HUMAN SUBJECTS RESEARCH

Policies and Procedures

OFFICE OF ACADEMIC AFFAIRS

ROBERT MORRIS UNIVERSITY

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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 (RMU) IRB must occur. Robert Morris University's Institutional Review Board consists of at least five members of varied disciplines with faculty status. One member is unaffiliated with the University. At least one representative is from each of RMU's five schools.

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, staff, 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 confidentiality 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.

Any research involving human subjects should be submitted to the IRB for review.

THE INSTITUTIONAL REVIEW BOARD

Purpose The role of the Institutional Review Board (IRB) is to review research that is federally regulated. The IRB is guided by Title 45 Code of Federal Regulations Part 46 and the Ethical Principles and Guidelines For the Protection of Human Subjects of Research provided by The Belmont Report. 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 (volunteers are nominated by School Deans). The IRB will have members with varying backgrounds representing each of RMU's five 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. Terms of committee membership are for 3 years and are renewable. Typically, a committee member may serve for two consecutive terms. Subsequent terms may be possible should there be a need. The Chair and Co-chairs are to be determined from the committee. All members are required to successfully complete the CITI program modules.

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. This is evidenced by the completion of appropriate training in human subject research and IRB policy, procedure, and protocol (i.e., CITI, NIH or equivalent).

- Reviewing and having the authority to approve, require modification, or disapprove research activities under review. Once a completed application (revised per requested modifications, if applicable) is received, a final decision will be provided within 10 business days during the regular September to May academic year. Holiday breaks, and the months of June, July, and August may and most likely delay the review process.

- 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

i. Adverse events that are serious and unexpected will be reported to the IRB Chair/Co-chairs by the researcher via email within 5 business days of the researcher becoming aware of them.
    1. If the Chair/Co-chairs judges that the adverse events are related to the research protocol, then the Chair/Co-chairs 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.
    2. If the Chair/Co-chairs 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.

ii. Adverse events that are neither serious nor unexpected will be reported to the IRB Chair/Co-chairs by the researcher within one month of the researcher becoming aware of them.

Administration

The Vice President and Senior Vice Provost for Academic Affairs or 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.

- For all federally or state regulated research, promptly reporting to the IRB and the Vice President and Senior Vice Provost 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.

TYPES OF REVIEWS

The investigator is responsible for carefully reviewing the criteria for exempt, expedited, and full-review studies as defined in the Code of Federal Regulations Title 45 Part 46.101. However, the IRB ultimately determines the category of approval. All research involving human subjects must be reviewed by the IRB, even if the investigator believes the study qualifies for exemption. If PI plans to publish research, the proposal must go before the IRB Committee, regardless of type of review application.

According to 46.101 of the Code, Exempt, Expedited, and Full Review are defined as following:

I. Exempt Review

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as
   i. research on regular and special educational 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 (b) (2) of this section, 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 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.

7. RMU Polling Institute -- opinion polls are traditionally considered exempt research.

8. The Oral History Center conducts interview projects that are exempt. (Language taken from Valerie Raleigh Yow, Recording Oral History: A Guide for the Humanities and Social Sciences, Second Edition (Walnut Creek: AltaMira, 2005):

    In 2003, the U.S. Office for Human Research Protection (OHRP), part of the Department of Health and Human Services (HHS), working in conjunction with the American Historical Association and the Oral History Association, has determined that oral history interviewing projects in general do not involve the type of research defined by HHS regulations and are therefore excluded from Institutional Review Board oversight.

    It is primarily on the grounds that oral history interviews, in general, are not designed to contribute to "generalizable knowledge" that they are not subject to the requirements of the HHS regulations at 45 CFR part 46 and, therefore, can be excluded from IRB review. Although the HHS

regulations do not define "generalizable knowledge," it is reasonable to assume that the term does not simply mean knowledge that lends itself to generalizations, which characterizes every form of scholarly inquiry and human communication. While historians reach for meaning that goes beyond the specific subject of their inquiry, unlike researchers in the biomedical and behavioral sciences they do not reach for generalizable principles of historical or social development, nor do they seek underlying principles or laws of nature that have predictive value and can be applied to other circumstances for the purpose of controlling outcomes. Historians explain a particular past; they do not create general explanations about all that has happened in the past, nor do they predict the future.

Moreover, oral history narrators are not anonymous individuals, selected as part of a random sample for the purposes of a survey. Nor are they asked to respond to a standard questionnaire administered to a broad swath of the population. Those interviewed are specific individuals selected because of their often unique relationship to the topic at hand. Open-ended questions are tailored to the experiences of the individual narrator. Although interviews are guided by professional protocols, the way any individual interview unfolds simply cannot be predicted. An interview gives a unique perspective on the topic at hand; a series of interviews offer up not similar "generalizable" information but a variety of particular perspectives on the topic.)

Exempt Research Involving Children*

Although under federal regulations exemptions <u>are</u> 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 Research conducted in educational settings, involving normal educational practices, such as:
    a) regular and special education instructional strategies.
    b) the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
    c) no identifying information is to be recorded or disclosed outside of research.

* 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.

II. Expedited Review (involves a sub-committee of the IRB)

Expedited review approval may be given if the study involves no more than minimal risk and falls within one of the expedited categories as described in the Code, which is subject to review and change:

1. Clinical studies of drugs and medical devices only when the drugs or devices have been approved for marketing and are used as prescribed.

2. Collection of blood samples by finger stick or venipuncture from non-pregnant healthy adults in amounts less than 550 ml in an eight-week period and no more than twice per week.

3. Prospective collection of biological specimens by non-invasive means (e.g. hair and nail clippings, extracted teeth, excreta and external secretions, uncannulated saliva, placenta removed at delivery, amniotic fluid obtained at rupture of membrane prior to or during delivery, dental plaque and calculus, mucosal and skin cells collected by swab and sputum collected after saline mist nebulization.)

4. Collection of data through non-invasive procedures routinely employed in clinical settings, excluding x-rays or microwaves (e.g. physical sensors that do not shock or invade the subject's privacy, weighing or testing sensory acuity, magnetic resonance imaging, EEG, EKG, moderate exercise or strength testing with healthy non-pregnant subjects.)

5. Research involving data, documents, records or specimens collected for non-research purposes, such as medical records.

6. Collection of data from audio or visual recordings.

7. Research on individual or group characteristics when considering the subject's own behavior (including perception, cognition, motivation, identity, language, communication, socio-cultural beliefs, practices or

behavior) or research employing survey, interview, oral history, focus group or program evaluation measures for purposes of research.

III. Full Review

A full review is conducted when research procedures pose risks to subjects or when subjects are, as a group, belonging to a vulnerable population. The IRB is particularly concerned with research involving the following:

1. subjects under the age of 18
2. pregnant subjects
3. frail elderly subjects
4. incarcerated subjects or persons under a correctional sentence (parolees)
5. mentally impaired subjects
6. false or misleading information to subjects
7. withholding information such that subjects' consent is in question
8. procedures for debriefing subjects
9. biomedical procedures
10. procedures that are novel or not accepted practice
11. risky procedures or harmful effects, including discomfort, risk of injury, invasive procedures, vulnerability to harassment, invasion of privacy, controversial information, or information creating legal vulnerability

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.

I. 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. They 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 the Selection of Subjects section of The Belmont Report.

Basic elements of informed consent as defined in Section 46.116 of the federal code must be described in all protocols:

1. Statement of the purpose of the research, duration of subject's participation, procedures and identification of any experimental procedures;
2. Foreseeable risks or discomforts;
3. Reasonable benefits to the subject or others;
4. Alternative procedures;
5. How confidentiality will be maintained;
6. Compensation, including whether and what type of medical treatment is available in case of injury;
7. Names and phone numbers of persons to contact for clarification about the research, the subject's rights and whom to contact in case of injury; and
8. Statement that participation is voluntary, refusal to participate involves no penalty and that subject may withdraw at any time without penalty.

Additional elements of informed consent that may be appropriate for certain types of studies:

1. Statement that the treatment may involve risks to subject or fetus if pregnant subject or may become pregnant during study;
2. Circumstances under which subject may be dropped from study without regard to subject's consent;
3. Additional costs to subject from participating in study;
4. Consequences of subject's decision to withdraw from study and procedures for orderly termination;
5. Statement that significant new findings of the study which might affect subject's willingness to continue will be provided to the subject; and
6. Approximate number of subjects in study.

II. Child Assent

In cases in which the research subject or participant is a child (defined as under the age of 18,) the researcher shall obtain the consent of the parents or guardian and the assent of the child. Assent is the agreement of the child to participate. The process for obtaining assent should follow the procedures for obtaining consent by the parents, with the form for assent written in age-appropriate language and sufficient attention given to explaining the study and answering the child's questions.

III. Waiving Consent

The IRB may waive some or all of the elements provided there is documentation that the research is to be conducted by or subject to approval by state or local government officials. In addition, it is possible to waive consent when the following conditions apply:

1. Risk is minimal;
2. No adverse effects on the rights of subjects;
3. Research could not practically be carried out; and
4. Subjects would be provided with additional pertinent information after participation.

IV. Documentation of Informed Consent

Written consent signed by the subject or guardian is necessary for most studies. The consent form must have all appropriate elements specified in the IRB Instructions to Researchers. Consent forms and assent forms must be submitted for IRB review. There are two consent/assent forms with original signatures, one for the subject and one for the researcher.

V. Waiver: Written Signed Consent

The IRB may waive the requirement for a written signed consent in either of the following cases:

1. The only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from breach of confidentiality. In this case the subject shall be asked whether he or she wants to sign a consent form.

2. The research involves no more than minimal risk and involves no procedures for which written consent is normally required outside the research context. (Example would be a questionnaire in which consent is implied by the fact of the subject returning the questionnaire.)

In either case, the researcher should provide the subject with a written description of the study that includes the elements of informed consent.

VI. 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 guidelines below:

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 Chair/Co-chairs of the IRB.

CONTINUING REVIEW

The IRB is required to review studies periodically to ensure that the protective conditions under which approval was given initially remain true. There are two conditions under which the IRB reviews protocols on a continuing basis: annual review of all studies approved by the IRB and review of studies in which there are changes to the study after approval.

Amendments to Approved Studies

Any significant changes to the methodology or key personnel must be approved by the IRB in writing prior to their initiation. Researchers proposing to change any aspect of an approved study should contact the IRB to determine if the changes require approval of an amended protocol. If they do require review, a representative or representatives will be designated to act as reviewers. Usually these are individuals in the same capacities as the reviewers of the original protocol. The proposed amendment should include all pertinent sections of the protocol, with explanations of how and why the researcher requests to amend the original methodology.

The IRB may request verification from sources other than the investigator that no significant changes have occurred since previous IRB review. This decision will be made by the IRB Chair/Co-chairs or board on a case-by-case basis, depending on the likelihood that the investigator cannot offer an adequate verification.

Unanticipated Problems

If unanticipated risks or hazards are discovered during the course of the research, the Principal Investigator (PI) shall immediately suspend research activities and notify the IRB in writing. The Chair/Co-chair will consult with the original IRB reviewer or reviewers to determine what actions to take. The researcher may not continue research activities until receiving permission from the IRB.

PROCEDURES FOR APPLICATION AND REVIEW PROTOCOLS

1. Prior to development of an IRB application, the Principal Investigator (PI) should review the Human Subjects Research Office (IRB) web site, irb.rmu.edu, for the latest policies, procedures and forms (since updates are made on a regular basis) and complete the training modules as specified on the site. Questions about policies and procedures should be directed to any IRB committee member, IRB Chair/Co-chairs or irb@rmu.edu.

2. The PI must complete IRB awareness training via the CITI website as instructed on the IRB web page before the application may be submitted. (Section 9 of the online application form is designated for uploading the CITI training completion certification.)

3. The PI should complete the IRB online application located on the IRB web page and submit the form electronically to the IRB office. If the PI is a student, the advisor's approval is also required in the application. Once the PI hits submit, the advisor's screen appears requesting the name and email of the advisor.

4. In exempt and expedited cases, the IRB reviews the proposal, requests revisions if needed, and when the protocol meets IRB requirements, approval will be granted. Researchers may not begin contact with subjects, soliciting them or collecting data, until after receipt of the approval letter from the IRB.

5. For full reviews, the IRB meets to discuss the study and vote as a group that human subject protections are adequate. It is acceptable for the PI to be available for questions, but this is not always necessary. After discussion, the vote is taken; a majority carries the vote. The approval letter is sent after the vote or, in the case of disapproval, informs the PI of required revisions. Communications about changes to protocols for student research will be copied to the faculty advisor. If the IRB requires further revisions or does not approve the research, the IRB shall communicate with the PI and advisor (if the PI is a student) as soon as possible after the meeting.

6. All official approvals are issued by the IRB Office. The PI may not collect data before receiving official approval from the IRB Office. Every attempt will be made to review protocols in a timely yet thorough manner. Ordinarily the PI will receive notification of the decision within 10 business days of the protocol's final submission to the IRB Office in exempt and expedited cases (excluding Holiday breaks and the months of June, July and August) and within two weeks after IRB committee meetings in full-review cases.

7. It is the responsibility of the PI to inform the IRB Office of termination of the study or changes in methodology or personnel.