INTRODUCTION TO THE PROCESS OF THE INSTITUTIONAL REVIEW BOARD (IRB) FOR RESEARCH WITH HUMAN SUBJECTS

Introduction to the Process of the Institutional Review Board (IRB) for Research with Human Subjects
Presented by
Elizabeth J. Sandell, Ph. D., Assistant Professor
Minnesota State University, Mankato, Minnesota
Compiled by:
Patricia M. Hargrove, Ph.D., IRB Coordinator
Minnesota State University, Mankato, Minnesota
And
Anne Blackhurst, Ph.D., Dean and IRB Administrator
College of Graduate Studies and Research
Minnesota State University, Mankato, Minnesota

Abstract

During the past 50 years, law-makers and researchers in the United States have sought legal and procedural methods to reduce risks and harms to research subjects. An important process has been the creation of IRBs at institutions of higher education. The purpose of laws and rules about research review are to:

· Safeguard the rights and welfare of human subjects in research and related activities.

· Assist faculty to avoid the possibility of unknowingly committing unethical acts.

This article describes three principles of conducting research with human subjects, steps in applying for IRB approval, three levels of research that require IRB review, characteristics of an informed consent form, and some cases for discussion and application of the principles.

Краткий обзор

За последние 50 лет законодательные органы и исследователи США разработали законный метод защиты человеческого фактора в процессе исследования, который снижает риск и защищает человека от разрушительного воздействия. Этот важный процесс был разработан IRB в институте высшего образования. Цель законов и правил:

· Защита прав и благополучия человека как предмета исследования в процессе проведения исследовании и относящихся к нему действиях.

· Ассистирование сотрудников факультета во избежание случайного или непреднамеренного совершения неэтичных действий.

Эта статья объясняет три принципа проведения исследования с включением человека как предмета исследования, шаги применения предложений IRB, три уровня исследования согласно требованиям IRB, характеристики формы согласия на получения информации, некоторые случаи/примеры для обсуждения и применения этих принципов.

Introduction

Throughout human history, scientific research with human subjects has resulted in many benefits in terms of reducing disease, treating illnesses and disabilities, and improving education and social services. However, there have been times when such research resulted in considerable risk and harm for the human subjects involved. This article describes processes of Institutional Review Boards (IRBs) to monitor research in higher education and research institutions in order to protect human subjects of that research.

During the past 50 years, law-makers and researchers in the United States have sought legal and procedural methods to reduce these risks and harms. An important process has been the creation of IRBs at institutions of higher education. The purpose of laws and rules about research review are to:

· Safeguard the rights and welfare of human subjects in research and related activities.

· Assist faculty to avoid the possibility of unknowingly committing unethical acts.

The 1974 National Research Act resulted in the establishment of IRBs at universities throughout the United States. The National Research Act

· required IRB approval for most human research conducted by faculty and staff members in higher education settings

· defined the policies and procedures that must be followed in IRB research

· established the national Commission for Protection of Human Subjects that issued a number of reports, including the Belmont Report, which is very important to current IRBs.

Some activities are <u>not</u> reviewed by the IRB. These activities include classroom activities, laboratory courses, or field assignments are normally not classified as research and typically are <u>not</u> reviewed by the IRB. These types of activities are considered to be exempt from IRB review.

Principles for Conduct of Research with Human Subjects

The Belmont Report was issued by the national Commission for Protection of Human Subjects in 1978. This report outlined three principles for conduct of research with human subjects: (a) Respect for Persons; (b) Beneficence; and (c) Justice.

Respect for Persons

The principle of "Respect for Persons" implies that research participants have the right to autonomy and self-determination, as well as the right to protection, in the case of vulnerable subjects. Investigators need to maintain the right of each person to determine his or her own identity. Researchers also need to protect persons such as children (who have special intellectual capacities and legal status in society), prisoners (who have forfeited basic personal liberties) and people with certain conditions (such as dementia or diminished capacity for self-determination). The principle provides that people who have diminished autonomy are entitled to protection in order to prevent exploitations.

IRBs' procedures offer protections to persons with diminished autonomy, such as:

(a) Researchers must exclude those with diminished autonomy; however, this has drawbacks too (prevention may violate respect for person principle because it denies self-determination)

(b) Researchers must get informed consent from 'well-educated and properly motivated surrogate decision maker' and obtain 'assent.'

(c) Researchers could test the research subjects' comprehension of important aspects of consent document before implementing the research.

In order for a researcher to demonstrate "respect for persons," the IRB requires that the investigators avoid coercion or undue influence, provide informed consent, maintain privacy and confidentiality, and insure the right to withdraw from participation without penalty.

Investigators must avoid coercion or undue influence over the research subjects. In fact, they must foster voluntary actions by the research subjects. Coercion occurs when the participants are in some way being force or strongly encouraged to be in the research. This force or strong encouragement is considered to be "undue influence." Instead, researchers must take care to be sure that participation is voluntary.

One way to show respect for persons is to inform the subjects about the research and obtain their consent to participate. The IRB requires that this be done before initiating any research with human subjects. Consent must be obtained from the subject/participant, or a legally authorized representative. That is, the person giving the consent must be informed and competent to make a decision. The person giving the consent must understand the consent form. The consent must be voluntary, without any penalty.

"Respect for persons" also means that investigators will respect the subjects' privacy and confidentiality. Privacy means that subjects have freedom (a) from intrusion, (b) from being observed by others, (c) from being seen, heard, or disturbed by others, or (d) having control over the extent, timing, and circumstances of sharing oneself (physically, behaviorally, intellectually) with others. Confidentiality means that the research is carried out under the expectation that anything done or revealed will be kept quiet in ways that are consistent with the understanding of the original research agreement. Possible harm associated with this principle may include "social harm" when it compromises an individual's or family's reputation or has an impact on their financial status, employability, insurability, stigmatization, or discrimination.

Beneficence

The principle of "Beneficence" implies that researchers should use procedures that insure the well-being of research participants and should balance the benefits of research with the benefits to the individual and to society. Beneficence means generosity or charity, including good or charitable acts, especially such as a generous gift. The idea is that research should maximize potential benefits and minimize potential risks to the research subjects.

Under the principle of "Beneficence," IRBs require investigators to: justify the risks of research by the potential benefits to subjects and/or society, design the study so that risks are minimized, and manage conflicts of interest adequately.

Justice

The principle of "Justice" calls for investigators to distribute the risks and potential benefits of research equally among those who may benefit from the research. Therefore, the risks should be borne by those who are likely to benefit from the research. This requires that the IRB review the characteristics of the population under study.

IRB requirements mean that the researchers must avoid targeting vulnerable subjects simply for convenience. Therefore, investigators must select research participants for reasons directly related to the research question; they must not select participants simply because they are easily available from among groups such as welfare recipients, prisoners, people confined to specific institutions, or specific racial or ethnic minorities.

IRB requirements also mean that researchers must avoid systematically excluding people who are likely to benefit from participation in the research. Historically, certain groups and classes of persons have been excluded from research (e.g., women of child-bearing age). When this occurs, potential benefits are missed.

Steps in Applying for IRB Approval

There are several steps to follow for a researcher to apply for IRB approval of their study:

1. The Principle Investigator (PI) must be university faculty or staff.
2. Go to the IRB webpage (http://grad.mnsu.edu/irb/) for information and procedures.
3. Review the IRB Information and IRB Proposal Guidelines.
4. Complete the application (according to the IRB Proposal Guidelines).
5. Submit the application to the IRB.
6. After the IRB gives approval, the investigators begin data collection.
7. Notify the IRB if there are any changes to the research design or data collection procedures.

Three Levels of Research

In general, there are three levels of research that require IRB review: (a) research with less than minimal risk, (b) research with minimal risk, and (c) research that involves serious risk. IRB procedures encourage the principle investigator to consult with the IRB Administrator, IRB Coordinator, and IRB Co-Chair(s) when trying to determine the level of the research or even if the project qualifies as research that is reviewed by the IRB.

Level 1: Less than minimal risk

Researchers in Level 1 may use data collected from pre-existing records or with standardized educational tests, surveys, interviews, and/or observations of public behavior. Existing public records do not require prior consent of subjects to review the records. In this type of data, individual participants cannot be identified directly or indirectly and disclosure of information does not put participants at risk for harm. IRB review of this type of research will be very straightforward and generally, very fast. Researchers are cautioned that review of private records involving access to and/or recording of identifiable information are not eligible for Level I review, and still requires written consent of the study subjects.

Level 2: Minimal risk

Researchers doing Level 2 research may record identifiable information, but with minor risks. This type of data may be about individual or group behavior and/or about characteristics of individuals. Data may be collected from studies of perception, game theory, or test development.

For research in Level 2, the investigator does not manipulate subjects' behavior and the research will not involve stress to subject. Recording of non-invasive data includes many types of data that are not necessarily used in educational research. Examples of Level 2 research include (a) recording of data from subjects 18 years of age or older by using non-invasive procedures routinely employed in clinical practice or (b) collection of blood samples in amounts not exceeding 450 milliliters in an eight-week period and no more often than two times per week.

Level 3: High risk

Research in Level 3 involves the most serious risks, including the potential for criminal or civil liability or the potential for damage to the participant's financial standing, employability, reputation, or health. Research in this category is unlikely to be approved in our departments of education in post-secondary education institutions.

Characteristics of an Informed Subject Consent Form

A good informed subject consent form will include these elements:

1. Purpose of research: Be sure to use the actual word "research."
2. Note that participation in the research is voluntary, without duress or extraordinary benefit. Participants should be informed that should they are free to refuse to provide consent or free to withdraw from the research at any time without fear of reprisal.
3. Research procedures. Note that, if a survey is used, subjects may skip items if they desire.
4. Risks and discomforts. Note that it is rare that research involves no risks at all. Even if the only problem is that the participant's/ subject's name could be revealed if there was a breach of security, it is still a risk.
5. Potential benefits. Be realistic. Be clear about possible benefits to the subject, to the community, and to others.
6. Alternative treatments for intervention research. If there are legal alternatives, identify the choices that research subjects might make in addition or in lieu of participating in this research.
7. Details of actions to protect confidentiality. Include a description of how the confidentiality of records (including consent forms) that may identify subjects will be maintained or stored. If the research will use the internet, explain that security can be breached and the steps you are taking to minimize risk.
8. An "assent form" for minors or vulnerable adults.
9. Contact information for principle investigator (who must be a faculty or staff member), student investigator (optional), or the IRB administrator.
10. Signatures of all investigators.
11. Number on each page.

Case Studies for Discussion

CASE # 1: A researcher wants to investigate the social experiences of elementary school children from migrant families. To obtain consent to interview the children, she sends a consent form home to their parents.

CASE # 2: A researcher wants to investigate the career aspirations of inner city youth. She advertises her study by posting fliers in several community centers. The fliers state that participants will be given an iPod in exchange for their participation.

CASE # 3: A researcher wants to study the effects of a stress reduction technique. She contacts a local halfway house and requests permission to recruit residents to participate in her study.

CASE # 4: A graduate student in English wants to compare the composition skills of high school students who are English language learners with students for whom English is their first language. She contacts a local high school teacher and requests access to students' writing assignments. The assignments will not include students' names. She contacts a local high school teacher and requests access to students' writing assignments. The assignments will not include students' names.

CASE # 5: A researcher wants to study the social networks that often form in assisted living facilities and long-term care facilities for older adults. She plans to obtain informed consent from the residents before conducting individual interviews and focus groups to explore the role of social networks in their lives.

CASE # 6: A researcher wants to investigate the effectiveness of an employee assistance program for chemically dependent employees. She contacts a local corporation for permission to deliver the program at their corporate headquarters. She plans to obtain informed consent to collect data on substance use and absenteeism from employees who voluntarily participate in the program.

CASE # 7: A researcher is interested in how teen girls make decisions about protection against unwanted pregnancy and against sexually-transmitted diseases. She plans to recruit girls who seek contraception or pregnancy counseling at a local Planned Parenthood clinic and interview them about their sexual histories and sexual decision making.

Conclusion

Following IRB review procedures helps protect researchers from potential issues and possible damage to persons or the community. When faculty peers are members of the IRB, they can help specify procedures and research designs to improve investigator ethical behavior.

Bibliography

Amdur, R.J., and E.A. Bankert. (2007). *Institutional Review Board: Member handbook* (2nd ed.) Sudbury, MA: Jones and Bartlett.

Institutional Review Board. (2008). *Institutional Review Board Procedures.* Mankato, MN: Minnesota State University, Mankato. Retrieved on May 23, 2008 from http://grad.mnsu.edu/irb/

☼