

**National-Louis University
Institutional Research Review Board**

Policies and Procedures for Conducting Research

Do No Harm

In research, as in all other forms of practice, there are ethical dimensions—subtle impositions of power disguised as “voluntary” participation; deceptions as to purpose or outcome; breaches of confidentiality and anonymity; distortions of convenience. Your research might represent an intrusion into people’s lives. Will you intervene, disrupt the lifeworld and appropriate thoughts and feelings of others as building blocks for your own project? Because of hegemony, your research can reproduce unquestioned power relationships, reinforce stereotypes, and foster economic and cultural inequities. While you may intend none of this, it is only through diligent reflection and preventative action that these unintended and possibly anti-democratic consequences of your research can be foreseen and minimized.

To assist you in examining the ethical implications of your work—and to protect both you and the university in matters of liability—the University has appointed an Institutional Research Review Board (IRRB) which can review your plans for the involvement of others in generating data for your research. Specific information on the procedures for the human participants review is contained within this document.

Ethical Principles and Guidelines*

Scientific research has produced substantial social benefits. It also has posed some troubling ethical questions. As less ethnocentric models of awareness evolve, demands have increased for rigorous codes of ethics for interaction (especially with oppressed, formerly marginalized groups of people), and for conducting and reporting research. Public attention has been drawn to abuses of human participants in biomedical experiments and in affronts to human dignity in ethnic and social characterizations of various groups of people. Most recently, media attention and academic scrutiny has been drawn by the published accusations of Patrick Tierney in his book *Darkness in Eldorado* concerning anthropological research with the Yanomami of Brazil and Venezuela. Currently, an American Anthropological Association task force is addressing the allegations concerning fieldwork practices, representations and portrayals that may have had a negative and harmful impact on Yanomami welfare, and biomedical research and other activities by anthropologists, scientists, and journalists that may have contributed to malnutrition, disease and disorganization. The task force has evidence to refute many of the allegations, and note as well the evolution of codes of ethics that may have provided different sets of guidelines for research historically. Many writers of ethnographies—especially of pre-literate (in

* The following material has been freely adapted with some additions from *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Participants of Research*. This public document, issued on April 18, 1979, was prepared for the U.S. Department of Health, Education, and Welfare.

terms of the written word) peoples—did not consider that those about whom they were writing would ever read what was written about them. Inadvertently, ethnocentricity may have provided a lens producing a less than accurate and distorted picture. Since the 1970's, more rigorous guidelines have been emerging about the protection of groups under study and about voice, multiple perspective, and personal reflections before developing depictions of individuals or groups or advancing theories from these depictions.

Historically, abuses of participants in biomedical experiments abound. The infamous Tuskegee Syphilis Experiment was allowed, in the name of science, to persist from 1932 until 1972. The United States Public Health Service conducted this forty-year study in Macon County, Alabama for the purpose of determining the “natural” course of syphilis. Participants selected for the study were 600 African American males, 399 of whom were in the final stage of syphilis and 201 of whom were not infected. These men lived in the rural south and typically were receiving inadequate health care because of racism. Some ethical issues in this study are as follows:

- Participants were not informed as to the purpose of the study
- Participants were not informed that they had syphilis or that the condition was in the final stage;
- Researchers purposefully told lies to the participants (so they would continue to be in contact with medical personnel) about receiving treatment for various disorders such as rheumatism; and
- Treatment was deliberately withheld, even when penicillin was discovered, resulting in the death of over 100 men and the infection of women (wives and girlfriends) and children.

As PHS researchers published and presented numerous papers at conferences and in medical journals between 1932 and 1972, obviously the medical community as a whole knew of this study, but were silent, presumably because of the still held view of the larger society that African Americans are members of a racially inferior group. The United States Department of Health, Education and Welfare finally ended the experiment only because an employee informed the Associated Press. Other abuses of human participants include the injection of live cancer cells into elderly and senile patients at Jewish Chronic Hospital in Brooklyn, New York in 1963. Also, in 1966, students at the Willowbrook State School were exposed to hepatitis without their knowledge.

The atrocities of World War Two biomedical experimentation include the well-known and not so well known. Nazi ideology and social Darwinism led to theories of racial hygiene which saw some groups as inferior and provided an ideological excuse for physicians and scientists to harm people for the state.¹ While it is unlikely that ethically violations of this scale and magnitude will occur again, it is instructive that ethical violations in research utilizing human participants continue to occur. These include: 1. U.S. military radiation experiments on soldiers in the 1950s; 2. Use of investigative drugs on U.S. soldiers during the Gulf War in 1991; and 3. Use of physicians in executions by lethal injection. In the United States, Quakers, because of their conscientious objectors status, were drafted as participants in medical research. In Europe, the physicians and scientists who conducted experiments on concentration camp prisoners drew international attention. During the

¹ One German physician at the Nuremberg trial argued that they were no more guilty of ethical violations than U.S. scientists who had conducted malaria experiments on prisoners during World War II at Stateville prison in Illinois. The justification for this argument was based on “biological thinking,” i.e., human subjects are merely objects and should receive no consideration at all.

Nuremberg War Crime Trials, the Nuremberg code was drafted as a set of standards for judging those physicians and scientists who knowingly conducted experiments on involuntary participants who were considered inferior. This code became the prototype of many later codes² intended to assure that research involving human participants would be carried out in an ethical manner.

The codes consist of rules, some general, others specific, that will guide you in your work. Such rules often are inadequate to cover complex situations and at times they come into conflict, are frequently difficult to interpret or apply. Broader ethical principles, however, will provide you with a basis on which specific rules may be formulated, criticized and interpreted.

Three principles, or general prescriptive judgments, that are relevant to research involving human participants are identified in this document. Other principles may also be relevant. These three are comprehensive, however, and are stated at a level of generalization that should assist you in understanding the ethical issues inherent in research involving human participants. These principles cannot always be applied so as to resolve beyond dispute particular ethical problems. The objective is to provide an analytical framework that will guide you in the resolution of ethical problems arising from your research.

The following sections will discuss the distinction between research and practice, three basic ethical principles, the application of these principles to your work as a researcher, and documentation required to demonstrate that these principles have been appropriately applied in your research.

Boundaries Between Practice and Research

It is important to distinguish between research and experimental practices in order to know what activities ought to undergo review for the protection of humans in research. The distinction between research and practice is blurred partly because both often occur together (as in research designed to evaluate an innovation), partly because notable departures from standard practice often are called "experimental," and partly because practitioner research/ teacher research/ action research consists of research undertaken specifically with an eye toward change—often of practice and/or structure.

For the most part, the term “practice” refers to interventions that are designed solely to enhance the well being of others and that have a reasonable expectation of accomplishing the goals you set. While research may be necessary before such interventions are undertaken, the two (research and practice) are not synonymous. By contrast, the term “research” designates an activity which might be designed to test an hypothesis, permit conclusions to be drawn, shed light on an articulated problem, develop or contribute to knowledge that might be generalized or context specific, or to create or enlarge upon theory. Research usually is described in a formal protocol that articulates a problem or sets forth an

² Since 1945, various codes for the proper and responsible conduct of human experimentation in medical research have been adopted by different organizations. The best known of these codes are the Nuremberg Code of 1947, the Helsinki Declaration of 1964 (revised in 1975), and the 1971 Guidelines (codified into Federal Regulations in 1974) issued by the U.S. Department of Health, Education, and Welfare. Codes for the conduct of social and behavioral research have also been adopted, the best known being that of the American Psychological Association, published in 1973.

objective and a method or set of procedures designed to investigate the problem or to reach an articulated objective.

When you depart in a significant way from standard or accepted practice, your innovation does not, in and of itself, constitute research. The fact that your pedagogy is “experimental,” in the sense of new, untested or different, does not automatically place it in the category of research. Although it should be noted, radically new pedagogies should probably be made the object of formal research at an early stage.

Research and practice may be carried on together when research is designed to evaluate the safety and efficacy of an intervention. This need not cause any confusion regarding whether or not the activity requires review; the general rule is that if there is any element of research in your innovative practice, that practice should undergo review for the protection of human participants.

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 cultural tradition, are particularly relevant to the ethics of research involving human participants: the principles of respect of persons, beneficence and justice.

▲ *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.

An autonomous person is an individual capable of deliberation about personal goals and of acting under the direction of such deliberation. To respect autonomy is to give weight to autonomous persons’ considered opinions and choices while refraining from obstructing their actions unless they are clearly detrimental to others. To show lack of respect for an autonomous agent is to repudiate that person’s considered judgments, to deny an individual the freedom to act on those considered judgments, or to withhold information necessary to make a considered judgment, when there are no compelling reasons to do so.

However, not every human being is capable of self-determination. The capacity for self-determination matures during an individual’s life, and some individuals lose this capacity wholly or in part because of illness, mental disability, or circumstances that severely restrict liberty. Respect for the immature and the incapacitated may require protecting them as they mature or while they are incapacitated.

Some persons are in need of extensive protection, even to the point of excluding them from activities that 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 participants, respect for persons demands that participants 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 participants in 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. Respect for persons would then dictate that prisoners be protected. Whether to allow prisoners to “volunteer” or to “protect” them presents a dilemma. Respecting persons, in most hard cases, is often a matter of balancing competing claims urged by the principle of respect itself.

▲ **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 your research, beneficence should be understood in a stronger sense—as an obligation. Two general rules have been formulated as complementary expressions of beneficent actions in this sense: do not harm and maximize possible benefits and minimize possible harms.

The Hippocratic maxim “do no harm” has long been a fundamental principle of medical ethics. Claude Bernard extended it to the realm of research, saying that one should not injure one person regardless of the benefits that might come to others. However, even avoiding harm requires learning what is harmful; and, in the process of obtaining this information, persons may be exposed to risk of harm. Further, the Hippocratic Oath requires physicians to benefit their patients “according to their best judgment.” Learning what will in fact benefit may require exposing persons to risk. The problem posed by these imperatives is to decide when it is justifiable to seek certain benefits despite the risks involved, and when the benefits should be foregone because of the risks.

The obligations of beneficence affect you as researcher 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, you and supporting members of your institution are obliged to give forethought to the maximization of benefits and the reduction of risk that might occur from the research investigation. In the case of research in general, members of the larger society are obliged to recognize the longer term benefits and risks that may result from the improvement of knowledge and from the development of innovative educational and other social interventions.

▲ **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. This requires explication. Who is equal and who is unequal? What considerations justify departure from equal distribution? 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. There are several widely accepted formulations of just ways to distribute burdens and benefits. Each formulation mentions some relevant property on the basis of which burdens and benefits should be distributed. These formulations are

- to each person an equal share,
- to each person according to individual need,
- to each person according to individual effort,
- to each person according to societal contribution, and
- to each person according to merit.

Questions of justice have long been associated with social practices such as punishment, taxation and political representation. Until recently these questions have not generally been associated with scientific research. However, they are foreshadowed even in the earliest reflections on the ethics of research involving human participants. For example, during the 19th and early 20th centuries the burdens of serving as research participants fell largely upon poor ward patients, while the benefits of improved medical care flowed primarily to private patients. We have previously discussed the horrendous examples of research undertaken by the Nazis during World War II and the Tuskegee syphilis study.

Against this historical background, it can be seen how conceptions of justice are relevant to research involving human participants. For example, the selection of your research participants needs to be scrutinized in order to determine whether some classes (e.g., welfare recipients, particular racial and ethnic groups, 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 new beneficial services and practices, 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.

Applications

Applications of the general principles to the conduct of your research leads to consideration of the following requirements: informed consent, risk/benefit assessment, and the selection of participants for research.

▲ *Informed Consent*

Respect for persons requires that the participants in your research, to the degree that they are capable, be given the opportunity to choose what shall or shall not happen to them. This opportunity is provided when adequate standards for informed consent are satisfied. Informed consent means the knowing consent of an individual (or of a legally authorized representative when a vulnerable or dependent person is to be involved) to his or her participation in a research activity without coercion or undue influence.

While the importance of informed consent is unquestioned, controversy prevails over the nature and possibility of an informed consent. Nonetheless, there is widespread agreement that the consent process can be analyzed as containing three elements: information, comprehension and voluntariness.

Information. Most codes of research establish specific items for disclosure intended to assure that participants are given sufficient information. These items generally include: the

research procedure, their purposes, risks and anticipated benefits, alternative procedures (where interventions are involved), and a statement offering the participant opportunity to ask questions and to withdraw at any time from the research. Additional items have been proposed, including how participants are selected, the person responsible for the research, etc.

However, a simple listing of items does not answer the question of what the standard should be for judging how much and what sort of information you should provide. You might want to consider a standard of “the reasonable volunteer:” the extent and nature of information should be such that persons, knowing that their involvement in your project is neither necessary for them nor perhaps fully understood, can decide whether they wish to participate in the furthering of knowledge. Even when some direct benefit to them is anticipated, the participants should understand clearly the range of risk and the voluntary nature of participation.

A special problem of consent arises where informing participants of some pertinent aspect of the research is likely to impair the validity of the research. In many cases, it is sufficient to indicate to participants that they are being invited to participate in research of which some features will not be revealed until the research is concluded. In all cases of research involving incomplete disclosure, such research is justified only if it is clear that

- Incomplete disclosure is truly necessary to accomplish the goals of the research;
- There are no undisclosed risks to participants that are more than minimal; and
- There is an adequate plan for debriefing participants, when appropriate, and for dissemination of research results to them.

Information about risks should never be withheld for the purpose of eliciting the cooperation of participants, and truthful answers should always be given to direct questions about the research. Take care to distinguish cases in which disclosure would destroy or invalidate your research from cases in which disclosure would simply inconvenience you, the investigator.

A specific consent form should usually be developed for each research project. This form would contain the following:

- A statement that the study involves research, an explanation of the purposes of the research and what is being asked of the participants;
- A description of any benefits or reasonably foreseeable risks or discomforts to the participants (see below);
- A statement describing whether and how confidentiality of records identifying the participants will be maintained;
- An explanation of whom to contact for answers to pertinent questions about the research and research participants' rights; and
- A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled, and the participant may discontinue participation at any time without penalty or loss of benefits to which the participant is otherwise entitled.

Comprehension. The manner and context in which you convey information is as important as the information itself. For example, presenting information in a disorganized and rapid fashion, allowing too little time for consideration or curtailing opportunities for questioning, all may adversely affect a participant's ability to make an informed choice.

Because the participant's ability to understand is a function of intelligence, rationality, maturity and language, it is necessary to adapt the presentation of the information to the participant's capacities. You are responsible for ascertaining that the participant has comprehended the information.

You should express that information—orally or in written form—verbally and in a language which is understandable to the participant or the participant's representative. The text of a consent form should not involve any exculpatory language through which the participant is asked to waive any legal rights, including release of you or your institutional sponsor from liability for negligence. All participants or their authorized representatives should be given a copy of any consent document that they have completed.

Voluntariness. An agreement to participate in research constitutes a valid consent only if voluntarily given. This element of informed consent requires conditions free of coercion and undue influence. Coercion occurs when an overt threat of harm is intentionally presented by one person to another in order to obtain compliance. Undue influence, by contrast, occurs through an offer of an excessive, unwarranted, inappropriate or improper reward or other overture in order to obtain compliance. Also, inducements that would ordinarily be acceptable may become undue influences if the participant is especially vulnerable.

Unjustifiable pressures usually occur when persons in positions of authority or commanding influence—especially where possible sanctions are involved—urge a course of action for a participant. A continuum of such influencing factors exists, however, and it is impossible to state precisely where justifiable persuasion ends and undue influence begins. But undue influence would include actions such as manipulating a person's choice through the controlling influence of a close relative or threatening to terminate employment.

▲ **Assessment of Risk and Benefits**

The assessment of risks and benefits requires a careful arrayal of relevant data, including, in some cases, alternative ways of obtaining the benefits sought in the research. Thus, the assessment presents both an opportunity and a responsibility to gather systematic and comprehensive information about your proposed project. For you, it is a means to examine whether your research is properly designed. For prospective participants in your research, the assessment will assist them in determining whether or not to participate.

The requirement that research be justified on the basis of a favorable risk/benefit assessment bears a close relation to the principle of beneficence, just as the moral requirement that informed consent be obtained is derived primarily from the principle of respect for persons. The term "risk" refers to a possibility that harm may occur. However, when expressions such as "small risk" or "high risk" are used, they usually refer (often ambiguously) both to the chance (probability) of experiencing a harm and the severity (magnitude) of the envisioned harm.

The term "benefit" is used in the research context to refer to something of positive value related to health or welfare. Risk is properly contrasted to probability of benefits, and

benefits are properly contrasted with harms rather than risks of harm. Accordingly, so-called risk/benefit assessments are concerned with the probabilities and magnitudes of possible harm and anticipated benefits. Many kinds of possible harms and benefits need to be taken into account. There are, for example, risks of psychological harm, physical harm, legal harm, social harm and economic harm and the corresponding benefits. While the most likely types of harms to participants of research in the social sciences are those of psychological pain or injury, other possible kinds should not be overlooked.

Risks and benefits of research may affect the individual participants, the families of the individual participants, and society at large (or special groups of participants in society). Previous codes and Federal regulations have required that risks to participants be outweighed by the sum of both the anticipated benefit to the participant, if any, and the anticipated benefit to society in the form of knowledge to be gained from the research. In balancing these different elements, the risks and benefits affecting the immediate research subject will normally carry special weight. On the other hand, interests other than those of the participant may on some occasions be sufficient by themselves to justify the risks involved in the research, so long as the participants' rights have been protected. Beneficence thus requires that we protect against risk of harm to participants and also that we be concerned about the loss of the substantial benefits that might be gained from research.

It is commonly said that benefits and risks must be "balanced" and shown to be "in a favorable ratio." The metaphorical character of these terms draws attention to the difficulty of making precise judgments. However, the idea of systematic, non-arbitrary analysis of risks and benefits should be emulated insofar as possible. This ideal requires you to be thorough in the accumulation and assessment of information about all aspects of your research, and to consider alternatives systematically. This procedure renders the assessment of your research more rigorous and precise, while making communication with IIRB members less subject to misinterpretation, misinformation and conflicting judgments. Thus, there should first be a determination of the validity of the presuppositions of the research; then the nature, probability and magnitude of risk should be distinguished with as much clarity as possible. The method of ascertaining risks should be explicit, especially where there is no alternative to the use of such vague categories as small or slight risk. It should also be determined whether your estimates of the probability of harm or benefits are reasonable, as judged by known facts or other available studies.

▲ ***Selection of Participants***

Just as the principle of respect for persons finds expression in the requirements for consent, and the principle of beneficence in risk/benefit assessment, the principle of justice gives rise to moral requirements that you use fair procedures and attain fair outcomes in the selection of your research participants.

Justice is relevant to the selection of participants in research at two levels: the social and the individual. Individual justice in the selection of participants would require that you exhibit fairness: thus, you should not offer potentially beneficial research only to persons who are in your favor or select only "undesirable" persons for risky research. Social justice requires that distinction be drawn between classes of participants that ought, and ought not, to participate in any particular kind of research, based on the ability of members of that class to bear burdens and on the appropriateness of placing further burdens on already burdened persons. Thus, it can be considered a matter of social justice that there is an order of preference in the selection of classes of participants and that some classes of potential

participants (e.g., the institutionalized mentally infirm or prisoners) may be involved as research participants, if at all, only on certain conditions.

Injustice may appear in the selection of participants, even if individual participants are selected fairly and treated fairly in the course of research. This injustice arises from social, racial, sexual and cultural biases institutionalized in society. Thus, even if you treat your research participants fairly, and even if the IRRB takes care to assure that participants are selected fairly within a particular institution, unjust social patterns may nevertheless appear in the overall distribution of the burdens and benefits of your research. Although you may not be able to resolve a problem that is pervasive in your social setting, you can consider distributive justice in selecting research participants.

One special instance of injustice results from the involvement of vulnerable participants. Certain groups, such as racial groups, the economically disadvantaged, the very sick, and the institutionalized may continually be sought as research participants, owing to their ready availability in settings where research is conducted. Such groups may, in the past, have cooperated with researchers in the mistaken belief that academic research would lead to an improvement of the social or economic conditions under which they live. Given their dependent status and their frequently compromised capacity for free consent, they should be protected against the danger of being involved in research solely for academic ends, or because they are easy to manipulate as a result of their political or socioeconomic condition.

Status of Research Projects

There are three categories used in evaluating research projects: projects requiring full review, projects requiring an expedited review, and projects exempt from IRRB review. It is assumed that all research will require the full review of the IRRB unless that research meets criteria specified below.

▲ Exempt from Review

When the involvement of human participants in research falls only in one of the following categories, such research is exempt from the Federal Human Subject Review Policy. Determination of exemption for student research is made by the committee chair or advisor *and* the program director or department chair on the basis of documentation submitted by the researcher(s). The declaration of exemption, together with accompanying documentation, is filed with the IRRB.

Categories (one of the following):

- ☐ Research in common educational settings, involving normal or special educational practices. (46.101b 1)³
- ☐ Research involving educational tests, surveys, interviews, or observation unless confidentiality cannot be maintained or disclosure places the participants at risk. (46.101b 2)
- ☐ Research involving elected or appointed public officials or candidates for office, even when confidentiality cannot be maintained or disclosure places the participants at risk. (46.101b 3)

³ Numbers refer to the *Code of Federal Regulations, Title 45, Public Welfare, part 46, Protection of Human Participants* (revised October 1, 1997).

- ☐ Research involving the study of existing data either publicly available or recorded by the researcher(s) in a manner that maintains confidentiality. (46.101b 4)
- ☐ Institutional or organizational research designed to improve service or benefits when approved by the agency's head. (46.101b 5)

▲ ***Expedited Review***

Expedited review by the IRRB Chair or a designated member of the IRRB will suffice for research proposals meeting either of two criteria AND falling into one of the categories below:

Criteria (either of the following):

- ☐ Research involves no more than minimal risk. (46.110b 1)
- ☐ Minor changes are proposed in previously approved research. (16.110b 2)

Categories:

- ☐ The collection of biological specimens or data for research purposes by noninvasive means. (63 FR 60364-60367F 1-4)
- ☐ Research involving materials (data, documents, records, or specimens) collected solely for non-research purposes (such as medical treatment or diagnosis). (63 FR 60364-60367F 5-6)
- ☐ Research employing survey, interview, program evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from review.) (63 FR 60364-60367F 7)

Documentation

To document the way you have attended to these criteria you will need to write a brief summary of your project, describing in non-technical terms what will happen in relation to the participants of your inquiry. Describe any benefits and any potential risks to them. To the best of your ability, give anticipated numbers of participants you will involve as sources, with attention to race, gender, class and age. Also specify how participants will be recruited and what procedures you propose to obtain informed consent.

Complete a copy of the form included at the end of this document—the Review of Research Involving Human Participants—and attach to that form any relevant documentation, for example any forms you will use related to “informed consent.” Sign the Review form along with your co-researchers, if any.

Documentation should be given to your department head or program director for an initial determination of status. If it is necessary for your project to receive full review by the IRRB, the department head or program director will inform you of this. You will receive written notification in either case indicating the decision of the reviewing body. The collection of data can only begin after your project has been reviewed and approved by a department head or program director (if the project is Exempt) or by the IRRB.