This manual was originally prepared in 2003 with the invaluable guidance of the St. Joseph's University Office of Research Services website: http://www.sju.edu/int/academics/resources/research/irb/

All material from this website was adapted to fit our University's needs. In 2017, The HSRB updated the Manual to include changes to federal guidelines as well as University guidelines important to the review of all applications submitted to the Roger Williams University Human Subjects Review Board.

Judith Platania, Ph.D. Chair, Professor of Psychology

Farbod Farhadi, Ph.D., Assistant Professor of Management
Benjamin McPheron, Ph.D., Associate Professor of Engineering
David Moskowitz, Ph.D., Associate Professor of Political Science
Melissa B. Russano, Ph.D., Professor, School of Justice Studies
Amiee Shelton, Ph.D., Associate Professor of Public Relations
Erin Tooley, Ph.D., Assistant Professor of Psychology
Ann G. Winfield, Ph.D., Associate Professor of Educational Foundations
Paris Pavkovic, M.A., Affiliated Member

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 m

Each committee member shall serve a three-year term renewable commencing and ending on September 1 each year. Committee member appointments are staggered so that only two new members will join the

- 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.

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.

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.

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

(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 consent from participants.

Research involving web-based (or online) data collection procedures.

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

- Research 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.

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

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VI. Length of Time for Review

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, including why these methods are necessary. The use of deception does not reduce 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 withholding or falsifying information likely to affect the willingness 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*

10.! Classroom Research Projects in which Undergraduate/Graduate Students

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, however the template provided on the HSRB website is a useful tool when creating an Informed Consent.

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:
-

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-

X. Proposal Cover Sheets

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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

XI. Procedures for Preparing

Human Subjects Review Board
Application for Annual Renewal/Progress Report/Completed Project

Date: Protocol #:

Investigator(s):

Title of Project:

Federal regulations require an annual review of approved projects. As such, please complete the following questionnaire by

1. Is this research ongoing: Yes No

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

2. If yes, please answer the following questions:

a. Provide the number of participants 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							

Human Subjects Review Board

Protocol Amendments/Consent Change Report Form

Date: _____

Protocol #: _____

Investigator/Faculty Advisor: _____

Project Title: _____

PROTOCOL: (Circle)

1. Amendment /Revision/Update/Addendum #____
   (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 occur during an approved study, it should be reported promptly to the HSRB Chairperson. The Adverse Event and Miscellaneous Report Form should be

Human Subjects Review Board Adverse Event & Miscellaneous Report Form

Date: _____

Protocol #: _____

XII. Special Populations

A.!

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

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 more than one Board only one Board reviews a particular research project 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:

(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 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.

§46.306 Permitted research involving prisoners.

(a)

XIII. 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.

1.1! Discussing the Limits of Confidentiality

(a) Researchers discuss with persons (including, to the extent feasible, persons who are

(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.

1.5! 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.

1.6! 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 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.

1.1! 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(ter

1.2!

8.14! Sharing Research Data for Verification

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. 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.

XIV. Conflict of

Definition of Terms

Annual renewal/progress report: a form used to obtain annual approval of continuing

References

Ethical Principles of Psychologists and Code of Conduct. (2002). Washington, DC: American Psychological Association.

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