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Your IRB: Educating Students, Monitoring Student Research, and Safeguarding Students as Research Subjects

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Your IRB: Educating Students, Monitoring Student Research, and Safeguarding Students as Research Subjects

By Judy Scheppeler and Christopher Kolar, Illinois Mathematics & Science Academy

The purposes of this article are to inform you about the formation of your school's Institutional Review Board (IRB), to present examples of research that IRBs often encounter, to elevate awareness of human subjects research concerns for faculty and staff, and to discuss how emerging requirements for science competitions may affect schools, staff and students.

An Institutional Review Board is the group charged with the protection of human subjects that are part of research endeavors. Throughout history, there have been multiple and egregious atrocities visited by individuals on others ostensibly in the name of research. One needs only to think of Auschwitz, the Tuskegee syphilis study, and Stanley Milgram's obedience studies to elicit feelings and visions of the gross abuse of humans. While we probably feel that such abuses are at an end, it has only been through national and international mandates – in the not-too-distant past – that the Federal system of laws and practices has been put into place to ensure that human subjects are treated in an ethical manner. Abuse and unethical treatment of human subjects still occur, although infrequently. In this article, we raise these issues specifically as they apply to non-biomedical research, the type of research that you are most likely to encounter at the secondary school educational environment.

With respect to the common forms of research among Consortium schools, there are several scenarios for your institution and your IRB to consider. First, Consortium schools are often teaching motivated, gifted and talented students who are interested in math and science, and, in a few schools, students gifted and talented in the arts. Therefore, our students are frequently of interest to researchers who may want to conduct

educational research on them or on our institutions and teaching practices. Second, as specialized schools, we are required to demonstrate our value to our stakeholders. We keep ordinary student records and also maintain archival records and sometimes conduct studies on graduates. Third, and perhaps most importantly, as we teach our students research skills related to the varied career paths they may follow, we often require that they conduct research projects. Many then enter their projects in local, regional, national, and international competitions. Whether they do research with human subjects or go into a field in which they will be involved in other ways with humans, it is our job to lay the foundation for them to succeed.

Keep these three scenarios in mind as you determine the roles and responsibilities of your IRB. In the area of non-biomedical research, the type of research that most of us will be involved in, there are many gray areas. Your institution and IRB will need to grapple with students as researchers and students as research subjects. Our goal is to provide you with information and resources to assist you in working with your students and in this challenging area. Your goals are to protect your students, to serve as a role model for their behavior, and to assist them in being ethical researchers. Be aware that some human subjects research issues can still stymie even experts who work in the area of non-biomedical research and non-biomedical IRBs.

Protection of Human Subjects in Research Competitions

Science competitions in which Consortium students typically participate require that student research involving humans, as well as animals,

certain biological agents, hazardous chemicals and equipment, etc. be reviewed and approved *prior* to starting the project. Society for Science and the Public (formerly Science Service), the organization that sponsors the Intel Science Talent Search (STS) and the Intel International Science and Engineering Fair (ISEF), publishes very specific human subject and IRB rules, regulations, and guidelines, “developed to help student researchers adhere to the Federal regulations and to, therefore, protect the rights and welfare of both the research subjects and the student researcher.” This information, an informative PowerPoint presentation, and all required forms may be accessed at http://www.societyforscience.org/isef/about/rules_regulations.asp.

The Siemens Foundation, which sponsors the Siemens Math, Science, Technology Competition, also provides clear criteria for what constitutes research involving vertebrates and for the protection of human and animal subjects, with similar rules and forms. They, however, state clearly that “high school IRBs are not permitted.” Research with human subjects and animals may only be conducted in a registered institution or laboratory under mentor supervision and with appropriate documentation. This information may be accessed at <http://www.collegeboard.com/student/pay/scholarships-and-aid/45104.html#research>.

Obviously, then, you need to review the competition’s guidelines before your students begin their investigations. You would not want any student’s project disqualified from a competition based because of its non-compliance with guidelines for research on humans.

IRB at IMSA

More and more Consortium schools are requiring research projects before students graduate. Along with the growing emphasis on STEM education and scientifically valid research, our institutions are becoming more frequent participants in educational research as well. The remainder of this article will focus on how these emerging functions and requirements, beyond the needs of competitions, must be addressed by your

institution. We will use our work at the Illinois Mathematics and Science Academy (IMSA) as exemplars.

The IRB at the Illinois Mathematics and Science Academy (IMSA) is the Human and Animal Subjects Review Committee (HASRC). IMSA policy dictates that we follow federal guidelines for human subjects research, and it also extends the committee’s charge to animal use in research. Our HASRC policies are more extensive than federal guidelines for human subjects.

Definitions

Most definitions of significance to an IRB derive from Federal Code 45 CFR 46, also known as the Common Rule. It is important to consider that the language of human subject research includes many *terms of art*. We outline some of the more significant concepts here.

Institutional Review Board (IRB): An IRB is a committee of employees and community members that follow widely accepted ethical principles, legally binding federal regulations, and campus policies and practices to ensure the ethical and legal conduct of human subject and animal research.

Human Subject: A human subject is a living individual about whom an investigator conducting research obtains data through intervention or interaction with the individual, or obtains identifiable private information.

Research: Research is a systematic investigation, including research development, testing, and evaluation designed to develop or contribute to generalizable knowledge (Title 45, subpart 46.102.d).

The definition of research is worth further discussion and scrutiny, both about what research involving human subjects is and what it is not. There are two phrases, *systematic investigation* and *generalizable knowledge*, that are key to understanding the definition. Keep in mind, however, that even the experts find gray areas, and your institution’s policies may dictate

practices and responsibilities in the area of research that go beyond what the federal definition includes, as our policies do.

Systematic Investigation: One thing that differentiates research from casual observation is that it must be systematic. This means that the collection of data is done in deliberate fashion, planned in advance, and the methods and techniques are identified prior to the commencement of work. A good school example is a qualitative study in which the student plans a series of interviews with identified persons, along with an accompanying plan for analysis. This is different than reporting where formal data collection and analysis techniques are not employed.

Generalizable Knowledge: The Common Rule also clearly identifies generalizability as an important component of defined research. This means that the findings of the work might be applied usefully by another person or in another situation. This applies even to case studies, for it is assumed that the reader of the study will learn something important about the world or their own circumstances. The researcher does not have to foresee the ways in which others could generalize the research; it is simply that the IRB determines that the work may be generalized. In applying the rule at IMSA, we consider all activities that may lead to publication or to a public presentation (e.g. a conference), which extends the federal guidelines slightly.

Special Groups: The Office for Human Research Protections considers some groups of research subjects as vulnerable. They include neonates, pregnant women, prisoners, some elderly individuals, comatose patients, some cognitively impaired individuals, the economically disadvantaged, terminally ill individuals, and minors and children. It is important to note that minors are in this group, and in high school settings most of our research subjects will be under age eighteen, so we have a responsibility to carefully consider what research investigations are permitted in our institutions with our students as

the subjects. For this reason, we conduct at least an expedited review of these research proposals. Our students may be unduly coerced, or feel that they cannot refuse an adult's request. Similarly, employees of an institution can feel coerced by the employer, so in some cases could also be considered a special group.

History of the Guidelines for the Protection of Human Subjects

The topic of research ethics is charged with emotion and history. It is fraught with emotion partly because a researcher's livelihood, student's grade, and sometimes an institution's reputation may be dependent on the results. History plays an enormous role in how we view, conduct, and regulate research that involves humans and animals. In the past, even after intense social scrutiny, individuals have been subject to abuse as research subjects. Briefly described below are the generation of guidelines that have led us to Title 45, Part 46 of the Code of Federal Regulations for the protection of human subjects (Amdur, 2002).

The Nuremberg Trials and the Nuremberg Code: Written in 1948 at the end of the Nuremberg trials that addressed the Nazi crimes against humanity that occurred during World War II, the Nuremberg Code delineates specific conditions for research to be conducted using humans as research subjects. They include:

- Subjects must be fully informed of the intent and purpose of the research.
- Subjects must voluntarily consent to participate in the research.
- Subjects may opt out of a study at any time, for any reason, without consequence.
- There must be a favorable risk/harm assessment of the research.

While the Nuremberg Code has had a significant impact upon how research with human subjects is conducted, other cases of unethical research on human subjects in the twentieth century have led to federal guidelines and regulation of research involving humans.

National Research Act/National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research:

Congressional hearings determined that federal oversight was necessary in order to protect human subjects. The National Research Act of 1974 was passed and essentially created the modern Institutional Review Board system. Title 45, Part 46 of the Code of Federal Regulations (45 CFR 46) provides the federal regulations concerning research with human subjects. These regulations have been adopted by almost all federal agencies and 45 CFR 46 is referred to as the Common Rule. The Code can be found at <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm>

The Belmont Report: The National Research Act created the National Commission for Protection of Human Subjects of Biomedical and Behavioral Research, which ultimately issued the Belmont Report and its three guiding principles for ethical research with human subjects: 1) respect for persons, 2) beneficence, and 3) justice. These principles should guide the design of research studies involving humans and are used by IRBs to determine whether a study is ethically sound (National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research).

Respect for persons means that people are treated as autonomous agents, and individuals who have diminished capacity are provided with special protection. Minors, individuals less than eighteen years of age, are considered to have diminished capacity because of both legal standing and experience. The IRB must find that the following requirements are met:

- Research subjects must voluntarily consent to participate; minors should assent;
- Informed consent will be obtained; and
- The privacy and confidentiality of the research subject is protected.

Beneficence means that individuals are treated as you would have them treat you. The IRB must find that the following requirements are met:

- The research is designed so that risks to the individual are minimized;

- Any risks of the research are justified by potential benefits to the individual and/or to society; and
- There is no conflict of interest by the researcher.

Justice means that any potential risks and benefits of the research are equitably distributed among all individuals who may benefit from the research. The IRB must find that the following requirements are met:

- Vulnerable subjects may not be targeted because they are easy to gain access to; and
- Individuals who are likely to benefit are not excluded from participating in the research.

What Kind of IRB Does Your School Need?

The above discussion outlines some of the ways in which the relationship between research and research subjects have been framed, and the treatments promulgated on or by your students leads to the question of the role of an IRB in your institution. Consider the following questions when determining what kind of an Institutional Review Board you need to establish. While the answers to these questions may be straightforward, the process of establishing your own IRB may be less so.

- Do your students enter IRB-regulated research competitions?
- Is anyone (students, staff, external parties) conducting research at your institution?
- Does anyone have or plan to obtain federal grants?
- Does your institution have assessment initiatives where the individuals being assessed can be identified, directly or indirectly (e.g., name, school ID)?
- Do you have a research office, or other entity, that has a data warehouse that contains information where the individuals being assessed can be identified directly or indirectly?
- Does your institution conduct surveys in which students or other subjects can be directly identified?
- Does your institution conduct assessments on special populations (for example, minors, adult education students, English as a second language students, developmentally disabled)?

If your answer is yes to any or all of these questions, you have several choices to consider. You may ignore the establishment of an IRB because the research is low risk or occurs in very rare situations. You may establish an IRB related to competitions based on their published rules. Or you may form what we will call a comprehensive IRB. In many cases, your district's mandate, your institution's policies, and/or other guidelines may have already dictated to you that you must form a comprehensive IRB.

Establishing a Comprehensive IRB Committee

There are many factors to consider when establishing a comprehensive IRB. The Office for Human Research Protections (OHRP) is the federal agency charged with overseeing human subjects research. Their web site contains the guidelines for establishing an IRB: <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm>

Under federal guidelines, your comprehensive IRB must have a minimum of five individuals, including one person who does not have, or has not had, an affiliation with your institution. There needs to be at least one member who is a non-scientist and one member must be someone knowledgeable about the population of subjects that you will be dealing with. You may have more than five individuals, but depending on the size of your institution and the number of proposals that you will need to process each year, it may be most efficient to keep the committee small.

Your IRB must have written policies and procedures. We suggest that you look at the policies and procedures of institutions like your own to begin establishing these. Googling "Institutional Review Board," visiting the IMSA HASRC web site at <https://www3.imsa.edu/learning/inquiry/irb>, or going to a local college's research office web site will provide you with examples of other organizations' IRB policies and procedures.

Your IRB must meet at least once each year and most likely is subject to an *Open Meetings Act*. You will need to establish a regular meeting

schedule, to post that schedule at a specific time prior to the meetings, and to post each meeting's agenda. You must also keep minutes of the proceedings of each meeting.

Include professional development at your IRB meetings. There are many published papers that deal with *mission creep*, non-biomedical research, and other pertinent topics. It is worth the time and effort to review one of these at each IRB meeting. The area of non-biomedical research is fraught with gray areas, so reviewing what the experts are discussing helps keep your committee grounded and focused on its mission. As members become aware of IRB issues, it is easy for them to become increasingly protective, proscriptive, and begin to develop a negative, authoritarian image within your institution. Regular discussions about articles among board members will help this form of mission creep from setting in and keep your board focused on protection of human subjects, though it is tempting (and easy) to digress into commentary on research questions and issues not related to the review (Oakes, 2002; Pritchard, 2001; UIUC Center for Advanced Study; Roberts, Geppert, Coverdale, Louie, & Edenharder, 2005).

Your IRB's Role in Student Research

Once you have established an IRB, you must decide how you are going to review and monitor the work that your students conduct both on and off campus. Suppose your students are conducting research as part of a class to learn about the process, such as by collecting survey data. This is strictly an educational activity, not requiring IRB review. However, this does not mean that students should not be conducting research in an ethical manner. This is an appropriate time to introduce the IRB to your students and to discuss the process. The historical cases of human subject abuse and other case studies can serve to generate discussion. Students should follow the established practices of providing information to potential subjects, obtaining informed consent (a verbal consent in most classroom situations would suffice), allowing students to opt out of participation, and ensuring the anonymity of the participants.

Students should also address research ethics as part of learning about survey design and research with human subjects (Thomas, Goudie, & Shapiro, 2004). Our IMSA IRB (HASRC) has developed written materials for our research course, and occasionally HASRC members participate in classroom discussions about the topic. Students may select topics that could cause other students psychological distress (see risks and harms below), so it is important that the course instructor review student investigations and avoid those that may be harmful.

If your students are conducting research on-campus or off-campus as part of a research program, you may be tempted to call these investigations educational activities and consider them exempt from requiring IRB review (Pospisil, 2004). We have chosen not to do this, your institution's policies may not allow it, and the research competitions that your students may want to participate in may require an IRB. Also consider whether your students may want to present or publish their investigation, such as in the *NCSSMST Journal* - most journals or conferences require that the work have been approved by an IRB.

Also consider your students' research subjects. Often they are minor students at your school and you have a responsibility to ensure that they are treated in an ethical manner. By monitoring what students do at your institution you can also ensure that the burden on individuals and your institution does not become too great. Students can suffer from *survey fatigue*, especially if the surveys are poorly constructed, and then not take seriously the institutional research surveys that you need them to complete.

It is important that the IRB proposal process be thorough but not burdensome on your students. It is especially important that they understand the purpose behind the rigorous IRB protocol. We use the items in Figure 1 to guide the content of the proposal. Students who have written a thorough research proposal can probably complete the IRB proposal in two to three pages (not including surveys or consents), and without a lot of additional time. We consider this a good learning experience for students as they are getting ready

to conduct their own investigation. Our IRB chair generally works with students as they write their IRB proposal and reviews it before submitting it to the committee for expedited review. Our research office staff is also very involved in assisting students with developing surveys, writing consent forms, collecting survey data on-line, and data analysis.

What about students who are working off-campus in businesses or research laboratories using humans or animals? We require that the student obtain and turn in a copy of that business or laboratory IRB (or animal care committee) approval letter. Your IRB has no jurisdiction over what an investigator is doing at another institution as long as it does not involve research using your students as subjects or is not conducted on the premises of your institution. You want to ensure, however, that your students are part of research that is being conducted by established practices and in an ethical manner. Having students obtain a copy of the researcher's approval letter provides an opportunity to teach your students about proper practices in research as they participate in it. We have not had any researcher object to providing this information to a student for inclusion in his or her research proposal. These investigations are all briefly documented in our IRB minutes.

Student Research Case Studies

Our IMSA HASRC reviews fifteen to twenty research proposals each year from students working on-campus, from external researchers who want to use our students or classrooms in their own research, or from our own staff members. Each year there are also one or two proposals from students working off-campus with a researcher that wants to conduct a study on-campus with students or staff members as research subjects. Nearly one-third of the one hundred and fifty students who work off-campus each year will conduct chart reviews, use samples obtained from humans, work with patients, collect data in psychological venues, or participate in research that uses animals – activities which must be reviewed by their respective host institutions.

Students are most engaged in learning when they

can ask their own questions, especially when that question relates to something with which they have personal experience. Below are brief descriptions of typical investigation topics from students that were considered by our HASRC. Following the examples are the types of questions raised by the studies.

PTC Tasting: The ability to taste PTC has different frequencies in different populations, and may be associated with likes and dislikes of various foods, such as broccoli or coffee. We frequently use this in our Methods of Scientific Inquiry course: students can design their own mini-investigation based on PTC tasting. Some students have found literature that suggests that PTC tasting may be associated with a family history of depression (Tepper, 1998). Because this information may impact students regardless of whether they are aware or unaware of such familial health issues, the HASRC ensures that researchers have a plan to deal with this data and student confidentiality.

Left-handedness at IMSA. It has been suggested that individuals who are left-handed are better at math than those who are right-handed, and that women who are left-handed have an increased risk for breast cancer. Your student wants to correlate SAT test scores with handedness.

Teasing: Students react differently to bullying and teasing. There is extensive psychological research in this area. One of your students would like to explore the social characteristics and personality types of students and how they have reacted to being teased when they were younger.

Music and Memory: Much research has been conducted on the effects of music on memory, blood pressure, heart rate, and so forth. Today most students are found walking around and even studying with their iPod. You have a student who would like to determine which types of music affect memory.

Potato Chip Study: Students asked the HASRC to approve a study that measures student snacking while watching television. The research outlines using two different types of potato chips and the

HASRC asked about the nature of the differences in the chips. Students replied that they were just ordinary chips that they would be receiving from their off-campus advisor, the director of a taste and smell institute. Attempts to reach the mentor for clarification failed but HASRC members found on the institute web site advertisements for a food additive that allowed users to “lose weight” while snacking and watching TV.

Social Groups: Prior to community day (an on-campus student research conference) the HASRC was notified of a presentation to be given on student social groups that had not been reviewed by the HASRC. The research consisted of observing students around the school and residential areas of the academy, classifying the students (e.g., jock, chess team member, cheerleader, nerd, druggie, student council member), and then developing social network maps of students observed speaking to one another. Because the classifications involved groups whose members are widely known, or that could have been potentially hurtful, and because the observations involved personal conversations at times when student participants would have reasonably expected privacy, the HASRC prevented the research from being presented.

Case Study Questions

The above are only a few examples of the types of proposals that our HASRC faces every year. The IRB proposal in Figure 1 is an important first step in enabling your IRB to begin to address the issues related to research proposals, including:

- Are the investigations permissible for students to conduct?
- What would your IRB want to consider when determining whether to approve a specific student investigation about the above topics? For example, would informed consent be required?
- How might the investigator minimize psychological distress?
- Are there conditions under which any of these studies would not be allowed? What are the conditions under which you would allow these studies to occur?

Biomedical versus Non-biomedical Research and Definition of Risk

While the risks and harms to individuals seem straightforward when the research is biomedical, non-biomedical research presents huge challenges in determining risk and harm to individuals. Risks and harms include inconvenience, physical harm, psychological harm, social harm, economical harm, and legal harm. The American Educational Research Association (<http://www.aera.org>) has a working group that has detailed these harms in relation to non-biomedical research and the ways that they can be prevented. Their web site and white papers in this area are valuable reading.

Psychological harm, which is of great concern in non-biomedical research, is challenging to predict and prevent. It is especially challenging in our typical population of research subjects – teenagers. One does not know what personal question will spark a serious reaction or memory in one student, but not in another. We have chosen not to avoid these subjects and instead carefully review the proposal. We often require informed consent and that data collection take place when a skilled staff member is available to counsel students or ensure that students seek assistance from one of our counselors if they are distressed by the questions. And there are some research questions that we do not allow students to pursue.

Your IRB's Role in Protecting your Students as Research Subjects

In addition to working with students to ensure ethical conduct during their own investigations, there are many instances requiring the oversight of the IRB for cases related to the use of institutional data, student records, or direct student participation.

Institutional Research: Institutional research refers to the practice of collecting and maintaining data to demonstrate the effectiveness of institutional programs. This includes not only traditional student records, but may include information collected for the purposes of demonstrating fulfillment of your institutional mission.

It is important that you not only have a good

sense of the records kept by your institution, but also that you develop written policies for their custodianship, use, and eventual destruction. In most cases there are clear state laws or policies dictating how long student records are kept and who may access the records. One of the key points of the definition of a research subject is related to identifiability, so whenever possible names and other identifying information should be removed from data for long term storage. Maintenance and use of this data is also subject to the Family Educational Rights and Privacy Act (FERPA), a federal law that protects the privacy of student educational records.

Teacher Research and Action Research:

It is very common for teachers and administrators who are seeking advanced degrees to engage in classroom research activities that utilize their students. It is important to note that, while these are classroom activities with respect to the teacher being the learner and may be exempt in terms of their university IRB, the involvement of students on your campus puts these activities under your purview. Your faculty and administration should be aware that the use of their classrooms or students means that the work should be reviewed by your IRB. It may be that the IRB determines the work does not fall into the category of generalizable results, though the issue of dissemination should also be carefully considered since IRB approval is required unless there are no plans for dissemination that may compromise student identities.

Your institution may also need to review existing policies regarding research consent. As a laboratory school, all IMSA students sign a consent form indicating that portions of their student records may be confidentially used for research purposes. As with teacher action research, the IRB will consider whether the research is simply meant to be used in-house, as traditional action research, or if the possibility exists that the staff member may eventually wish to publish or present the results.

External Research: Working in a school with a special population, it is likely that you will be

asked to make your students available as research subjects by a researcher external to your institution. Again, because you are working with a special group of subjects, this type of research should always be reviewed by your IRB. We have often received pressure from a researcher who believes that their project is exempt from IRB review because of minimal risk. The single most important rule that your IRB members can learn is that exemption is determined by the IRB, not the researcher. Nobody can ever tell the IRB that his or her research is exempt, period.

When working with external researchers it is also important to consider jurisdiction. An IRB has sole authority on its campus. External researchers may have already approached their own IRB, but the board at hypothetical University X can only provide conditional permission for the researcher to do work on behalf of the institution. The review undertaken by your school IRB issues the binding ruling about any work conducted on your campus and with your students.

Retroactive Review

As mentioned in the institutional research section, institutional data collected on students in the past remains subject to IRB review and oversight. One of the most common problems that the IRB experiences is when a student or staff member begins conducting research and only later approaches the IRB for a retroactive review. An IRB must be prepared to respond to the statement "I wasn't planning on presenting it when I collected the data, but now that I see the results I want to. I am free to use existing data, right?" As difficult as the conversation may be, this is operationally an unintentional (or intentional) means of circumventing the IRB. It is important for staff and students to understand that if they think that they might some day want to present or publish work derived from the data, the data needs to be collected from the beginning with IRB approval.

There may be a difficult day when you will have to end a student or staff research project because of IRB violations. Existing institutional data collection is done with established policies guiding its use

and the protection of students. It is important that the IRB process become part of your institutional culture and an expected early step when planning a research effort.

In Conclusion

Establishing your own IRB protects your students and also protects your institution. It is an excellent way for you to model professional behavior with your students. IMSA and its HASRC have decided to embrace all forms of student research as well as research using our students as subjects, providing that the investigations can be conducted in an ethical manner and that students are kept in as safe an environment as we can maintain. Some institutions choose not to allow students to conduct surveys as part of research investigations. There can be good reasons for this, including not having the ability to monitor these effectively or not being able to provide counseling services if required. Student generated questions can be valuable for your institution, and since students own their own questions, these investigations are generally very meaningful to the student and the students are highly engaged.

How to Learn More

There are many excellent resources available about establishing an IRB, the use of human subjects in research, and the various gray areas of non-biomedical research. Following are just a few that we recommend for both experienced individuals and novices to this field.

- Additional historical cases as well as questions to use with students: <https://www3.imsa.edu/learning/inquiry/irb>
- Dept. of Health and Human Services – Office for Human Research Protections (OHRP): <http://www.hhs.gov/ohrp/>
- OHRP IRB guidebook: http://www.hhs.gov/ohrp/irb/irb_guidebook.htm
- American Educational Research Association (AERA): <http://www.aera.net/>
- AERA: Social and Behavioral Sciences Working Group on Human Research Protections: <http://www.aera.net/humansubjects/risk-harm.pdf>

- IRB Forum: <http://www.irbforum.com>
- International Science and Engineering Fair human subjects documents: <http://www.societyforscience.org/sts/intfrm.pdf>
- Siemens criteria for live subjects: <http://www.collegeboard.com/student/pay/scholarships-and-aid/45104.html>

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Author Information

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