Ensuring the Rights of Study Participants

Resource Documents for Philanthropic Organizations

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Prepared by: BTW informing change
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Preface

ABOUT BTW informing change

At BTW we are driven by our purpose of informing change in the nonprofit and philanthropic sectors. We partner with our clients to improve their effectiveness and build a culture of learning and continuous improvement through applied research, evaluation, and strategy projects. We develop products that present useful information in an easy-to-understand format, designed to be readily applied to practice. Our information-based services focus on the fields of health, education, youth engagement, and philanthropy.

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Overview

PURPOSE
When conducting evaluation or research studies, it is important to ensure that the people who participate in these projects are treated fairly, equitably, and with the utmost respect.

Federally funded evaluation and research studies are required by law to protect human subjects—study participants—through an Institutional Review Board (IRB).\(^1\) For other studies that are not under the same legal obligation, going through an IRB process acts as a safeguard to ensure that the study design meets ethical standards. The actual ethical implementation of the study is ultimately the responsibility of the study investigators. Thus, it may be that a study involving individuals is not reviewed by an IRB, but is still implemented with rigorous ethical standards.

The purpose of these resources is to provide basic knowledge and useful tools necessary for staff in philanthropic organizations to spot potential issues for their grantees to consider to ensure ethically sound studies that involve individuals. For example, the resources can be used when:

- Reviewing grants, contracts, and program-related investments (PRIs) that a foundation directly supports
- Guiding and working with grantees tasked with evaluating other grantees’ work and/or the foundation’s strategies

While these documents cover topics that can be applied to all types of evaluation or research studies involving individuals, they are primarily written for US-based projects. Rules, regulations, and procedures can vary in other countries.

KEY DEFINITIONS

Evaluation: The systematic determination of merit, worth, or significance of something for the purpose of developing or contributing to a body of knowledge.

Research: A systematic investigation or experimentation to establish facts or advance knowledge.

IRB (Institutional Review Board): A committee that reviews evaluation and research plans and materials to ensure that the rights and welfare of individual participants are protected.

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\(^1\) In this capacity, the term “human subjects” is defined as living individuals/human beings; it does not include deceased individuals or other animals.

\(^2\) There are a number of cases where studies not funded by the federal government are also obligated to obtain IRB approval. These include studies involving children and public schools, or studies that will be published in a peer-reviewed journal.
WHAT IS IRB?

An Institutional Review Board (IRB) is an independent committee of at least five individuals (from different relevant academic disciplines) who function as “human subjects protection” advocates. The IRB reviews protocols (e.g., surveys and focus group discussion guides) and related materials (e.g., informed consent documents and investigator brochures) in order to:

- Assess the ethics of the study and its methods;
- Promote fully informed and voluntary participation by prospective participants who are capable of making such independent choices; and
- Maximize the safety of participants once they are enrolled in the study.

ENSURING THE RIGHTS OF RESEARCH AND EVALUATION STUDY PARTICIPANTS

The steps necessary to ensure that individuals are protected in evaluation and research studies vary according to the issues of each particular project and the nature of the organization conducting the study.

Universities are required to submit all of their evaluation and research plans to an IRB regardless of the scope of the project. Many large, research-focused organizations are very familiar with the IRB process and may even have a similar requirement. However, small organizations and independent consultants may have limited experience with IRB and may need guidance on how to minimize the risks within their studies and, if appropriate, whether to consider IRB approval. Independent firms provide IRB services on a contract basis to these types of organizations.

USING THESE RESOURCES

Among these resources, the Issue Spotting Guidelines and Data Collection Decision Tree will help to identify if there may be a potential risk to individuals participating in a study and to determine potential next steps. The next steps could range from simply taking extra precautions in the study design to highly considering an IRB process. It is important to note that these guides are not meant to replace the IRB process if it is warranted, nor help users determine the level of IRB review that may be required (i.e., exempt, expedited or full).

These resources also contain examples of the IRB process, participant consent forms, and IRB language for interview protocols.

Studies presenting minimal risk should be handled diligently, but expeditiously, while those involving high risk should receive extra time and attention. Even if a study does not warrant an IRB review, study leaders should take steps to provide the appropriate protections of study participants (refer to the definition of standard ethical guidelines in the Definition Guide document).

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3 If this is not possible, then informed permission is given by a suitable proxy.
Depending on certain risk factors, some researchers and evaluators should go through an official IRB process. If a study includes any of the following, an IRB review should be highly considered:

- Participants will experience risks that may be deceptive, psychological, coercive, and/or physical.
- Participants are considered part of a vulnerable population—children and adolescents, pregnant women, prisoners, homeless people, or people with chronic diseases or mental illnesses.
- The data collected in the study are sensitive and/or identifiable.
- The results will be published in a peer-reviewed journal.\(^4\)

**Disclaimer:** These documents do not constitute legal advice. They are meant to educate readers about the protection of study participants and introduce them to the IRB process.

\(^4\) Peer-reviewed journals require research or evaluation to be conducted with IRB approval.
Tools & Guidelines

- Issue Spotting Guidelines
- Data Collection Decision Trees
This list of **Issue Spotting Guidelines** is designed to help staff in philanthropic organizations identify potential issues related to protecting the rights of individuals who participate in evaluation or research studies conducted by the foundation’s grantees or contractors. The guidelines are described in greater detail in the following pages.

### A. Potential Risks
- Does the study pose potential risks (e.g., physical, psychological, legal, economic, social)?
- Are risks to participants minimized?
- Are risks to participants reasonable in relation to anticipated benefits?

### B. Equitable Selection
Is participant selection equitable?

### C. Informed Consent
Are there appropriate processes for:
- Disclosing information to potential participants?
- Ensuring that participants clearly understand the nature of the study?
- Ensuring that individuals voluntarily agree to participate?

### D. Privacy & Confidentiality
- Does the study make adequate provisions to protect the privacy interests of participants?
- Does the study make adequate provisions to maintain the confidentiality of data?

### E. Identifiable & Sensitive Information
Will identifiable and/or sensitive information be collected about participants?

### F. Vulnerable Populations
- Are there measures in place to protect vulnerable populations?
- Does the study include collecting data from children?

### G. Research in Public Schools
Will the study be conducted in public schools?

### H. International Research/Evaluation Studies
- Have social and cultural factors been taken into account in planning international studies?
- Have political and legal factors been taken into account in planning international studies?

### I. Publishing Findings
Are there plans to publish the study’s findings in peer-reviewed journals?
A. POTENTIAL RISKS

Study participants must not be put in a situation where they might be at risk of harm as a result of their participation. If there is a risk of harm, steps must be taken to minimize the risk to the extent possible.

Key Questions for Potential Risks Issue Spotting:

- Does the study pose potential risks (e.g., physical, psychological, legal, economic, social)?
- Are risks to participants minimized?
- Are risks to participants reasonable in relation to anticipated benefits?

Common social and behavioral research and evaluation data collection methods include surveys, individual and group interviews or observations, record and database analyses, experimental interventions, and manipulations of an individual’s environment. All of these methods range in risk level due to the nature of how information is obtained from participants. For example, observing public behavior is significantly less risky than conducting interviews.

Potential harms to individuals who participate in social and behavioral studies are generally non-physical; nevertheless, these harms must still be taken seriously. Even basic surveys or interviews have the potential to cause psychological harms, such as discomfort, stress, anxiety, pain, trauma, guilt, or instability; or social harms, including disruption of family and social relationships, stigmatization, or damage to an individual’s reputation, employability, insurability, or financial standing.

In addition, the study design and methodology should take into account any potential real or perceived conflicts of interest between the study investigators and their organization, the study funder (if applicable), and/or the participants.

If potential risks are identified in a study design, it will be important for funders to explore with the study investigators whether or how these risks could be minimized. The design should not only minimize risk to the fullest extent, but also take into account the anticipated benefits (e.g., participants’ personal well-being, the contribution of general knowledge within an ethical context) of putting participants in any type of risky situation.
B. EQUITABLE SELECTION

All study participants should be treated fairly and equitably in every aspect of recruitment, enrollment, treatment, and compensation.

Key Question for Equitable Selection Issue Spotting:

Is participant selection equitable?

Defining the appropriate group of participants for a study involves a variety of factors—requirements of the study design, susceptibility to risk, likelihood of benefit, practicality, and fairness. It is important to pay particular attention to the needs and issues of vulnerable populations—children, prisoners, pregnant women, mentally disabled persons, or economically/educationally disadvantaged persons—while at the same time to be careful not to overprotect vulnerable populations so that they are unnecessarily excluded from participating.

To determine whether participant selection is equitable, the study investigators should consider the following issues:

- What is the purpose of the study?
- What is the setting in which the study will be conducted?
- Will prospective participants be vulnerable to coercion or undue influence to participate?
- What are the selection (inclusion/exclusion) criteria?
- How will participants be recruited and/or enrolled?
- (If applicable) What is the amount and timing of payments/rewards to participants?
C. INFORMED CONSENT

Prospective study participants must be fully informed about and understand the purpose of the study, including the duration of participation, procedures/methods, risks and benefits, and the terms of confidentiality. Finally, their participation must be voluntary—and they must know this—at every point in the project.

Key Questions for Informed Consent Issue Spotting:

Are there appropriate processes for:

- Disclosing information to potential participants?
- Ensuring that participants clearly understand the nature of the study?
- Ensuring that individuals voluntarily agree to participate?

Informed consent can be verbal or written, depending on the risks that participants may experience. The informed consent process involves three elements: information, understanding, and voluntariness.

Disclosing Information

There are eight basic elements of information to disclose to prospective participants during the informed consent process (some elements may not be required in all studies, depending on the particular study).

1. A statement of the type of study (evaluation or research), its purpose, the expected duration of participation, and the study process

2. A statement describing the extent to which any confidential records will be maintained

3. The contact person for questions about the study, its procedures, and participants’ rights

4. A statement that participation is voluntary, can be discontinued at any time, and that refusal to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled

5. A description of any potential benefits to the participant or others from the study

6. A description of any reasonably foreseeable risks or discomforts to the participant

7. (If applicable) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the participant

8. (If applicable) For studies involving more than minimal risk, an explanation regarding whether any compensation is available

Ascertaining Understandability

Informed consent conversations and written materials should be in simple, direct language so that participants clearly understand what is being communicated. All communication should be modified to the individual’s capacities and characteristics. For example, if the participant has limited English proficiency, consent documents and conversations should be written in simple English or translated into the participant’s native language. The study investigator must take all reasonable measures to ensure that the participant understands the information.
Ensuring Voluntary Participation

The informed consent process should provide an opportunity for participants to make informed decisions about participating in the study. Participants should be given the time and space to consider the information they receive and to ask any questions. A central goal of the informed consent process is to ensure voluntariness, so steps should be taken to ensure that there is no coercion and undue influence shaping participants’ decisions. It is also important for the informed consent process to take place throughout the implementation of the study so that participants can have any concerns addressed on an ongoing basis.

If a study is conducted with individuals who have “diminished autonomy” (e.g., children), consent should generally be obtained from an individual who has the legal authority to make decisions about the individual’s participation. However, even when parental permission is obtained, children are not obligated to participate in a study. In most cases, investigators must also receive assent from children in an age-appropriate manner (i.e., verbal assent from young children and written assent from older children). All study participants should have the opportunity to choose, to the extent that they are able, whether or not to participate in the study.
**D. PRIVACY & CONFIDENTIALITY**

Study investigators must protect the confidentiality and privacy of participants through the informed consent process, the methods for obtaining data, the storage of data, and the reporting of the data collected.

**Key Questions for Privacy and Confidentiality Issue Spotting:**
- Does the study make adequate provisions to protect the privacy interests of participants?
- Does the study make adequate provisions to maintain the confidentiality of data?

Privacy addresses whether the investigator has legitimate access to information for research or evaluation purposes. Confidentiality addresses whether there are sufficient protections against unauthorized disclosure of information once information has been obtained.

Study protocols should ensure that data privacy and confidentiality are commensurate with the degree of risk associated with the type of data collected.

**Methods of Protecting Participant Privacy & Confidentiality of Data**

Methods to protect the confidentiality of data include: legal agreements (e.g., data use agreements), encryption and codes, locked storage files or rooms, limiting access to certain staff, and keeping paper files at particular sites. If codes are used, it is important for investigators to consider who holds the link to identities and how the data are stored. For example, if identifiable information is replaced with codes, the file explaining how codes were created should be kept in a separate file that is not easily accessible.

**Informing Participants About Privacy & Confidentiality**

During the informed consent process, participants should be informed about who will have access to the data and for how long; what data security measures will be employed; and what, if anything, will be disclosed to others, by whom, and under what conditions. If sensitive and/or identifiable information is being collected, participants should be informed about the harm that could occur in the case of privacy breaches. If the only identifier linking a participant to his/her data is a written informed consent document, the option of an alteration or waiver of consent to protect confidentiality may be needed.

It is important to use the correct terminology when informing participants about privacy measures for a study. Anonymity means that the study does not collect identifying information of participants (e.g., name, contact information) or cannot link specific responses to participants’ identities. Confidentiality, on the other hand, means that the investigator can identify the individual responses of participants, but measures are taken to ensure that the identifying information is not released to anyone outside the study.
E. IDENTIFIABLE & SENSITIVE INFORMATION

Collecting **sensitive** information, particularly with **identifiable** information, is considered **high risk**. When collecting sensitive information, funders should discuss obtaining IRB approval with study investigators.

**Key Question for Identifiable and Sensitive Information Issue Spotting:**

Will identifiable and/or sensitive information be collected about participants?

Information is considered individually identifiable when the data elements have personal information that can be linked to an individual’s identity or other characteristics that (alone or in combination) could allow the person to be identified. Potential identifiers include name, birth date, dates of hospital admission and discharge, dates of diagnosis, zip code, Social Security number, and demographic details.

Information is considered sensitive if it might cause perceivable damage to someone or something if it is revealed to people who are not entitled to the information. Examples include HIV status, religious beliefs, sexual history, information about drug use, and information about prescribed medications.

Study investigators should take measures to keep identifying and sensitive data secure at all stages of the study—from the time information is collected through the completion of analyses and publication of results—and for as long as the data are stored.

**Reporting or Publishing Sensitive Data**

Along with taking measures to store identifying and/or sensitive data according to the study’s confidentiality procedures, investigators must also ensure that the information reported at the end of the study follows the original disclosure agreement that participants agreed upon. In most cases, reporting sensitive data should not be identifiable to a specific individual.
F. VULNERABLE POPULATIONS

Study designs should include special measures to protect the rights and welfare of vulnerable populations. Unless it is considered minimal risk, any study that involves vulnerable populations should be considered for IRB approval. **In the case of a study dealing with vulnerable populations and sensitive data, IRB approval is strongly recommended.**

**Key Questions for Issue Spotting with Vulnerable Populations:**

- Are there measures in place to protect vulnerable populations?
- Does the study include collecting data from children?

In general, the following types of individuals can be considered to be vulnerable to coercion or undue influence in a study setting:

- They have difficulty providing voluntary, informed consent (e.g., children)
- They live in special situational circumstances, as in the case of prisoners or the homeless
- They are at a higher risk for exploitation (e.g., the terminally ill)

Conducting evaluation or research studies with vulnerable populations requires special measures to protect the rights and welfare of these individuals, especially the criteria for selecting participants, procedures for obtaining informed consent and ensuring voluntary participation, and possible sources of coercion and undue influence. The study design should consider the nationality, ethnicity, and socioeconomic status of potential participants. Throughout the implementation of the study, investigators must be mindful of whether they are putting the vulnerable population at a specific disadvantage, ensuring that every step in participation is understood (e.g., translating documents to appropriate languages), and ensuring that the participants are comfortable declining participation and/or have no incentive to lie.

Recruiting children for research or evaluation study purposes poses specific risks because children often have limited ability to provide informed consent. For example, children may not understand the concept of voluntary participation and may not know that they can withdraw at any point. Therefore, any study involving child/youth participation should have appropriate parental permission and child assent processes. In addition, it is important to consider the sensitivity of the data being collected (e.g., asking a child about his/her opinion about a class is not nearly as risky as asking him/her about sexual activity). **Any study that entails collecting sensitive information from children should seek IRB approval.**
G. RESEARCH IN PUBLIC SCHOOLS

Because schools that are public are federally funded, they are also governed by federal laws and regulations. Consequently, any study that is conducted in public schools must follow the federal regulations that are in place, including written consent by parents/legal guardians of student participants. Study investigators who collect data in public schools should consider seeking IRB approval, unless the method used is observation; investigators may also consider similar procedures when collecting data in private schools.

Key Question for Issue Spotting in Public School Research:

Will the study be conducted in public schools?

Conducting research in public schools introduces multiple challenges; there are federal regulations and laws that apply specifically to studies done within public schools.

The Family Education Rights and Privacy Act (FERPA) gives parents certain rights over the content of their children’s educational records. As a result of FERPA, schools must have written permission from the parent or eligible student before releasing any identifiable information from a student’s record, such as religious affiliation, citizenship, disciplinary status, attendance, gender, ethnicity, grades/exam scores, and progress reports.

The Protection of Pupil Rights Amendment (PPRA) is designed to provide parental control over the content of surveys, particularly in cases when surveys inquire about sensitive information. Sensitive information includes the following eight categories:

1. Political affiliations or beliefs of the student or the student’s parent
2. Mental and psychological problems of the student or the student's family
3. Sexual behavior or attitudes
4. Illegal, anti-social, self-incriminating, or demeaning behavior
5. Critical appraisals of other individuals with whom students have close family relationships
6. Legally recognized privileged or analogous relationships, such as those with lawyers, physicians, or ministers
7. Religious practices, affiliations, or beliefs of the student or student's parents
8. Income (other than that required by law to determine eligibility for participation in a program or for receiving financial assistance under such a program)

Studies that entail collecting data in public schools should consider seeking IRB approval.
H. INTERNATIONAL RESEARCH/EVALUATION STUDIES

Study investigators will come across many more contextual issues when working in another country due to different cultures, social factors, politics, laws, and regulations. A local country expert should be consulted to determine whether or not the study should seek IRB approval.

**Key Questions for Issue Spotting with International Research/Evaluation:**

- Have social and cultural factors been taken into account in planning international studies?
- Have political and legal factors been taken into account in planning international studies?

While the fundamental principles (i.e., respect, beneficence, and justice) in protecting the rights of study participants should be used in research and evaluation studies conducted in any locality, the international realm creates another level of complexity. These issues arise when considering the contextual background of the host country, which includes cultural and social factors, political conditions, laws, and regulations.

Understanding and following US ethical guidelines and regulations may not be sufficient; other countries may have systems that are more or less developed and may require taking additional measures. Because there currently are no established and agreed upon guidelines, regulations, or codes for international research and evaluation, study investigators must use their own judgment and vigilance to ensure ethical standards are upheld.

The social and cultural norms to consider in conducting international studies include a population’s values and ethics, codes of conduct, traditions, and language differences, all of which can create barriers to the study. For example, protocols and consent forms may need to be translated into other languages—and they should also be translated so that specific terminologies *mean* something to the population. Another important factor could be the established legal age for an adult, which varies from country to country.

In addition to the social and cultural context of a country, there are legal implications that must be followed. There could be governmental regulations and laws that are in place, or even lacking, that may require certain modifications of the study. Funders will want to ensure that investigators decide what ethical standards will be used and whether those standards align with what is allowed in that country. There may also be existing organizations that oversee the protection of study participants, where cooperation and collaboration may be needed.

Because of the differences in each country, it is suggested that funders ensure that investigators consult a local expert before deciding whether or not the study is appropriate or if an IRB review is required. These local experts must be knowledgeable about the country and local community to be able to provide recommendations on the design of the study to follow ethical codes. While designing the study, logistical issues should also be considered, including:

- What national or international standards will be used?
- What are the legal and/or appropriate obligations of study investigators, sponsors, host country governments, and agencies in protecting study participants?
- What is the procedure for cases in which the protection of study participants is violated?
I. PUBLISHING FINDINGS

Any study that will be published in a peer-reviewed journal requires IRB approval.

Key Question for Issue Spotting Regarding Publishing:

Are there plans to publish the study’s findings in peer-reviewed journals?

If the results of a study will ultimately be published or presented in a public forum, such as a peer-reviewed journal, then it is important to obtain IRB approval prior to collecting data. Most peer-reviewed journals will not print results of a study that was not approved by an IRB. If the study findings will only be used internally by an organization (e.g., evaluating a classroom protocol, determining the success of an awareness campaign), then IRB approval is not usually necessary, unless otherwise required.
Is the study considered research or evaluation?

**Research** is a systematic investigation or experimentation to establish facts or advance knowledge. **Evaluation** is the systemic determination of merit, worth, or significance of something for the purpose of developing or contributing to a body of knowledge.

The study is research or evaluation.

Will the study investigator be obtaining information about living individuals?

What **data collection methods** will be used?

- **Analysis of existing data, documents, or records**
  - See Chart A

- **Observations**
  - See Chart B

- **Surveys**
  - See Chart C

- **Individual Interviews & Focus Groups**
  - See Chart D

*LOWER*  

**Risk Level**  

*HIGHER*

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1 Video and photography could fall into any of the methods listed, depending on how they are obtained (e.g., existing public videos), in what context (i.e., where would the video footage and/or photographs be obtained, and what setting do they portray?), and the type of information collected (e.g., private imagery of individuals taking drugs, interviews on video).
The study does not warrant IRB approval since there is no direct interaction with living individuals.

Most likely the study does not require IRB approval since there is no direct interaction with living individuals.

Talk to the grantee to ensure that the study design has protocols to:

- Obtain permission to review the information
- Take appropriate measures to safeguard any confidential information.
Data Collection Decision Tree

Chart B – Observations

Will the study investigator be observing individuals or groups?

Yes

Will the observation take place in a **public setting** (e.g., a school, a conference)?

Yes

The study does not warrant IRB approval as long as the information gathered is on **non-private matters** (i.e., an individual can reasonably assume that observation and recording could take place).

Talk to the grantee to ensure that the study design has protocols to ensure that investigators do not participate in the observation in any way.

No

The observation will take place in a non-public setting (e.g., the participant’s home).

Is the information gathered from the observation considered sensitive or confidential?

Yes

**Data are sensitive or confidential.**

Talk to the grantee to consider obtaining IRB approval.

No
Data Collection Decision Tree

Chart C – Surveys

Will the study investigator be administering surveys?

Yes

Will the survey ask respondents to provide sensitive information about themselves or others (e.g., medical information)?

Yes

Data are not sensitive.
Will respondents provide identifiable information?

Yes

These data are sensitive and can be linked to participants, which makes this high risk.

Talk to the grantee to consider obtaining IRB approval, particularly if respondents are vulnerable populations.

No

The study does not warrant IRB approval because these data are not sensitive and cannot be linked to participants.

No

These data are not sensitive but can be linked to participants.

Talk to the grantee to ensure that the study design has protocols to ensure participant anonymity, as necessary.

No

Data are sensitive.
Will respondents provide identifiable information?

Yes

These data cannot be linked to participants but are still very sensitive, which makes this high risk.

Talk to the grantee to consider obtaining IRB approval, particularly if respondents are vulnerable populations.

No

These data are not sensitive but can be linked to participants.

Will respondents provide identifiable information?

Yes

These data are sensitive and can be linked to participants, which makes this high risk.

Talk to the grantee to consider obtaining IRB approval, particularly if respondents are vulnerable populations.

No

The study does not warrant IRB approval because these data are not sensitive and cannot be linked to participants.
**Data Collection Decision Tree**

*Chart D – Individual Interviews & Focus Groups*

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**Will the study investigator be conducting individual interviews or focus groups?**

- **Yes**
  - **Do interviews involve vulnerable populations?**
    - **Yes**
      - Regardless of the data collected, this is high risk.
      - Talk to the grantee to consider obtaining IRB approval.
    - **No**
      - Interviews are not with vulnerable populations.
      - Will interviewees be asked about sensitive information (e.g., medical information)?
        - **Yes**
          - Sensitive information is being collected. This is high risk.
          - Talk to the grantee to consider obtaining IRB approval.
        - **No**
          - The information collected is not sensitive.
          - Might participants encounter one or more of the following risks: deception, coercion, psychological risk, physical risk, or social risk?
            - **Yes**
              - Most likely the study does not require IRB approval because the adult participants are not vulnerable, are not being asked to disclose sensitive information, and are not being exposed to risks.
              - Talk to the grantee to ensure that the study design has protocols to take appropriate measures to protect the participants’ rights and welfare.
            - **No**

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Example Materials

- Example Grant Scenario
- Example IRB Approval Process
- Example Information & Consent Form for Study Participants
- Example Human Subjects Protection Language for Interview Protocols
Example Grant Scenario

EVALUATION OVERVIEW

The goal of this example foundation program area is to build publicly sustainable systems that promote enriched, extended-learning opportunities for elementary- and middle-school-aged children. The intended end result is a coordinated after-school system that is well implemented and becomes a platform for expansion into summer enrichment programs.

The foundation awarded a grant to an evaluation consulting firm to develop written and video case studies as part of its overall evaluation of this program area. These case studies would inform the foundation about how its investments in technical assistance systems, workforce development, and the collaboration of system leaders are resulting in tangible system-level change.

What follows is a description of each of the evaluator’s data collection methods and the considerations for assessing the risk that this evaluation could pose to study participants.

DATA COLLECTION METHODS & IMPLICATIONS

Review materials, such as program documentation, reports, and resources that are publicly available or provided by the foundation.

Because these data are already published, public, and do not involve direct interaction with people, the data collected pose no risk to participants in the study. The evaluators should ensure that any sensitive materials from the foundation are kept confidential and securely stored.

Observe and videotape students and staff at an after-school program.

Although the evaluators will be observing students, they will not have any formal interaction with, or collect data from, students. Generally, observing public behavior is considered to pose little risk to individuals, even if they are children. However, the video component in this evaluation could pose a risk because children’s identities and association with the after-school program could become public. In addition, because the observation occurs at a public school, elements of federal law and regulation that give parents certain rights to student information are applicable.

Conduct group and individual interviews by phone and in person with thought leaders, after-school program providers, and the California Department of Education staff.

The evaluators will be collecting identifiable information (e.g., name) from interviewees. However, all interviews will be held with non-vulnerable populations. In addition, interview questions are about system-level changes rather than about after-school program participants, which poses significantly fewer risks to the people involved in the study. However, videotaping interviews precludes them from being confidential and thus could pose some risk to interviewees.
SUMMARY

Although the foundation’s program area ultimately addresses children, the majority of the data collection for this evaluation pose minimal risk to participants because interviews are with non-vulnerable populations and the subject matter is not sensitive or confidential (i.e., after-school and summer enrichment field systems change). The key component of this evaluation that poses a potential risk is videotaping individuals, specifically children. Although this alone does not necessarily warrant IRB approval, it is important that individuals are fully informed about their confidentiality and participation rights, and that parental consent is obtained prior to children being videotaped. Appropriate measures should be considered to ensure that all individuals, particularly children, are not harmed through this study.
Example Institutional Review Board (IRB) Approval Process

This document provides an overview of what an Institutional Review Board (IRB) is and does. It also describes the key steps in the IRB process, approximate costs, benefits, and challenges, as experienced by BTW informing change (BTW), an independent consulting firm. Because this description is based on a particular foundation grantee’s experience applying for one type of review, it does not illustrate the process every organization will undergo when seeking IRB approval.

WHAT IS AN IRB?

An IRB is an independent committee of at least five individuals (from different relevant academic disciplines) who function as “human subjects protection” advocates. Originally, IRBs were committees at academic institutions and medical facilities to monitor research studies involving human participants, primarily to minimize or avoid ethical problems.

Today some IRB reviews are conducted by for-profit organizations known as independent or commercial IRBs. The responsibilities of these IRBs are identical to those based at academic or medical institutions, and they are governed by the same federal regulations.

The IRB reviews protocols (e.g., surveys and focus group discussion guides) and related materials (e.g., informed consent documents and investigator brochures) to ensure that the rights and welfare of individuals in research or evaluation studies are protected. The chief objectives of every IRB review are to:

- Assess the ethics of the study and its methods;
- Promote fully informed and voluntary participation by prospective participants who are capable of making such independent choices; and
- Maximize the safety of participants once they are enrolled in the study.

KEY STEPS IN THE IRB APPROVAL PROCESS

1. Select a Vendor

Upon finalizing the study design, the first step in the IRB approval process is to select a vendor that hosts an independent IRB. BTW chose Ethical and Independent Review Services (E&I) based on prior experience working with the firm and the availability of extensive resources on the firm’s Web site. E&I staff members were also accessible via phone and e-mail to answer questions as they arose.

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1 BTW prepared this description of the steps in the IRB approval process based on its experience in the evaluation of the David and Lucile Packard Foundation’s After-school and Summer Enrichment Subprogram.

2 If this is not possible, then informed permission is given by a suitable proxy.

3 In 2010, Independent Review Consulting, Inc. (IRC) and the Ethical Review Committee (ERC) merged to become Ethical and Independent Review Services (E&I). BTW started working with IRC before the merger occurred.
2. Identify the Most Appropriate Type of Review

According to the E&I Web site, there are five possible initial review routes:

1. Deferral, to accept the decision of another IRB if a study has more than one IRB
2. General approval, to provide preliminary IRB approval of federal grant applications before they are funded
3. Exemption, to exempt research activities from IRB approval that have low perceived risk and do not involve human subjects
4. Expedited review, to have one IRB member review activities that create less than a minimal risk of harm
5. Full board review, to fully review proposals that do not qualify for other types of review

BTW reviewed documents on the independent reviewer’s Web site and contacted staff with questions regarding the details of this particular study. BTW determined that an expedited review was most appropriate for its evaluation; while this evaluation does involve human subjects, these individuals are exposed to minimal risk.

3. Prepare & Submit Materials

The next step is to obtain and complete all necessary application forms. BTW’s application for expedited review included the following materials: (1) cover letter; (2) business forms, including an indemnification form and business description; (3) study materials, including an application cover form, expedited review request, research protocol, application for consent waiver, recruitment materials, surveys, and interview guides; and (4) investigator materials, including the principal investigator application form and curriculum vitae for key personnel. E&I requires all documents to be submitted on company letterhead and include both the study name and date of submission.

4. Obtain Human Research Training Certification

Key personnel must obtain Human Research Training certification. The online Social and Behavioral Course, administered through the Collaborative Institutional Training Initiative (CITI) Program, contains several modules that each culminates in a quiz; individuals can start and stop as needed. After completing the training (which requires a passing grade of at least 80%), the CITI Program forwards certification status to E&I. Two BTW staff members became certified; the training took approximately three to four hours per person to complete.

5. Revise Application Based on Feedback

Applicants for IRB approval should expect to make at least one set of revisions to original materials. In this case, E&I requested that BTW add more specific confidentiality language to the research protocol, as well as to all survey instruments and interview guides. The reviewer requested that the documents: (1) clarify that participation

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4 According to E&I, when the selected IRB vendor serves as an institution’s internal IRB, they must review all research at that institution. As a result, there are cases in which an investigator may need to apply to several IRBs for approval. If institutional policy allows, the investigator may request one IRB to accept the decision of the other. Source, accessed February 2010: http://www.irb-irc.com/theirb/3.2.1__Review_Processes.pdf

5 According to E&I, minimal risk “means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.” Source, accessed February 2010: http://www.irb-irc.com/theirb/3.2.1.b____Expedited.pdf

6 At the time of submission, key personnel are required to have initiated the training process but not to have completed it. BTW specified in the application materials that key personnel were currently “in process of completing the course” as to expedite the submission process. Key personnel completed the training shortly thereafter.
is voluntary and participants may stop answering questions at any time; (2) provide more detailed information about privacy and confidentiality measures; (3) provide contact information for the BTW representative whom participants should contact with questions about the study; and (4) provide E&I’s contact information for participants to contact if they have questions about their rights as participants. BTW clarified these requests with E&I staff and updated the documents accordingly. E&I required revisions to be identified with track changes and documents to include updated version dates.

After reviewing the revised documents, E&I approved the study overall, but raised two minor concerns not previously noted. The reviewer requested that: (1) BTW staff give participants a copy of the survey introduction and interview language to keep for their reference; and (2) offer a toll-free phone number for participants to use if they have questions for the Principal Investigator. BTW agreed to share the consent and confidentiality document with interviewees via e-mail and ask online survey respondents to print the introductory screen of the survey for their records. Since BTW does not have a toll-free phone number, the firm agreed to include the Principal Investigator’s e-mail address to relieve the burden on individuals who cannot or wish not to pay for a long-distance phone call. As with the first round of revisions, E&I required edits to be identified with track changes and all submitted materials to include updated version dates.

6. Confirm Approval

E&I awarded approval of the study promptly via e-mail and sent a hard copy of the approval letter shortly thereafter. If the vendor does not respond in a timely fashion, it is imperative to follow-up as study activities cannot commence until the study has received IRB approval.

7. Conduct Post-approval Activities, as Needed

Researchers’ engagement with the IRB does not end with IRB approval, but rather continues through the end of the study. There are three types of events about which researchers need to notify the IRB: (1) adverse events and unanticipated problems involving risk to subjects or others (events and problems generally related to clinical studies such as an adverse drug experience); (2) modifications to approved research (prospective changes to the research protocol or addendums to it); and (3) violations of approved research (exceptions made to the research protocol to accommodate the needs of individual subjects).

In June 2009, BTW submitted an application for study modification to account for additional data collection activities focused on the pilot of the summer enrichment strategy. BTW submitted a study modification form and new data collection guides. E&I did not require any revisions to the application materials and approved the modification within one week.

**APPROXIMATE TIME & COSTS**

The initial review process took approximately three months to complete: two months to identify the required tasks, prepare materials, and hear back from E&I (steps one to four), and one month to make revisions and confirm approval (steps five and six). The process of securing approval for study modifications takes approximately one to three weeks to complete.

The approximate total cost for securing initial IRB approval for the study was over $8,000. This includes the E&I fee of $1,550 and roughly $6,500 in staff costs. Staff cost estimates include the time to prepare the initial study application, make two rounds of revisions to the materials, and complete the online human research training.

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7 The fees listed in this document were paid by BTW in 2009, and therefore may be different from E&I’s current fee structure. The staff costs were based on consulting billing rates but could vary depending on the consultant.
through CITI. The cost for obtaining approval of the study modification was approximately $800, which includes the $300 modification fee and roughly $500 of staff time.

**BENEFITS**

Though this was a time intensive process, it enabled BTW staff to develop and organize all study documents well in advance of beginning data collection activities. BTW developed survey instruments and interview guides months before needing to use them and, as a result, had ample time to pilot test, revise, and finalize the tools. Though similar to the evaluation plan, the research protocol was more specific and emphasized different components of the study. In the process of developing this document, BTW was able to describe in greater detail the specifics of the evaluation, thereby enhancing the overall quality of the design. BTW staff also became more aware of the guidelines for the protection of study participants, both through the required training and completion of application materials. This heightened knowledge of and sensitivity to study participants helped provide a frame to guide BTW staff through the data collection activities. Preparing and submitting the application for IRB approval not only improved BTW’s planning process but also served as a natural and valuable transition into the next stages of evaluation implementation.

**CHALLENGES**

The primary challenge BTW experienced throughout the IRB approval process was the amount of staff time necessary to complete all required steps. There were many forms, several of which seemed duplicative, and various specifications for the ways in which forms had to be completed. The process also required that all study materials be completed at the outset of the study and that changes be resubmitted for approval; this presented challenges for scheduling data collection activities and completing them within a desired timeframe. BTW staff also had to negotiate E&I’s concerns about consent and confidentiality, such as the desire that all study participants receive a separate document detailing their rights as study participants. Overall, it was a challenge to work within a structure designed for handling much more sensitive studies (e.g., clinical, children as subjects, etc.).
Example Information & Consent Form for Study Participants

[Title of research]

Research Information & Consent Form

INTRODUCTION
You are invited to participate in a research study investigating [state what is being studied]. This study is being conducted by [researcher name and organization]. You were selected as a possible participant in this research because [state how and why the subject was selected]. Please read this form and ask questions before you decide whether to participate in the study.

BACKGROUND INFORMATION
The purpose of this study is to [state what the study is designed to discover or establish]. Approximately XX people are expected to participate in this research.

PROCEDURES
If you decide to participate, you will be asked to [in a step-by-step fashion, describe all steps and procedures you will follow, including their purposes, how long each step will take, any repetitions, and where the research will take place]. This study will take approximately [indicate the length of time the individuals will be participating in the study during each interval] minutes/hours over XX sessions.

RISKS & BENEFITS
The study has several [or use the word minimal, if that is the case for your study] risks. First, ___________________________ second, ______________________ [Risks must be explained, including the likelihood of the risk. Describe discomforts and inconveniences the participants may reasonably expect. If the individuals will be told of significant physical or psychological risks to participation, they also must be told under what conditions the researcher will terminate the study. If there is risk of causing significant emotional distress on the part of participants, list resources such as crisis lines or counseling centers].

The benefits to participation are [state benefits. If there are no direct benefits to the participants, which is often the case, state, “There are no direct benefits to you for participating in this research.” If applicable, describe appropriate alternative procedures that might be to the participant’s advantage, if any. Any standard treatment that is being withheld must be disclosed].

COMPENSATION
If you participate, you will receive [include payment or reimbursement information here. Explain when disbursement will occur and conditions of payment. Delete this section if it is not applicable].

[If this study involves a physically invasive procedure, or an exercise component which may have even a slight risk of injury, you must include the following statement in the consent form. Omit this section if the study does not]
In the event that this research activity results in an injury, we/I will assist you [give an example of a potential problem/injury and describe how you will assist study participants]. Any medical care for research-related injuries should be paid by you or your insurance company. If you think you have suffered a research-related injury, please let me/us know right away.

CONFIDENTIALITY

Any information obtained in connection with this research study that could identify you will be kept confidential. In any written reports or publications, no one will be identified or identifiable, and only group data will be presented. [If it applies to your study, include ways in which you will maintain confidentiality, e.g., “No one in the daycare center will know your child’s results.” If you release information to anyone for any reason, you must state the persons or agencies to whom the information will be furnished, the nature of the information to be furnished, and the purpose of the disclosure.]

We/I will keep the research results in a password-protected computer and/or a locked file cabinet in [state where] and only I [or the researcher(s) named in this form] and our/my advisor will have access to the records while we/I work on this study. We/I will finish analyzing the data by [specify the ending date of your research]. We/I will then destroy all original reports and identifying information that can be linked back to you. [If tape or video recordings are made, explain who will have access to them, if they will be presented to others for educational purposes, and when/if they will be erased or destroyed.]

VOLUNTARY NATURE OF THE STUDY

Participation in this research study is entirely voluntary. Your decision whether or not to participate will not affect your future relations with [the name of any other cooperating institution] in any way. [If the study includes survey items or an interview, you may state that participants can refuse to answer any question if they choose.] If you decide to participate, you are free to stop at any time without affecting these relationships, and no further data will be collected. [Explain here if monetary benefits will be adjusted if the individual withdraws early.]

NEW INFORMATION

If during the course of this research study we/I learn about new findings that might influence your willingness to continue participating in the study, we/I will inform you of these findings. [This section is optional. Consult your advisor to decide if it applies to your study.]

CONTACTS & QUESTIONS

If you have any questions, please feel free to contact me, [name] at [phone number] or [e-mail address] (or one of the researchers at [phone number] or [e-mail address]). You may ask questions now, or if you have any additional questions later, the Principal Investigator, [name and phone number], will be happy to answer them. If you have other questions or concerns regarding the study and would like to talk to someone other than the researcher(s), you may also contact [name and/or IRB institution], the ethics review board that reviewed this study, at [phone number] or [e-mail address].

Please keep a copy of this form for your records.
STATEMENT OF CONSENT

You are making a decision whether or not to participate. Your signature indicates that you have read this information and your questions have been answered. Even after signing this form, please know that you may withdraw from the study at any time and no further data will be collected.

I consent to participate in the study. [If you are video- or audio-taping your participants, include a statement such as “and I agree to be videotaped.”]

Signature of Participant Date

Signature of Parent, Legal Guardian, or Witness Date
[If applicable, otherwise delete this line]

Signature of Principal Investigator Date

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1 This consent form was taken from St. Catherine University’s Institutional Review Board and Human Subjects Protection Web site and slightly modified. Accessed February, 2010: http://minerva.stkate.edu/irb.nsf/pages/consentform
Example Human Subjects Protection Language for Interview Protocols

NOTE: Important information for the study participant. Please read in its entirety.

Information collected through these interviews is confidential, and responses will not be attributed to specific individuals or organizations. The study report will include a list of all individuals interviewed. In order to maintain respondent confidentiality, illustrative quotes and anecdotes described in the report will be attributed only to the general role of the respondent (e.g., government representative, school administrator) in order to maintain confidentiality.

We encourage and appreciate any candid responses that can contribute to both learning and improvement. **You are free to limit your answers or choose not to answer any questions if you do not wish to be quoted.** Synthesized responses will be used to inform our understanding of this particular effort. Some findings that share more general lessons learned may be disseminated in a public report. You will receive a copy of the final report.
Additional Resources

- Definition Guide
- History of Human Subjects Protection
- List of Additional External Resources
<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anonymity</td>
<td>An anonymous study is one that does not collect identifying information of participants (e.g., name, contact information) or cannot link specific responses to participants' identities.</td>
</tr>
<tr>
<td>Assent</td>
<td>A verbal or written affirmation of participation in a study by a potential participant with “diminished autonomy” (e.g., children). Assent occurs after the parent or other individual who has the legal authority to make decisions about the person’s participation has given informed consent.</td>
</tr>
<tr>
<td>Confidentiality</td>
<td>A confidential study is one that allows the investigator to identify the individual responses of participants, but also takes measures to ensure that the identifying information is not released to anyone outside the study.</td>
</tr>
<tr>
<td>Evaluation</td>
<td>Evaluation is the systematic determination of merit, worth, or significance of something for the purpose of developing or contributing to a body of knowledge.</td>
</tr>
<tr>
<td>Existing Data, Documents, or Records</td>
<td>Existing data, documents, or records are information that have already been collected and are in existence prior to the current study (i.e., from a different study that was conducted in the past). This information could be publicly available or private, depending on where they were obtained (e.g., the Internet or a funder's private records).</td>
</tr>
<tr>
<td>Focus Group</td>
<td>Focus groups are planned group discussions in which a small number of open-ended questions are posed to a group to generate in-depth conversation about a specific topic of interest. Focus groups typically examine perceptions, opinions, attitudes, and ideas. Participants in focus groups are targeted and recruited, so they are identifiable.</td>
</tr>
<tr>
<td>Human Subject</td>
<td>In research and evaluation studies, a human subject is a living individual/human being; this does not include deceased persons or animals.</td>
</tr>
<tr>
<td>Individually Identifiable Information</td>
<td>Information is individually identifiable when the data elements have personal information that can be linked to a participant’s identity or other characteristics that (alone or in combination) could allow him/her to be identified. Potential identifiers include name, birth date, dates of hospital admission and discharge, dates of diagnosis, zip code, Social Security number, and demographic details.</td>
</tr>
<tr>
<td>Informed Consent</td>
<td>A verbal or written process in which a subject voluntarily indicates willingness to participate in a study after having been informed about the components and purpose of the study and the requirements for participation.</td>
</tr>
<tr>
<td>IRB (Institutional Review Board)</td>
<td>A committee that reviews evaluation and research plans and materials to ensure that the rights and welfare of individual participants are protected.</td>
</tr>
<tr>
<td>Interview</td>
<td>Interviews are structured, one-on-one conversations conducted by phone or in person with selected individuals. Questions are generally open-ended and encourage the respondent to reflect on his/her own experience and understanding of the topic.</td>
</tr>
<tr>
<td>Observation</td>
<td>Observation is an unobtrusive method for gathering information about people, individually or in groups. Observation generally takes place during meetings, events, or activities. The observer does not engage in the activity content, but rather, allows it to flow without interruption.</td>
</tr>
<tr>
<td>Term</td>
<td>Definition</td>
</tr>
<tr>
<td>-----------------------------</td>
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</tr>
<tr>
<td>Psychological Harm</td>
<td>Psychological harms include discomfort, stress, anxiety, pain, trauma, guilt, or instability.</td>
</tr>
<tr>
<td>Research</td>
<td>Research is a systematic investigation or experimentation to establish facts or advance knowledge.</td>
</tr>
<tr>
<td>Risk</td>
<td>Any potential harm that could be put or brought upon individuals participating in a study. This includes psychological, social, and physical harms.</td>
</tr>
</tbody>
</table>
| Standard Ethical Guidelines | The following standard guidelines should be ensured for all study participants:  
1. An informed consent process is in place  
   a. Participants are disclosed information  
   b. Participants understand what has been disclosed  
   c. Participation is completely free and voluntary  
2. Adequate provisions are in place to protect the privacy of participants and maintain data confidentiality  
3. All methods of data collection (e.g., surveys, interviews) have been designed to minimize psychological, physical, and/or social harms  
4. Participant selection is equitable |
| Safeguarding Confidential Information | Measures to safeguard confidential data include substituting codes for identifiers, maintaining code lists, and storing data files and code lists in separate locations.                                                                                                                                                                    |
| Sensitive Information       | Information is considered sensitive if it might cause perceivable damage to someone or something if it is revealed to people who are not entitled to the information. Examples include HIV status, religious beliefs, sexual history, where someone lives, information about drug use, and information about prescribed medications. |
| Social Harm                 | Social harms include disruption of family and social relationships; stigmatization; damage to reputation, employability, insurability, or financial standing; or civil or criminal sanctions.                                                                                                                                 |
| Survey                      | Surveys gather data from representatives of a population of interest and can be administered electronically or in print. Survey instruments generally include a combination of closed- and open-ended questions, yielding a range of information about respondents’ opinions or actions regarding a particular topic.                                    |
| Vulnerable Populations       | People in these populations include children/adolescents, pregnant women, prisoners, people with economic and/or educational disadvantages, and people with physical and/or intellectual disabilities.                                                                                                                                     |
History of Human Subjects Protection

HISTORY & EVOLUTION

Two significant events—Nazi atrocities during WWII and the Tuskegee Syphilis Study—made a particular and direct impact on the development of the ethical principles for research and evaluation studies that remain today. They demonstrate a violation of human rights in the context of research, in particular, in a time when ethical standards and principles did not exist, and thus were not enforced.

Nazi World War II Atrocities (1942–1946)

During World War II, Nazi doctors and scientists conducted experimental medical research on prisoners in concentration camps. Their methods resembled forms of torture and sometimes resulted in death. Inmates did not have the option to decline participation, nor did they give consent. After the war, the Nazis involved in these atrocities were put on trial in Nuremberg as part of a series of post-war military tribunals for the inhumane treatment and deaths of concentration camp prisoners.

Public Health Service Syphilis Study at Tuskegee (1932–1972)

The Tuskegee Syphilis Study was a 40-year clinical study carried out by the US Public Health Service to track the natural history of syphilis in African American men. Participants, mainly illiterate sharecroppers in Alabama, were misinformed about the purpose, necessary procedures, benefits, and risks of the study. For example, to ensure that more patients participated, they were told that spinal taps were a “special free treatment” for their ailments. After the discovery of penicillin in the early 1940s as the cure for syphilis, the study continued without the infected participants being treated for the disease.

ETHICAL STANDARDS & CODES

The protection of human subjects (i.e., study participants) is based on a set of rules and regulations that guide study investigators in designing ethical studies. Some leading examples that are particularly relevant to research and evaluation studies involving individuals are provided below.

The Nuremberg Code (1947)

The Nuremberg Code was created as a result of the verdict from the Nuremberg Trials on Nazi atrocities. The Code is the first international code of research ethics and outlines basic ethical principles that should be considered in human experimentation. The key guidelines infer that:

- Voluntary consent of research participants is essential;
- Research should be beneficial to society; and
- The experiment should avoid unnecessary suffering and injury.
The Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects (1964)

First published in 1964, the Declaration of Helsinki makes clear that the “well-being of the human subject should take precedence over the interests of science and society.” The current Declaration of Helsinki emphasizes independent review of research, special protections for vulnerable populations of study participants, informed consent, risk/benefit analysis, use of placebo controls, and access to the best proven care for patients after the study.

The Belmont Report: Ethical Principles & Guidelines for the Protection of Human Subjects of Research (1979)

Through the recommendations given by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, the US Department of Health and Human Services created the Belmont Report. The document provides the foundation for conducting research involving living individuals and pinpoints three fundamental ethical principles that must be followed:

1. Respect for Persons
2. Beneficence
3. Justice

Application of Principles & Guidelines to Research & Evaluation Studies

While these first steps toward protecting participants in research apply to the medical and scientific professions, they have laid the foundation for ethical principles and standards that would eventually span into other areas of study, including evaluation studies.

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1 Source, accessed October 2011: http://www.fda.gov/ohrms/dockets/dockets/06d0331/06D-0331-EC20-Attach-1.pdf

2 This commission was the first public, national body to oversee and regulate the ethical principles behind biomedical and behavioral research.

3 Formerly (at that time) called the US Department of Health, Education, and Welfare.
List of Additional External Resources


