

REQUIRED INSTITUTIONAL REVIEW BOARD (IRB) EDUCATIONAL READING FOR FLETCHER SCHOOL RESEARCHERS APPLYING FOR EXEMPTION FROM IRB

Please read the following text, adapted from the “CITI Education Module” (Braunschweiger, P and K. Hansen. 2000. “Collaborative IRB Training Initiative (CITI) Course in the Protection of Human Research Subjects”. Miami: Univ. of Miami. <https://www.citiprogram.org>) on the Tufts IRB website, having to do with IRB rules and reasons for describing your research parameters, sign it on last page, and return last page to Jenifer Burckett-Picker with your application for exemption.

1. History and Ethical Principles of Protection of Human Subjects in Research

The Belmont Report, released in 1979 by the National Commission for the Protection of Human Subjects in Biomedical and Behavioral Research, provides the ethical framework for the Federal Regulations designed to protect human research subjects.

Summary of Belmont Report: On July 12, 1974, the National Research Act was signed into law, thereby creating the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. One of the charges to the Commission was to identify the basic ethical principles that should underlie the conduct of biomedical and behavioral research involving human subjects and to develop guidelines which should be followed to assure that such research is conducted in accordance with those principles. Basic Ethical Principles : The expression "basic ethical principles" refers to those general judgments that serve as a basic justification for the many particular ethical prescriptions and evaluations of human actions. Three basic principles, among those generally accepted in our culture, are particularly relevant to the ethics of research involving human subjects: **the principles of respect of persons, beneficence and justice.**

A. Respect for Persons. -- Respect for persons incorporates at least two ethical convictions: first, that individuals should be treated as autonomous agents, and second, that persons with diminished autonomy are entitled to protection. The principle of respect for persons thus divides into two separate moral requirements: the requirement to acknowledge autonomy and the requirement to protect those with diminished autonomy. Some persons are in need of extensive protection, even to the point of excluding them from activities which may harm them; other persons require little protection beyond making sure they undertake activities freely and with awareness of possible adverse consequence. The extent of protection afforded should depend upon the risk of harm and the likelihood of benefit. The judgment that any individual lacks autonomy should be periodically reevaluated and will vary in different situations.

In most cases of research involving human subjects, respect for persons demands that subjects enter into the research voluntarily and with adequate information. In some situations, however, application of the principle is not obvious. The involvement of

prisoners as subjects of research provides an instructive example. On the one hand, it would seem that the principle of respect for persons requires that prisoners not be deprived of the opportunity to volunteer for research. On the other hand, under prison conditions they may be subtly coerced or unduly influenced to engage in research activities for which they would not otherwise volunteer.

B. Beneficence. -- Persons are treated in an ethical manner not only by respecting their decisions and protecting them from harm, but also by making efforts to secure their well-being. Such treatment falls under the principle of beneficence. The term "beneficence" is often understood to cover acts of kindness or charity that go beyond strict obligation. In this document, beneficence is understood in a stronger sense, as an obligation. Two general rules have been formulated as complementary expressions of beneficent actions in this sense: (1) do not harm and (2) maximize possible benefits and minimize possible harms.

The obligations of beneficence affect both individual investigators and society at large, because they extend both to particular research projects and to the entire enterprise of research. In the case of particular projects, investigators and members of their institutions are obliged to give forethought to the maximization of benefits and the reduction of risk that might occur from the research investigation.

C. Justice. -- Who ought to receive the benefits of research and bear its burdens? This is a question of justice, in the sense of "fairness in distribution" or "what is deserved." An injustice occurs when some benefit to which a person is entitled is denied without good reason or when some burden is imposed unduly. Another way of conceiving the principle of justice is that equals ought to be treated equally. Almost all commentators allow that distinctions based on experience, age, deprivation, competence, merit and position do sometimes constitute criteria justifying differential treatment for certain purposes. It is necessary, then, to explain in what respects people should be treated equally.

For example, the selection of research subjects needs to be scrutinized in order to determine whether some classes (e.g., welfare patients, particular racial and ethnic minorities, or persons confined to institutions) are being systematically selected simply because of their easy availability, their compromised position, or their manipulability, rather than for reasons directly related to the problem being studied. Finally, whenever research supported by public funds leads to the development of therapeutic devices and procedures, justice demands both that these not provide advantages only to those who can afford them and that such research should not unduly involve persons from groups unlikely to be among the beneficiaries of subsequent applications of the research.

2. Basic IRB Regulations and Review Process

An Institutional Review Board (IRB) is a review committee established to help protect the rights and welfare of human research subjects. University regulations require IRB

review and approval for all research involving human subjects at Tufts University, whether or not it is federally funded. Federal funding could be withdrawn from the university if there is non-compliance. Although federal regulations refer to IRBs, an institution may have chosen a different name for this committee. To clarify when IRB review is required, let's define some terms:

Research: Federal regulations define research as: "a systematic investigation designed to develop or contribute to generalizable knowledge." If an investigator is unclear about whether a planned activity is research, the investigator should contact his/her IRB office.

Human Subjects: The Department of Health and Human Services (DHHS) regulations define a human subject as "a living individual about whom an investigator (whether professional or student) conducting research obtains:

1. Data through intervention or interaction with the individual, or
2. Identifiable private information."

IRB Regulations: Institutions and IRBs vary in the practices that assure they meet the federal regulations and in the details of the standards they apply. What follows are the minimum federal requirements.

IRB applications usually contain, at a minimum, information that allows IRB members to assess the risks / anticipated benefits analysis, determine that risks are minimized, determine that risks are reasonable in relation to potential benefits, observe informed consent process and documentation/ assent (The affirmative agreement of a minor or decisionally impaired individual to participate in research), observe selection of subjects (equitable in terms of gender, race, ethnicity), benefits (distributed fairly among the community's populations), and additional safeguards that provide for vulnerable populations, and that ensure subject's privacy and confidentiality of information.

Additionally, IRB applications usually contain the following:

Research plan for collection, storage, and analysis of data.

Research design / methods that are appropriate, scientifically valid and therefore, justify exposing subjects to research risks.

Additional information about identification, recruitment and safeguards if the research involves special populations

Research that is exempt: The following six categories of research are eligible for exemption status:

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices. An example of this would be a comparison of the effectiveness of two generally accepted instructional strategies.

2. Research involving the use of educational tests, survey procedures, interview procedures, or observation of public behavior UNLESS the information is recorded in a manner in which the subject can be identified AND disclosure would place the subject at risk of criminal or civil liability or be damaging to financial standing, employability, or reputation. This does not apply where the subjects are children except where it involves passive observation of public behavior. (This exempt status category, for research involving survey or interview procedures or observation of public behavior, does not apply to research with children, Subpart D, except for research involving observations of public behavior when the investigator(s) do not participate in the activities being observed.)

3. Research involving the use of educational tests, survey procedures, interview procedures or observation of public behavior where subjects are elected or appointed officials or candidates for public office.

4. Research involving the collection or study of EXISTING data, documents, records, or specimens if the sources are publicly available or the information is recorded by the investigator in such a manner that subjects cannot be identified directly or through identifiers or codes. (Note: Even brief use of identifier or code disqualifies the exemption.)

5. Research and demonstration programs designed to study, evaluate, or examine Federal public benefit or service programs (The research must be sponsored by the program/government and approved at a very high level within the organization. This is a very narrow exemption that will rarely apply).

6. Taste and food quality evaluation and consumer acceptance studies involving wholesome foods without additives or with additives or chemicals below established "safe" levels.

3. Privacy and Confidentiality

The Common Rule states that in order to approve research the IRB shall determine that, when appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

According to the IRB Guidebook, published by the Office of Human Research Protections, privacy can be defined in terms of having control over the extent, timing, and circumstances of sharing oneself (physically, behaviorally, or intellectually) with others. Confidentiality pertains to the treatment of information that an individual has disclosed in a relationship of trust and with the expectation that it will not be divulged to others in ways that are inconsistent with the understanding of the original disclosure without

permission. Most research involves asking subjects to provide or release information voluntarily following an informed consent process.

4. Informed Consent

Obtaining informed consent involves:

- Providing information to the subject.
- Ensuring the subject understands by answering questions the subject may have.
- Obtaining the voluntary agreement of the subject to participate in the study.

Guidelines for providing information include:

- Advertising cannot be coercive or make false promises or claims.
- The information should be communicated in a manner and language that is clear and understandable, be communicated in an organized fashion, and allow for questions the subject may have to be answered.
- No informed consent, whether oral or written, may include any exculpatory language through which the subject is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence.
- Procedures to screen potential subjects for eligibility must protect the rights and welfare of prospective subjects.

Oral Consent -- Signed consent may be waived and oral consent used under the following circumstances: When study participation presents minimal risk to the subject and the research involves no procedures requiring consent outside the context of participation in a research study. The IRB may require the investigator to provide the subject with written materials about the research. This applies to research that is exempted from the full IRB approval process.

5. Assessing Risk

One of the most important and challenging tasks that investigators face is identifying and evaluating risks associated with participation in research. Unlike biomedical research studies or clinical trials, in which the sources of risk may be more readily identifiable and quantifiable, risks associated with participation in social and behavioral science research are often more elusive and less predictable. However, this does not mean that these risks are any less serious or less real. For example, discrimination due to an inadvertent

disclosure of sensitive personal information, such as sexual orientation or a diagnosis of mental illness, could have serious consequences.

Perhaps the primary source of risk in the social and behavioral sciences is that information obtained by researchers could harm subjects if disclosed outside the research setting. Confidentiality can be compromised through an unauthorized release of data, which could have a negative impact on the subjects' psychological, social, or economic status. In some cases, simply participating in research can put subjects at risk. For example, responding to questions about a sensitive topic or traumatic event may be distressing to a subject, even if the information divulged is kept in strict confidence.

When assessing risk associated with participation in a research study, there are two distinct elements of risk that need to be considered. One is the probability of harm – the likelihood that a specific harm might occur. Not all possible harms are equally probable, and this fact should be taken into consideration when assessing risk. The second element of risk is the magnitude of such harm. Risks in research participation are specific to time, situation, and culture. Thus, what may be a socially sensitive issue or topic at one time or place may not be so at another time or place. For example, asking women if they have had abortions would carry very different risks a country where abortion is a routine medical practice, a country where it is illegal, and a country in which it is legal but the issue is fraught with religious and political controversy.

Balancing Risks and Potential Benefits

Federal regulations, based on the ethical principle of beneficence, require that risks associated with research be reasonable in relation to the anticipated benefits. A great deal of research in the social and behavioral sciences offers little potential for direct benefits to the subjects themselves. The benefits of the research often lie in the importance of the knowledge to be gained, the contributions it makes to science, or the contributions to society in general. There might also be cases in which a specific community, rather than individual subjects, benefits from the research. On the other hand, most research in the social and behavioral sciences poses little or no risk to the subject.

Federal regulations also stipulate that potential risks must be minimized

Potential research subjects need to be given sufficient information to make a decision about whether they are willing to accept potential risks. If questions will be of sensitive nature, subjects need to be forewarned. Subjects also need to know what steps will be taken to protect confidential information, including disposition of recorded material. Any limits to the extent to which a researcher can protect identifiable personal information should be clearly explained. State and local laws may limit confidentiality, such as reporting requirements for child and elder abuse. Confidentiality cannot be guaranteed for information shared in a focus group.

**I have read the preceding “Required IRB Educational Reading for
Fletcher School Researchers Applying for Exemption from the IRB”**

Your signature

Your name printed

date

Please return this page with your signature to Jenifer Burckett-Picker, Cabot 403D or
Fletcher mailbox

If you have any questions, please contact Jenifer.Burckett-Picker@tufts.edu 12-07-06