

*Human Subjects Review Board  
Policy Manual*



*May 2003*

## **Special Thanks**

This manual was prepared by the committee members listed below with the invaluable guidance of the St. Joseph's University Office of Research Services website < [http://www.sju.edu/offices/research/human\\_subjects.html](http://www.sju.edu/offices/research/human_subjects.html)>. All material from this website was adapted to fit our university's needs.

### **Human subjects review board design committee:**

Susan Pasquarelli, Chair, Associate Professor, School of Education  
Susan Bosco, Assistant Professor, Gabelli School of Business  
Rachel McCormack, Assistant Professor, School of Education  
Robert McKenna, Assistant Dean, School of Justice Studies  
Eleftherios Pavlides, Professor, School of Architecture, Art and Historic Preservation  
Harold Pomeroy, Professor, Feinstein College of Arts and Sciences  
Jessica Skolnikoff, Assistant Professor, Feinstein College of Arts and Sciences  
June Speakman, Associate Professor, Feinstein College of Arts and Sciences  
Charles Trimbach, Professor, Feinstein College of Arts and Sciences  
Laura Turner, Assistant Professor, Feinstein College of Arts and Sciences  
Bruce Thompson, Professor, University College  
Donald Whitworth, Professor, Feinstein College of Arts and Sciences  
Rachael Whitworth '01

## **Table of Contents**

	<b>Page No.</b>
<b>I. Human Subjects Research Policy</b>	4
<b>Mission Statement</b>	4
<b>Ethical Issues</b>	4
<b>Federal Regulations</b>	4
<b>General Policies and Procedures</b>	5
<b>Definition of Human Research</b>	5
<b>II. Human Subjects Research Board</b>	7
<b>Administrative Duties</b>	7
<b>Membership</b>	7
<b>Responsibilities of the Chair</b>	8
<b>III. Types of Research Projects</b>	9
<b>New Individual Research Projects</b>	9
<b>Class Projects</b>	9
<b>Grant Proposals</b>	11
<b>IV. Criteria for Review</b>	12
<b>Exempt Review</b>	12
<b>Expedited Review</b>	13
<b>Full Review</b>	14
<b>V. Route of Submission</b>	15
<b>VI. Length of Time for Review Process</b>	16
<b>Expedited and Exempt</b>	16
<b>Full Review Proposals</b>	16
<b>Summer Class Projects</b>	16
<b>VII. Schedule of Submission, Approvals, and Full Board Meetings</b>	17
<b>VIII. Proposal Guidelines</b>	18
<b>Faculty/Staff/Graduate student New Individual Research Projects</b>	18
<b>Classroom Research Projects in which Graduate/Undergraduate Students Engage in Identical Projects</b>	20
<b>Classroom Research Projects in which Graduate/Undergraduate Students Conduct Individual Projects</b>	20
<b>IX. Guidelines for Creating Informed Consent Forms</b>	21
<b>Guidelines for Creating Informed Consent Form for Special Populations</b>	22
<b>X. Proposal Cover Sheets</b>	23
<b>Cover Sheet for Individual Research Project Proposals</b>	24
<b>Cover Sheet for Classroom Research Proposals</b>	25
<b>Cover Sheet for Class Project Student Research Proposals</b>	26
<b>XI. Proposal Checklist</b>	27
<b>XII. Procedures for Preparing</b>	28
<b>Annual Renewal/Progress Report/Completed Projects</b>	28
<b>Annual Renewal/Progress Report/Completed Projects Submission Deadlines</b>	28
<b>Annual Renewal/Progress Report/Completed Project Submission</b>	28

<b>Procedures</b>	28
<b>Application for Annual Review/Progress Report/Completed Project</b>	30
<b>Significant Change of Protocol and/or Informed Consent</b>	31
<b>Protocol Amendments/Consent Change Report Form</b>	32
<b>Reporting of Adverse Effects and Other Unanticipated Problems</b>	33
<b>Adverse Event and Miscellaneous Event Form</b>	34
<b>XIII. Special Populations</b>	35
<b>Children as Research Subjects</b>	35
<b>Protection for Prisoners as Subjects</b>	36
<b>XIV. Ethical Principles for the Protection of Human Subjects</b>	40
<b>XV. Conflict of Interest</b>	45
<b>Glossary</b>	46

---

## **I. Human Subjects Research Policy**

### **A. Mission Statement**

The Roger Williams University Human Subjects Review Board (HSRB) ensures the health, safety, privacy and dignity of all persons participating in research under the auspices of the University.

### **B. Ethical Issues**

In accordance with federal regulations, Roger Williams University (RWU) has adopted a policy that controls procedures that may be used in research involving the participation of human respondents or subjects.

Roger Williams University is guided by the ethical principles set forth in the report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research entitled [\*Ethical Principles and Guidelines for the Protection of Human Subjects of Research\*](#), also known as *The Belmont Report*. The Belmont Report, published in 1979 by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, provides the philosophical underpinnings for current federal laws that govern research involving human subjects.

### **C. Federal Regulations**

Regulations protecting human subjects first became effective on May 30, 1974 in the United States with the intention of protecting the civil rights of all citizens. The Department of Health and Human Services (DHHS) policy as expressed in Title 45, Part 46 of the Code of Federal

Regulations, also known as [45 CFR Part 46](#), is the heart of the federal policy on protecting human subjects in research. In 1991, many federal agencies adopted [Subpart A](#), the general provisions of 45 CFR Part 46, as the federal *Common Rule*. Each "Common Rule agency" publishes an identical version of this *Federal Policy for the Protection of Human Subjects* in its own section of the Code of Federal Regulations. The [DHHS Office for Human Research Protections \(OHRP\)](#) exercises an important leadership role among Common Rule agencies.

The Federal Policy applies to all research sponsored by the Common Rule agencies. Roger Williams University has pledged that the institution and all investigators will follow the US Department of Health and Human Services (DHHS) [regulations for protecting human research subjects](#). Additionally, the National Institutes of Health (NIH) requires that all key research personnel complete a human subjects training program before an NIH-sponsored project can begin.

Further information concerning research funded by federal monies can be obtained at the following website: <http://ohrp.osophs.dhhs.gov/irb/irbguidebook.htm>

#### **D. General Policies and Procedures**

Each institution that engages in federally sponsored human subject research must provide the government with a written assurance that it will comply with the Common Rule. In accordance with concern for human dignity, individual freedom and integrity, and the civil rights of all citizens, Roger Williams University has adopted a policy that controls procedures that may be used in research involving the participation of human respondents or subjects. This policy ensures the health, safety, privacy and dignity of all persons participating in research under the auspices of the University.

#### **E. Definition of Human Research**

Human research is defined as any systematic investigative activity including research development, testing and evaluation, interviews, questionnaires, or treatments of any kind requiring the participation of human subjects or respondents with the intent of contributing to generalized knowledge. At RWU, activities that meet this definition include faculty and student research projects, classroom demonstration, service programs, and other university classroom research whether conducted on or off campus, as a classroom or research exercise, with or without the intent to publish. Specifically, it requires that the principal investigator determine and be prepared to demonstrate:

- that all methods and procedures to be employed are safe and involve no undue risk to life, health, safety or well-being of subjects;
- that the risks to the subject are clearly outweighed by the potential benefits to him or to her, or by the importance of the knowledge to be gained;

- that the methods and procedures reflect respect for the feelings and dignity of respondents or subjects and avoid unwarranted invasion of privacy or disregard for anonymity in any way;
- that participation is informed and completely voluntary, and that procedures for obtaining such consent are adequate and appropriate;
- that data be retained for at least 3 years according to the federal code of regulations ([45 CFR46.115](#)).
- that data be used only for the purposes for which such consent was obtained and then appropriately destroyed; and that methods of data collection, analysis, storage and reporting are consistent with these principles;
- that proposed recruitment materials such as phone calls, fliers, brochures, advertisements, e-mail, have received the approval of the HSRB before posting. (Adapted from St. Joseph University, Pennsylvania, RRB policies)

Roger Williams University has delegated to the Human Subjects Review Board (HSRB) the responsibility of review and written approval of all research and related teaching activities involving the use of human subjects, conducted under the auspices of a school, department, or other unit within the University.

Administrative responsibility for overseeing these functions has been delegated to the chair of the HSRB who is appointed by the Chief Academic Officer (CAO) of the University. The CAO also serves as the research oversight official as required by federal policy.

Each institution may file an "Assurance of Compliance with DHHS Regulations for Protection of Human Research Subjects." Roger Williams University is preparing to apply for federal assurances. Nonetheless, the RWU policy stipulates that all research involving human subjects at RWU will be reviewed and approved by the HSRB, whether Federally sponsored or not.

Any faculty member or student preparing proposals for research or class projects involving human subjects should arrange to have his/her proposal or class project protocol reviewed by the HSRB prior to initiation of the project. In addition, any changes in research protocols involving human subjects must be approved by HSRB as the need arises.

## **II. Human Subjects Research Board**

### **A. Administrative Duties**

Roger Williams University has delegated to the Human Subjects Review Board (HSRB) the responsibility of review and written approval of all research and related teaching activities involving the use of human subjects, conducted under the auspices of a school, department, or other unit within the University.

Administrative responsibility for overseeing these functions has been delegated to the chair of the HSRB who is appointed by the Chief Academic Officer (CAO) of the University. The CAO also serves as the research oversight official as required by federal policy. In essence, the CAO of the University shall serve as an ex officio member of the committee, but not as its chair. The CAO will sign off on all recommendations of the committee, as s/he has the legal authority to speak and act for the institution and thus bears responsibility for oversight of research conducted under the aegis of the University.

### **B. Membership**

The Roger Williams University Human Subjects Review Board (HSRB) shall have five members from the RWU faculty/administrative staff and one member from outside of the University who has competence in the field of human subject research. The five members from the University shall be nominated by their deans and officially appointed to the committee by the CAO of the University. Deans should appoint members who have experience with research.

In addition, according to federal regulations, there must be one non-University member on the HSRB. In the case of reviews involving prisoners, an alternate member, the prisoner or his designee, must sit on the board when the review takes place. See Section 13, special populations: prisoners, for further explanation.

The five RWU members chosen should have demonstrated evidence of a background in research involving human subjects and shall come from the following units of the University:

- Two members from the College of Arts and Sciences (one scientist, one social scientist)
- One from the School of Education
- One from the School for Justice Studies
- One from the School of Architecture, Art and Historic Preservation

The non-University member shall be appointed to the committee by the CAO of the University and shall serve without compensation. This person will be chosen for his/her background in research involving human subjects (such as a physician, psychologist) and/or his/her familiarity with the legal and ethical implications of such research (such as an attorney or a member of the clergy). Note: This outside member must be a psychologist if no faculty/staff psychologist sits on the Board.

Each committee member shall serve a three-year term commencing and ending on September 1 each year. Committee member appointments are staggered so that only 2 new members will join the board at any given time.

**C. Responsibilities of the Chair**

- reviewing expedited and exempt proposals calling on one board member if there is a procedural issue with a proposal;
- leading the process of developing and refining Board guidelines and processes;
- communicating to the faculty changes in guidelines as well as meeting times and Board rulings;
- scheduling and chairing meetings;
- maintaining the information on the website;
- notifying the CAO when new committee members need to be chosen; and,
- maintaining HSRB records and archives.

The taking of minutes, including all rulings of the Board, shall occur at every meeting. The responsibility for this shall rotate among the Board members. Minutes and rulings shall be published on the website no later than 10 working days after the Board meeting, as consistent with RWU policy.

### **III. Types of Research Projects**

The proposal categories for purposes of HSRB review are New or Annual Renewal. Proposals may fall into either a "specific project" category or a "grant proposal" category. The Principal Investigator or Faculty Advisor, if the Principal Investigator is a student, must first select the appropriate categories before writing a proposal.

#### **A. New Individual Research Projects**

##### **1. Definition**

The category of specific project should be used for any study (Exception: Class Projects, see below) involving human subjects that is about to be undertaken. HSRB approvals of specific projects remains in effect for one year or until there are significant protocol changes, whichever occurs first. Researchers should submit a single proposal for each study even if it involves similar protocols. *This applies to graduate students engaged in individual research projects.*

##### **2. Submission Procedures**

The Principal Investigator and/or faculty advisor prepares a Cover Sheet, a Research Protocol Form, and an Informed Consent Form, and submits them to the HSRB chair. Additional documents may be attached as necessary and as specified in the instructions. *See Section VIII* for directions in preparing the protocol forms.

#### **B. Class Projects**

##### **1. Definition**

Class projects refer to research studies involving human subjects to be conducted by graduate/undergraduate students in fulfillment of a course requirement and where multiple students are conducting similar studies.

##### **2. Categories of Classroom Research for Human Subjects Consideration**

###### **a. No Requirement for Submission**

If the research assignment will involve only activities among students in the class and does not present the potential for harm, or will only require natural observations by the students (e.g. observing participants' behavior on campus or in public; observing behaviors on an elevator, at a rock concert), there is no need to submit the project for HSRB approval. The faculty advisor is responsible for ensuring that the research is conducted in an ethical manner. If college student participants are under 18 years of age, parental consent must be obtained. If the under 18 years of age college student is an investigator/researcher, parental consent is not necessary.

**b. Possible Required Submission**

This category applies when the project meets the general guidelines as stated in #1 above, but has the potential to be physically or psychologically invasive, intrusive, or stressful. In this case, the faculty advisor is responsible for seeking guidance from the chair of the HSRB. If college student participants are under 18 years of age, parental consent must be obtained. If the under 18 years of age college student is an investigator/researcher, parental consent is not necessary.

**c. Required HSRB Approval**

- Studies that include identifiable people other than students in the class, or that involve questions about sexual history, abuse history, or alcohol or other drug history are to be submitted for HSRB approval.
- Studies that involve vulnerable populations (e.g. minors, prisoners) must be submitted.
- Studies that involve extra credit or compensation for student participants.
- Studies that involve potentially sensitive, personal, or incriminating information that could place the participants at risk, physically, psychologically, or legally must be submitted for HSRB approval.

**d. Submission Procedures**

**NOTE:** There is a difference in protocol if all students are conducting an identical study (*Type 1* below) vs. students conducting individual projects (*Type 2* below).

**i. *Type 1: Classroom research projects in which undergraduate students engage in an identical research project:***

- The Faculty Advisor (FA) will prepare and endorse a single Cover Sheet and Research Protocol - Class Projects as Principal Investigator (PI) for groups of identical studies assigned as class projects. *See Section VIII* for directions in preparing the protocol forms.
- The FA will assign a study # to each student project.
- The FA will complete all remaining protocol questions, and append student project descriptions, consent forms, and other materials before submitting to the HSRB Chair.
- If college student participants are under 18 years of age, parental consent must be obtained. If the college student is an investigator/researcher, parental consent is not necessary.

**ii. *Type 2: Classroom research projects in which undergraduate students conduct individual projects:***

- The Faculty Advisor (FA) will prepare and endorse a single Cover Sheet and Research Protocol - Class Projects as Principal Investigator

(PI) for groups of similar studies assigned as class projects. *See Section VIII* for directions in preparing the protocol forms. There is a difference in protocol if all students are conducting the same study vs. students conducting different studies.

- Each student conducting a research study under the protocol, will prepare and attach a one page summary of his or her study, including a description of the study, the research design, and sequence of activities to be followed by the student researcher. A copy of the consent form, questionnaires, or other interview materials must also be included, if appropriate.
- The FA will assign a study number to each student project.
- The FA will complete all remaining protocol questions, and append student project descriptions, consent forms, and other materials before submitting to the HSRB Chair.
- If college student participants are under 18 years of age, parental consent must be obtained. If the college student is an investigator/researcher, parental consent is not necessary.

## **C. Grant Proposal**

### **1. Definition**

A proposal falls into this category if the investigator is submitting a grant application to a Federal agency or other funding source for support of the proposed research.

### **2. Submission Procedures**

A grant proposal developed in sufficient detail that the research design, protocol and procedures for safeguarding human subjects are fully specified may also be indicated as a specific project. *See Section VIII* for directions in preparing the protocol forms.

The grant proposal and grant submission may precede the HSRB approval; however, the grant project is still subject to HSRB review before the research commences.

## **IV. Criteria for Review**

### **A. Exempt Review**

The following types of research may be exempt from extensive committee review if proper procedures to assure confidentiality are evident, and informed consent is provided and participants are exposed to no more than “minimal risk”. Research in this category includes:

- The study of existing historical documents, records, literature, books, monographs, or research, if these sources are publicly available or the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or indirectly, through identifiers linked to subjects and the data is used solely for the purposes of meta-analysis or research review.
- Research involving surveys or observations of public behavior except where the information obtained is recorded in a manner to identify a participant or place the participant at risk of criminal or civil liability or damaging to a participant’s reputation.
- Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (a) research on regular and special education instructional strategies; or (b) research on the effectiveness or comparison among instructional techniques, curricula, or classroom management methods.
- Research involving use of educational tests (cognitive, diagnostic, aptitude, achievement, affective), survey procedures, interview procedures or observation of public behavior, if (a) the data are recorded so that participants cannot be identified either by the use of names or special coding; and, (b) any disclosure of the human subjects’ responses outside the research could not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subject’s financial standing, employability, or reputation.
- 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 preceding paragraph, if (a) the human subjects are elected or appointed public officials or candidates for public office; or (b) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
- Research and demonstration projects which are conducted by or subject to the approval of State/Federal Department or Agency heads, and which are designed to study, evaluate, or otherwise examine: (a) public benefit or service programs; (b) procedures for obtaining benefits or services under those programs; (c) possible changes in or alternatives to these programs or procedures; or (d) possible changes in methods or levels of payment for benefits or services under those programs.
- Taste and food quality evaluation and consumer acceptance studies, (a) if wholesome foods without additives are consumed, or (b) 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.

**1. Exceptions to the Exempt category listed above:**

*(Expedited or Full Board Review is required. See criteria below):*

- Research activities involving the following subject populations require either full board or expedited review: (a) prisoners; (b) minor subjects; (c) persons incompetent to provide informed consent; (d) pregnant women where pregnancy is the focus of the research. *See Section XIII.*
- Research involving the use of medical, academic, disciplinary, and other personal records (including psychological records) without subjects' consent.
- Research involving web-based (or "online") data collection procedures.

**B. Expedited Review**

Expedited review takes place when the research involves no more than minimal risk and when the involvement of human participant falls into one of the following categories:

- Research involving (a) the following special classes of subjects: minor subjects (under 18) , persons incompetent to provide informed consent, and pregnant women where pregnancy is the focus of the research, and (b) the criteria for research proposals fit into the categories deemed "expedited" as listed below.
- Research on individual or group behavior, or characteristics of individuals such as studies of perception, cognition, game theory, test development, where the investigator may or may not manipulate participants' behavior but does not involve more than minimal risk.
- Research that involves video or audio taping of a participant being interviewed, surveyed, or participating in a scenario that has been manipulated by the researcher that involves no more than minimal risk.
- Voice recordings made for research purposes such as investigations of speech defects. *Note:* In other words, voice recordings in which the information of interest is produced by the process of speaking itself, without regard to what is being said.
- The research is funded by a source outside the University.
- Moderate exercise by healthy volunteers.
- The study of existing human personal data, documents, records, pathological specimens, or diagnostic specimens.

**1. RWU Exceptions to the Expedited category listed above:**

*The expedited categories below may not be used in research projects:*

- where identification of the participants and/or their responses would reasonably place them at risk of criminal or civil liability.
- that may be damaging to the participant's reputation.
- that may be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.

## C. Full Review

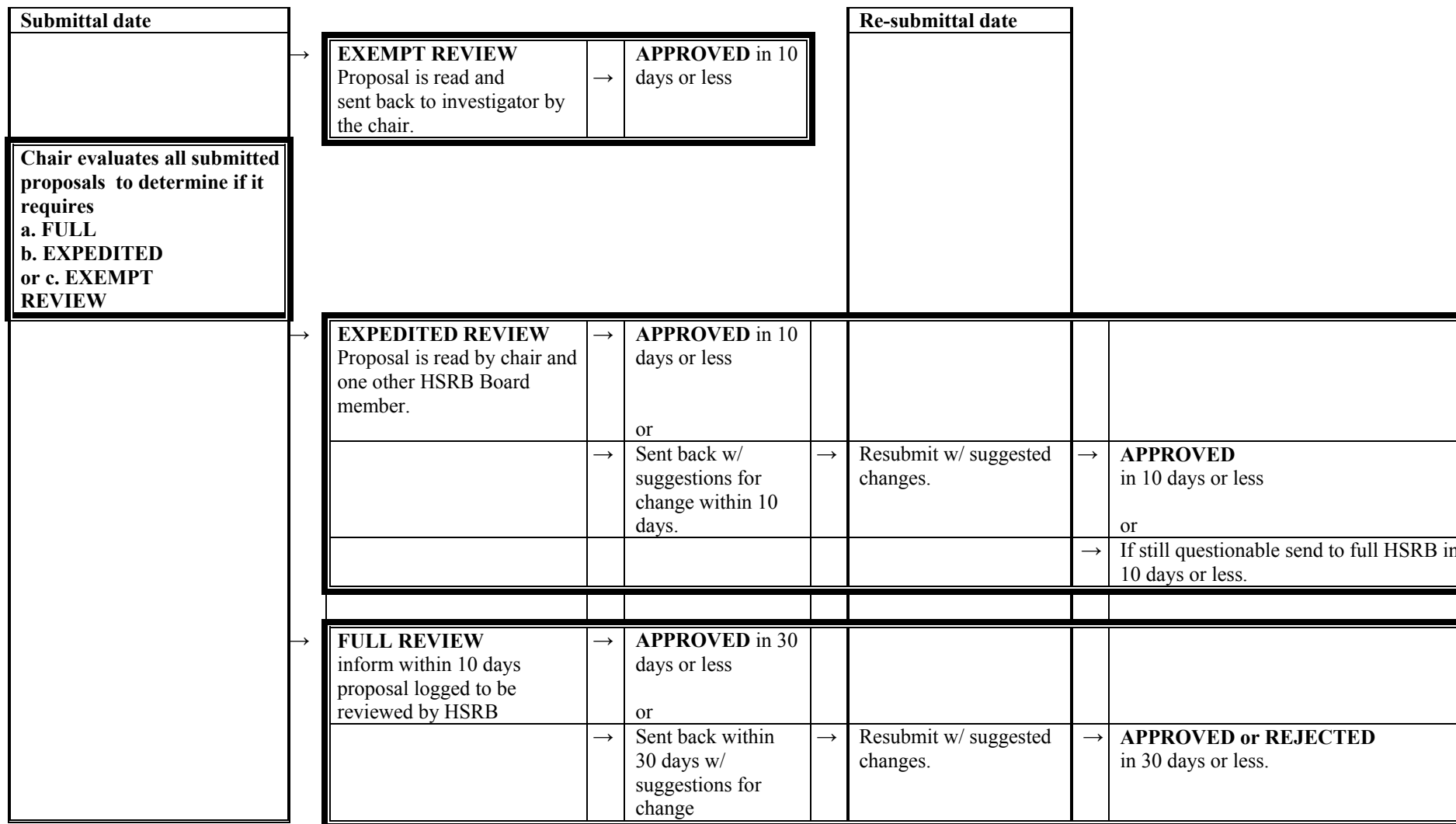
The following types of research require full Board Review:

- Research involving prisoners as participants. *See Section XIII.*
- Research involving: (a) the following special classes of subjects: minor subjects (under 18), persons incompetent to provide informed consent, and pregnant women where pregnancy is the focus of the research and, (b) one or more of the following: the criteria for research proposals fit into the categories deemed “full review” as listed below.
- Research studies that include monetary compensation for participants.
- Research projects that involve potentially sensitive, personal, or incriminating information or that could place participants at risk, physically, psychologically, emotionally, or legally.
- The research involves survey or interview procedures that include responses that are recorded in such a manner as to allow for identification of the participant; the research deals with sensitive aspects of the participant’s behavior such as those instances in which embarrassment or danger would result for the participants should these behaviors become known.
- Procedures are used that might cause physical harm to research participants.
- Procedures are used that might cause emotional distress to participants.
- Participants will be administered chemical substances, including drugs and pharmaceuticals.
- Physical stimuli are administered, such as: ambient pressure, cold or wind, electric shock, gravitational fields, heat or humidity, ionizing radiation, magnetic fields, noise, non-ionizing radiation, e.g. ultraviolet, visible light, infrared radiation, microwaves, vibration, etc.
- Participants are exposed to sensory deprivation, sleep deprivation, exhaustive physical activity or special diets.
- Adult participants or guardians/designees are not able to give free and informed consent.
- Participants are required to participate in activities that may be illegal or are likely to offend prevailing standards of morality.
- The research involves deception that could reasonably cause emotional or physical harm to the participants.

Note: In certain cases, a proposal for a full review may be rerouted by the HSRB for an expedited review.

## V. Route of Submission

### HSRB - Human Subject Review Board Research Approval Process



## **VI. Length of Time for Review Process**

### **A. Expedited and Exempt Proposals**

When class projects and new individual research proposals reach the HSRB, exemptions and expedited proposals will be processed within 10 working days.

### **B. Full Review Proposals**

Full reviews should be forwarded to the chair of the HSRB. The chair has 30 days to convene a meeting of the full board.

### **C. Summer Class Projects**

For Summer I and Summer II class projects, the chair of the HSRB will attempt to review exempt and expedited proposals whenever possible within 5 working days. The chair will also call the board together for full reviews at the end of the first week so that research may be approved and completed by the end of that summer session.

Note: Under exceptional circumstances, delays may be incurred if the HSRB requires additional information from the investigators.

## **VII. Schedule of Submissions, Approvals, and Full Board Meetings**

The schedule of submissions, approvals, and full board meetings will be posted on the Human Subjects Review Board website yearly.

## VIII. Proposal Guidelines

The proposal format for research investigations involving human subjects is included in this section. Researchers should provide sufficient elaboration in order to facilitate a speedy review.

Researchers need to type all responses and be as non-technical as possible, avoiding jargon. Researchers should also keep in mind that the protocol will be read by people outside of their field. Unless otherwise indicated, all questions must be answered for specific projects.

### A. Faculty/Staff/Graduate Student New Individual Research Projects

#### 1. Project Description

State the purpose of the research and rationale. Indicate what participants will be told, what will be done to them, and what they will have to do.

#### 2. Participants

If the subjects are from a special population, such as children and prisoners, researchers should see *Section XIII* of this document before writing a proposal. If the participants are mentally or physically disabled, or are institutionalized, particular care is required to ensure that participation is not coerced and participants' rights are protected. If advertisements are used to recruit subjects, copies of the ads must be included with the proposal.

#### 3. Research Procedures and Methodology

This section provides a comprehensive description of the research methodology including:

- Setting of the research study
- Procedures
- Data collection
- Data analysis
- How participants will be affected by the research.

In this section describe any illegal activities and/or deception that may be involved in the research. Also include why these methods are necessary. The use of deception in no way reduces the need for informed consent. Deception includes not only the presentation of false information to subjects, but also the intentional withholding of information in a manner designed to mislead subjects. Under no condition can deception involve the withholding or falsification of information likely to affect the willingness of subjects to participate in the research.

- If monetary payment is used, it may be considered a benefit to the subject. However, neither the amount of payment nor the method of disbursement should

present problems of coercion or undue influence. Such problems might occur, for example, if the entire payment were contingent upon completion of the study or if the payment were unduly large.

- Finally, in an appendix include any informal and formal testing instruments, surveys, questionnaires, etc. Citations are also necessary if you are using published materials.

#### **4. Consent Procedures**

Informed consent must be obtained from each subject who is legally, mentally, and physically able to provide it. Submit a copy of the written consent form. See *Section IX* for informed consent procedures. For subjects not able to provide informed consent themselves, written informed consent must be obtained from others (e.g., parents, guardians, etc.) *Section IX* also addresses informed consent of children and prisoners.

In all cases, describe how informed consent will be obtained. If the subjects are children or challenged mentally/emotionally, describe how their "assent" will be obtained.

#### **5. Data Confidentiality**

Maintaining anonymity is an ethical consideration. Describe how you will report the findings of the research while maintaining participants' confidentiality.

#### **6. Risks /Discomfort to the Participants**

Participants are at risk if they are exposed to the possibility of physical, mental, or social discomfort, harm or danger, or otherwise beyond minimal risk. If subjects are at risk, describe all steps to minimize risk, and, if necessary, attach a justification for these procedures based on the scientific literature.

#### **7. Benefits of the Study**

Anticipated benefits to any one individual or society should be described such that a risk/benefit judgment may be made.

#### **8. Signatures**

All investigators must read and sign the cover sheet (*see Section X*) assuring compliance with the ethical code for researchers.

#### **9. Appendix**

Attach any additional sheets, along with any supporting documents (e.g., consent forms, instruments, questionnaires, tests, interview protocols, etc.) to the Research Protocol Form if appropriate.

**B. Classroom Research Projects in which Undergraduate/Graduate Students Engage in an Identical Project**

- The Faculty Advisor (FA) will prepare and endorse a single Cover Sheet and Research Proposal - Class Projects as Principal Investigator (PI) for groups of identical studies assigned as class projects. See *Section III* for types of projects.
- The Faculty Advisor will be sure that all students have read the APA ethical code of researchers found in *Section XIV* of this document and have students agree that they will comply. Faculty Advisors will prepare a class signature sheet to assure that all students have agreed to abide by the ethical code of researchers. See sample below:

**I declare that I have read the Roger Williams University Statement of Researchers' Ethical Principles for the Protection of Human Subjects of Research and am familiar with my obligations thereunder. Furthermore, I agree to abide by that Statement of Ethical Principles adopted by Roger Williams University as part of the Human Subject Review Board Policy.**

Student signatures:

_____	_____
1. Student name	Signature
_____	_____
2. Student name	Signature

**C. Classroom Research Projects in which Undergraduate/Graduate Students Conduct Individual Projects**

- The Faculty Advisor (FA) will prepare and endorse a single Cover Sheet and Research Protocol - Class Projects as Principal Investigator (PI) for groups of similar studies assigned as class projects. See *Section III* for types of projects.
- Each student conducting a research study under the protocol, will prepare and attach a one- page summary of his or her study, including a description of the study, the research design, and sequence of activities to be followed by the student researcher. A copy of the consent form, questionnaires, or other materials must also be included, if appropriate.
- Each student must agree to abide by the researcher's code of ethics by writing the following on their summary and sign:

**Researcher code of ethics: I declare that I have read the Roger Williams University Statement of Researchers' Ethical Principles for the Protection of Human Subjects of Research and am familiar with my obligations thereunder. Furthermore, I agree to abide by that Statement of Ethical Principles adopted by Roger Williams University as part of the Human Subject Review Board Policy.**

## **IX. Guidelines for Creating Informed Consent Forms**

According to federal guidelines, informed consent forms must be created for each research project. There is no "standard" form; every researcher must create an informed consent form specific to the study.

The Roger Williams University HSRB stipulates that the following information must be included in every informed consent. For research involving special populations (minors, prisoners), see the addendum to this section.

- Title of Project:
- Principal Investigator(s)
- Other Investigators:
- Purpose of the Study: Provide a brief summary of the purpose of the study. This should be written in terms that the layperson would understand. Include the number of participants that will be involved in the study.
- Procedures to be Followed: Indicate all procedures that will require the participants' involvement and what is required of them. Be specific. This includes the use of any audio, or audio/visual or other technological equipment that will be used.
- Time Duration of the Procedures and Study: Explain how much of the participant's time will be required to complete his/her participation in this research (e.g. minutes, hours, days). Also include the period of time during which this participation will occur (e.g. over 1 month, during the course of 1 year).
- Statement of Confidentiality: Explain the extent to which participants' records and data will be held confidential. An appropriate sample statement: Your participation in this research is confidential. Only the investigator and his/her assistants will have access to your identity and to information that can be associated with you. In the event of publication, pseudonyms will be used.
- Right to Ask Questions: This statement should explain whom to contact for answers to pertinent questions about the research. In the case of student research, the sponsoring faculty should be listed here with email, telephone, and university address.
- Compensation: Explain any additional costs that may result from participation including travel expenses. Also include any compensation that will be provided to participants including a stipend or extra credit in a course.
- Voluntary Participation/ Risks: In a final statement, explain that participation in the study is voluntary and that a participant can withdraw at any time. If applicable, explain any conditions under which the participant's involvement may be terminated by the investigator without regard to the participant's consent. In addition, describe any reasonably foreseeable risks or discomforts to the participant.
- Signatures:
- Write a one-line statement that ensures the participant is signing under his/her own consent. A suitable statement may include:

This is to certify that I consent to or give permission for my participation as a volunteer in this research study. I have read this form and understand the content. (In the case of parental permission, change language to read: my child's participation).

\_\_\_\_\_  
Participant's signature

\_\_\_\_\_  
Date

- Write a one-line statement that ensures that you explained the study to the participant.

A suitable statement may include:

This is to certify that I have defined and explained this research study to the participant named above.

\_\_\_\_\_  
Investigator's signature

\_\_\_\_\_  
Date

## A. Guidelines For Creating Informed Consent Forms For Special Populations

### 1. Informed Consent Form Modifications for Prisoners as Research Subjects

Use the adult informed consent form and include a statement that participation or nonparticipation in the research will have no effect on the subject's current or future status in the prison.

### 2. Informed Consent Form Modifications for Children as Research Subjects

Use the adult informed consent form and add a statement noting that the parent is providing permission for the child as suggested below.

This is to certify that I, \_\_\_\_\_, hereby give my permission to have my child participate as a volunteer in this study as an authorized part of the education and research program of Roger Williams University under the supervision of [insert name and degree of the supervisor of the project – e.g., *Laura Turner, Ph.D.*].

I hereby consent to the participation of \_\_\_\_\_, a minor, as a subject in the study described.

\_\_\_\_\_  
Signature of minor subject's parent/guardian

\_\_\_\_\_  
Date

I, the undersigned, have defined and fully explained the investigation to the parent/guardian of the subject listed above.

\_\_\_\_\_  
Investigator's signature

\_\_\_\_\_  
Date

## **X. Proposal Cover Sheets**

The format on the following page is the required cover sheet for RWU HSRB proposals.

*Note there is a cover sheet for all types of projects:*

- New Individual Projects
- Classroom Identical Projects
- Classroom Different Projects

*Individual Research Project Proposals*

**ROGER WILLIAMS UNIVERSITY  
HUMAN SUBJECT REVIEW BOARD  
COVER SHEET FOR NEW INDIVIDUAL RESEARCH PROJECT PROPOSALS**

Name of Principal Investigator: \_\_\_\_\_

Date of Submission: \_\_\_\_\_

Department: \_\_\_\_\_

School: \_\_\_\_\_

Names of Principal Investigators: \_\_\_\_\_

Name of Faculty Advisor: \_\_\_\_\_  
(required for students)

Title of Research Project: \_\_\_\_\_

Grant funding supporting this research: \_\_\_\_\_

**Researcher code of ethics: I declare that I have read the Roger Williams University Statement of Researchers' Ethical Principles for the Protection of Human Subjects of Research and am familiar with my obligations thereunder. Furthermore, I agree to abide by that Statement of Ethical Principles adopted by Roger Williams University as part of the Human Subject Review Board Policy.**

\_\_\_\_\_  
**Investigator's signature**

**Review status sought by principle investigator.** Circle one using the guidelines published by the HSRB. Note that the HSRB may change the status of the review.

**EXEMPT**

**EXPEDITED**

**FULL**

For HSRB Board use only:

**Committee decision regarding review status:**

**EXEMPT**

**EXPEDITED**

**FULL**

\_\_\_\_\_  
Approved  
\_\_\_\_\_  
Resubmit

\_\_\_\_\_  
Signature of Chairperson                      Date

\_\_\_\_\_  
Signature of Chief Academic Officer                      Date

**Classroom Project #1: For Class/ Student Research Project in which All Students will be Conducting Identical Research Projects**

**ROGER WILLIAMS UNIVERSITY  
HUMAN SUBJECT REVIEW BOARD  
COVER SHEET FOR CLASSROOM RESEARCH PROPOSALS**

Name of Faculty Advisor: \_\_\_\_\_

Date of Submission: \_\_\_\_\_

Department: \_\_\_\_\_

School: \_\_\_\_\_

Course Number, title, section of course: \_\_\_\_\_

Attach a course roster to this cover sheet if all/most students are participating in research.

Title of Research Project: \_\_\_\_\_

Grant funding supporting this research: \_\_\_\_\_

**Researcher code of ethics: I declare that I have read the Roger Williams University Statement of Researchers' Ethical Principles for the Protection of Human Subjects of Research and am familiar with my obligations thereunder. Furthermore, I agree to abide by that Statement of Ethical Principles adopted by Roger Williams University as part of the Human Subject Review Board Policy.**

**Faculty signature:** \_\_\_\_\_

**Review status sought by principle investigator.** Circle one using the guidelines published by the HSRB. Note that the HSRB may change the status of the review.

**EXEMPT**

**EXPEDITED**

**FULL**

For HSRB Board use only:

**Committee decision regarding review status:**

**EXEMPT**

**EXPEDITED**

**FULL**

\_\_\_\_\_ Approved

\_\_\_\_\_ Resubmit

\_\_\_\_\_  
Signature of Chairperson

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature of Chief Academic Officer

\_\_\_\_\_  
Date

**Classroom Project #2: For Class/ Student Research Project in which Students will be Conducting Different Research Projects.**

**ROGER WILLIAMS UNIVERSITY  
HUMAN SUBJECT REVIEW BOARD  
COVER SHEET FOR CLASS PROJECT STUDENT RESEARCH PROPOSALS**

Name of Student: \_\_\_\_\_

Name of Faculty Advisor: \_\_\_\_\_

Date of Submission: \_\_\_\_\_

Department: \_\_\_\_\_

School: \_\_\_\_\_

Course Number, title, section of course: \_\_\_\_\_

Attach a course roster to this cover sheet if all/most students are participating in research.

Types of Research Projects: \_\_\_\_\_

Grant funding supporting this research: \_\_\_\_\_

**Researcher code of ethics: I declare that I have read the Roger Williams University Statement of Researchers' Ethical Principles for the Protection of Human Subjects of Research and am familiar with my obligations thereunder. Furthermore, I agree to abide by that Statement of Ethical Principles adopted by Roger Williams University as part of the Human Subject Review Board Policy.**

**Faculty signature:** \_\_\_\_\_

**Review status sought by principle investigator.** Circle one using the guidelines published by the HSRB. Note that the HSRB may change the status of the review.

**EXEMPT**

**EXPEDITED**

**FULL**

For HSRB Board use only:

**Committee decision regarding review status:**

**EXEMPT**

**EXPEDITED**

**FULL**

\_\_\_\_\_ Approved

\_\_\_\_\_ Resubmit

\_\_\_\_\_  
Signature of Chairperson

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature of Chief Academic Officer

\_\_\_\_\_  
Date

## **XI. Proposal Checklist**

### **A. Proposal Checklist for Individual Projects**

- Cover Sheet
- Proposal
- Informed Consent Form
- Appendix: copy of grant funding project, interview protocol, informal/formal testing instruments, surveys, questionnaires, etc.

### **B. Proposal Checklist for Classroom projects**

- Cover Sheet
- Student signatures agreeing to researcher's code of ethics
- Informed Consent Form
- Individual student summaries
- Appendix: copy of grant funding project, interview protocol, informal/formal testing instruments, surveys, questionnaires, etc.

## **XII. Procedures for Preparing**

- A. Federally Funded Projects: Annual Renewal/ Progress Report/Completed Project
- B. All Projects: Significant Change of Protocol and/or Informed Consent
- C. All Projects: Reporting Adverse Events

### **A. Federally Funded Projects: Annual Renewal/Progress Report/Completed Project**

#### **1. Definitions**

*Annual Renewal* refers to the annually required resubmission for HSRB approval of research still in progress. This form is only necessary for those projects funded by federal monies.

*Progress Report* refers to a brief statement of the status of data collection and of problems encountered in collecting the data. This form is only necessary for those projects funded by federal monies.

*Completed project* is a project in which no further data collection or interaction with subjects will take place. This form is only necessary for those projects funded by federal monies.

#### **2. Annual Renewal/Progress Report/Completed Project Submission Deadlines**

The HSRB strongly recommends your annual renewal be submitted at least 30 days (approx. 4 weeks) before the date of expiration of HSRB approval. Unless your project is re-reviewed and re-approved by the HSRB within twelve (12) months from the date the protocol was last reviewed by the HSRB, Federal Regulations require the HSRB to immediately suspend its approval.

#### **3. Annual Renewal/Progress Report/Completed Project Submission Procedures**

Submit the original HSRB Application for Annual Renewal (form is below) and attach a copy of the most recently signed consent form. In order to facilitate HSRB re-review of your project and to avoid unnecessary delays, please ensure that each applicable section of the Application form is completed according to the instructions. Information must be provided in sufficient detail to allow the HSRB to perform the required review. Failure to provide all necessary information may delay HSRB re-approval of your protocol and could result in a suspension if there is not sufficient time for the HSRB to complete its

review before the 12-month expiration of approval. Federal Regulations prohibit the HSRB from getting granting extensions or temporary approval. Should suspension occur, all data collection must cease as of the date of suspension. In addition, research related procedures can no longer be performed on human subjects who are currently enrolled in the study for follow-up or other reasons unless this restriction represents a health hazard to the subjects. In this case, the HSRB will grant an exception upon receipt of written justification.

Upon HSRB re-approval of your research project, you will be given an approval letter to continue the project. The HSRB approved consent/assent originals should be kept on file as masters.

The application follows on the next page.

**Human Subjects Review Board  
for the Protection of Human Subjects in Research  
Application for Annual Renewal/Progress Report/Completed Project**

Date: \_\_\_\_\_ Protocol #: \_\_\_\_\_

Investigator(s): \_\_\_\_\_

Title of Project: \_\_\_\_\_

**Federal regulations require an annual review of approved projects. To this end, please complete the following questionnaire by \_\_\_\_\_.**

1. Is this research still being conducted? Yes \_\_\_\_\_ No\* \_\_\_\_\_

*\*If no, please complete #2a ONLY, sign, and return.*

2. If yes, please answer the following questions:

a. Provide the number of subjects in the study on the following table:

	American Indian or Alaskan Native	Asian or Pacific Islander	Black, not of Hispanic Origin	Hispanic	White, not of Hispanic Origin	Other or Unknown	Total
Female							
Male							
Unknown							
Total							

b. Have there been any:

1. Adverse events or unanticipated risks to subjects or others? Yes \_\_\_\_\_ No \_\_\_\_\_

2. Withdrawal of subjects from the research? Yes \_\_\_\_\_ No \_\_\_\_\_

3. Complaints about the research? Yes \_\_\_\_\_ No \_\_\_\_\_

4. Changes made to your study? Yes \_\_\_\_\_ No \_\_\_\_\_

5. Have these changes been approved? Yes\* \_\_\_\_\_ No \_\_\_\_\_

*\*If "yes," please attach explanatory material.*

c. Has there been any recent literature, findings, or other information about risks associated with your type of research project? Yes\* \_\_\_\_\_ No \_\_\_\_\_

*If "yes," attach summary of relevant information.*

3. Submit a copy of your current informed consent document.

Researcher's Signature: \_\_\_\_\_ Date: \_\_\_\_\_

Please return this form to: **HSRB Chair**

For HSRB Use Only: Reapproved for the period: \_\_\_\_\_ to \_\_\_\_\_

Print or Type Name: \_\_\_\_\_

Chair, HSRB Signature: \_\_\_\_\_

Chief Academic Officer Signature: \_\_\_\_\_

**B. All Projects: Significant Change of Protocol and/or Informed Consent**

**1. Definition**

A significant protocol change refers to any change in the protocol that renders incorrect, statements or descriptions of procedures that led to the HSRB approval or exemption currently in effect.

**2. Significant Change of Protocol and/or Informed Consent Submission Procedures**

Prepare an application and attach an explanation of changes. There is no need to attach a copy of the original proposal. The new application and explanation are endorsed by the school, department, or unit head and are then submitted to the HSRB chair. For a **minor change** in ongoing, previously full review HSRB approved research, the HSRB may use expedited review procedures during the period for which approval was granted. Follow procedures for request of an expedited review. This review may be carried out by the HSRB Chairperson or a designee.

For a **substantial change** to a research study (e.g., procedure involving increased risk or discomfort are to be added), the HSRB must review and approve the proposed change at a convened meeting before the change can be implemented. The only exception is a change necessary to eliminate apparent immediate hazards to the research participants. In such a case, the HSRB should be promptly informed of the change following its implementation and should review the change to determine that it is consistent with ensuring the subject's continued welfare. The request for review form is to be completed, noting that it is a protocol change.

The application form follows on the next page.

**Human Subjects Review Board**

***Protocol Amendments/Consent Change Report Form***

Date: \_\_\_\_\_ Protocol #: \_\_\_\_\_

Investigator/Faculty Advisor: \_\_\_\_\_

Project Title: \_\_\_\_\_

PROTOCOL: (Circle)

1. Amendment /Revision/Update/Addendum # \_\_\_\_\_ Date \_\_\_\_\_  
*(Attach copy of amendment/revision/update/addendum)*

Description: \_\_\_\_\_

\_\_\_\_\_  
\_\_\_\_\_

2. *Check appropriate statement.*

\_\_\_ This amendment does not require consent form revision.

\_\_\_ Consent Form Revision: Date: \_\_\_\_\_  
*(Attach copy of consent with deletions lined through and additions highlighted)*

Description: \_\_\_\_\_

\_\_\_\_\_  
\_\_\_\_\_

---

For HSRB Use Only:

Your protocol amendment and/or consent form revisions have been received, reviewed, and approved by the Chairman of the HSRB on \_\_\_\_\_. It will be placed on file. Should further action be required, please contact me.

---

Print or Type Name

---

Signature, Chair, HSRB

Date

---

Signature, Chief Academic Officer

Date

### **C. All Projects: Reporting of Adverse Effects and Other Unanticipated Problems**

Investigators have the obligation to keep the HSRB informed of unexpected findings involving risks to subjects and to report any occurrence of serious harm to subjects.

When an adverse effect and/or other unanticipated problem occurs during an approved study, it should be reported promptly to the HSRB Chairperson. The Adverse Event and Miscellaneous Report Form should be completed as indicated for any unanticipated problems involving risks to subjects or others, or any serious or continuing noncompliance with the research policy or the requirements or determinations of the HSRB.

The HSRB has the authority to suspend or terminate approval of research that is not being conducted in accordance with the HSRB requirements or that has been associated with unexpected serious harm to subjects. If the HSRB decides to suspend or terminate approval of a project, the HSRB Chairperson shall report its decision promptly to the investigator, appropriate institutional officials and federal department or agency head (if federally funded). The HSRB report must include a statement of the reasons for suspension or termination.

The form follows on the next page.

**Human Subjects Review Board  
Adverse Event & Miscellaneous Report Form**

Date: \_\_\_\_\_ Protocol #: \_\_\_\_\_

Investigator/Faculty Advisor: \_\_\_\_\_

Project Title: \_\_\_\_\_

**ADVERSE EVENT:** \_\_\_\_\_ Date of incident: \_\_\_\_\_

Description: \_\_\_\_\_

Was the adverse event related to study?

\_\_\_ Yes \_\_\_ No \_\_\_ Probably \_\_\_ Possibly \_\_\_ Unlikely \_\_\_ Unknown

**The certification below is necessary for an adverse event submission:**

CERTIFICATION OF PRINCIPAL INVESTIGATOR: Your signature here certifies that you have assessed the information concerning the adverse event and that in your judgment the risks of this research are minimized to the greatest extent possible and continue to be outweighed or balanced by the potential benefits.

\_\_\_\_\_  
Signature of Principal Investigator

\_\_\_\_\_  
Date

OTHER: (please specify)

Miscellaneous Correspondence \_\_\_\_\_

---

**For HSRB Use Only**

Your adverse event/communication has been received, reviewed, and acknowledged by the Chairman of the HSRB on \_\_\_\_\_. It will be placed on file. Should further action be required, please contact me.

\_\_\_\_\_  
Print or Type Name

\_\_\_\_\_  
Signature, Chair, HSRB

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature, Chief Academic Officer

\_\_\_\_\_  
Date

## **XIII. Special Populations**

### **A. Children as Research Subjects**

Children may become research subjects if *any* of the following three conditions are met (documents 45 CFR 46.404, 46.405, 46.406):

Condition 1: The research entails no greater than minimal risk, *or*

Condition 2: The research involves greater than minimal risk, but provides the possibility of a direct benefit to individual participants, *or*

Condition 3: The research entails only slightly greater than minimal risk. Although the research does not provide any direct benefit to the individual subject, the research will yield generalized knowledge about the subject's disorder or condition that is of vital importance for the understanding or amelioration of the subject's disorder or condition. In addition, the research presents experiences to subjects that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational settings.

#### **1. Permission by Parents or Guardians**

- According to federal regulations, the permission of one parent is sufficient for research described by conditions 1 or 2.
- Research falling under condition 3 requires permission from both parents, unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child.
- Parental permission for children's participation must be written. Refer to the guidelines on informed consent forms for the necessary modifications when children are subjects.

#### **2. Children's Assent**

- In addition to parental permission, federal regulations require that children who are able to understand their participation in the research project are given the opportunity to provide assent. Assent is defined as a child's affirmative agreement to participate in research. Mere failure to object should not be construed as assent.
- Although federal regulations allow HSRB's to determine on a case-by-case basis when assent should be mandatory, the regulations are typically interpreted as requiring the assent of children ages 7 and older, and encouraging the assent of younger children, if their assent is judged to be meaningful. Typically, verbal assent is sufficient. However, when written assent is deemed appropriate, the written form should contain, in language appropriate to the child's abilities, a

simple explanation of the project, including a description of possible benefits, risks, and safeguards.

- Assent is not always necessary in research that may yield a direct benefit important to the health or well being of the child and available only in the context of research. A child's dissent, which is usually respected, may be overruled by the parents at the HSRB's discretion.

## **B. Protection for Prisoners as Subjects**

The following section of this document has been scribed from the federal Common rule.

When some or all of the research subjects are prisoners the [Federal Common Rule](#) requires that the project include additional safeguards to protect the rights and welfare of these subjects. In light of that requirement, the research protocol must describe these protections and conform with Subpart C of Title 45, Part 46 of the Code of Federal Regulations cited below that contains the federal policy on research that involves prisoners.

<b>Subpart C</b>	<b>Additional DHHS Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects</b>
	<b>Source:</b> 43 FR 53655, Nov. 16, 1978.

### **§46.301 Applicability.**

(a) The regulations in this subpart are applicable to all biomedical and behavioral research conducted or supported by the Department of Health and Human Services involving prisoners as subjects.

(b) Nothing in this subpart shall be construed as indicating that compliance with the procedures set forth herein will authorize research involving prisoners as subjects, to the extent such research is limited or barred by applicable State or local law.

(c) The requirements of this subpart are in addition to those imposed under the other subparts of this part.

### **§46.302 Purpose.**

Inasmuch as prisoners may be under constraints because of their incarceration which could affect their ability to make a truly voluntary and uncoerced decision whether or not to participate as subjects in research, it is the purpose of this subpart to provide additional safeguards for the protection of prisoners involved in activities to which this subpart is applicable.

### **§46.303 Definitions.**

As used in this subpart:

(a) "Secretary" means the Secretary of Health and Human Services and any other officer or employee of the Department of Health and Human Services to whom authority has been delegated.

(b) "DHHS" means the Department of Health and Human Services.

(c) "Prisoner" means any individual involuntarily confined or detained in a penal institution. The term is intended to encompass individuals sentenced to such an institution under a criminal or civil statute, individuals detained in other facilities by virtue of statutes or commitment procedures which provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing.

(d) "Minimal risk" is the probability and magnitude of physical or psychological harm that is normally encountered in the daily lives, or in the routine medical, dental, or psychological examination of healthy persons.

#### **§46.304 Composition of Institutional Review Boards where prisoners are involved.**

In addition to satisfying the requirements in [§46.107](#) of this part, an Institutional Review Board, carrying out responsibilities under this part with respect to research covered by this subpart, shall also meet the following specific requirements:

(a) A majority of the Board (exclusive of prisoner members) shall have no association with the prison(s) involved, apart from their membership on the Board.

(b) At least one member of the Board shall be a prisoner, or a prisoner representative with appropriate background and experience to serve in that capacity, except that where a particular research project is reviewed by more than one Board only one Board need satisfy this requirement.

#### **§46.305 Additional duties of the Institutional Review Boards where prisoners are involved.**

(a) In addition to all other responsibilities prescribed for Institutional Review Boards under this part, the Board shall review research covered by this subpart and approve such research only if it finds that:

(1) the research under review represents one of the categories of research permissible under [§46.306\(a\)\(2\)](#);

(2) any possible advantages accruing to the prisoner through his or her participation in the research, when compared to the general living conditions, medical care, quality of food, amenities and opportunity for earnings in the prison, are not of such a magnitude that his or her ability to weigh the risks of the research against the value of such advantages in the limited choice environment of the prison is impaired;

(3) the risks involved in the research are commensurate with risks that would be accepted by nonprisoner volunteers;

(4) procedures for the selection of subjects within the prison are fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners. Unless the principal investigator provides to the Board justification in writing for following some other procedures, control subjects must be selected randomly from the group of available prisoners who meet the characteristics needed for that particular research project;

(5) the information is presented in language which is understandable to the subject population;

(6) adequate assurance exists that parole boards will not take into account a prisoner's participation in the research in making decisions regarding parole, and each prisoner is clearly informed in advance that participation in the research will have no effect on his or her parole; and

(7) where the Board finds there may be a need for follow-up examination or care of participants after the end of their participation, adequate provision has been made for such examination or care, taking into account the varying lengths of individual prisoners' sentences, and for informing participants of this fact.

(b) The Board shall carry out such other duties as may be assigned by the Secretary.

(c) The institution shall certify to the Secretary, in such form and manner as the Secretary may require, that the duties of the Board under this section have been fulfilled.

#### **§46.306 Permitted research involving prisoners.**

(a) Biomedical or behavioral research conducted or supported by DHHS may involve prisoners as subjects only if:

(1) the institution responsible for the conduct of the research has certified to the Secretary that the Institutional Review Board has approved the research under [§46.305](#) of this subpart; and

(2) in the judgment of the Secretary the proposed research involves solely the following:

(A) study of the possible causes, effects, and processes of incarceration, and of criminal behavior, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects;

(B) research on conditions particularly affecting prisoners as a class (for example, vaccine trials and other research on hepatitis which is much more prevalent in prisons than elsewhere; and research on social and psychological problems such as alcoholism, drug addiction, and sexual assaults) provided that the study may proceed only after the Secretary has consulted with appropriate experts including experts in penology, medicine, and ethics, and published notice, in the **Federal Register**, of his/her intent to approve such research; or

(C) research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the subject. In cases in which those studies require the assignment of prisoners in a manner consistent with protocols approved by the IRB to control groups which may not benefit from the research, the study may proceed only after the Secretary has consulted with appropriate experts, including experts in penology, medicine, and ethics, and published notice, in the **Federal Register**, of the intent to approve such research.

(b) Except as provided in paragraph (a) of this section, biomedical or behavioral research conducted or supported by DHHS shall not involve prisoners as subjects.

## **XIV. Ethical Principles for the Protection of Human Subjects**

The RWU Human Subjects Review Board has adopted, with permission, sections of the American Psychological Association (APA, 2002) standards for RWU research ethics. All RWU faculty and student researchers must comply with these principles and sign-off their compliance on the proposal cover-sheet.

### **4. Privacy and Confidentiality**

#### **4.01 Maintaining Confidentiality**

Researchers have a primary obligation and take reasonable precautions to protect confidential information obtained through or stored in any medium, recognizing that the extent and limits of confidentiality may be regulated by law or established by institutional rules or professional or scientific relationship.

##### **1.01 Discussing the Limits of Confidentiality**

(a) Researchers discuss with persons (including, to the extent feasible, persons who are legally incapable of giving informed consent and their legal representatives) and organizations with whom they establish a scientific or professional relationship (1) the relevant limits of confidentiality and (2) the foreseeable uses of the information generated through their psychological activities.

(b) Unless it is not feasible or is contraindicated, the discussion of confidentiality occurs at the outset of the relationship and thereafter as new circumstances may warrant.

(c) Researchers who offer services, products, or information via electronic transmission inform clients/ patients of the risks to privacy and limits of confidentiality.

##### **1.02 Recording**

Before recording the voices or images of individuals to whom they provide services, researchers obtain permission from all such persons or their legal representatives.

##### **1.03 Minimizing Intrusions on Privacy**

(a) Researchers include in written and oral reports and consultations, only information germane to the purpose for which the communication is made.

(b) Researchers discuss confidential information obtained in their work only for appropriate scientific or professional purposes and only with persons clearly concerned with such matters.

##### **1.04 Disclosures**

(a) Researchers may disclose confidential information with the appropriate consent of the organizational client, the individual client/patient, or another legally authorized person on behalf of the client/patient unless prohibited by law.

(b) Researchers disclose confidential information without the consent of the individual only as mandated by law, or where permitted by law for a valid purpose such as to (1) provide needed professional services; (2) obtain appropriate professional consultations; (3) protect the client/patient, researcher, or others from harm; or (4) obtain payment for services from a client/patient, in which instance disclosure is limited to the minimum that is necessary to achieve the purpose.

### **1.05 Consultations**

When consulting with colleagues, (1) researchers do not disclose confidential information that reasonably could lead to the identification of a client/patient, research participant, or other person or organization with whom they have a confidential relationship unless they have obtained the prior consent of the person or organization or the disclosure cannot be avoided, and (2) they disclose information only to the extent necessary to achieve the purposes of the consultation.

### **1.06 Use of Confidential Information for Didactic or Other Purposes**

Researchers do not disclose in their writings, lectures, or other public media, confidential, personally identifiable information concerning their clients/patients, students, research participants, organizational clients, or other recipients of information concerning their services that they obtained during the course of their work, unless (1) they take reasonable steps to disguise the person or organization, (2) the person or organization has consented in writing, or (3) there is legal authorization for doing so.

## **8. Research and Publication**

### **1.01 Institutional Approval**

When institutional approval is required, researchers provide accurate information about their research proposals and obtain approval prior to conducting the research. They conduct the research in accordance with the approved research protocol.

### **1.01 Informed Consent to Research**

(a) When obtaining informed consent as required in Standard 3.10, Informed Consent, researchers inform participants about (1) the purpose of the research, expected duration, and procedures; (2) their right to decline to participate and to withdraw from the research once participation has begun; (3) the foreseeable consequences of declining or withdrawing; (4) reasonably foreseeable factors that may be expected to influence their willingness to participate such as potential risks, discomfort, or adverse effects; (5) any prospective research benefits; (6) limits of confidentiality; (7) incentives for participation; and (8) whom to contact for questions about the research and research participants' rights. They provide opportunity for the prospective participants to ask questions and receive answers.

(b) Researchers conducting intervention research involving the use of experimental treatments clarify to participants at the outset of the research (1) the experimental nature of the treatment; (2) the services that will or will not be available to the control group(s) if appropriate; (3) the means by which assignment to treatment and control groups will be made; (4) available treatment alternatives if an individual does not wish to participate in the research or wishes to withdraw once a study has begun; and (5) compensation for or monetary costs of participating

including, if appropriate, whether reimbursement from the participant or a third-party payor will be sought.

### **1.02 Informed Consent for Recording Voices and Images in Research**

Researchers obtain informed consent from research participants prior to recording their voices or images for data collection unless (1) the research consists solely of naturalistic observations in public places, and it is not anticipated that the recording will be used in a manner that could cause personal identification or harm, or (2) the research design includes deception, and consent for the use of the recording is obtained during debriefing.

### **1.03 Client/Patient, Student, and Subordinate Research Participants**

(a) When researchers conduct research with clients/patients, students, or subordinates as participants, researchers take steps to protect the prospective participants from adverse consequences of declining or withdrawing from participation.

(b) When research participation is a course requirement or an opportunity for extra credit, the prospective participant is given the choice of equitable alternative activities.

### **1.04 Dispensing With Informed Consent for Research**

Researchers may dispense with informed consent only (1) where research would not reasonably be assumed to create distress or harm and involves (a) the study of normal educational practices, curricula, or classroom management method conducted in educational settings; (b) only anonymous questionnaires, naturalistic observations, or archival research for which disclosure of responses would not place participants at risk of criminal or civil liability or damage their financial standing, employability, or reputation, and confidentiality is protected; or (c) the study of factors related to job or organization effectiveness conducted in organizational settings for which there is no risk to participants' employability, and confidentiality is protected or (2) where otherwise permitted by law or federal or institutional regulations.

### **1.05 Offering Inducements for Research Participation**

(a) Researchers make reasonable efforts to avoid offering excessive or inappropriate financial or other inducements for research participation when such inducements are likely to coerce participation.

(b) When offering professional services as an inducement for research participation, researchers clarify the nature of the services, as well as the risks, obligations, and limitations.

### **1.06 Deception in Research**

(a) Researchers do not conduct a study involving deception unless they have determined that the use of deceptive techniques is justified by the study's significant prospective scientific, educational, or applied value and that effective nondeceptive alternative procedures are not feasible.

(b) Researchers do not deceive prospective participants about research that is reasonably expected to cause physical pain or severe emotional distress.

(c) Researchers explain any deception that is an integral feature of the design and conduct of an experiment to participants as early as is feasible, preferably at the conclusion of their participation, but no later than at the conclusion of the data collection, and permit participants to withdraw their data.

### **1.07 Debriefing**

(a) Researchers provide a prompt opportunity for participants to obtain appropriate information about the nature, results, and conclusions of the research, and they take reasonable steps to correct any misconceptions that participants may have or which the researchers are aware.

(b) If scientific or humane values justify delaying or withholding this information, researchers take reasonable measures to reduce the risk of harm.

(c) When researchers become aware that research procedures have harmed a participant, they take reasonable steps to minimize the harm.

### **8.10 Reporting Research Results**

(a) Researchers do not fabricate data.

(b) If researchers discover significant errors in their published data, they take reasonable steps to correct such errors in a correction, retraction, erratum, or other appropriate publication means.

### **8.11 Plagiarism**

Researchers do not present portions of another's work or data as their own, even if the other work or data source is cited occasionally.

### **8.12 Publication Credit**

(a) Researchers take responsibility and credit, including authorship credit, only for work they have actually performed or to which they have substantially contributed.

(b) Principal authorship and other publication credits accurately reflect the relative scientific or professional contributions of the individuals involved, regardless of their relative status. Mere possession of an institutional position, such as department chair, does not justify authorship credit. Minor contributions to the research or to the writing for publications are acknowledged appropriately, such as in footnotes or in an introductory statement.

(c) Except under exceptional circumstances, a student is listed as principal author on any multiple-authored article that is substantially based on the student's doctoral dissertation. Faculty advisors discuss publication credit with students as early as feasible and throughout the research and publication process as appropriate.

### **8.13 Duplicate Publication of Data**

Researchers do not publish, as original data, data that have been previously published. This does not preclude republishing data when they are accompanied by proper acknowledgment.

#### **8.14 Sharing Research Data for Verification**

(a) After research results are published, researchers do not withhold the data on which their conclusions are based from other competent professionals who seek to verify the substantive claims through reanalysis and who intend to use such data only for that purpose, provided that the confidentiality of the participants can be protected and unless legal rights concerning proprietary data preclude their release. This does not preclude researchers from requiring that such individuals or groups be responsible for costs associated with the provision of such information.

(b) Researchers who request data from other researchers to verify the substantive claims through reanalysis may use shared data only for the declared purpose. Requesting researchers obtain prior written agreement for all other uses of the data.

#### **8.15 Reviewers**

Researchers who review material submitted for presentation, publication, grant, or research proposal review respect the confidentiality of and the proprietary rights in such information of those who submitted it.

## **XV. Conflict of Interest**

- Where any member of the HSRB is personally involved in the research, that individual shall not participate in the review or approval of the research by the HSRB. An alternate member should be appointed by the HSRB chair to act in his/her stead during the review process for the proposal involved.
- If the chair of the HSRB is concerned about a conflict of interest with a proposed research project within or outside of the university, she/he may take this project to the full board to determine if indeed this project's implementation is a conflict of interest and may have negative repercussions on the university or any of its members. If the board is undecided, the matter will be forwarded to the Chief Academic Officer who will then make a final decision after having been advised by the HSRB chair.

## Definition of Terms

**Annual renewal/progress report:** a form used to obtain annual approval of continuing project and to provide information about completed projects.

**Assent:** a child's affirmative verbal agreement to participate in research.

**Cover sheet:** a form completed by the principal investigator or faculty advisor to request a review of research using human subjects. A sample cover sheet is included in this manual.

**Exempted from further HSRB review:** the proposed research poses minimal risks to subjects and satisfies other criteria listed in section 4 of this manual. The chair of the HSRB will review and determine if a proposal is exempt from further review. If so, as soon as the chair notifies the investigator(s), the research may proceed.

**Expedited from further HSRB review:** the proposed research poses minimal risks to subjects and satisfies other criteria listed in section 4 of this manual. The chair of the HSRB and one other board member will review and approve all expedited proposals. If the two HSRB members decide that a proposal needs a design change, they will contact the principal investigator. Once the design has been revised and approved, the chair then notifies the investigator(s) that the research may proceed.

**Full HSRB review:** the proposed research poses a change in a subject's daily life therefore all members of the RWU HSRB will review the submitted research proposal. Once the design has been approved, the chair will notify the investigator(s) that the research may proceed.

**Grant proposal:** a proposal for HSRB review of research for which a grant application is being submitted to a funding agency.

**Human subject:** a living individual about whom an investigator conducting research obtains data through intervention or interaction with the individual, or uses identifiable private information including the observation or recording of behavior not generally exposed to public scrutiny.

**HSRB approval:** the determination of the HSRB that the research has been reviewed and may be conducted at an institution within the constraints set forth by the HSRB, the University, and federal requirements

**Informed consent:** the process whereby a subject agrees to participate in an experiment or study after achieving a full understanding of what is involved in the study. See section 9 of this manual for procedures for obtaining informed consent.

**Intervention:** includes physical, social, and behavioral procedures by which data are gathered and manipulations of the subject's environment are performed for research purposes.

**Interaction:** includes communication or interpersonal contact between investigator and subject.

**Minimal risk:** the probability and magnitude of harm or discomfort anticipated in the 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.

**Research proposal:** a form submitted by the Principle Investigator(s) or Faculty Advisor that provides specific information about the proposed research. A sample research proposal form is included in this manual.

**Research:** a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.

**Significant protocol change:** a change in the research procedures that renders incorrect statements or descriptions of procedures that led to the HSRB approval or exemption currently in effect.

## References

- Ethical Principles of Psychologists and Code of Conduct*. (2002). Washington, DC: American Psychological Association.
- St. Joseph's University Office of Research Services. (2003). *Institution Review Board Policy and Procedures Manual*. Available from St. Joseph's University, [http://www.sju.edu/offices/research/human\\_subjects.html](http://www.sju.edu/offices/research/human_subjects.html)
- US Department of Health and Human Services. (2003). *Code of Federal Regulations*. [Title 45 Public Welfare Part 46 Protection of Human Subjects] Available from US Department of Health and Human Services, <http://ohrp.osoph.dhhs.gov/humansubjects/guidance/45cfr46.htm>
- US Department of Health and Human Services. (2003). *IRB Guidebook* [Guidebook for Institutional Review Boards]. Available from US Department of Health and Human Services, <http://ohrp.osoph.dhhs.gov/irb/irb.html>
- US Department of Health and Human Services. (2003). *The Belmont Report*. Available from US Department of Health and Human Services, <http://ohrp.osoph.dhhs.gov/humansubjects/guidance/belmont.htm>
- University of Wisconsin-Madison. (2003). *Institution Review Board* [Human Subjects Review Board]. Available from University of Wisconsin-Madison, <http://rsp.wisc.edu/humansubjects.html>