of Florida IRB-02, and because the employees of those institutions would NOT be "engaged in" or

"performing" the research, no formal IRB application would be required at those sites. Seven institutions that I have already visited fit this category. It appears that a very important distinction to most institutions concerns what exactly their employees will be doing in terms of actual performance of the research. It made no difference to these institutions that their employees and students would be the research subjects (participants), but is was important for them to know that their employees (library staff) would not be running the research – would not be consenting the participants, would not be present in the room in which the research was being performed, would not have access to identifiable data in any way. If I did not submit a formal IRB application at these institutions, how did they know enough about my research that they could make this decision? It was all due to the groundwork performed by my site hosts; more on that later in the paper.

"Home Run" Institutions took a little more effort to work with, but overall the experience was relatively simple. Two institutions fell into this category. Again, in the end, both institutions accepted my UF IRB-02 approval and did not impose any additional requirements on my research. However, these institutions did require a more back and forth conversation to come to this conclusion. Once the IRB officials at these institutions were made aware of the research project(s), they had a number of clarifying questions, all of them surrounding how "engaged" their employees (library staff) would be in the research. In both instances, formal IRB submission commenced, but as the IRB officers asked more questions via e-mail, it was clear that approval was not required, just as in the Grand Slam institutions described above.

Two **"Ground-rule Double"** universities did require me to go through the IRB process, with one successfully exempting my study, and the other granting expedited

approval. In both cases, the status was initially "provisional"; both sites required slight changes to the informed consent forms (see below in "Take Home" section). One of the two sites also required that final advertising be reviewed by their IRB, and that I undergo IRB training via their online modules.

One institution pitched a **"Shut Out"**, and I have not yet been able to visit this university. Because this site does not have an IRB-02, I am required to complete their online large-scale regular IRB that is much more appropriate for a medical researcher than for one doing the kind of work usually performed by librarians. This institution requires that all projects undergoing IRB review provide evidence that the work has undergone scientific review, provide a statistical justification for the number of participants that are to be recruited, and include a complete and detailed "emergency plan" in case someone is injured during the research.   While these requirements are not impossible to meet, they have caused a delay. Initial indications by that institution's IRB were that the project would be exempt since it was unlikely to pose risk to the participants. However, once that IRB learned that the UF IRB-02 required consent, the expectations changed and the new ruling required the project undergo expedited review.   As we have worked through the process, an additional issue has arisen – that site's need for "signed", rather than solely "informed" consent (more on this below). For the time being, my work at Shut Out University is in limbo.

Finally, one institution proved to be a **"No Hitter"**, and the ruling did not come from the IRB, but instead from the library's director. Via e-mail and through a preliminary visit to the institution, the library director agreed to host the project, and seemed quite interested in her library's participation. When it came time to schedule a visit and work through the IRB process, the director indicated that this was unworkable

at her institution; that their IRB would never approve someone from the outside to come in and hold focus groups at their institution. It became clear that the director would not support the project, and as such, that site has been dropped.

Take Home Messages from my Year in IRB-land

There are a number of steps that you can take to smooth the way through the multi-institutional IRB process. The first actually takes place at your home institution – **get to know your local IRB officer**. A good relationship with this person can make this process exponentially simpler and more pleasant, whether in dealing with the local rules or with distant institutions. At the University of Florida, we are lucky to have a knowledgeable, competent and pleasant person who does this work.

For multi-institutional studies, it is important for **your institutional hosts to lay the groundwork at their home institutions**. These hosts will likely make at least the first pass through their local IRB process – they will identify the correct IRB office/officer, describe the project and the ways in which that institution's employees are or are not "participating" in the research, etc. From my experience, the most effective and efficient process was for me to send an e-mail to my host, outlining everything possible about the research. I attached a copy of my UF IRB-02 approval, as well as any documentation demonstrating that I had completed IRB training. My hosts added an introductory sentence or two asking for assistance, and then sent the e-mail to their IRB to determine what sort of process we would have to go through. As seen above, in many instances once the IRB had been introduced to the research by my host, the research was determined to be exempt from IRB approval or even from any official IRB

scrutiny. In other instances, the local host laid the groundwork, and I answered any questions posed by IRB over e-mail.

In your dealings with your host and with their IRB, be sure to **highlight what is important**. For example, if you know that a sticking point for IRB often relates to local participation in the research (consenting, whatever), make sure that you make it clear to your host/their IRB that individuals from their institution will not be consenting participants (if that is the case).   But be totally honest – don't try to finesse approval.

If there is the **choice to use IRB-02** at your partner's institution, choose it. If your institution does not yet have an IRB-02, work with your library to lobby for the creation of one. It won't help you on your current project, but may be available the next time you want to do research.

E-mail can provide an excellent paper trail, just be sure to keep all correspondence related to your project - correspondence with your IRB, your hosts' IRB, and your hosts.   Sometimes it is necessary to talk on the phone or in person, but once you have done this, be sure to confirm the content of the conversation over e-mail.

If possible, **check out the rules in advance** to submitting your protocol to IRB.   Find out whether your institution or others require **training** prior to IRB approval, and if so, complete the training as early as possible and keep all documentation (certificates, e-mails, whatever) that indicates you have successfully completed the training. If your institution does not require training you may not be off the hook – any one of your partner institutions may require it. Know their rules. Do you have to take training from their institution, or will training from your institution or one of your other partner institutions suffice? Do they require CITI (Collaborative Institutional Training

Initiative) training, and how do you go about getting this if your institution is not a member of CITI?

Check out the rules concerning **compensation** for participation. One Florida rule was quite surprising to me; I suspect that similar rules exist in other states as well. Because the online assessments would be held in a computer laboratory environment and were expected to draw a large number of participants, it was decided that compensation would be minimal (perhaps a $5.00 gift card) in order to stay within the grant budget. However, I expected to be able to raffle off in each session a larger prize, for example, a National Library of Medicine t-shirt or mug. However, my IRB-02 informed me that "The General Counsel's office has recommended that IRBs not approve studies that involve games of chance. Games of chance in research projects, per General Counsel, constitutes a lottery under Florida law and the state prohibits any person in the state to conduct any lottery drawing for the distribution of a prize or prizes by lot or chance, or advertise any such lottery scheme or devise. However, we were advised that drawings could be a part of the study if the participants did not know about it beforehand. In addition a sum of money may be awarded as part of the project if based on merit (i.e, the chance to win the money would be intended as reimbursement for participation in the project, but the money would be awarded based on some merit, and not through a drawing by chance.) Or, each participant can be compensated the same amount. Remove drawing from on line assessment consent."

Another issue concerning compensation came from one of my Grand Slam institutions. One day in preparation for my trip to that state, I received an e-mail from someone I did not know, with the subject line "Gift Cards for Bioinformatics Research Study." The individual politely informed me that he oversees management of gift cards

at that institution, and that if the gift cards were to be paid for by his institution, the purchase would have to be approved by that institution's Finance Office. Luckily all gift cards were paid for through UF, so this did not affect my research. Although this is not an IRB problem, it does demonstrate the types of institutional differences that should be considered when performing a multi-institution project.

Give yourself plenty of time and expect delays, as a number of factors may spawn them.   Not every IRB will immediately know how to deal with your request since you are not a member of its institution's community. As such, your host's request for guidance may sit on the IRB's desk or in their in-box until they can determine how to handle it. In my case, because the outside institution's librarians would not be authors on the Lindberg project, some IRBs felt it was low priority – someone from UF was going to use their facilities but their institution was going to get little out of it – translation - low priority.

More likely your IRB may have interpreted requirements differently than your host's IRB. For example, the consent form that was approved by UF was sent back from a Ground-rule Double institution because they wanted additional wording indicating in two places on the form that respondents had to be 18 years of age or older. That required a change to my home institution's approved consent form, and therefore a run through our IRB-02 revision procedure.   Another Ground-rule Double institution required a change to my focus group informed consent form – "Please give a better indication of when the recordings will be transcribed ... I think 'within months' should be stated more specifically to say the tapes will be transcribed within a set number of months. Also, the timeline for the destruction of the tapes should be specified (i.e. after data analysis or within 1 year of transcription etc)."   Because this was a change to my

UF IRB-02-approved protocol, I was required to submit another revision to my IRB-02, to be used only at this "ground-rule double" institution. Another Ground-rule Double institution provided "provisional" approval, but would not provide final approval until they saw the absolute final advertising – which meant that sessions had to be scheduled, rooms reserved, etc. so that that information could be included in the advertising which would then be submitted for IRB approval. All of these instances caused significant slowdowns in exemption or approval.

In other instances, the process truly does become a nightmare, and it may be necessary to delay or scrap plans. When the Shut Out institution decided that they would require expedited review through their main IRB, including the development of an emergency plan, scientific review, statistical justification, final advertising, etc., it became clear that protocol submission, let alone approval, was nowhere in sight. At that point, the scheduled research visit was canceled. In other words, **ALWAYS make refundable, non-penalty airline and hotel reservations.**

Note that institutional variation can be perplexing, and even contradictory. The Shut Out institution clearly stated that a ruling of exemption with required consent was inconsistent, like trying to mix "oil and water" (their terminology.) In contrast, a Ground-rule Double institution indicated that "Exemption from review does not always equate to exemption from consent." Signed consent is often another bone of contention. While my IRB-02 required "informed" consent, it did not require that that all consent be "signed". Focus group and structured interview consent forms did require signatures. Online assessments and one-on-one observations, on the other hand, required participants simply click on statements that read "I have read the procedure described above. I voluntarily agree to participate in the procedure" or "I do not wish to

participate in this study." All of the partner IRBs accepted this arrangement except for Shut Out U, which will require a "waiver" of signed consent (another whole application process). There is no guarantee that the waiver will be granted; if not, this will require another trip through UF IRB-02 revisionville.

Choose your site/host wisely - Considering the complexities and time-consuming nature of multi-institutional IRB submission and approval, it is essential to choose your partner institutions and your hosts very carefully. While it is most important that you will choose your host institutions on the basis of intellectual merit (how well that institution and its library or clients match your research project), the importance of choosing a site with a dedicated and energetic host can not be overestimated. In my studies, the host at each institution had a number of responsibilities including identifying the appropriate IRB and helping negotiate that path. They also scheduled classrooms, arranged focus group lunches, advertised for the sessions, signed up potential participants, and sometimes purchased incentives. The project could not move forward at an institution without the complete dedication of the host, and the host's library director as well. Sometimes even with the best possible host you end up at bat against a No Hitter IRB, but your chances of a positive resolution and a good research experience are much higher with a dedicated host.

Summary

A multi-institution study can be extremely rewarding – it allows the researcher to learn about instances outside his or her regular environment and can foster collaborations with distant colleagues. Although IRB approval can seem a daunting task

when multiple institutions are involved, knowing the rules, starting early, and choosing a responsible and interested host can make the process relatively simple.

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