

FREQUENTLY ASKED QUESTIONS ABOUT THE  
NEW JERSEY INSTITUTE OF TECHNOLOGY'S  
INSTITUTIONAL REVIEW BOARD

Approved 9/29/05

## A. GENERAL INFORMATION

### 1. Who should be contacted for questions about IRB policy and procedures?

For questions (other than what is found on this page), please contact Dr. Dawn Hall Apgar, IRB Chair, by telephone at (973) 642-7616 or by email at: dawn.apgar@njit.edu.

### 2. How can investigators obtain IRB forms?

All of the IRB forms are available for download from the NJIT IRB website: <http://www.njit.edu/research/irb>. Researchers are encouraged to download the latest form instead of re-using saved applications.

### 3. What is the IRB?

The Institutional Review Board for the Protection of Human Subjects in Research (IRB) is the body at the New Jersey Institute of Technology (NJIT), charged with the protection of individuals who participate in research conducted by University personnel, students, or staff. All research protocols that involve human subjects must be reviewed and approved by the IRB PRIOR to initiation of study procedures. The IRB is an autonomous body, (i.e., decisions of the Board may not be influenced by any individual, department, office or other University entity).

### 4. Who serves on the IRB?

IRB members are appointed by the Associate Vice President for Research and Development. In accordance with applicable federal regulations, the Board must have a minimum of five members, including at least one individual who would be considered a non-scientist. Members are selected from faculty, staff, students, and community members. Considerable effort is expended to recruit individuals who have expertise in different areas. This diversity helps to ensure that protocols are evaluated fairly by knowledgeable individuals. If necessary, non-voting consultants may be enlisted to review specific protocols for which there is no IRB member with sufficient knowledge of the research method or scientific discipline to conduct a substantive review.

## B. POLICY

### 1. Upon what federal regulations is IRB policy based?

The primary regulation that pertains to human subjects research is Title 45 of the Code of Federal Regulations, Part 46 (45 CFR 46). This statute defines relevant terms and describes all aspects of human subjects protection, including the composition of review boards, criteria for protocol review, guidelines for informed consent, requirements for record-keeping, special protections for vulnerable populations, types of review, and procedures for dealing with non-compliance. It is based on the ethical principles identified in the Belmont Report. As written, 45 CFR 46 applies only to federally funded research, however, NJIT maintains an agreement with the federal Department of Health and Human Services (DHHS) that extends the protections of 45 CFR 46 to all research conducted by University personnel, students, and staff, regardless of the source of funding, or lack thereof. This agreement is the Federal Wide Assurance (No.: HHS FWA 00003246) and is required before the institution may receive federal research funds.

If a protocol includes the use of FDA-regulated drugs, devices, or biologics, then Title 21 of the Code of Federal Regulations (21 CFR) is applicable. The terms described in 21 CFR and 45 CFR 46 are similar in many ways, but there are important differences that investigators should be aware of (comparison of regulations: <http://www.fda.gov/oc/ohrt/irbs/appendix.html>).

### 2. What is the Belmont Report and how has it influenced federal regulations regarding the protection of human subjects?

On July 12, 1974, the National Research Act (Pub. L. 93-348) 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. In carrying out the above, the Commission was directed to consider: **(i)** the boundaries between biomedical and behavioral research and the accepted and routine practice of medicine, **(ii)** the role of assessment of risk-benefit criteria in the determination of the appropriateness of research involving human subjects, **(iii)** appropriate guidelines for the selection of human subjects for participation in such research and **(iv)** the nature and definition of informed consent in various research settings.

The Belmont Report attempts to summarize the basic ethical principles (respect for persons, beneficence, and justice) identified by the Commission in the course of its deliberations. Unlike most other reports of the Commission, the Belmont Report does not make specific recommendations for administrative action by the Secretary of the Department of Health and Human Services (formerly the Department of Health, Education, and Welfare). Rather, the Commission recommended that the Belmont Report be adopted in its entirety, as a statement of the Department's policy.

3. **How do the ethical principles identified in the Belmont Report relate to human subjects protection?**

**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. In most cases of research involving human subjects, respect for persons demands that subjects enter into the research voluntarily and with adequate information (informed consent). Respect for the immature and the incapacitated may require protecting them as they mature or while they are incapacitated (e.g., assent of the subject, permission from a parent/guardian).

**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 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. In the case of scientific 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 novel medical, psychotherapeutic, and social procedures.

**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.

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 subjects. For example, during the 19th and early 20th centuries the burdens of serving as research subjects fell largely upon poor ward patients, while the benefits of improved medical care flowed primarily to private patients. Against this historical background, it can be seen how conceptions of justice are relevant to research involving human subjects. 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.

## **C. IRB REVIEW**

### **1. How often does the IRB meet?**

The IRB meets approximately monthly or as needed to review protocols which require approval by the full committee and discuss human subjects' policy issues. Please contact Dr. Dawn Hall Apgar, IRB Chair, by telephone at (973) 642-7616 or by email at: [dawn.apgar@njit.edu](mailto:dawn.apgar@njit.edu) to find out when the next meeting will occur.

### **2. What is the deadline for submission of protocols for IRB review?**

Applications for full review must be received at least a week prior to the scheduled meeting date. Applications for expedited review may be submitted at any time and are reviewed on a rolling basis.

### **3. How long does the IRB review process take?**

Review of expedited protocols may take up to 10 business days, while applications requiring full review may take a month or longer to complete. If there are substantive revisions required to research protocols at the request of the IRB, it is usually necessary to return to the full board for review at the next regularly scheduled IRB meeting. Be sure to allow sufficient time in your research plan to complete IRB review process. Note: You may not begin your research until the IRB has provided written approval.

### **4. How do I know when my application has been approved?**

You will receive written notification of the status of your application following IRB review. The IRB will identify any required revisions at that time. Note: You may not begin your research until the IRB has provided written approval.

### **5. Do I have to attend the IRB meeting when my application is reviewed?**

If a full review is necessary, the Principal Investigator (PI) will be asked to attend the meeting where it will be reviewed. An e-mail detailing the time and place of the meeting will be sent to the PI.

### **6. What are the criteria for IRB review of a protocol?**

When reviewing a protocol, the IRB must make the following determinations:

(1) Risks to subjects are minimized: (i) by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.

(2) Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

(3) Selection of subjects is equitable. In making this assessment, the IRB should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disable persons, or economically or educationally disadvantaged persons.

(4) Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by §46.116.

(5) Informed consent will be appropriately documented, in accordance with, and to the extent required by §46.117.

(6) When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.

(7) When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, persons with cognitive impairments, or persons who are economically or educationally disadvantaged, additional safeguards have been included in the study to protect the rights and welfare of these subjects.

**7. Why is it necessary for the federal government to require that institutions review proposed research projects? Don't all researchers take the appropriate steps to protect subjects on their own?**

The vast majority of researchers plan and conduct their research in accordance with sound ethical principles. However, there is adequate documentation that some investigators do not take the necessary steps, either through conscious choice or as a result of ignorance, to protect the individuals who volunteer to participate in their research. When the researcher is affiliated with an academic institution, repercussions for failing to protect subjects affect not only the investigator, but the institution as well. For this reason, oversight by an institutional review board is necessary to ensure that projects include the appropriate safeguards to protect human subjects. The federal regulations postulated at 45 CFR 46 and 21 CFR describe those protections and form the basis for IRB policy.

**8. When is IRB review required?**

IRB review is required whenever an investigator who is affiliated with the institution conducts *research with human subjects*.

Research is defined in 45 CFR 46 as "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge". Student projects are considered to be research whether or not there is intent to disseminate study results, if all other conditions are met.

A human subject is defined in 45 CFR 46 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".

**9. What are the different types of IRB review, and how do they differ from one another?**

There are two main levels of IRB review: expedited and full review.

**Expedited Review:** Protocols that present no more than minimal risk to subjects may qualify for expedited review. The investigator must complete an IRB application and attach all relevant documents. It is the decision of the IRB Chair to determine whether expedited or full review is needed.

**Full Review:** The investigator must complete an IRB application and attach all relevant documents. After determination that it does not qualify for expedited review, the protocol is presented and discussed at a convened meeting of the full IRB. The investigator is notified of the outcome shortly after the meeting by email.

**10. How is minimal risk defined?**

A risk is minimal where the probability and magnitude of harm or discomfort anticipated in the proposed 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 [Federal Policy 45 CFR 46.102(i)].

**11. Do I have to let the IRB know when my project is completed?**

YES. Keeping the IRB informed about the status of each approved IRB protocol is the responsibility of the PI. The IRB requires that PIs formally close their research projects. The end of data collection is not when you should close your IRB protocol; the protocol should be kept active through the analysis portion of the research and through publication.

**12. If the project will not be completed by the IRB expiration date, what is the procedure for requesting continuation?**

Federal regulations require that all approved studies involving human subjects be reviewed by the IRB at least annually. Approximately a month prior to the expiration date of a protocol, the investigator will receive an e-mail reminding him/her of the need to complete a Human Services Review Form for Annual Review. If the project, including data analysis, will not be completed by the expiration date, then the investigator should complete the form and return it as quickly as possible so that there is no interruption in the approval period.

**13. When it is necessary to change or add procedures on an approved protocol, what is the process for obtaining IRB approval of the change?**

Note that any deviation from the approved research protocol *must* be reviewed by the IRB *prior* to implementation of those changes. For example, any changes in the consent form or the questionnaires/interview guides must be submitted to the IRB prior to use.

To request an amendment (change) or addendum (addition) to an approved protocol, send the information to Dr. Dawn Hall Apgar, IRB Chair, by telephone at (973) 642-7616 or by email at: [dawn.apgar@njit.edu](mailto:dawn.apgar@njit.edu).

Include the following information: description of the change or addition, rationale for the modification, unmarked copy of new documents (e.g., consent form, study instrument,

advertisement), and the revised documents (noting all changes by **bolding** additions and deletions via ~~strike through~~; or via the track-changes feature in MSWord).

After IRB review, a Notice of Approval or will be sent to the investigator. Changes to approved protocols may not be implemented until the change is approved by the IRB.

Amendments to applications approved through full review must be received at least a week prior to a scheduled meeting date in order to be considered at that meeting. Amendments to applications approved through expedited review may be submitted at any time and are reviewed on a rolling basis.

**14. What are the researcher's responsibilities if an adverse or unexpected event occurs on an approved protocol?**

An Adverse/Unexpected Event is defined as: (1) any medical, psychological or behavioral event that is undesirable and unintended, although not necessarily unexpected; (2) an event in which the outcome is fatal or life threatening, causes permanent disability, causes hospitalization or prolongation of hospitalization; (3) an overdose; or (4) a complaint by a research subject or family member of a research subject concerning the research or the protocol.

All fatal or life-threatening events occurring at NJIT must be reported in writing to the IRB Chair, Dr. Dawn Hall Apgar, within 24 hours, even if all the information is not available. Follow-up written notification must be submitted within 5 days.

All other serious adverse events must be reported within 5 days.

It is the responsibility of the PI to ensure that written notification of such adverse events is submitted to the IRB. The PI must include all information necessary to evaluate severity of the event.

**15. If research is being done by NJIT faculty and staff in collaboration with those from other institutions and the project has been approved by the other institutions' IRBs, is NJIT IRB approval necessary?**

YES. All research involving human subjects conducted by members of the NJIT faculty or staff at other institutions, must be approved by the NJIT IRB prior to initiation. NJIT faculty or staff can often submit copies of the IRB applications which have been approved by other institutions, along with the written notifications of approval, for consideration by the NJIT IRB. In some instances, it may be requested by the NJIT IRB that faculty or staff transfer the information onto the NJIT IRB application forms. However, attempts to minimize additional work for PIs will be made as long as all of the required elements are submitted.

**16. What, if any, education is required of research personnel seeking IRB approval?**

NJIT requires a web-based education program for all PIs and other key personnel who are named on protocols that involve human subjects. As a requirement for an assurance of compliance, which allows an institution to receive federal funding for research involving human subjects, the federal Office for Human Research Protections (OHRP) has mandated that PIs and other key personnel involved in human subject protocols participate in education designed to increase understanding of the regulations, policies, and ethical standards governing the

protection of human subjects. Certification of successful completion of the education program is required before IRB approval will be granted.

This program can be accessed by going to the US Department of Health and Human Services' Office for Human Research Protection website (<http://www.hhs.gov/ohrp/>) and clicking on "Education." At the bottom of this page, you will see the tutorial for the training module for assurances. All certificates indicating course completion must be submitted with the IRB application.

## D. INFORMED CONSENT

### 1. What is informed consent?

Informed consent is one of the primary ethical requirements underpinning research with human subjects; it reflects the basic principle of respect for persons. It is too often forgotten that informed consent is an ongoing process, not a piece of paper or a discrete moment in time. Informed consent assures that prospective human subjects will understand the nature of the research and can knowledgeably and voluntarily decide whether or not to participate. The prospective subject should be presented with the information, then given an opportunity to ask questions and have them answered, prior to signing the consent document.

### 2. What are the rights of a research subject?

A research subject has the right to read and discuss the informed consent before participating in any research. A research subject has the right to ask any questions regarding the research and to have these questions answered in a satisfactory manner. The subject's decision whether or not to participate in the research is completely voluntary. The subject has the right to information concerning, but not limited to, the study procedures and purpose, risks and benefits, confidentiality, compensation and contact names. The subject has the right to withdraw from the study at any time without penalty.

### 3. What elements should be included in a consent document?

Basic elements of informed consent that should be included are:

(1) a statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;

(2) a description of any reasonably foreseeable risks or discomforts to the subject and a statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable;

(3) a description of any benefits to the subject or to others which may reasonably be expected from the research;

(4) a disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;

(5) a statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;

(6) for research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;

(7) an explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject;

(8) a statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled;

(9) anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent (if applicable); and

(10) the approximate number of subjects involved in the study.

PIs are encouraged to see the NJIT Policies on Research with Human Subjects at <http://www.njit.edu/research/irb> for a complete listing of informed consent elements.

#### **4. Are sample consent forms available for review?**

YES. A sample consent form is found within the initial IRB application which is available for download from the NJIT IRB website: <http://www.njit.edu/research/irb>. Researchers do not have to use this model form as long as their consent documents contain all of the required elements.

#### **5. What is assent?**

Assent is defined as, "A child's affirmative agreement to participate in research." While children may be legally incapable of giving informed consent, they nevertheless may possess the ability to assent to or dissent from participation. Out of respect for children as developing persons, children should be asked whether or not they wish to participate in the research, particularly if the research: (1) does not involve interventions likely to be of benefit to the subjects; and (2) the children can comprehend and appreciate what it means to be a volunteer for the benefit of others.

Assent is an indication of agreement by children as to their involvement in the research protocol, which must be explained to them in language they can understand. This personal assent must be documented on the written consent form.

There are only two circumstances in which children may be enrolled in a research protocol without their assent. The first situation is when the IRB (not the PI) determines that the understanding of some or all of the children involved is so limited that they cannot be reasonably consulted (because of age, maturity, or mental state). A child's assent may also be waived when it is evident that the intervention or procedure involved in the research shows a prospect of direct benefit that is important to the health or well-being of the specific child (subject) and is available only in this context.

#### **6. Under what conditions may documentation of informed consent be waived by the IRB?**

Under certain conditions, the requirement to provide documentation of the informed consent process can be waived. In this process, the PI obtains informed consent through the use of an oral consent script. Similar to a written consent, the script would include information regarding

the nature and duration, risks and benefits, alternatives, and cost to subjects. The subject will either verbally agree or not agree to participate in the study. PIs are not required to secure written documentation of consent obtained orally.

To qualify for oral consent, one of the following criteria must apply:

- a. The only record linking the subject and the research would be the consent document and the principal risk would be the potential harm resulting from a breach of confidentiality.
- b. The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

In situations in which signed consent will not be obtained, it is often advisable to present subjects with an information sheet or letter that contains the elements of informed consent, for their future reference.

**7. Under what conditions may some or all of the elements of written informed consent be waived by the IRB?**

Written consent is required from any human subject in research unless it has been specifically waived by the IRB. The IRB may waive written informed consent under two sets of circumstances:

- a. if the project involves no more than minimal risk; the waiver doesn't adversely affect subjects; the research couldn't practicably be carried out without the waiver; and, where appropriate, subjects are given information about the project afterwards.
- b. the research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine: (i) public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs; and the research could not practicably be carried out without the waiver or alteration.

Otherwise, written informed consent must be obtained. For additional information, review the applicable federal regulation online at:

<http://ohrp.osophs.dhhs.gov/humansubjects/guidance/45cfr46.htm#46.116>.