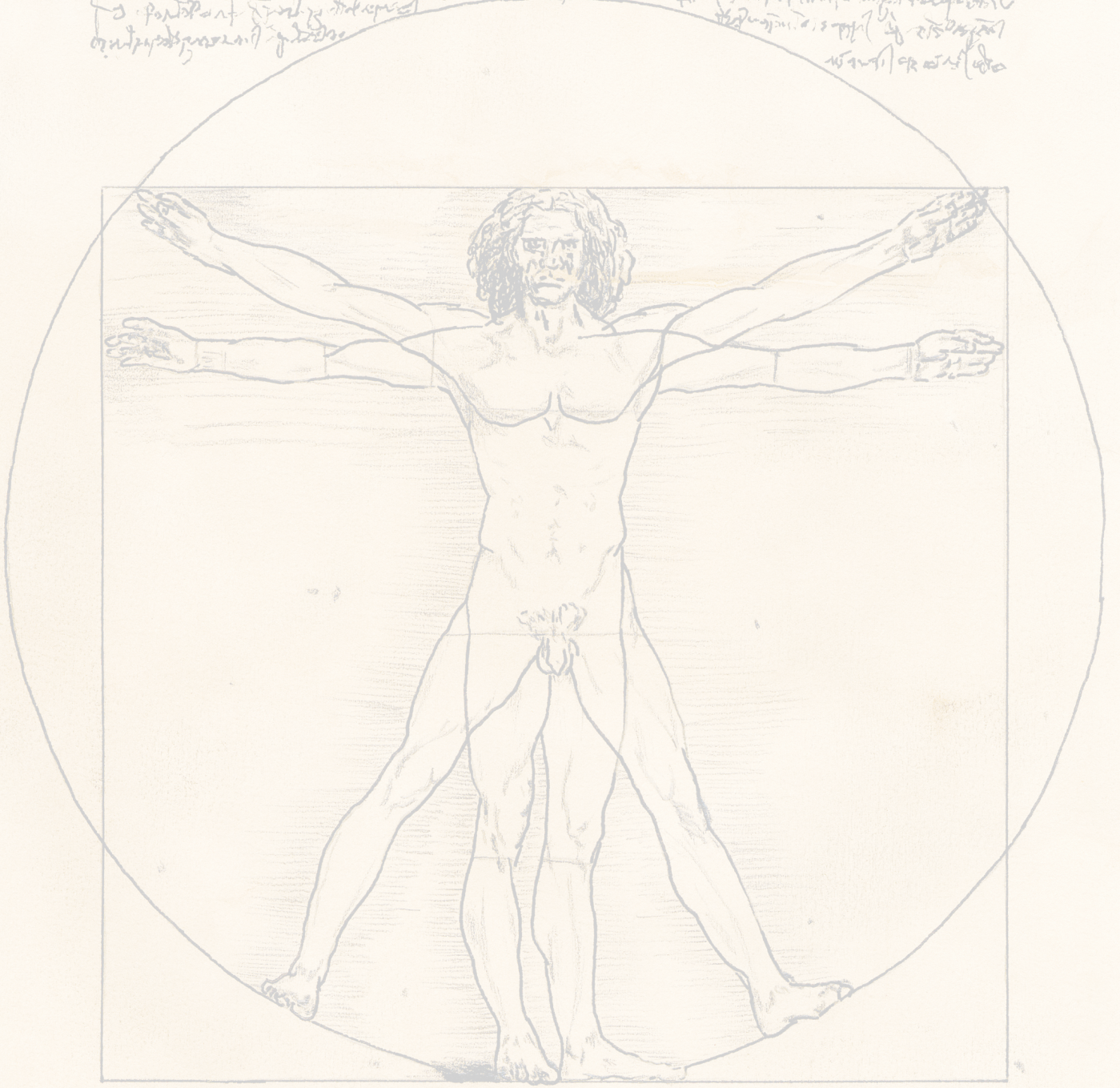


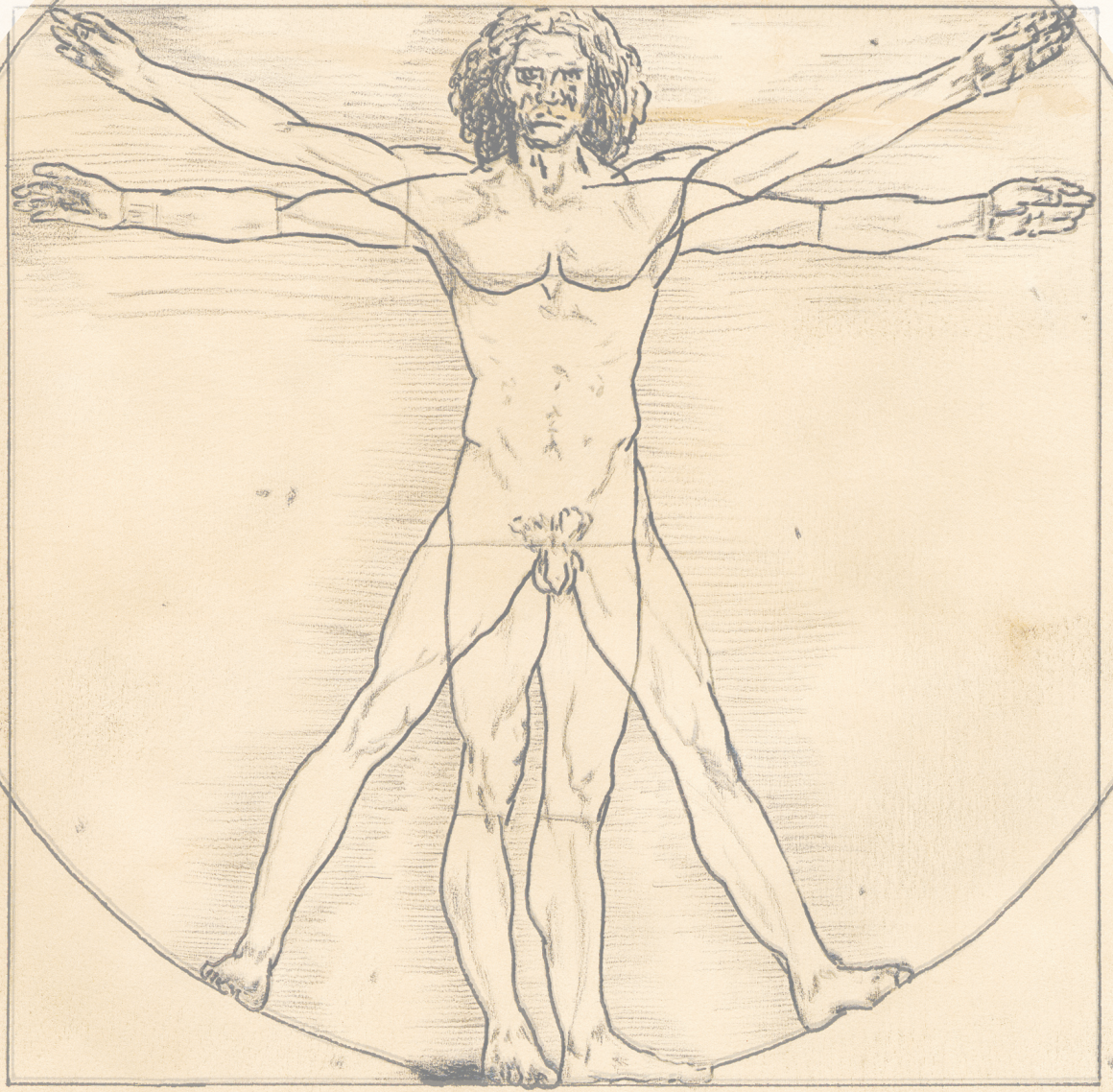
Faint, illegible handwritten text at the top of the page, likely bleed-through from the reverse side.



Faint, illegible handwritten text at the bottom of the page, likely bleed-through from the reverse side.

INSTITUTIONAL REVIEW BOARD

2017-2018



POLICIES AND PROCEDURES

ADELPHI
UNIVERSITY
NEW YORK

TABLE OF CONTENTS

I.	INTRODUCTION	2
II.	THE AUTHORITY OF THE IRB	2
III.	RESPONSIBILITY	2
IV.	MEMBERSHIP	3
V.	OPERATIONS OF THE IRB	4
VI.	TYPES OF IRB REVIEW	5
VII.	RESEARCH EXEMPT FROM IRB REVIEW	6
VIII.	REVIEW PROTOCOLS	8
IX.	AUDITS	10
X.	SUSPENSION OR TERMINATION OF RESEARCH	11
XI.	IRB RECORD REQUIREMENTS	11
XII.	ELEMENTS OF INFORMED CONSENT	12
XIII.	DOCUMENTING INFORMED CONSENT	13
XIV.	HIPAA AND RESEARCH	14
XV.	INTERNET RESEARCH POLICY	14
XVI.	SOCIAL MEDIA	18
XVII.	RESEARCH METHODS COURSES	18
XVIII.	ORAL HISTORY	19
XIX.	ATTACHMENTS	20
XX.	ACKNOWLEDGMENTS	39

I. INTRODUCTION

Regulations protecting human subjects were issued by the United States Department of Health, Education and Welfare (DHEW) on May 30, 1974, in its regulatory document titled "Policies for the Protection of Human Subjects." The regulations established the **Institutional Review Board (IRB)** as one mechanism through which human subjects would be protected.

Adelphi University (hereafter known as Adelphi) demands the highest ethical standards in the conduct of research in and among its facilities, and in collaboration with other educational institutions, agencies and organizations. As such, the Adelphi IRB reviews all proposals involving human participants conducted by AU faculty, students and staff. While respecting the right of the researcher to full academic freedom in research, Adelphi is firmly committed to adhering to the basic ethical principles underlying the acceptable conduct of research involving human subjects, as set forth in "The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research" (see <http://research-grants.adelphi.edu/irb/belmont-report> for the full text of the report). These principles are now accepted as the three essential requirements for the ethical conduct of research involving human subjects.

Respect for persons involves recognition of the personal dignity and autonomy of individuals, and special protection of persons with diminished autonomy.

Beneficence entails an obligation to protect persons from harm by maximizing anticipated benefits and minimizing possible risks.

Justice requires that the benefits and burdens of research be distributed fairly.

"The Belmont Report" describes how these principles apply to the conduct of research. Specifically, the principle of respect for persons underlies the need to obtain informed consent; the principle of beneficence underlies the need to engage in a risk/benefit analysis and to minimize risks; and the principle of justice requires that subjects be fairly selected.

The Adelphi University Institutional Review Board (hereafter known as IRB) is charged with reviewing all research proposals that employ human subjects to ensure that they conform to national and local standards of ethical conduct and treatment, and to ensure the safety and rights of all individuals involved in the proposed research. Approval by this committee is a precondition for conducting any such study by investigators of Adelphi University.

II. THE AUTHORITY OF THE IRB

The IRB is an administrative body established to protect the rights and welfare of human research subjects recruited to participate in research activities conducted by Adelphi faculty, adjunct faculty, administrators and students under the auspices of Adelphi University.

The IRB functions independently of other committees. The IRB makes its independent determination whether to approve or disapprove the protocol based upon whether or not human subjects are adequately protected. The IRB reports its recommendations to the Associate Provost for Faculty Advancement and Research for informational purposes by sending a copy of the monthly minutes.

The IRB has the authority to approve, require modifications as a condition of approval or disapprove research on human subjects at Adelphi that fall within its scope of authority. Research that has been reviewed and approved by the IRB may be subject to review and disapproval by officials of the institution. However, those officials may not approve research if it has been disapproved by the IRB (HHS regulation 45 CFR 46.112).

The IRB has the authority to verify that ongoing studies comply with regulations and it may suspend or terminate approval for ongoing studies under its jurisdiction. Furthermore, the IRB has the authority to determine whether or not any activity is covered under these policies and procedures, and whether it requires review by the IRB.

III. RESPONSIBILITY

Research is defined by federal regulations as "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge." **Human subjects**

are defined by the regulations as “living individual(s) about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual or (2) identifiable private information.”

The IRB must review all proposed research to assure that:

- Research performed at Adelphi protects the welfare and rights of human subjects
- Informed consent is obtained from each prospective subject or from the subject’s legally authorized representative and that it is documented in accordance with, and to the extent required by law
- Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may be expected to result
- No research performed at Adelphi places human subjects at unreasonable physical, mental or emotional risk
- Selection of subjects is equitable
- There are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data in accordance with Adelphi policy
- Appropriate additional safeguards have been included in the study to protect the rights and welfare of subjects who are members of a particularly vulnerable group
- Risks to research subjects are minimized by using, whenever appropriate, procedures already being performed on the subject(s) for diagnostic or treatment purposes

It is the responsibility of the IRB to ensure a regular review of these policies and procedures, and to update and maintain familiarity with this document. A review and discussion will be reflected in the minutes, at least once in two years. Any proposed change(s) and amendments may be presented at any regular IRB meeting when placed on the agenda as new business, prior to regular meeting notification. Any IRB member or IRB staff may be asked to ensure review of newly promulgated regulations and review of this document for compliance.

Some research that involves human subjects may be exempt from the regulations requiring IRB review. Examples include educational testing and survey procedures where no identifying information will be recorded that can link subjects to the data, and disclosure of the data could not reasonably place the subjects at risk of civil or criminal liability or be damaging to the subjects’ financial standing, employability or reputation; and research that involves the use of existing data, documents or specimens, where no identifying information will be recorded that can link subjects to the data. The IRB chairperson, one other member of the IRB and the Adelphi administrative representative will determine if a proposed study is exempt. These exempt studies will be reported at the next official meeting of the IRB (**see Attachment C for Anonymous Survey Policy**).

IV. MEMBERSHIP

A. Standing Memberships

The IRB shall consist of at least eight and no more than 15 members. The members will vary in racial, ethnic, cultural and sexual subgroupings and profession as much as possible. A minimum of one, preference for two, representatives from each school/college engaged in human research (College of Arts and Science, Gordon F. Derner Institute School of Psychology, Robert B. Willumstad School of Business, Ruth S. Ammon School of Education, College of Nursing and Public Health, School of Social Work) is required. Membership should be proportionally representative of all divisions conducting human research (research that involves human subjects). Members will be nominated by the dean of their respective school and appointed by the provost. Members will be persons knowledgeable about institutional standards, institutional commitments, applicable law and the standards of professional conduct and practice, and who are sensitive to community issues. In addition, a minimum of one community member must be included on the IRB. The community member may not be affiliated with Adelphi, and may not be a member of the immediate family of a person

who is affiliated with Adelphi. The chairperson of the IRB will be confirmed by a majority vote of the IRB, confirmed by the provost and will serve for two years. Chairs can serve consecutive terms.

B. Alternate Members

Alternate members are appointed and serve only when a primary member will be unable to attend meetings for an extended period of time (e.g., when a primary member is on a sabbatical leave or extended medical leave). The dean may approve alternate members for any of its primary members, limited in number to no more than one alternate per member. The alternate members shall have similar qualifications to the members that they are representing and shall have received and reviewed the same material that the primary member received or would have received for the meeting the alternate shall be attending. Alternate members shall have the same voting rights as primary members and should be counted when determining the existence of a quorum at a meeting.

C. Consultants

The IRB may, at its discretion, invite individuals with competence in special areas to assist in the review of issues which require expertise beyond or in addition to that available on the IRB. These individuals may not vote.

D. Term, Appointment, Removal, Attendance

Members shall be appointed for a term of two years. Members are expected to attend two thirds of the IRB meetings per year. Members may be removed for good cause by the provost at the request of the chairperson of the IRB. Reasons for removal may include failure to meet attendance requirements and/or to complete assignments. If a member is eligible for removal, the chairperson must first seek the committee's approval to ask for the resignation of a nonattending/nonperforming member and, if the member does not resign, the chairperson must seek the committee's approval to remove the member from the committee.

E. Conflict of Interest

Individuals or their immediate family members directly involved in the conduct, design or reporting of research involving human subjects should not have more than a minimal personal or financial interest in the company that sponsors the research or owns the technology being studied. A conflict of interest arises when a researcher or member of his/her immediate family is or may be in a position to put his or her own interest before the best interest of the research subjects. To manage such conflicts, the IRB must be informed of potential conflicts of interest. Researchers submitting protocols using human subjects must disclose all interests that may be perceived as a conflict for the research to be considered for approval (see Attachment B for Conflict of Interest Policy).

HHS regulations at 45 CFR 46.107(e) stipulate that no IRB member may participate in the IRB's initial or continuing review of a project in which the member has a conflicting interest except to provide information requested by the IRB. Except when requested by the IRB to be present to provide information, IRB members will be absent from the meeting room when the IRB reviews research in which they have a conflicting interest. When an IRB member must be absent from review of any study, a quorum must remain (defined in section V. A.) to hold a vote. If no quorum remains, an alternate member (per section V. A.) may vote. The attendance of the alternate member for the vote must be documented. If the alternate member leaves the meeting after a vote, this must be reflected in the minutes.

V. OPERATIONS OF THE IRB

A. Quorum

The presence of a majority (51 percent) of the appointed members (including the chair and one community member whose primary concerns are not scientific) will constitute a quorum for the conduct of business at regular meetings of the IRB. All decisions will be reached by a simple majority of the appointed members present.

Scheduling of Meetings

The IRB will have at least nine scheduled meetings per year, or as needed, to adequately review initial submissions and ongoing studies. IRB members will be advised in advance regarding the date, time and place of each meeting. Meetings will be held during the fourth Monday of each month at a time mutually acceptable to a majority of the members, unless otherwise noted. A meeting schedule will be conveyed by

email to members of the IRB.

For regular meetings, members shall receive an agenda and the research proposal applications at least five days prior to the meeting. If there is no IRB business for the month, the chairperson may cancel the meeting and notify all members of such action.

The IRB chairperson may convene additional meetings. Emergency meetings may be convened, as appropriate, and require at least a 48-hour notice. Alternate members (defined in section IV. B.) may be utilized when IRB members are unable to attend.

VI. TYPES OF IRB REVIEW

All research involving human subjects conducted by faculty, adjunct faculty, administrators or students under the auspices of Adelphi University is subject to full review. Full review is recognized as optimal, even for protocols that may qualify for expedited review under federal regulations. *Note: All research must be conducted within the proposed time frames. If an approved proposal is not initiated within one year of approval, resubmission is required. It is incumbent upon the submitter to notify the IRB of cancellation.*

All materials submitted for full review, continuing review, reconsideration and cooperative review must be received in the IRB office no later than the **10TH OF THE MONTH IN WHICH THE COMMITTEE MEETING TAKES PLACE. One electronic copy and ONE hard copy (original with signatures) of each required document are to be submitted to the Office of Research and Sponsored Programs.**

A. Full Review

A full review consists of a review of research involving human subjects by the entire IRB in accordance with the requirements set forth in 45 CFR 46.110 and depicted in this document. This includes submission of the Adelphi University IRB Research Review Form and all attachments prior to the deadline, review by the entire IRB and a decision by a simple majority of a quorum of IRB members. (See Attachment A for the IRB Review Form.)

Full review is required for all proposals except those that may be expedited or exempt. Exempt and expedited policies are detailed in the following sections.

B. Multiyear Consideration and Review

To better address the needs of our faculty, the IRB will consider proposals for multiyear approvals with a maximum of a three-year request. To ask for a multiyear approval, complete the required forms and include a cover letter requesting approval for up to three years, detailing the reasons to support your request. The cover letter is the only new element needed. As with any IRB-approved protocol, any changes from the original proposal require a modification request. The principal investigator must submit an annual report to the IRB before the first anniversary of the initial approval. The report must contain a review of any adverse reactions or unanticipated problems that occurred since the original approval, as well as the current status of the research (ongoing, suspended, discontinued). In addition, the research is subject to an annual review at the discretion of the IRB.

C. Continuing Review

Almost all proposals at Adelphi are approved for a one-year period. Proposals that continue beyond the one-year approval must be submitted for continuation before the end of the approval period. The request for continuation is reviewed by the IRB administrator and IRB chair and may include one other IRB member if the chair and administrative liaison require additional feedback. HHS regulations at 45 CFR 46.108(b) and 109(e) require an IRB to conduct continuing review of research at intervals appropriate to the degree of risk, but not less frequently than once per year. (See Attachment D for Continuation/Modification Form.)

D. Intermittent Review

All ongoing research at Adelphi may be subjected to intermittent review(s) for a periodic update of the progress and issues encountered. The IRB will inform the researcher or primary investigator of the review.

E. Expedited Review

An expedited review procedure includes submission of three copies of the Adelphi University IRB Research

Review Form and all attachments prior to the deadline, review by a subcommittee of the IRB (e.g., the IRB chair, at least one other member of the IRB and the administrative liaison to IRB) in accordance with the requirements set forth in 45 CFR 46.110, a decision by a simple majority of the subcommittee and the report of the action at the next full IRB meeting.

The Adelphi IRB recognizes that this review process does not afford the greater safeguards for research subjects provided by the full review. Thus, full review is recognized as optimal, even for protocols that may qualify for expedited review under federal regulations.

Certain types of research may be reviewed and approved without convening a meeting of the IRB. A list of research categories that may be reviewed through the expedited review procedure is in the November 9, 1998 publication of the Federal Register (63 FR 60353), and includes the following:

- Research employing subjects who are not from a vulnerable (e.g., physically, psychologically or socially) population
- Research involving minimal risk: Minimal or no-risk projects are those which involve no foreseeable danger to the subjects and would not require written informed consent; examples of no-risk procedures include: administration of anonymous opinion questionnaires, measurements such as reaction time or hand-eye coordination and interviews on nonthreatening topics
- Modifications to approved proposals not yet initiated may be submitted through the expedited review process described in section VIII. C.

The IRB may also use the expedited review to scrutinize minor changes proposed for previously approved research during the period covered by the original approval. (See Attachment E for the full text from the November 9, 1998, Federal Register.)

F. Appeal Process

If a protocol is not approved, then that protocol must be resubmitted for full review. The full review may take place at the next regularly scheduled meeting of the IRB.

G. Review of Cooperative or Facilitated Research

When Adelphi is involved in multi-institutional studies, it may rely on another qualified IRB to avoid duplication of effort (Federal B regulation covering joint review Appendix C 21 CFR Part 56 Institutional Review Boards Subpart C, IRB Functions and Operations 46.114 Cooperative Research). A review performed by such a board will be referred to as a facilitated review.

The Adelphi IRB will decide on a case-by-case basis if it may be possible to rely on an IRB at either a neighboring institution or another local IRB. The familiarity of a neighboring/local IRB with the Adelphi community, once established, will be taken as evidence of its ability to provide some degree of valid local review.

Research approved by other IRBs must be presented to Adelphi's IRB with documentation of its approval (letter or stamped document). The Adelphi review should determine if the institution would accept the study protocols as approved by the cooperative IRB. Adelphi recognizes that alterations to study protocols (i.e., to materials other than the Consent Form to be utilized at Adelphi), which have been approved by a larger IRB, may impose hardships to the researcher. The Adelphi review pertains only to Adelphi participation.

H. Adverse Reactions

Any injury, adverse reaction or unanticipated problem must be reported to the IRB administrator and current IRB chair within 48 hours of the incident. Reports should be sent to the director of the office of research and sponsored programs.

VII. RESEARCH EXEMPT FROM IRB REVIEW

All studies conducted by Adelphi faculty, adjunct faculty, administrators or students must be brought to the attention of the IRB chair for determination of review category and possible exemption from review (45 CFR 46.101(b)).

For a research project to be exempt from IRB review, **all items in Part A of this section must apply AND at least one item in Part B of this section must apply.**

Part A (All items must apply.)

1. The research does not involve as subjects: prisoners, fetuses, pregnant women, the seriously ill or mentally or cognitively compromised adults.
2. The research does not involve subjects under the age of 18 (Exception: Research with subjects under the age of 18 may still be considered exempt if the subjects are participating in projects that fall under categories 1, 3, 4 and/or 5 in Part B). Studies under Part B-2 that include minors should be submitted for expedited review.
3. Study participants are not exposed to greater than minimal risks (i.e., those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests performed by a qualified professional).

Part B (At least one item must apply.)

1. Research is conducted in established or commonly accepted educational settings, involving normal educational practices, such as research on regular and special education instructional strategies, the effectiveness of or the comparison among instructional techniques, curricula or classroom management methods.
2. Research involves the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior unless: (a) information obtained is recorded at any point in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (b) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability or reputation.
3. Research involves the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior if: (a) the human subjects are elected or appointed public officials or candidates for public office; and (b) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
4. Research involves the collection or study of existing data, documents, records, pathological specimens or diagnostic specimens, if these sources are publicly available or if the information is provided to the investigator in such a manner that subjects cannot be identified directly or through identifiers linked to the subjects.
5. Research and demonstration projects are conducted by or subject to the approval of department heads, and 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 those programs or procedures; or (d) possible changes in methods or levels of payment for benefits or services under those programs.
6. Taste and food quality is evaluated and consumer acceptance studied: (a) if wholesome foods without additives are consumed; or (b) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminants 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.

If an application is deemed to satisfy the criteria to be considered as exempt, the chair will advise the principal investigator (PI):

"Your application (#XX) was reviewed by the IRB and determined to be exempt. Should you wish to make any modifications to your research, you are required to submit an amendment to the IRB to have your classification as exempt reconfirmed. Please note that you remain obligated to observe the Belmont principles with respect to the protection of human subjects."

VIII. REVIEW PROTOCOLS

A. Full Review

1. Information that the investigator provides to the IRB

The investigator shall provide the IRB Review Form and any and all materials that the IRB may reasonably request to be fully informed regarding the nature of the study. The Review form and related materials (**an electronic copy and 15 hard copies**) should be sent to the Office of Research and Sponsored Programs. The IRB Review Form requires the following information: (**see Attachment A**)

- Date submitted to the IRB
- The title of the project (proposed investigation)
- Principal investigator and faculty adviser (if appropriate) information including name, address, phone, email and contact person
- Date of certification in human subject protections **and copy of certification attached**
- Series of basic informational questions
- The purpose of the study
- Planned dates for initiation and completion of the project
- Number of subjects
- Characteristics of subjects with reference to inclusion/exclusion criteria, justification for use of any special/vulnerable subject populations (decisionally impaired, children)
- Method of recruitment
- A brief description of the project's methods
- Experimental design and appropriateness of research methods
- Sequence of activities required of the subject
- Estimated time commitment required of the subject
- The potential risks, discomforts or stresses and the precautions taken to minimize them
- Signature and date of **all researchers** who will be working in direct contact with study participants, including the faculty for student submissions
- The informed consent document containing all the requirements set forth below or otherwise required by law (**see Attachment G for Informed Consent Template**)
- Debriefing form, if necessary (**see Attachment H for Debriefing Form Template**)
- Representative sample of materials/test/questionnaire items
- Sign-up sheet, solicitation script or advertisement (whichever is applicable)

Double-sided copies are preferred; number all pages of proposal for ease in discussing; font size should be roughly Times New Roman 12; do not use small font.

B. Full Review Process

For the IRB to approve a study, the proposal must be determined by the IRB to demonstrate the criteria listed in section VIII. A.

1. A full review of proposed research shall take place at convened meetings at which a **quorum (as defined in section V. A.) of voting IRB members is present (45 CFR 46.108(b))**.
2. **A simple majority of the members present must approve the proposal (45 CFR 46.108(b)).**

C. Full Review Determinations

1. Approved: Protocols may be approved as submitted. Approval is made for use of the study tools, including the informed consent documents, as submitted. Once a protocol is approved, no protocol changes, amendments, addenda or changes in the Consent Form may be made without re-review and approval of the protocol by the IRB. (Expedited review of changes may be available at the discretion of the chair; see below.) Time frames for continuing reviews will be described at the discretion of the IRB.
2. Approved Pending: Protocols may be approved, contingent on specified changes being made and/or on confirmation of the IRB's interpretation of ambiguous information (45 CFR 46.111). Conditional approval may require that certain minor changes be made to the protocol. Changes and/or modifications must be resubmitted within 45 days of notification to the investigator or the protocol will be closed and will require resubmission in its entirety to be reconsidered. The IRB will determine the nature and extent of the corrections or omissions to be made. A small subcommittee will examine the requested corrections and approve the proposal as an expedited review. Alternatively, the IRB may elect to review the proposal with corrections in a future regular meeting.
3. Not approved: The level of risk involved may be deemed by the IRB to be inappropriate for research conducted at Adelphi. The protocol may have inadequate information or fail to meet certain required conditions.

D. Notification

Email notification should be within two business days of the IRB meeting. The IRB will issue a final written notification of an approved project which will be sent to the principal investigator or submitter within **five business days** of the determination. Investigators are responsible for notifying the sponsor of the research of the IRB's decision.

E. Other Types of Review

A project approved by the IRB may be subject to review or disapproval by administration of Adelphi University. Other Adelphi officials may not approve protocols disapproved by the IRB.

1. Expedited Review

IRB Expedited Review Process - Expedited review is a procedure through which certain kinds of research may be reviewed and approved without convening a meeting of the IRB per section VII. C. and Attachment E. If the IRB chair does not concur that expedited review is warranted, the investigator shall be asked to submit the proposal for full IRB review.

- a. The submission must comply with a **full review submission but only an electronic copy and one signed hard copy is required.**
- b. Expedited review determination—**The subcommittee of the IRB (e.g., IRB chair, at least one other IRB member and the administrative liaison to the IRB) may administratively approve the project without convening the full committee (45 CFR 46.110(b)(1)).** In reviewing the research, the reviewer may exercise all of the authorities of the IRB except the reviewer may not disapprove the research. Research may only be disapproved in **full review**. Thus the study may be approved or referred for full review.
- c. notification process: The IRB chair shall then inform the IRB of the nature of the research and the outcome of the review at the next convened meeting of the IRB. A full report of expedited reviews submitted and determinations made will be listed as an agenda item for the next regular meeting.

2. Review of Cooperative or Facilitated Research

Information that the investigator provides to the IRB

- All materials required for full review
- Documentation of approval (letter or stamped document) from the cooperative IRB(s)

The Adelphi review should determine if the AU IRB will accept the study protocols as approved by the

cooperative IRB(s). Adelphi recognizes that alterations to study protocols (i.e., to materials other than the Consent Form to be utilized at Adelphi) which have been approved by a larger IRB, may impose hardships to the researcher. The Adelphi review pertains only to Adelphi participation.

a. Cooperative or Facilitated Research Review Process

- For the IRB to approve a study, the proposal must be determined by the IRB to meet the criteria required in a full review
- A full review of proposed research shall take place at convened meetings at which a quorum is present
- A simple majority of the quorum must approve the proposal

b. Cooperative or Facilitated Research Review Determinations

Approved: The Adelphi IRB may approve protocols approved by another institution's IRB for implementation at Adelphi. Approval is made for use of the study as submitted. Once a protocol is approved, no protocol changes, amendments, addenda or changes in the Consent Form may be made without re-review and approval of the protocol by the AU IRB. (Expedited review of changes may be available at the discretion of the chair as described in section VII. C.). Time frames for continuing reviews will be described at the discretion of the IRB as specified in section VII. B.

Approved Pending: Protocols approved by another institution's IRB may be approved, contingent upon answers to informational questions posed by AU IRB members. The principal investigators or their designees may be asked to present the materials in person to answer questions without delay. If a delay of 45 days results, the protocol will be closed and will require resubmission in its entirety to be reconsidered.

Not Approved: The study approved by another institution's IRB may be deemed inappropriate (any factor may be identified such as, but not limited to, the level of risk involved to the study subject, a lack of complete/appropriate informed consent, etc.) or, if requested for implementation at Adelphi, the study may be deemed by the AU IRB to be inappropriate for initiation at Adelphi.

c. Notification

The IRB will issue written notification of the result of the review to the individual named as the principal investigator or their designee within five business days. Rationale for the result will be provided in the written notification. The principal investigator is responsible for notifying the sponsor of the research of the IRB's decision.

The IRB reserves the right to audit any research activity it has approved under any approval category. The IRB, the University and the sponsor may conduct periodic random audits of investigators' protocol records and/or any component (e.g., Consent Forms). If any audit of an approved project is scheduled (including the sponsor), the IRB shall be informed so that a representative may attend the audit.

IX. AUDITS

A. Grounds for Audit

Sufficient grounds for implementing an IRB audit may include, but are not limited to:

- Questions of noncompliance with the approved protocols in the conduct of the study, such as informed consent not being obtained
- Subject complaint
- Serious adverse events reported to the IRB by the principal investigator or study sponsor

Random audit: The IRB may carry out random audits of active protocols to provide internal quality assurance, and to protect the rights and welfare of the human subjects; principal investigators shall be prepared to undergo an internal audit, which may be initiated at any time, without prior notice

B. Audit Personnel

Audits may be conducted by the IRB chair and at least two standing members of the IRB.

X. SUSPENSION OR TERMINATION OF RESEARCH

A. Grounds for Suspension or Termination

The IRB shall have the authority to suspend or terminate research that is not being conducted in accordance with the protocol(s) approved by the IRB, other institutional, federal or regulatory requirements, or has been associated with any serious harm to participants. Concerns regarding the conduct of research shall be reported immediately to the chair of the IRB by any individual having such knowledge.

B. Notification of Suspension or Termination

Any suspension or termination of research shall include a statement of the IRB's action and the chair shall report its decision promptly to the principal investigator and the provost. Notification must be given to departments in which research activities are taking place within one business day. Notification may occur via email and/or letter. Both the investigator and the study particulars shall be stated in the notification, as well as the date of suspension of operations. It is the responsibility of the investigator to report suspensions or terminations to the sponsor.

For more detailed information, review the Adelphi University Research Misconduct Policy at research-grants.adelphi.edu/research-misconduct-policy

XI. IRB RECORD REQUIREMENTS

The chair and administrative staff liaison of the IRB shall be responsible for preparing and maintaining adequate documentation of IRB activities regarding research involving human subjects to include the following:

A. IRB Membership Roster Showing Qualifications

The IRB shall maintain a list of IRB members identified by name, highest earned degree, affiliation and contact information.

B. Written Procedures and Guidelines

The IRB shall maintain and follow written procedures for (1) conducting initial and continuing review of research and for reporting its findings and actions to the investigator and Adelphi in particular (e.g., as a matter of public record to the Adelphi community); (2) determining which projects require review more often than annually and which projects need verification from sources other than the investigator that no material changes have occurred since the previous IRB review; (3) ensuring prompt reporting to the IRB of changes in research activity; (4) ensuring that changes in already approved research are not initiated without further IRB review and approval except where necessary to eliminate apparent immediate hazards to human subjects; and (5) prompt reporting to the IRB, appropriate institutional officials and the Food and Drug Administration of (a) any anticipated problems involving risks to human subjects or others; (b) any instance of serious or continuing noncompliance with laws or regulations, or the requirements or determinations of the IRB; or (c) any suspension or termination of IRB approval.

The IRB shall perform regular reviews of the Adelphi IRB policy and procedures at least once every two years. Reviews shall occur with meeting minutes to reflect discussion and a vote of the full IRB membership to adopt the document, as it stands or with modifications, for the next term. Any policies and procedures governing the IRB may be changed at a regularly convened IRB meeting by a vote of the majority of the members present, based on a quorum vote. Any changes made will be to facilitate the effective and efficient operation of the IRB and in no way shall be in conflict with the rules and regulations set forth in federal statutes and regulations relating to the protection of human subjects. Any changes in policy and procedures will be distributed to all members and shall be included as (an) amendment(s) to this manual. The following academic year manual will contain all amendments passed as inclusions in the manual.

C. Meeting Materials

1. Meeting Packets—All IRB members participating in the review process must review each protocol

submitted for approval. These will be provided to the IRB members at least five days prior to each meeting. Packets will be formulated whenever possible for emergency meetings, but available 48 hours prior to the meeting.

- 2. Meeting Minutes**—The IRB shall maintain minutes of IRB meetings which shall be in sufficient detail to show attendance at the meetings; actions taken by the IRB; the vote on these actions, including the number of IRB members voting for, against and abstaining; the basis for requiring changes in or disapproving research and a written summary of the discussion of controverted issues and their resolution (45 CFR 46.115(a)(2)). Documentation of votes will follow the format recommended by the Office for Human Research Protections (OHRP). The format shall conform to the following example: Total=10; Vote: For=9, Opposed=0, Abstained=1 (list names). Meeting minutes will be maintained in the IRB files for review for a period of three years. After this period they shall be permanently archived as historical documents, available to the membership upon request. Sign-in sheets will be maintained with meeting minutes to verify attendance. **(See Attachment G.)**
- 3. Record Retention**—The IRB shall maintain copies of all research proposals reviewed, scientific evaluations (if any) that accompany the proposals, approved sample consent documents, progress reports submitted by investigators and reports of injuries to subjects. The IRB staff will be charged to maintain records of approved proposals for a period of three years after project completion (per 45 CFR 46.115(b)). Disapproved proposals will remain on file for three years after the date of the IRB disapproval. Retained records shall be accessible for inspection and copying by authorized representatives of the sponsor and HHS at reasonable times in a reasonable manner.

D. Correspondence and Communications

The IRB shall maintain copies of all correspondence and communications between the IRB and the principal investigators. The principal investigator is responsible for all correspondence and communication(s) with sponsors.

E. Documentation of Adverse Reaction(s)

(Adverse reaction refers to the participant in the research study)

Reports on all decisions will be kept for three years and then archived. The IRB shall maintain copies of the adverse reaction reports concerning a study, and shall document in the minutes that the reports have been reviewed and what action, if any, the IRB will take with regard to such reports. Documentation should reflect data viewed as individual cases and aggregate data for that study.

XII. ELEMENTS OF INFORMED CONSENT

A. Contents of Consent Documents

The Common Rule expects consent forms to include a concise explanation at the beginning of the document of the key information that would be most important to individuals contemplating participation in a particular study, including the purpose of the research, the risks and benefits and appropriate alternative treatments that might be beneficial to the prospective subject.

Consent Forms include all of the following basic elements:

- Listing of Adelphi University on the first page
- Protocol title
- Principal investigator name
- A statement that the study involves research
- An explanation of the purpose of the research and the expected duration of the subject's participation
- A description of the procedures to be followed and the identification of any procedures which are experimental
- A designation of where the research will take place
- The disclosure of alternative procedures

- The description of potential risks and possible discomforts to the subject
- A description of foreseeable benefits to the subject and others
- An explanation of whom to contact if questions arise or an adverse event occurs (e.g., principal investigator with contact information; if PI is a student, include name and contact information for the faculty adviser)
- A description of the extent to which confidentiality will be maintained
- An explanation as to treatments available if injury occurs (for research involving more than minimal risk)
- A statement that participation is voluntary, refusal to participate involves no penalty and the subject may discontinue participation and have any data already collected destroyed at any time
- No language through which the subject is made to waive any of his or her legal rights, or which releases the investigator, the sponsor or the institution from liability for negligence
- Signature line and name of person obtaining consent as well as the study participant(s)

The following statement **must** be included in all informed consent documents: This research study has been reviewed and approved by the Adelphi University Institutional Review Board. If you have any questions, concerns or comments, you can contact Dr. Carolyn Springer, Ph.D., chair of the Adelphi IRB, at 516.877.4753 or springer@adelphi.edu.

B. Documentation

1. Informed consent shall be documented by using a written Consent Form approved by the IRB. The form shall be signed by the subject or the subject's authorized representative. A copy shall be given to the person signing the form.

C. General Requirements for Informed Consent

The process of obtaining informed consent shall contain the following elements (CFR title 21, 50.25):

1. It should be obtained from the subject or the subject's legally authorized representative.
2. It should be in language understandable to the subject or his or her legal representative.
3. It should be obtained under circumstances that provide the subject with the opportunity to consider whether or not to participate and that minimizes the possibility of coercion or undue influence.

D. Discretionary Elements

When required by the IRB, one or more of the following elements shall be provided to each subject.

- Statement that the procedure may involve unforeseeable risks to the subject.
- Statement that significant new findings developed during research which may relate to subject's willingness to continue will be provided to the subject.

XIII. DOCUMENTING INFORMED CONSENT

A. Exceptions to Documenting Informed Consent

1. The IRB may waive the requirement to obtain a signed Consent Form for some or all subjects if:
 - The only record linking the subject and the research would be the consent document and the principal risk would be harm resulting from breach of confidentiality
 - The research presents no more than minimal risk and involves no procedures for which written consent is normally required
2. In cases where informed consent is waived, the IRB may require the investigator to provide subjects with an oral or written statement regarding the research. The document to be used shall be submitted to the IRB and is subject to edits by the IRB.

B. Exceptions From Requirements for Informed Consent

1. DHHS Exceptions

The IRB may approve a consent procedure which does not include or which alters some or all of the elements of informed consent (45 CFR 46.116(d)). The IRB may vote to waive the requirement to obtain informed consent provided the IRB finds and documents that:

- The research involves no risks to participants (i.e., in the case of exempt studies)
- The rights and welfare of subjects will not be adversely affected
- The research could not practicably be carried out without the waiver or alteration
- Whenever appropriate, the subjects will be provided with additional pertinent information after participation
- The research is to be conducted for the purpose of demonstrating or evaluating federal, state or local service programs that are not research programs, etc.

C. Oral Informed Consent Only

If informed consent is obtained orally, a written description of the process must be submitted to the IRB.

XIV. HIPAA AND RESEARCH

On April 14, 2003, the Department of Health and Human Services (DHHS) released the final privacy regulations under the Health Insurance Portability and Accountability Act of 1996 (HIPAA). For the first time, the HIPAA regulations created national standards to protect the personal medical records and health information of individuals. The Privacy Rule requires all covered entities (e.g., health plans, healthcare clearinghouses and healthcare providers) who engage in the electronic transmittal of protected health information to notify patients about their privacy rights and how their information can be used.

Protected health information (PHI) is defined as individually identifiable health information, such as name, address, employer, relative's names, dates (of birth, admission, discharge, death), age, telephone number, fax number, email or IP address, Social Security number, medical record number, account numbers, certificate/license numbers, vehicle identifiers, voice/ fingerprints, photos and any other unique identifying numbers, characteristics or codes.

The Privacy Rule affects research because it may affect access to information, but it does not regulate research or independent researchers. HIPAA authorization is written permission to disclose PHI for research purposes. This does not replace informed consent, which represents the individual's agreement to participate in the study, as required under the Common Rule. Researchers must still obtain informed consent and detail that process, as well as HIPAA authorization.

XV. INTERNET RESEARCH POLICY

Computer- and Internet-based methods of collecting, storing, utilizing and transmitting data in research involving human participants have become widespread. The Institutional Review Board believes that computer- and Internet-based research protocols must address fundamentally the same risks (e.g., violation of privacy, legal risks, psychosocial stress) and provide the same level of protection as any other types of research involving human participants. All studies, including those using computer and Internet technologies, must (a) ensure that the procedures fulfill the principles of voluntary participation and informed consent, (b) maintain the confidentiality of information obtained from or about human participants and (c) adequately address possible risks to participants including psychosocial stress and related risks.

The IRB further recognizes that computer and Internet technologies are evolving rapidly, that these advances may pose new challenges to the protection of human participants in research and both the IRB and researchers employing new technologies must maintain their diligence in addressing new problems and issues as they arise in the coming years.

The purpose of these guidelines is to help researchers plan, propose and implement computer- and

internet-based research protocols that provide the same level of protection of human participants as more traditional research methodologies. The guidelines are composed of requirements and recommendations that are consistent with the basic IRB principles applied to all research involving human participants.

It is the policy of the Adelphi Institutional Review Board to review the use of the Internet for human research activities in human subject research conducted under its jurisdiction. Internet data collection via email, listservs, electronic bulletin boards and Web surveys falls under the purview of the IRB. The IRB must review all research activities involving the use of the Internet with the same considerations and standards as all other research activities under the jurisdiction of the Adelphi IRB.

The IRB must review and approve all materials used for posting recruitment materials on the Internet (e.g., through a website, a banner advertisement or an email solicitation).

The IRB review must consider the delineation of boundaries between private and public space of the Internet. Access to private space must include permission from the administrator of that space, while access to public space is considered similar to traditional research conducted in the public domain.

The informed consent process and its documentation must include all relevant elements of informed consent as listed in the federal regulations, included in the Adelphi Informed Consent Template and specific Internet recommendations found within this document.

The IRB must consider the risks to participants and must ensure that there is an appropriate level of protection.

The IRB must consider that each communication carries the risk of a breach of confidentiality. Even when data are collected without names, Web sites or email programs may still be capable of collecting identifiers. Accordingly, investigators should keep in mind that they may be unable to guarantee anonymous collection of data.

The IRB must consider that admonishing participants that they must meet any demographic criteria, including a requirement to be 18 years of age to participate, does not guarantee compliance.

The IRB must consider all requirements for the approval of research that involves a vulnerable population.

Telephone conversations, post office mail and the Internet are not secure media, as data in transit are vulnerable. Therefore, Internet data collection has breach of confidentiality risk as is inherent in all mediums of research acquisition and may not be private, anonymous or even confidential. Every computer connected to the Internet has a unique identifier called an IP (Internet Protocol) address. On many networks, the IP address of a computer is always the same (i.e., fixed or static). On other networks, a random IP address is assigned each time a computer connects to the network (i.e. dynamic). The potential source of risk is harm resulting from a breach of confidentiality. This risk is accentuated if the research involves data that places subjects at risk of criminal or civil liability or could damage their financial standing, employability, insurability, reputation or could be stigmatizing. As with all research, the IRB must consider the potential subject risk relative to the method and type of data acquisition.

The following procedures are required for Internet research:

A. Adelphi IRB Research Review Form (proposal/application)

1. Question 5 of the IRB Research Review Form, asks: Are you requesting that written informed consent be waived? Since Internet research seldom obtains signed informed consent, if you are not requiring written informed consent, describe specifically how you will obtain and demonstrate informed consent (e.g., include the final line of the informed consent as: By completing the survey, you are agreeing to participate in this research; and for Web-based surveys, add a click-through button.)
2. Item IV, Characteristics of Subjects: Describe how you will ensure participants are 18 and older. Because at this point in time it is difficult, if not impossible, to authenticate that the participants fit within a specific demographic, it may be impossible to ensure that participants are not minors (under 18 years old). This may preclude approval of certain types of research for these or other vulnerable populations.
3. To address Item V, Method of Subject Recruitment, prior to posting a survey on a listserv, discussion board or email group, you should first obtain permission from the listserv manager, moderator or list

owner, and also obtain community consent. A posting to an Adelphi listserv must follow Adelphi policies regarding spam. To observe a chat room, first obtain authorization from the chat room manager. Pretending to be a member, engaging in other acts of deception or lurking is not permitted.

4. To address Item VI, Brief Description of Project's Methods and Research Design, state the procedures to be employed to secure data transmission. If data transmission does not require specific security, please indicate. However, if data acquired are sensitive, indicate plans to use a secure server SSL or S-HTTP. SSL (secure sockets layer) is a protocol developed by Netscape for transmitting private documents via the Internet. SSL works by using a public key to encrypt data that is transferred over the SSL connection. Many websites use the protocol to obtain confidential user information, such as credit card numbers. By convention, URLs that require an SSL connection start with "https:" instead of "http:".

Another protocol for transmitting data securely over the Web is Secure HTTP (S-HTTP). Whereas SSL creates a secure connection between a client and a server, over which any amount of data can be sent securely, S-HTTP is designed to transmit individual messages securely. SSL and S-HTTP, therefore, can be seen as complementary rather than competing technologies.

Stripping identifiers from data, storing identifiers and data in separate files and auditing the security of data directories should be routine procedures. If participant identity is not necessary, the researcher is encouraged not to collect these data or limit their data collection to basic demographics, such as age, sex, etc.

Consider using a commercial Web-based survey software program such as SNAP. Adelphi University holds a license to the SNAP program, which addresses the issue of security and data transmission.

For assistance in implementing the SNAP program with your investigation, contact the Faculty Center for Professional Excellence at **516.877.4220**.

B. Informed Consent Document

1. An Internet consent document should be written like a cover letter and should include all the elements of the regular signed consent, including the confidentiality disclaimer given below. **The consent line should say: By completing the survey, you are agreeing to participate in the research; for Web-based surveys, add a click-through button.**
2. Include the following confidentiality disclaimer in the consent document: **There is a limit to the confidentiality that can be guaranteed due to the technology itself. Specifically, although the risk is small, no guarantees can be made regarding the interception of data sent via the Internet by any third parties.** While the researcher may ensure the confidentiality of a participant by utilizing standard procedures (pseudonyms, etc.), when the researcher writes up the final research product, the researcher cannot ensure confidentiality during the actual Internet communication procedure.
3. For a chat room that is not open to the public, inform participants that an observation is taking place, and that any information exchanged may be used for research purposes. Based on the frequency of participants entering or exiting a chat room, the researcher should inform participants a minimum of every 30 minutes.
4. If the participant may be at significant risk from a breach of confidentiality during Internet transmission, the researcher must provide the prospective subject with an alternative means of obtaining information. The use of this alternative is at the discretion of the subject, who may use the Internet medium, the alternative medium or decline participation. For example, allow the participant to complete the survey, etc., and send it via snail mail to the researcher. Ensure that the researcher's contact information is prominently displayed on both the cover letter and the survey instrument to avoid having the survey misdirected to the IRB.
5. Online consent may not be suitable for vulnerable populations and/or high-risk studies (e.g., children, prisoners, questions or scenarios which may invoke strong psychological responses). If a high-risk study is approved, it may require double informed consent. Specifically, a preliminary informed consent is provided, which adheres to all the content of an informed consent and is approved by the IRB. If after reading the initial informed consent, the participant wishes to continue, he/she presses a click-through button to access a second informed consent. The second informed consent emphasizes the risk/benefit of participation and the fact that because of the nature of Internet research, on-site assistance cannot be provided. The prospective participant must agree to the second informed consent prior to gaining access to the study.

C. Survey

1. The instrument should be formatted in a way that will remind participants when they have not answered a question. At the discretion of the researcher, the instrument can be formatted to not allow the participant to continue unless all questions are answered or to allow the researcher to disregard the entire survey.
2. For research in which the researcher does not require responses to every survey question, the instrument should be formatted in a way that will allow participants to skip questions if they wish to or provide a response like: I choose not to answer; or proceed to next question.
3. At the end of the survey, there should be two buttons: one to allow participants to discard the data and another to submit data for inclusion in the study.

D. Requirements for Consideration of Data Collection and Security

If a moderate or high level of security is necessary, data collected from human participants over computer networks must be transmitted in an encrypted format. This helps ensure that any data intercepted during transmission cannot be decoded and individual responses cannot be traced back to an individual respondent. Additionally, all databases storing identifiable information or data must be protected regardless of the source creating the data (e.g., encryption of the database, de-identifying the data). If using the Adelphi Office of Information Technology, contact OIT for further assistance at **516.877.3340**.

1. In parallel to the degree of risk inherent in the study and within the limits of availability and feasibility, the highest level of data encryption must be used that will ensure security. Note that in some cases, this may require that the study participants be required to use a specific type or version of browser software.
2. Researchers are cautioned that encryption standards vary from country to country and that there are legal restrictions regarding the export of certain encryption software outside U.S. boundaries.
3. If authentication is performed, it must protect the confidentiality of the respondent. Investigators are advised that authentication—that is, proper qualification and/or identification of respondents—is a major challenge in computer- and Internet-based research and one that threatens the integrity of research samples and the validity of research results. Researchers are advised to take steps to authenticate respondents, if necessary, for the integrity of the study. For example, investigators can provide each study participant (in person or by U.S. Postal Service mail) with a personal identification number (PIN) to be used for authentication in subsequent computer- and Internet-based data collection. Investigators must provide information regarding the transmission and storage of the data. With research involving subjects only from Adelphi University, authentication may be implemented. Contact OIT for further assistance at **516.877.3340**.
4. If a researcher chooses to perform data collection and/or storage through an external vendor (non-Adelphi), the IRB requires that:
 - a) The server is administered by a professionally trained person with expertise in computer and Internet security
 - b) If encryption is a requirement, the server must possess an SSL certificate issued by VeriSign, Entrust or other common browser trusted authority
 - c) If authentication is a requirement, access must be restricted and protected by username and password or other combination of credentials; credentials must be encrypted; private URLs do not imply authentication
 - d) A legal confidentiality agreement must exist between a researcher and data collectors no matter what the medium
 - e) Access to the server is limited to key project personnel
 - f) There are frequent, regularly scheduled security audits of the server
 - g) Evaluation of the external vendor will be performed by the Adelphi Office of Information Technology
5. If a server is used for data storage, personal identifying information should be kept separate from the data.
6. In a procedure similar to the archiving of traditional research data, data must be stored in a safe location, such as a secure data room that is environmentally controlled and has limited access.

7. It is recommended that competent data destruction services be used to ensure that no data can be recovered from obsolete electronic media.
8. When using Survey Monkey, you must choose the option to make the IP addresses anonymous; the default is to identify the IP addresses.

E. Tips

1. Consider using gift certificates from online retailers and displaying the unique certificate redemption number to respondents at the completion of a questionnaire. This allows participants to receive an incentive without revealing their identity. Alternatively, lotteries have been used as an incentive, but that requires the identification of the lottery winner.
2. The level of security should be appropriate to the risk. For most research, standard security measures like encryption and secure socket layer (SSL) will suffice. However, with sensitive topics, additional protections include certified digital signatures for informed consent, encryption of data transmission, technical separation of identifiers and data and strong verification of assent.
3. Researchers working with children online are subject to the Children's Online Privacy Protection Act (COPPA) (ftc.gov/ogc/coppa1.htm) in addition to the human subject regulations. Researchers are prohibited from collecting personal information from a child without posting notices about how the information will be used and without getting verifiable parental consent.
4. If the risk of participation outweighs the benefit for specific demographic populations (e.g., minors) and provisions cannot be made to screen out that population (e.g., minors screened with Internet monitoring software like SafeSurf and RSACi ratings or using Adult Check systems), the internet may not be the appropriate medium for data collection.
5. Because there is no standard for identifying distressed participants online, the IRB must take into consideration potential participant experiences (the sensitive nature of the research) that may be distressing when evaluating the risk/benefit ratio. **Research that places human subjects at high risk may not be appropriate for the internet.**

XVI. SOCIAL MEDIA

More and more research is being conducted online using social media to advertise, recruit and distribute surveys and questionnaires. All of the IRB's policies and procedures also apply to research involving social media.

XVII. RESEARCH METHODS COURSES

IRB Requirements for Research Conducted in Research Methods Courses Involving Human Subjects

Research methods courses include any course within the jurisdiction of Adelphi University that is designed to examine the ethics, methods, analysis and/or dissemination of research. The prime focus of such a course is to understand research methodology, but not to conduct research. However, demonstration research projects may be included in the curriculum to provide exposure to research methods.

Research is defined as any systematic investigation, including research development (pilot testing), designed to develop or contribute to generalizable knowledge [Title 45 Code of Federal Regulations (CFR) Part 46.102(d)].

Generalizable knowledge refers to any systematically gathered data intended for dissemination through various means (e.g., publications by paper or electronically, conference presentations, poster presentations, internet postings and presentations to outside constituencies) and which might reasonably be generalized beyond the research sample.

Demonstration research projects are snapshots of research, included in the course curriculum and designed to expose students to the methods of research, but not disseminate the information to generalizable knowledge.

1. **Most class assignments are not research, but demonstration research projects, because** the intent is to teach methods, do not contribute to generalizable knowledge. **Review and approval by the IRB is not required for demonstration research projects.**
2. Students who wish to do work that constitutes research (i.e., work that is systematic investigation designed to contribute to generalizable knowledge as evidenced by intent to disseminate) and uses human subjects must submit an application to the IRB and receive approval prior to initiating the study.
3. Students who think they might want to broadly disseminate their work (or expand it into an honors thesis) must request IRB authorization (**through IRB proposal review**) before starting their work. **Requests for review by the IRB will not be considered after the study is initiated.**
4. Research conducted for a thesis, even at the undergraduate level, **requires IRB review and approval** if the research uses human subjects.
5. Demonstration research projects **may not involve studies of vulnerable populations** (i.e., children, the elderly, prisoners, fetuses, pregnant women, the seriously ill, mentally or cognitively compromised adults and institutional populations) that do not fit within exempt categories. For example, students could do public observation of any population or observation in an educational setting [often required of Scholar Teacher Education Program (S.T.E.P.) students who may be enrolled in a methods course and use those observations as data for the course]. Demonstration research projects **may not include research on sensitive subjects**, even when the purpose is teaching methods rather than research.
6. Methods research course instructors are **required to submit current Human Subjects' Certification to the Adelphi Institutional Review Board** prior to the start of each semester.
7. Students in research methods courses are required to **protect confidentiality** of all human subjects from whom they collect information.
8. The IRB recommends that students in research methods courses complete an online tutorial in human subjects and acquire Human Subject's Certification. Certification is valid for three years.
9. The IRB recommends that instructors of all research methods courses include information on protection of human subjects as mandated by the Adelphi University Institutional Review Board Policies and Procedures.
10. All proposed demonstration research projects must assure that:
 - a. Research performed at Adelphi protects the welfare and rights of human subjects
 - b. Instructors have students follow written or oral informed consent procedures, when engaged in a demonstration project that would normally require such procedures, if classified as research; although informed consent procedures are not required for observations, they are recommended for interviews, experiments and some surveys
 - c. Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may be expected to result
 - d. No research performed at Adelphi places human subjects at unreasonable physical, mental or emotional risk
 - e. Selection of subjects is equitable
 - f. There are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data in accordance with Adelphi policy
 - g. Risks to research subjects are minimized by using, whenever appropriate, procedures already being performed on the subject(s) for diagnostic or treatment purposes

XVIII. ORAL HISTORY

According to the U.S. Department of Health and Human Services (HHS), most oral history interviewing projects are not subject to the requirements of the Federal Policy for the Protection of Human Subjects (i.e., the Common Rule) and can be excluded from IRB oversight because it does not involve research as defined by the HHS regulations. Therefore, the U.S. Office for Human Research Protection (OHRP), part of the Department of Health and Human Services, working with the advice of the American Historical

Association (AHA) and the Oral History Association (OHA), has determined that oral history interviewing activities, in general, are not designed to contribute to generalizable knowledge and, therefore, do not involve research as defined by Department of Health and Human Services regulations at 45 CFR 46.102(d) and do not need to be reviewed by an Institutional Review Board.

XIX. ATTACHMENTS

Attachments mentioned in the manual are on the following pages.

ATTACHMENT A—IRB Review Form

IRB ID # (to be completed by the committee)

This application should be completed by principal investigators (PIs) after they have completed protection in human participant training and after a detailed review of the IRB Manual.

Date of completed certification, please list for each investigator_____. If not on file with the Office of Research and Sponsored Programs, please attach certification to this proposal. All researchers who will have contact with study participants and identifiable subject data must complete training in the protection of human participants prior to submitting this application.

Please type all entries

Date submitted to IRB _____

TITLE OF PROJECT _____

Principal Investigator _____

Professional Address _____

Department Affiliation _____

Principal Investigator University Status _____
(i.e., full-time faculty, graduate student, undergraduate, etc.)

Professional Phone _____

Professional Email _____

Faculty Adviser (if not the PI) _____

Please note: students and part-time faculty are required to have a full-time faculty adviser

Professional Address _____

Department Affiliation _____

University Status _____
(i.e., full-time faculty, graduate student, undergraduate, etc.)

Professional Phone _____

Professional Email _____

Please answer Yes or No to the following, and provide an explanation, if requested:

1. Does this research intentionally recruit individuals from groups that are vulnerable to harm or coercion such as children, the elderly, prisoners, fetuses, pregnant women, the seriously ill, mentally or cognitively compromised adults, students within their educational setting or other vulnerable groups, such as institutionalized populations? Yes No

If **YES**, please explain the rationale for including the specific population(s) and the precautions you will use to protect them.

2. Does this research intentionally recruit and intend a large-scale **survey** of individuals who are affiliated with Adelphi, including current or former students, alumni, staff or faculty? Yes No

If **YES**, researchers must review the University's (i) requirements for surveying such groups (orap.adelphi.edu/survey-registration/) and contact Office of Research, Assessment and Planning, Levermore Hall, Room 307, phone 516.877.3233 to determine whether that policy imposes registration requirements for their study.

Researchers must familiarize themselves with the University's (ii) Anti-discrimination, Harassment (Including

Sexual Misconduct) and Retaliation Policy (<http://hr.adelphi.edu/files/2015/06/Anti-Discrimination-Harassment-and-Retaliation-Policy.pdf>) to determine appropriate language to be included in Informed Consents when addressing these subjects in their research.

3. Do you believe this proposal should be exempt from IRB review? (See IRB Policies and Procedures Manual, section VII RESEARCH EXEMPT FROM IRB REVIEW [Part A and B].) Yes No

If **YES**, please explain why and how this research qualifies for exemption. Cite the specific exempt criteria from the Manual (parts A and B) that qualifies this proposal for exemption and justify your responses.

4. Does this proposal involve the use of deception (whether by providing false information or omitting relevant information)?

Yes No

If YES, does this deception understate or misrepresent possible risks?

Yes No

If **YES**, would participants' willingness to agree to participate in the research be reasonably expected to be different had there been no false or omitted information?

Yes No

If YES to any of the above, please explain, justify and describe mitigating actions in the Risks section (IX) and attach debriefing materials.

5. Are you requesting that the requirement participants sign and return written informed consent be waived? (See IRB Policies and Procedures Manual, section XIII DOCUMENTING INFORMED CONSENT [B and C].)

If YES, please explain.

6. Are any other IRB approvals necessary for this proposal (whether related to researchers from other institutions or the site at which data is to be collected)? Yes No

If YES, please explain and attach copies of any other IRB applications and approvals that have been obtained.

7. Is this proposal supported by external funding? Yes No

If YES, the PI must complete the Adelphi Conflict of Interest Disclosure Form. <http://research-grants.adelphi.edu/conflict/>

8. Do any researchers, including the faculty adviser have financial or any other conflicts of interest related to this proposal as set forth in <http://research-grants.adelphi.edu/conflict/>? Yes No

If YES, please explain how the researchers will address such conflicts.

9. Does this study include a planned intervention/experimentation involving participants? Yes No

If yes, please complete the following sections.

10. Reporting of unanticipated events and adverse events. The Office for Human Research Protections (OHRP) describes these as "unanticipated problems involving risks to participants or others." Reports of adverse events must include written notification to the current chair of the IRB and the office of research and sponsored programs.

Describe your plans for reporting unanticipated or adverse events.

11. Describe your plans for securing and protecting data collected by this project.

I. BRIEF DESCRIPTION OF THE PROJECT'S PURPOSES

II. PLANNED DATES FOR INITIATION AND COMPLETION OF THE PROJECT

III. NUMBER OF PARTICIPANTS

IV. CHARACTERISTICS OF PARTICIPANTS (e.g., age range, special populations, etc.)

V. METHOD OF SUBJECT RECRUITMENT

VI. BRIEF DESCRIPTION OF PROJECT'S METHODS AND RESEARCH DESIGN

VII. SEQUENCE OF ACTIVITIES REQUIRED OF THE SUBJECT (e.g., advertisement, consent, debriefing, etc.)

VIII. ESTIMATED TIME COMMITMENT REQUIRED OF THE PARTICIPANTS

IX. ANY POTENTIAL RISKS, DISCOMFORTS OR STRESSES AND THE PRECAUTIONS TAKEN TO MINIMIZE THEM (including data storage and protection)

SIGNATURES AND DATE OF ALL RESEARCHERS WHO WILL BE WORKING IN DIRECT CONTACT WITH STUDY PARTICIPANTS. IN ADDITION, FACULTY ADVISERS MUST SIGN BELOW. THESE SIGNATURES INDICATE THAT ALL THE RESEARCHERS HAVE FAMILIARIZED THEMSELVES WITH UNIVERSITY POLICIES REGARDING THE LEGAL AND ETHICAL TREATMENT OF HUMAN PARTICIPANTS IN RESEARCH, AND ARE CERTIFIED IN HUMAN PARTICIPANTS PROTECTIONS TRAINING

Principal Investigator

Name _____

Date _____

Signature _____

Affiliation (Institution or organization) _____

Faculty Adviser

Name _____

Date _____

Signature _____

Adelphi University School/Department (Institution or organization) _____

ATTACHMENTS CHECKLIST

YES	N/A	
		Current Human Participant Training Certificates for all researchers
		Recruitment / Solicitation Materials (letters, flyers, postings, scripts)
		<p>Informed Consents. (Please note that the IRB has decided that all consent forms/ letters should include the following statement:)</p> <p>This research has been reviewed and approved by the Adelphi University Institutional Review Board. If you have any questions, concerns or comments, please contact the IRB chair, Dr. Carolyn Springer, 516.877.4753; springer@adelphi.edu</p>
		Parental Permission
		Assents
		All survey items / questions
		Interview questions / scripts
		Debriefing materials. Note: the IRB usually requires debriefing only for proposals involving deception.
		<p>Letters of cooperation from any external organization or entity (including listserv) which are involved with proposal, including subject recruitment. Note: evidence of registration with Adelphi's Office of Research, Assessment and Planning does not need to be attached)</p>
		IRB approvals from cooperating institutions
		Letters authorizing the use of existing secondary data
		Any other information that is relevant to the application

ATTACHMENT B—CONFLICT OF INTEREST POLICY

I. PURPOSE

Federal regulations require that IRB members abstain from participating in an initial or continuing IRB review for a project in which the member has a conflicting interest (45CFR46.107e). IRB members who have a conflicting interest regarding a project which is scheduled to undergo IRB review should disclose the conflicting interest to the IRB and not participate in the review.

It is recognized that real, potential and apparent conflicts of interest [hereinafter referred to as conflict(s)] may naturally occur from time to time in the course of conducting the affairs of the Institutional Review Board of Adelphi. It is the IRB's responsibility to safeguard the rights and welfare of persons participating in research projects (research subjects) under the auspices of the Adelphi IRB. This policy is intended to guide the conduct of the IRB when conflicts arise. This policy is not intended to eliminate all situations of conflict of interest, but rather to enable individuals to recognize situations that may be subject to question and resolve them so as to avoid conflicts of interest. For purposes of this policy, the IRB's review includes all aspects of review, including the review of continuing review reports, adverse event reports and similar reports and is not limited to the review of new protocols.

As a consequence of the potential for conflicts to arise and the significance of conflicts, Adelphi's affirmative policy shall be to require that all direct and indirect financial interests and other relationships which may pose a potential conflict be disclosed promptly and fully to all necessary parties. It shall also be Adelphi's affirmative policy to prohibit involvement, except as set forth in this policy, in the IRB's review of the specific research project forming the basis of the conflict by persons having such a conflict.

II. DEFINITIONS

Conflict(s) exist under this policy when an IRB member or investigator also has a financial interest or any other professional or personal relationship, which may make it difficult for the member or investigator to exercise independent judgment in safeguarding the rights and welfare of research subjects.

More specifically, conflict(s) exist under this policy when an IRB member or investigator or a member of his or her immediate family have a direct or indirect financial or other personal or professional interest in:

- The sponsor of any research project which the IRB is reviewing;
- The provider of any product being investigated through any research project which the IRB is reviewing; or
- Other entities whose financial interests would reasonably appear to be affected by the outcome of any research which the IRB is reviewing.

Immediate family means the member of the IRB spouse and investigator, children of the IRB member, and parents, spouses of children, brothers and sisters or spouses of brothers and sisters of the IRB member, if such individuals reside in the same household as the IRB member or if the IRB member has knowledge of such an individual's financial interests.

Financial interests include the following:

- Any ownership interest in a company held by the IRB member or investigator or his or her immediate family (excluding any interest arising solely by reason of investment in a business by a mutual, pension or other institutional investment fund over which the IRB member or his or her immediate family does not exercise control);
- A position held by the IRB member or investigator or his or her immediate family as employee, director, officer, partner or any position of management;
- Any income (e.g., consulting, salary to the IRB member or investigator or his or her immediate family) received or promised;
- Any loan to the IRB member or investigator or his or her immediate family; and
- Any gift to the IRB member or investigator or his or her immediate family.

III. POLICY

A. General Requirements

1. IRB members shall disclose all current conflicts to other IRB members at meetings of the IRB. An IRB member shall not participate in the IRB's review of any research project in relation to which the IRB member has a conflict, except to provide information requested by the IRB, if any.

B. Required Disclosures

1. Each relationship or financial interest of an IRB member or investigator must be disclosed to IRB. All investigators are required to complete the AU financial conflict of interest forms (<http://research-grants.adelphi.edu/conflict/>).
2. The chair of the IRB and the representative(s) of the IRB administrative office shall determine whether a conflict exists or can reasonably be construed to exist.

C. If a Conflict Is Deemed to Exist

1. The disclosing person shall make a prompt, full and frank disclosure of his or her conflict to the IRB prior to its action on the research project forming the basis of the conflict;
2. An IRB member shall not participate in the IRB's review of any research project in relation to which the IRB member has a conflict, except to provide information requested by the IRB, if any. Specifically, the IRB member shall not participate in discussions and/or votes relating to the research project forming the basis for the conflict;
3. The IRB shall determine any action to be taken on the research project in question by a vote of the non- interested members present.
4. The IRB shall take appropriate disciplinary action against any IRB member or investigator who violates this policy to protect the best interests of Adelphi and the research subject; and
5. The minutes of all IRB meetings involving conflicts shall include the names of the IRB member or investigator who disclosed the existence of a conflict. In addition, the minutes shall set forth the names of the persons who were present for votes relating to the research project forming the basis of the conflict, the content of those discussions and a record of the vote.

D. Direct or Indirect Involvement in Research Where a Conflict Exists

1. IRB members or investigators are prohibited from being directly or indirectly involved in any research project where a conflict exists. This includes discussions with other IRB members regarding the research study and voting.
2. This section shall not be construed to prohibit IRB members who are also principal investigators with regard to a particular study from presenting such study to the IRB and interacting with the IRB as required for the protection of research subjects.
3. Any other exceptions to this section may be made on a case-by-case basis only by the IRB.

ATTACHMENT C—ANONYMOUS SURVEY POLICY

Subjects are recruited through advertisements, announcements, etc., without coercion. Professors, coaches or other individuals having direct supervision of the intended audience may announce the opportunity but cannot be the contact person for recruitment. Surveys cannot be distributed, supervised or collected by an individual with direct supervisory capacity over the participant.

An IRB-approved informed consent is read to the participants in a group setting and the informed consent is contained on the survey. If a survey is truly anonymous, there should be no opportunity for participants to sign an informed consent or identify themselves in any way on the survey or associated forms. Implied consent is obtained by completing the survey. If a prospective participant does not complete the survey, it indicates that he or she did not consent. The consent is only obtained by completing the survey.

All surveys should be distributed and returned in a blank envelope. This negates any knowledge of whether a prospective participant has participated or not.

Participants are supplied with a writing implement. It is at the discretion of the prospective participant to complete the survey, or to merely place a blank or partially complete survey into the provided envelope.

Envelopes will be placed in a container by the prospective participant.

ATTACHMENT D—CONTINUATION/MODIFICATION FORM
Modification/Amendment/Continuation to
Approved Research Activities Involving Human Subjects

Date: _____

Protocol IRB #: _____

Project Title: _____

PI Name: _____

PI Address: _____

PI telephone and email: _____

Faculty adviser name and email if applicable: _____

Date of Approved Protocol: _____

Name and Date of Human Subjects Protection Certification for each investigator:

1. _____
2. _____
3. _____
4. _____

Indicate request by circling the correct statement below:

1. Update personnel only
2. Request for Continuation, no modifications involved
3. Request for Modification/amendment to previously approved protocol

-
1. If this is a request to update personnel only, then list any new personnel here and attach certification in human subjects protection training to this form
 2. If this is a request for continuation only, no modifications to the study documents and/or procedures, then provide the following information
 - a. Current status of study:
__study not begun __enrolling subjects __enrollment has ended
 - b. Number of subjects currently involved in study:
 - c. Total number of subjects expected:
 - d. Expected end date for subject enrollment:
 - e. Report any study-related incidents here:
 3. If this is a request for amendments/modifications, then provide the following:
 - a. Current status of study:
__study not begun __enrolling subjects __enrollment has ended
 - b. Number of subjects currently involved in study:

- c. Total number of subjects expected:
- d. Expected end date for subject enrollment:
- e. Report any study-related incidents here:
- f. Reason(s) for the proposed change(s):
- g. Describe any impact of the proposed change(s) on the risk to subjects:
- h. If your proposed change(s) requires a change(s) in recruitment, describe here:
- i. If your change(s) requires modifications to the solicitation script, include copy of revised solicitation script:
- j. If your change(s) requires modifications to the informed consent, include revised informed consent:
- k. If your change(s) requires the use of additional measures (or changes to existing measures, include the new measures or revisions:

Please check all that apply:

I have attached an Informed Consent/Parental Permission Form(s), Assent Script, Project Summary or Measures that will be used in addition to the current one(s).

I have attached an Informed Consent/Parental Permission Form(s), Assent Script, Project Summary or Measures that will replace the current one(s).

The proposed modification does not call for changes in the Informed Consent/Parental Permission Form(s), Assent Script, Project Summary or Measures.

Signature of Principal Investigator

Email Address

Campus Telephone Number

Name of Faculty Sponsor, if applicable

Signature of Faculty Sponsor, if applicable

ATTACHMENT E—CATEGORIES OF RESEARCH THAT MAY BE REVIEWED BY EXPEDITED REVIEW

Source (excerpted verbatim from): 63 FR 60364-60367, November 9, 1998, Categories of Research that May Be Reviewed by the Institutional Review Board (IRB) through an Expedited Review Procedure

Applicability

- A. Research activities that (1) present no more than minimal risk to human subjects, and (2) involve only procedures listed in one or more of the following categories, may be reviewed by the IRB through the expedited review procedure authorized by 45 CFR 46.110 and 21 CFR 56.110. The activities listed should not be deemed to be of minimal risk simply because they are included on this list. Inclusion on this list merely means that the activity is eligible for review through the expedited review procedure when the specific circumstances of the proposed research involve no more than minimal risk to human subjects.
- B. The categories in this list apply regardless of the age of subjects, except as noted.
- C. The expedited review procedure may not be used where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, insurability, reputation or 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.
- D. The expedited review procedure may not be used for classified research involving human subjects.
- E. IRBs are reminded that the standard requirements for informed consent (or its waiver, alteration or exception) apply regardless of the type of review—expedited or convened—utilized by the IRB.
- F. Research Categories (A) through (I) pertain to both initial and continuing IRB review.

Research Categories

- A. Clinical studies of drugs and medical devices only when the conditions below are met. See 21 CFR Part 56 Section 56.110 for more information.
 - 1. Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. Note: Research on marketed drugs that significantly increase the risks or decrease the acceptability of the risks associated with the use of the product is not eligible for expedited review.
 - 2. Research on medical devices for which (1) an investigational device exemption application (21 CFR Part 812) is not required or (2) the medical device is cleared or approved for marketing and the medical device is being used in accordance with its cleared or approved labeling.
- B. Collection of blood samples by finger stick, heel stick, ear stick or venipuncture as follows:
 - 1. From healthy, non-pregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an eight-week period and collection may not occur more frequently than two times per week; or
 - 2. From other adults and children, considering the age, weight and health of the subjects, the collection procedure, the amount of blood to be collected and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an eight-week period and collection may not occur more frequently than twice per week.
- C. Prospective collection of biological specimens for research purposes by noninvasive means

Examples: (a) hair and nail clippings in a nondisfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax, or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and

the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab or mouth washings; (j) sputum collected after saline mist nebulization

D. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving X-rays or microwaves; where medical devices are employed, they must be cleared or approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)

Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment and flexibility testing where appropriate, given the age, weight and health of the individual.

E. Research involving materials (data, documents, records or specimens) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis). (Note: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.)

F. Collection of data from voice, video, digital or image recordings made for research purposes

G. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices and social behavior), or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation or quality assurance methodologies. (Note: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. (45 CFR 46.101(b)(2) and (b)(3)). This listing refers only to research that is not exempt.)

H. Continuing review of research previously approved by the convened IRB as follows:

1. Where (a) the research is permanently closed to the enrollment of new subjects, (b) all subjects have completed all research-related interventions and (c) the research remains active only for long-term follow-up of subjects; or
2. Where no subjects have been enrolled and no additional risks have been identified; or
3. Where the remaining research activities are limited to data analysis.

I. Continuing review of research not conducted under an investigational new drug application or investigational device exemption where Categories B through H do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

1. An expedited review procedure consists of a review of research involving human subjects by the IRB chair or by one or more experienced reviewers designated by the chair from among members of the IRB in accordance with the requirements set forth in 45 CFR 46.110.
2. Children are defined in the HHS regulations as persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted. (45 CFR 46.402(a))

Source: 63 FR 60364-60367, November 9, 1998

ATTACHMENT F—CHILD ASSENT TEMPLATE

Identify yourself to the child and let him or her know what you will be doing. For example:

I work for xxxx and we are trying to find out more about how (state what the study is about in simple terms appropriate to the child's maturity and age).

If you agree to answer some questions about (describe, using appropriate language), you may help us to understand xxxx or (state direct benefits to the child).

Please talk this over with your parents before you decide if you want to be in this study. I will also ask your parents if it is OK with them for you to be in the study. But even if your parents say yes, you can still say no. Remember that no one will be upset with you if you do not want to take part in the study; it is up to you. Whatever you decide is fine with everyone.

Even if you decide to start and then change your mind and don't want to continue with the questions, that's OK. We can stop whenever you want to.

Do you have any questions? You can ask me anything about the study. If you think of a question later on, you can still ask me.

Would you like to be part of?

If the study takes place in a school, children should know that their teacher and classmates will not know what they've said, and whether they participate or not will not affect their grades. You may also want to reassure the child that there are no right or wrong answers.

ATTACHMENT G—INFORMED CONSENT TEMPLATE

IRB protocol title

Principal investigator, name, title, contact info

Co-investigator, name, title, contact info

Research purpose: Explain the global research purpose in one or two sentences in lay language.

Description of research: provide a concise explanation of the key information that would be most important to a person considering participation in a study, such as what will happen in the research in one or two sentences. Explain that you will be asked to complete a survey, take a test, participate in an interview, etc.

Potential risks: Explain any conceivable potential risk—explain if it will be minimal or if there is something you are planning to do to ameliorate the risk.

Potential benefits: Explain potential benefits—both direct and indirect.

Costs/Compensation: Tell participants that there will be no compensation or explain the nature of any compensation (e.g., you will be entered into a lottery or receive a gift certificate or cash, etc.).

Additional Information

Contact persons: If you have any questions at any time about this research or want to discuss any possible study-related injuries, please contact **(insert the principal investigator’s name here)** at **(insert PI’s number and email here)**. If the PI is a student, include name and contact information for faculty adviser.

Confidentiality: Explain the nature of the confidentiality that you wish to assure the participant. For example: Your identity as a participant in this research study will be kept confidential in any publication of the results of this study. The information obtained during this research (research records) will be kept confidential to the extent permitted by law. However, this research record may be reviewed by government agencies (such as the Department of Health and Human Services), the agency sponsoring this research, individuals who are authorized to monitor or audit the research or the Institutional Review Board (the committee that oversees all research in human subjects at Adelphi University), if required by applicable laws or regulations. The material will be maintained for **up to seven years**.

Explain how the records will be kept confidential and who will have access as a part of the study (e.g., the principal investigator and other researchers). For focus groups add: While we cannot guarantee that all focus group members will maintain confidentiality, we are asking that you and all participants in this study not talk about the discussions that occur within the focus group session outside of the group.

Voluntary participation: Participation in this study is voluntary. For example: If you decide not to participate, this will not affect... Any new information that develops during this study, which might affect your decision to participate, will be given to you immediately. A signed copy of this consent form will also be given to you.

Institutional Review Board approval: This research has been reviewed and approved by the Adelphi University Institutional Review Board. If you have any questions, concerns or comments, please contact **Dr. Carolyn Springer, chair of the IRB, at 516.877.4753 or springer@adelphi.edu**.

Consent for minors or people with legal guardians: When the study involves minors or legally incapacitated individuals, simplify the language so that it is appropriate to the target population. Also, make sure to get both consent from the guardian and consent from the minor or legally incapacitated individual.

Person Obtaining Consent

Print name _____ Signature _____ Date _____

Study Coordinator (if applicable)

Print name _____ Signature _____ Date _____

Study Participant

Print name _____ Signature _____ Date _____

ATTACHMENT H—ELEMENTS OF A DEBRIEFING FORM

1. Thank you for the participation
2. What the study was about/the hypothesis (or hypotheses)
3. What the participants did
4. Practical application of the study
5. Compensation, if applicable
6. Contact information

Debriefing Form (SAMPLE)

Thank you for your participation. The study in which you have served as a participant is concerned with how bundled pricing influences consumers' purchase intentions of a product. The hypothesis for this study is that bundled pricing will increase consumer purchase intentions and increase demand of products. You filled out some demographic questions and two questionnaires. The practical application of this research concerns how to help marketers' design prices. For completing all parts of this study, you will receive two extra points toward the next exam in this class. If you have any questions about this research or if you would like a copy of the results, please call Dr. XYZ at **999.999.9999**.

ATTACHMENT I—SAMPLE APPROVAL LETTER

July 17, 2017

Ms. XXXX

Dear Ms. Grippi:

Adelphi University's Institutional Review Board (IRB) met to consider your proposal, XXXXXX (Submission #062517). As you know, the University's IRB reviews faculty, student and staff research to ensure the protection of study participants. The committee has voted to approve your proposal as amended. We have reviewed your research design and are satisfied that the welfare of the participants is ensured.

Your approval is valid for one year from this approval date; you will have to request a continuation should your project extend beyond one year. In addition, we are in receipt of your certification in human subjects training, a requirement for all researchers at Adelphi University. Certifications are valid for three years, after which you will need to renew and send the IRB a copy.

If you have any questions, please feel free to contact me at 516.877.4753 or email me at springer@adelphi.edu. Good luck with your study.

Sincerely,

Carolyn Springer, Ph.D., Chair

Adelphi University Institutional Review Board

cc: faculty adviser if applicable

ATTACHMENT J—SAMPLE EXPEDITED LETTER OF APPROVAL

March 14, 2017

Dear (name):

The chair of the Adelphi University's Institutional Review Board (IRB) has reviewed and approved your proposal, XXXX, which has been approved at Stony Brook University.

If you have any questions, please feel free to contact Dr. Carolyn Springer, chair, Adelphi University Institutional Review Board at 516.877.4753 or springer@adelphi.edu.

Good luck with your study.

Sincerely,

Carolyn Springer, Ph.D.

Chair, Adelphi University

Institutional Review Board

cc: Dr. xxxx

ATTACHMENT K—ADELPHI UNIVERSITY INSTITUTIONAL REVIEW BOARD SCREENING FORM

(This page is completed by the University-wide IRB and is used for both full and expedited review.)

DATE OF RECEIPT OF PROPOSAL BY THE UNIVERSITY IRB _____

NAME OF UNIT _____

TITLE OF PROJECT _____

PRINCIPAL INVESTIGATOR _____

FACULTY ADVISER _____

DATES OF CERTIFICATIONS _____

COMMITTEE REVIEW

REVIEWER'S NAME	DECISION	SIGNATURE	DATE
1. Frank T. Alfieri	_____	_____	_____
2. Aditi Bandyopadhyay	_____	_____	_____
3. Roni Berger	_____	_____	_____
4. Michael D'Emic	_____	_____	_____
5. Patricia Donohue-Porter	_____	_____	_____
6. William Jacobowitz	_____	_____	_____
7. Nicholas Koumbiadis	_____	_____	_____
8. Michael O'Loughlin	_____	_____	_____
9. Robert Otto	_____	_____	_____
10. Melissa Randazzo	_____	_____	_____
11. Carolyn Springer (chair)	_____	_____	_____

*A=Approve N/A=Not approved Comments AP=Approve pending modifications (See Comments)

UNIVERSITY CHAIR'S SIGNATURE AND DATE

ATTACHMENT L—2017–2018 IRB MEMBERSHIP

Name	Title	Department	Address	Phone	Email
Frank Alfieri	community member				FTA142@optonline.net
Aditi Bandyopadhyay	Associate Professor	Library	204 Swirbul	877.4166	bandyopa@adelphi.edu
Roni Berger	Professor	Social Work	303 Social Work	877.4365	berger@adelphi.edu
Michael D’Emic	Assistant Professor	A&S	118 Science	877.4210	mdemic@adelphi.edu
Patricia Donohue-Porter	Associate Professor	Nursing	353 Nexus	877.4532	donohue-porter@adelphi.edu
William Jacobowitz	Associate Professor	Nursing	361 Nexus	877.4559	wjacobowitz@adelphi.edu
Nicholas Koumbiadis	Associate Professor	Business	317 Hagedorn	877.4658	nkoumbiadis@adelphi.edu
Michael O’Loughlin	Professor	Education	230 Harvey	877.4108	oloughli@adelphi.edu
Robert Otto	Professor	Education	068 Woodruff	877.4276	otto@adelphi.edu
Melissa Randazzo	Assistant Professor	Education	119 Hy Weinberg	877.4769	mrandazzo@adelphi.edu
Carolyn Springer, chair	Associate Professor	Derner Institute	210 Blodgett	877.4753	springer@adelphi.edu

XX. ACKNOWLEDGMENTS

This manual is the result of the dedicated efforts of Dr. Robert Otto and the members of the Adelphi IRB.

Portions of this Institutional Review Board Policies and Procedures manual were obtained from the United States Department of Health and Human Services, Office of Human Research Protections (OHRP), IRB Guidebook, The Greater Baltimore Medical Center Institutional Review Board By-Laws, University of Texas at Austin IRB Manual and Indiana University/Purdue University of Indiana IRB Manual.

Approved by IRB: January 30, 2006; Effective date: February 1, 2006 Revised: July 2017