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Blog Series on Institutional Review Board (IRB) Considerations in Informal Science Education Settings

These blog posts were written by researcher Andee Rubin in 2013 & 2014 as a way to provide technical assistance to investigators planning to carry out research in informal settings. The first post provides a history of human subjects protection as it emerged from medical research and thoughts about the application of these principles to informal settings. The second discusses the set of federally-mandated rules that Institutional Review Boards (IRBs) use to protect human subjects and describes how and when researchers need to seek IRB approval for their work. The third describes techniques for limiting risk to participants, even in the case that the research involves video- or audio-taping. The fourth provides a set of resources, including sample IRB applications, sample consent forms, and a list of IRB organizations recommended by the Informal STEM education (ISE) community.

Contents:

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Navigating the Complexities of Research on Human Subjects in Informal Settings

May 31, 2013

Over the past decade, there has been increased interest in the details and depth of visitors' experiences in informal educational settings. National Science Foundation (NSF) and other agencies have funded research projects studying visitors in museums, zoos, aquaria and parks. Evaluation studies, as well, now more often examine visitor behavior and attitudes, rather than just tracking traffic patterns and dwell times. Given these changes, issues around working with human subjects have become more salient, and people doing research in informal settings have struggled with defining appropriate procedures for human subject protection. This post is the first of a series in which CAISE will provide resources and an ongoing forum for the growing community of people who are doing research with human subjects in informal STEM learning environments.

Why Worry?

It's important to start any discussion of human subjects protection with an awareness of the source and importance of the issues. Many cite the Tuskegee[1] or Milgram[2], experiments as examples of (egregious) ethical violations, but I think the story of Henrietta Lacks is more relevant. Henrietta Lacks was a poor black tobacco farmer in Maryland whose tumor cells, which were harvested without her knowledge in 1951, became one of the most important tools in medicine, used for developing the polio vaccine and in vitro fertilization, among others. Henrietta's cells have been bought and sold by the billions, yet she remained virtually unknown until the publication of The Immortal Life of Henrietta Lacks[3] by Rebecca Skloot in 2010. Current human subjects regulations, laid out in the Belmont Report[4] in the mid-1970's, would have mandated that Henrietta Lacks be informed of possible uses for her cells and that she provide consent for such use. The three principles set forth in the Belmont Report are: Respect for Persons (including the principle of informed consent), Beneficence (maximizing benefits and minimizing risks), and Justice (fairly distributing costs and benefits).

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[1] "The Tuskegee Syphilis Experiment," Pearson Education, accessed May 31, 2013, http://www.infoplease.com/ipa/A0762136.html

[2] Josh Gutwill, "Ethical and practical solutions for evaluation studies: Protecting human subjects" (presentation at CAISE PI Summit July 26, 2008)

[3] Rebecca Skloot, The Immortal Life of Henrietta Lacks (New York: Random House, 2010)

[4] "The Belmont Report," The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, accessed May 31, 2013, http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html

Protecting Human Subjects in Informal Settings

When we think about research on human subjects in informal STEM education institutions like museums or zoos, we are first struck by how different these settings are from those for which the rules were written. The research we conduct does not put people at risk of bodily harm or long-term discomfort and there is hardly ever any profit to be made based on our research results! Research in informal settings isn't risk-free, though. If we audio- or video-record people, we risk invading their privacy in ways that can be personally disrespectful. If we collect data that can be traced back to individuals, we also risk exposing them to scrutiny they would find unacceptable. Especially if we work with children, which most of us do, we must remember that their parents are the only ones who can decide what research they can participate in. These are not insurmountable issues, but problems often arise when those doing research in informal contexts need to have their data collection procedures approved by an Institutional Review Board (IRB). A major source of difficulty is that many IRBs, especially those at universities, have been organized to deal with high-risk medical procedures and such as have a perspective that is at odds with the opportunities and constraints of informal science education. While they are all working from the same general guidelines, IRBs have inconsistent and variable interpretations of these principles and sometimes a procedure that one IRB has approved is rejected by another. It's not surprising, given these conditions, that many researchers in informal education contexts consider the need to negotiate human subjects issues and obtain IRB approval to be barriers to carrying out their work.

How CAISE Will Help

CAISE will publish a series of blog posts on navigating issues related to human subjects protection in informal STEM settings. These posts will be accompanied by an ongoing conversation in which contributors will be able to share approaches they have found to be useful and raise questions they are grappling with. The next posts will focus on:

- What counts as research? What makes research "exempt," thus simplifying the IRB process?
- What are the latest advances in techniques for getting informed consent in an informal setting?
- What are some examples of IRB and informed consent procedures that might be transferrable to other, similar settings? We will post samples of completed, approved IRB applications, appropriately edited to protect the privacy of the human subjects in question. We will also post samples of approved consent forms.
- What are some IRB organizations, either university-based or private, who have a history of working well with researchers in informal settings? We will encourage

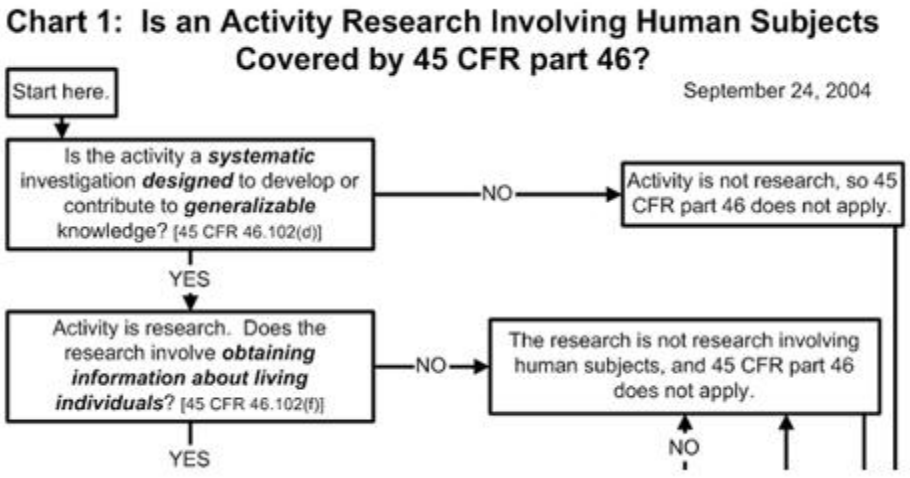
contributors to share their contacts with others who are looking for an IRB to work with.

Is there a particular human subjects issue that you would like to see addressed in this blog? If so, let me know.

Going Through the Institutional Review Board (IRB) Process for Informal Education Organizations

August 23, 2013

Human subjects regulations are designed to protect participants in very particular settings: those in which research is taking place and in which participants may be "at risk." Institutional Review Boards (IRBs) decide on the procedures researchers need to follow based on a set of definitions and regulations. The first of these is the definition of "research involving human subjects." If an activity is considered "human subjects research," then it must follow certain procedures for getting informed consent from those human subjects unless it is considered "exempt" from these procedures. The United States Department of Health and Human Services (HHS) Office for Human Research Protections (OHRP) has provided a set of decision charts[5] for deciding what kinds of procedures a researcher needs to carry out to protect human subjects. This post provides a guide to the decision charts that define human subjects research and those that describe the most common exemptions, highlighting some of the most important questions from the perspective of informal settings.



A note about federally-funded and non-federally-funded research

All federally-funded research that involves human subjects requires official IRB approval. This requirement is enforced by U.S. agencies such as the National Science

[5] "Human Subject Regulations Decision Charts." United States Department of Health and Human Services.http://www.hhs.gov/ohrp/policy/checklists/decisioncharts.html. 23 Aug. 2013.

Foundation, the Department of Education, and the National Institutes of Health, among others, by requiring an approval letter from an official IRB before funds are released. Since evaluation often builds knowledge that is also generalizable, in practice all proposals to the NSF Division of Research on Learning in Formal and Informal Settings (DRL) require IRB review in order for an award to be made. Some private foundations also require IRB approval. Research at an informal education institution that is funded in other ways (e.g., out of operating expenses or from some private foundations) may not legally be required to have official IRB approval. However, the ethical issues are no different, so many professionals believe that all research studies that involve human subjects, regardless of funding source, should be under the supervision of an IRB. Most formal education institutions such as universities or K-12 schools have institutional policies that require IRB approval for all research, regardless of the funding source.

Is your activity "research that involves human subjects?"

The first important question is: does what you're doing count as research? In order to be considered research, an activity has to have two main characteristics: 1) it has to be a systematic investigation; and 2) it has to be designed to contribute to generalizable knowledge. While these criteria sound somewhat heady, they describe most of what we do when we investigate questions about learners. Research involves human subjects if you're obtaining information about living individuals. Again, this is almost always true in informal educational settings. This information may be obtained directly from the individual (e.g., by asking) or by indirect methods such as observation. Many of the studies conducted in informal education organizations are designed to be generalized, or applied beyond a specific program, project, or organization. Our questions usually aren't just about the 20 families who happened to come to the exhibit or visit our website during our "research time," but about the larger group of potential learners whom they represent. We hope that what we learn from our study generalizes to a larger group.

Here is where the decision chart gets a little more complicated. If the research involves intervention or interaction with the individuals who are involved, then it is definitely considered "human subjects research." This would be the case if you were interviewing people or if you were engaging them in an activity. Even if you don't actually interact with people, though, your activity is considered "human subjects research" if the information you are collecting is individually identifiable, that is, if the identity of the person will be associated with the information that is collected and if this information is private.

The definitions of "individually identifiable" and "private" can be tricky. Information is individually identifiable if a person's identity can be discerned from it. So, video and

photos are definitely individually identifiable, as are a person's name, address, or social security number. A zip code, however, is not individually identifiable information, as it usually applies to a large number of people.

Amy Niedbalski and Jaclyn Johnson conduct research at Stingrays at Caribbean Cove, Saint Louis Zoo. Image credit: Samantha Ressler

Informal settings complicate the definition of "private," as people's expectations about being observed or having their behavior recorded are influenced by the context. When people are in a hospital, for example, they might expect to be monitored for security but they probably do not expect that they will be observed for other purposes without their knowledge. Visitors to informal institutions are likely in a similar situation. They can get upset if they feel they are being observed without their permission. On the other hand, some observations might seem normal, such as a supervisor watching how an after-school program is going or a program keeping track of how long a person dwells on a particular webpage, as long as no identifying information is collected. In deciding what consent procedures a researcher must follow, IRBs will often consider what an individual's assumptions are about the "privacy" of their behavior in a particular setting.

Even if your activity is "research involving human subjects," might it be exempt from IRB approval?

The OHRP regulations stipulate that some activities entail so little risk to subjects that formal oversight of the research by an IRB is unnecessary. They are declared exempt. A study that is exempt is not monitored by the IRB, but an exempt study would still need

to be conducted ethically, and therefore, may need to include informed consent, protection of confidentiality, and other ethical obligations. Only an IRB can determine if a study is exempt, so having a project that meets the criteria for exemption does not eliminate the need to consult with an IRB. It may, however, reduce the cost of an IRB's involvement, as they would need to spend less time and effort on reviewing an application that qualifies as exempt.

A research study may be exempt if it involves ONLY educational tests, surveys, interviews, or observations of public behavior AND:

- There is no identifiable information collected
- There are no children (or what are considered "at risk" populations, like prisoners or mentally challenged individuals) involved
- There would be no risk to subjects' reputation if their responses were disclosed

More generally, research projects in informal contexts are most likely to be exempt if they don't involve children under the age of 18. While it is not impossible to have an exempt project that involves children, IRBs tend to be especially concerned with data collected about them, as they are considered more vulnerable than adults.

Another kind of study that is likely to be judged exempt because it does not put individuals at risk is one that uses a database that already exists and that contains no identifying information, such as clickstream data about web or multimedia access.
The next blog post will contain suggestions for other research designs that minimize risk to subjects and therefore may not require getting informed consent from participants. However, it is not always possible to avoid risk entirely, so the next post will also describe advances in techniques for getting informed consent.

Facilitating the IRB Process: Limiting Risk to Research Participants and Obtaining Implied Consent

November 15, 2013

In my last post, I described the idea of an “exempt” project, that is, one that an IRB has determined does not require ongoing oversight. This post has two parts. The first contains suggestions for designing your project so that it is more likely to be exempt by minimizing risk to participants. Within the limits of doing a good job protecting human subjects, it is to the advantage of a project designer to figure out how to make the IRB process relatively smooth, either by creating a project that is exempt or by streamlining the consent process. Remember, however, that you still need to go through the IRB process for an exempt determination to be made. The suggestions in this post are NOT a substitute for that step.

The second part of this post describes a method for obtaining consent in situations where there is minimal risk to participants—but not so little that consent can be avoided altogether. This “implied consent” method is particularly helpful in situations where audio or video recording is happening in a public space.

Limiting the Risk to Study Participants

Much of the risk to people who participate in educational or visitor research comes from information about them being identifiable, as opposed to the kind of injury that might result in a medical trial. Therefore, one of the key ways to limit risk is to make sure that no identifying information about participants is collected. Thus, if you are doing research by collecting clickstream data from a website or by administering a survey that has no identifying information associated with it, your research is likely to be exempt. Collecting anonymous keystroke data from games is also a limited-risk situation. Similarly, if you are doing a timing and tracking study that involves unobtrusively following visitors and collecting their start and stop times at exhibits, as well as a few demographic details such as gender and age category, that is likely to be an exempt study. Even if you conduct interviews with visitors, your study may be exempt if you do not collect names and addresses of the interviewees. In these kinds of cases, you would probably not have to get informed consent from participants, as there is virtually no risk.

Do you have other suggestions for “limited-risk research designs” (i.e., those that limit risk to participants enough that informed consent may not be necessary?) Please add your ideas as comments on this post.

Video Recording and Taking Photographs Can Constitute Risk

Things get more complicated when you are video recording research subjects, since the image of a person on a video recording or even a still photo constitutes identifiable information. Some people object to being photographed or video recorded for religious or cultural reasons. If you want to do individual video recorded interviews, it’s relatively easy to let people know what will be done with the resulting data and to give them the option of refusing to be interviewed. But if you’re interested in setting up a video camera in an exhibit space to capture what visitors in general are doing, the consent process can get unwieldy, given the large number of people who might enter the space. Getting signed consent forms from a large number of individual visitors can be expensive, difficult and close to impossible in some settings.

Sign indicating to visitors that they may be "videotaped" while they view an exhibit. From Gaining Visitor Consent: Testing the Posted-Sign Method.

To deal with this quite-common situation, Josh Gutwill, Director of Visitor Research at the Exploratorium (who is a frequent and helpful commenter on this blog), tested an "implicit consent" scenario in which he posted signs letting visitors know that "videotaping" was taking place in a particular area of the museum for research purposes[6]. This technique had been used previously by several researchers, with the assumption that visitors would notice the signs and avoid that area if they had an objection to being video recorded. But Josh went a step further and actually tested this assumption by questioning visitors to make sure they had seen the signs and had considered the implications of entering the area where taping was happening. In his first study, Josh found that 75 percent of the over 200 visitors who were interviewed had seen and read the sign. Of those who had not noticed the sign, only a few were concerned about the "videotaping" or said that if they had read the sign, they would not have entered the area.

Josh was not satisfied with the 75 percent rate, however, and did a further study to try to increase the percentage of people who noticed the signs. In this second study, in addition to posting signs at the entrance to the museum and the entrance to the exhibit area being video recorded, he posted signs on individual exhibit elements and made sure the camera itself was obvious by putting a blinking light and a "recording" sign on it. With these enhanced measures, almost all visitors (99%) reported knowing that they were being recorded and the few who didn't reported that they didn't mind[7].

These two studies—Gaining Visitor Consent for Research: Testing the Posted-Sign Method and Gaining Visitor Consent for Research II: Improving the Posted-Sign Method—are available in the research library on InformalScience.org.

It is important if you are using an "implicit consent" method such as this to post signs at the entrance to your venue, so that visitors don't find themselves in a situation in which they have paid to enter, but do not feel comfortable viewing the very exhibit they came to see because of the video recording. It's also important to use this approach judiciously where children are concerned. Since children cannot officially make informed consent decisions, it's important that a parent—or, at least, an adult who has taken responsibility for the child's presence at your venue—be present. This is not a method that can be used for field trips where large numbers of children without their parents might visit.

[6] Gutwill, J. (2002). Gaining visitor consent for research: Testing the posted-sign method. Curator 45(30): 232-238.
[7] Gutwill, J. (2003). Gaining visitor consent for research II: Improving the posted-sign method. Curator 46(2): 228-235.

Sign indicating to visitors that they are being "videotaped" while they view an exhibit. From [Gaining Visitor Consent: Improving the Posted-Sign Method].

The final blog post in this series will contain links to resources such as IRBs that have been recommended by members of the informal science education community, sample IRB protocols, and sample consent forms, particularly those that have been written with care to keep the reading level reasonable.

Resources for Dealing with the IRB Process: Sample Applications, Consent Forms, & Organizations

February 24, 2014

In my three previous posts, I discussed IRB issues around the definition of generalizable research and the associated issues of risk and consent. In this post, I get more practical and provide some resources to help you navigate the IRB process for your own project. I have included three kinds of resources: examples of completed approved IRB applications, examples of consent forms, and links to independent commercial IRB organizations who have experience with research in informal contexts.

IRB Applications

Several organizations have been kind enough to share completed IRB applications for the benefit of the informal science education community. In order to make these available, they had to first remove any information in the application that would violate the privacy of the organizations involved. Reading these completed applications requires careful attention. They are complex and each is slightly different, as they all used a different IRB application form. Rather than including complete applications, I have excerpted the most relevant parts of the longer ones.

National Science Festival Network

Exempt application from the University of California, San Diego

This is a relatively simple application that requested (and received) an exemption from the consent requirement. The key in this application is that all data collection was done anonymously. The project's purpose was to gather feedback and outcomes data for science festivals in four locations around the country. Data were collected both at the science festivals themselves and at student activities held throughout the year. In both cases, survey instruments were administered to a sample of participants, who filled them out without providing any identifying information. Hence, not only was there no risk to participants, but the process of gaining consent would have actually constituted more of a risk, as identifying information would have to be collected.

Oregon Museum of Science and Industry (OMSI)

Umbrella Protocol for Access Algebra

Thanks to Marcie Benne and the Evaluation and Visitors Studies Division of OMSI for providing this approved application for the Access Algebra project, which produced an exhibit called Design Zone, focusing on algebraic reasoning. This application is much more complex than the previous one because it covers data collection from both visitors and staff, using a variety of methods: questionnaires, surveys, interviews, observation photography, audiotaping, and videotaping. I've excerpted the most relevant parts from this long application. This portion describes OMSI's overall approach to consent, differentiating between adults and minors and between adults who have been explicitly "invited" to participate and those who are in non-invitational settings, then describes details of consent for each method and audience.

This portion shows the signs that they posted for implied consent for videotaping adults; these are similar to those I described in my last post and derive from Josh Gutwill's work.

This portion includes consent forms for adults and minors in both English and Spanish. Note an important point on pages 3 and 4: before they were actually used, the language in these forms was simplified to be appropriate for minors between the ages of 7 and 14, who were the target audience for the Access Algebra project.

Sharing Recordings: Excerpt from an Exploratorium Protocol

In the comments around my second blog post, there was a discussion about how the sharing of data – including in publications – affects consent. If data are collected strictly for internal purposes, there is less risk to participants. As soon as data leave the setting in which they were collected, there is more chance that privacy issues will arise. The Exploratorium has developed a policy to determine where they can share video recordings of minors, based on whether or not they have obtained parental consent. The distinctions are shown here.

Basically, the Exploratorium has a general policy that identifiable recordings of either adults or minors made in public spaces (e.g., on the exhibit floor) can be shared in educational settings, which they define explicitly in the linked document. In these public spaces, permission for a minor can be obtained through implicit consent or by the signature of either a parent or a non-parental adult. However, in the case of minors recorded in non-public spaces (e.g., in focus groups or interviews in classrooms), implicit consent is not acceptable. If a non-parental adult signs the consent form, the video can only be shared within the Exploratorium.

Working with Staff: Excerpts from the Zoo and Aquarium Action Research Collaborative

In the last few years, several projects have designed and studied professional development programs for educators in informal contexts. The staffs involved in these projects are themselves the subjects of research and, as such, need to give their informed consent to be studied. The Zoo and Aquarium Action Research Collaborative (ZAARC) is a project I have been leading along with John Falk; its goal has been to support zoo and aquarium educators in doing action research about issues that arise from their practice, and to study the professional development process and its outcomes. The consent form for staff participating in ZAARC explains to participants what data will be collected, how it will be used, and how much identifying information about the project will be included in writing.

The Art of Consent Forms: A Very Simple Example

One of the challenges in doing research with a diverse public audience is crafting consent forms that are appropriate for people with a wide range of reading abilities. It's easy for consent forms to get unwieldy and complicated and thus fail in successfully informing visitors of their options. This form, which was part of a TERC project developing and evaluating math materials in libraries, does a great job of keeping the form short and readable. This form has a readability level between 5th and 6th grade; many word processors will calculate a readability level for you automatically. Thanks to Marlene Kliman at TERC for letting me share this example.

Commercial IRBs

Several commercial IRB organizations have been recommended to me as having particular expertise in dealing with IRB issues in informal contexts. I list them here because credible, professional colleagues in the field have suggested them. If you know of any other "informal-context-friendly" IRBs – or represent one yourself – please add the contact information in the comments section at the end of this post.

- Heartland IRB
- Ethical and Independent Review Services
- Solutions IRB
- Chesapeake IRB
- Aspire IRB

Final Thoughts

As funders require evidence of the impact of educational interventions in informal contexts, more projects will have to design and carry out substantial research as part of their work. The recent National Science Foundation Advancing Informal STEM Learning (AISL) solicitation, for example, includes a Research in Service to Practice project type category that "specifically focuses on research that advances knowledge and the evidence base for practices, assumptions, broadening participation, and emerging educational arrangements in STEM learning in informal environments." We hope that the IRB issues discussed in this blog series will be relevant and useful for the growing community of researchers and evaluators who are engaged in building knowledge to better understand and improve practice across the many sectors of the ISE field. Let's keep the discussion going.