



# ***HUMAN SUBJECTS RESEARCH***

## ***Policies And Procedures***

***OFFICE OF ACADEMIC AFFAIRS***

***ROBERT MORRIS UNIVERSITY***

**October 2002**

**REVISED 09/03**

## TABLE OF CONTENTS

|  |    |
|--|----|
| 1. Introduction.....                                 | 2  |
| 2. Exempt Research... ..                             | 3  |
| 2.1. Research Involving Adult Subjects.....          | 3  |
| 2.2. Research Involving Children.....                | 4  |
| 3. Non-Exempt Research and Review Procedure.....     | 5  |
| 3.1. The Institutional Review Board.....             | 6  |
| 3.2. Human Subjects Research Review Application..... | 7  |
| 3.3. Administration.....                             | 8  |
| 4. Informed Consent.....                             | 8  |
| 4.1. Definitions.....                                | 9  |
| 4.2. Informed Consent in Exempt Research.....        | 10 |

### APPENDICES

|   |    |
|---|----|
| Appendix A-Human Research Review Application Form.....                | 12 |
| Appendix B-Informed Consent Guidelines and Example.....               | 18 |
| Appendix C-Example a Cover Letter for Informed Consent Document ..... | 29 |
| Appendix D- Confidentiality .....                                     | 30 |
| Appendix E-Confidentiality Form.....                                  | 32 |
| Appendix F-Certification of Investigator Responsibilities .....       | 33 |
| Appendix G-Code of Federal Regulations .....                          | 34 |

## 1. INTRODUCTION

Past abuses in clinical research have led the Federal Government to mandate that researchers safeguard the rights and welfare of the people who are the subjects of their activities. An increasing number of colleges and universities are electing to apply the same protections to human subjects involved in all types of research.

The regulations that govern human subject protection specify the processes required for such protection. Institutions that undertake clinical and/or government-funded research, including government facilities, are required to have an “Institutional Review Board (IRB)” and appropriate procedures and documentation to ensure that human subjects are protected. These organizations conduct at least a brief review of all research performed under their aegis. The research that presents risk to its subjects or which is specifically identified in the regulations is subject to more extensive scrutiny. This document provides guidelines for when review by the Robert Morris University IRB must occur. Robert Morris University’s Institutional Review Board consists of at least five members of varying backgrounds. One member is unaffiliated with the University. At least one representative from each of the schools is appointed.

Federal law, based on the principles of individuals’ rights to privacy and protection of citizens from harm by others, has led to clear rules about the conditions under which we may do research using human subjects. Robert Morris University is committed to these laws based on moral, ethical, and legal grounds. All research that comes under the aegis of the University must meet the procedures established to ensure the privacy and protection of human subjects. These procedures are followed by faculty and students in any research they conduct regardless of where it is actually conducted. The researchers must also inform all subjects that they are part of a study, what the likely stresses for them will be in the study, must secure their written consent {or parent/guardians’}, must preserve their anonymity with every possible effort, and fully inform the subjects of their right to withdraw from the study at any time for any reason with no penalties.

Certain categories of research are exempted from federal regulatory requirements, and if the research is identified as exempt, an IRB review is not required. This type of research will be referred to as “Exempt Research” in this document. Appendix G includes Code of Federal Regulations-Title 45, Part 46 Protection of Human Subject (Public Welfare, Department Of

Health And Human Services, National Institutes Of Health Office For Protection From Research Risks).

If the research is not exempt, than the research proposal must be submitted to the IRB for review. At least two-weeks is required for a review of the research proposal. See Appendix A - Directions For The Summary of Proposed Research For Institutional Review.

## 2. EXEMPT RESEARCH

At 46-101 (b) of Part 45 of the Code of Federal Regulations (Appendix G), a number of categories of research are exempted from federal regulatory requirements. The following guidelines must be used to determine exemptions:

### 1.1. Research Involving Adult Subjects

Section 46.101 (2)(b) of the CFR states that... Research activities in which the only involvement of human subjects will be in one or more of the following categories **are exempt**:

“(1) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

(2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:

(i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

(3) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (2)(B) of this section 46.101), if:

(i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

(4) Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

(5) Research and demonstration projects which are conducted by or subject to the approval of Department or Agency heads, and which are 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.

(6) Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.”

## **1.2. Research Involving Children**

Although under federal regulations exemptions are permitted where children are participants in research, research involving children must be reviewed by the IRB except as noted below:

- (1) Chart/Medical Record Review
  - a. A chart/medical record review may be conducted if permission was granted at the time of admission for chart reviews for such purposes, and
  - b. No identifying information is to be collected from the chart/medical record (i.e., name, address, phone number...)
- (2) Observational Studies
  - a. Observational studies may be considered exempt as long as videotaping or audiotaping is not involved, and no identifying information is recorded.
- (3) Educational Studies (Appendix G- 46.101 for definition of educational studies).

Note: “Children” are persons who have not attained the legal age for consent to treatments or procedures involved in research under the applicable law of the jurisdiction on which the research will be conducted. In Pennsylvania the following stipulations apply:

- (1) If the minor is between the ages of 13 and 17, the parent or guardian and the child must give informed consent.
- (2) If the minor is below the age of 13, the informed consent of the parent or guardian must be obtained and the child must be given an explanation of the research. This may entitle the use of a consent form especially prepared to facilitate the understanding by a minor of such age.

### **3. NON-EXEMPT RESEARCH AND REVIEW PROCEDURE**

Research that requires IRB review (those that do not qualify for Exempt), are distributed to each member of the IRB for detailed review. The protocol and consent form(s) are either:

- a. Recommended for approval as is;
- b. Recommended for approval subject to suggested changes which must be reviewed and approved by the Chairperson or his/her designee;
- c. Recommended for reconsideration at the next meeting; or
- d. Recommended for denial of approval.

If the protocol and consent form(s) are to be reconsidered, the comments and the suggestions of the board are sent to the investigator. If the protocol and consent form(s) are disapproved, written comments are sent to the investigator for possible resubmission at a later date. The procedure for the human subject research review is discussed in later sections. The procedures at Robert Morris University address the use of human subjects in research that is not exempt. Both the state and federal governments control human subject research at Robert Morris University. As a policy, all Robert Morris University faculty, students, staff, and administrators are responsible for protecting the rights and well-being of human subjects of research. The following are the basis for Robert Morris University’s human subject procedure:

- All research involving humans as subjects must protect the subjects’ safety, privacy, health, and welfare.

- The benefit of the research must outweigh the risk to the subjects.
- The participation of humans as research subjects is voluntary. Voluntary means that the subject has given consent. The researchers must document informed consent except where the law explicitly waives such documentation.
- A human subject surrenders no rights by participating in research. A human subject will not lose benefit or entitlement by refusing to participate. Furthermore, subjects may withdraw from research at any time without penalty.
- Researchers will protect private information about human subjects that is obtained in the conduct of the research.
- The researcher, whether student, faculty member or staff, will ensure that his/her research complies with this procedure and applicable laws, regardless of the location of the research.

### **3.1. The Institutional Review Board**

**Purpose.** The role of the Institutional Review Board (IRB) is to review research that is federally regulated. Except for those categories specifically exempted or waived under 45 CFR 46.101 (b) (1-6) all other research will be reviewed by the IRB.

**Composition.** The IRB will have at least five members appointed by the Senior Vice President for Academic Affairs. The IRB will have members with varying backgrounds representing each of the schools to provide an adequate review of the research activities. The IRB will include at least one member who is not affiliated with the University.

**Meeting Schedule.** The IRB will meet at least quarterly, and may meet more frequently as required. Official meetings will not begin until at least a majority of members are present.

**Responsibilities.** The responsibilities of the IRB include:

- Each member of the IRB being reasonably knowledgeable about the applicable laws and diligent in reviewing human subject research submitted to the IRB.

- Reviewing and having the authority to approve, require modification, or disapprove research activities under review.
- Providing notice of its decisions and requirements for modifications and accompanied reasons for modifications and disapproval to the researcher.
- Ensuring that informed consent is obtained and documented in a manner that satisfies federal regulations.
- Evaluating whether the protection for human research subjects is adequate in accordance with the criteria found at 45 CFR 46.111.
- Where appropriate, determining that adequate additional protections are ensured for pregnant women, prisoners, and children as required by subparts B, C, and D of 45 CFR 46.

**Review of Adverse Event Reports.** Adverse events that are serious and unexpected will be reported to the IRB chairperson by the researcher within 5 business days of the researcher becoming aware of them.

- If the chair judges that the adverse events are related to the research protocol, then the chair will report to the full board at its next meeting, or call an emergency meeting of the board. The board will review the risks and the benefits of the research protocol and consider changes in the protocol, informed consent, and possible termination of research.
- If the chair judges that an adverse event is unlikely to be related to the research protocol, then the event will be reported to the full board at its next meeting.
- Adverse events that are neither serious nor unexpected will be reported to the IRB chair by the researcher within one month of the researcher becoming aware of them.

### **3.2. Human Subject Research Review Application**

It is the researcher's responsibility to comply with all applicable laws and regulations. The researchers are strongly advised to be aware of any deviations between sponsoring federal agencies. If the researcher is a student, then the faculty advisor bears supervisory responsibility for the conduct of the research and compliance with all applicable regulations.

For non-exempt research, the researcher will submit the following to the IRB no later than two-weeks prior to the next IRB meeting:

- Completed “Human Subject Research Review Application” (Appendix A).
- An “Informed Consent Document” (Appendices B-D).
- A “Confidentiality Form” (Appendix E).
- All research protocols, any questionnaires and documents that the subjects are required to complete.

Please contact the IRB Chairperson for more information and for handouts that outline the regulations governing IRB and the procedures for developing an informed consent or cover letter document.

### **3.3. Administration**

The Associate Vice President for Academic Affairs, or the Senior Vice President’s designee will serve as the research administrator (RA) responsible for oversight of the human subjects review process. Their responsibilities will include:

- Ensuring communication among administrators, deans, researchers, human subjects, as a mean of the rights and well-being of human subjects.
- Maintaining copies of this procedure, 45 CFR 46, pertinent federal policies, and state laws related to human subjects research.
- Ensuring adequate membership and proposing committee membership to the Senior Vice president for Academic Affairs.
- For all federally or state regulated research, promptly reporting to the IRB and the Senior Vice President for Academic Affairs any injuries to human subjects, any unexpected problems, any serious noncompliance, and/or any termination of IRB approval for research.
- Maintaining federal research records.

## **4. INFORMED CONSENT**

Prospective participants in a research study must understand the purpose, the procedures, the potential risks and benefits of their involvement, and their alternatives to participation. While a consent document gives this information, the opportunity to discuss any questions or

concerns with a knowledgeable research team member is also important. Informed consent is about one's understanding and willingness to participate in a study and not about signing a form. Informed consent for minor children (under the age of 18) must be obtained from their parents or legal guardians. Making an informed decision about participating in research includes subjects' having an understanding of the possible risks and benefits to their involvement, and knowing that they do not have to volunteer and can withdraw at any time.

#### **4.1. Definitions**

To discern the key components of informed consent, it is necessary to understand the ethical issues of research involving human subjects. The principles of autonomy, beneficence, and justice are basic to these ethical issues and are worthy of considerations as described below:

**Autonomy.** Autonomy means that each person should be given the respect, time, and opportunity necessary to make his or her decisions. Prospective participants must be given the information they will need to decide to enter a study or not to participate. There should not be pressured to participate. The principle of autonomy requires that protection be given to potentially vulnerable populations such as children, the elderly, the mentally ill, or prisoners. Individuals in these groups may be incapable of understanding information that would enable them to make an informed decision about study participation. They are considered potentially "vulnerable." Consequently, careful consideration of their situation and needs is required and extra care must be taken to protect them.

**Beneficence.** Beneficence obligates the researcher to secure the well-being of all study participants. It is the researcher's responsibility to protect participants from harm, as well as ensure that they experience the possible benefits of involvement.

**Justice.** The concept of justice may be questioned when decisions are being made regarding who will be given the opportunity to participate and who (and for what reason) will be excluded. Participants should not be selected due to class, gender socioeconomic status, or race unless justified by study objectives. See Appendices B-F for Informed Consent Procedures and Forms.

## 4.2. Use of Consent Forms in Exempt Research

Under Section 46.117 © the requirement for a signed consent form for some or all subjects **are exempt** following the below guidelines:

- (1) No consent form is necessary if that document is the only identifier. A subject must, however, be given a consent form to sign if that is his/her wish.
- (2) In the event that a consent form is signed, it must be separated from other information that the participant has filled out in order to avoid identification.
- (3) Where no consent form is used, an informational sheet must be provided to the participant giving the same information that a signed consent form would (i.e., information about the study, risks, and benefits, etc.).

If there are any questions regarding interpretation of any of the above guidelines or federal regulations, please notify the Chairperson of the IRB.