

**Institutional Review Board
Assumption College**

**Guidelines for Review of
Research Involving Human Subjects**

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General Guidelines

Research involving human beings as subjects and having any of the following attributes shall not be initiated until it has been approved or exempted by the Assumption College Institutional Review Board (IRB): 1) the research is sponsored by Assumption College; 2) the research is conducted by or under the direction of faculty and staff of Assumption College, or students under the direction of faculty or staff of the College, even if the research is conducted off campus; 3) the research is conducted on the premises of Assumption College.

The only exception to the above may be in the case of research that has already been reviewed and approved by an IRB in another institution. In such a case, the investigator is responsible to notify the Assumption IRB, and submit a copy of the outside IRB approval. The Assumption IRB has the discretion to accept or reject the approval of an outside IRB in lieu of an Assumption review process.

Scope and Purpose of IRB Review

The purpose of the IRB is to review each research plan, and, as appropriate, the process for obtaining informed consent, in order to safeguard the welfare and rights of human subjects of research. The Board's review is limited to the determination that each study conforms to various ethical standards including: 1) a research design which minimizes risks to subjects; 2) a reasonable balance of risks and anticipated benefits; 3) as appropriate, adequate provision for informed consent, taking into account differences in research methodologies; 4) an equitable selection of subjects, considering the methodology, purpose, and setting of the research; and 5) *as appropriate*, the research plan makes adequate provision to protect the privacy of the subjects and to maintain the confidentiality of data. When the IRB lacks the required expertise in a given field, it may avail itself of the expertise of consultants from within or outside of the College.

Basis of Guidelines

These guidelines are based primarily on regulations provided by the U.S. Department of Health and Human Services, as well as relevant professional and ethical guidelines. IRB members and researchers submitting proposals are encouraged to consult those regulations for further information. (U.S. Department of Health and Human Services: <http://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html#>)

Definitions

Research is defined as systematic investigation designed to develop or contribute to generalizable knowledge. Investigation that is designed for proprietary use only, or the result of which is not to be used in any public forum or published, is not defined as research under these guidelines.

Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

Children are 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.

Categories of Research

Persons intending to carry out research involving human subjects will submit to the IRB an application under one of the following three categories: Exempt Research, Expedited Research Review, or Full Research Review.

An investigator who believes his/her project is not research as defined by these guidelines must submit in writing a brief description of the project to the IRB chair. The chair will either: 1) certify in writing that the project does not fall under the purview of the IRB; or 2) affirm that the project must be submitted for IRB review under one of the three categories. However, even in cases determined not to be research under IRB guidelines, the IRB chair will inform the principal investigator that s/he is responsible to ensure that the safety and rights of human subjects participating in the project are protected, and proper methods followed.

A. Exempt Research

The federal Policy for Protection of Human Research Subjects exempts the following categories of research, and these will be exempted by the IRB. However, such research projects must still be submitted to the IRB for certification of exemption before research begins.

Exempt are research activities in which the only involvement of human subjects will be in one or more of the following categories. The categories in this list apply regardless of the age of subjects, except as specified in part 2 below.

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as:
 - a. research on regular and special education instructional strategies, or
 - b. research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior, unless:
 - a. information taken from these sources is recorded in such a manner that 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, academic standing, employability, or reputation.

Exceptions to Part 2:

- a. Survey or interview procedures involving children are not exempt.
- b. Observation of public behavior which involves children is exempt only if the investigator(s) do not participate in the activities being observed.
- c. Test, survey, or interview procedures that expose participants to disturbing content, such as violent or sexual behavior, are not exempt.

3. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under part 2 of this section, if:
 - a. The human subjects are elected or appointed public officials or candidates for public office; or
 - b. Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
4. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that the subjects cannot be identified, directly or through identifiers linked to the subjects.

B. Research Qualifying for Expedited Review

Expedited review of research projects may be employed in cases that: a) involve no more than minimal risk to human subjects; and b) involve only procedures listed in one or more of the following categories. The categories in this list apply regardless of the age of subjects.

1. 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.
2. Research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.
3. Collection of data from voice, video, digital, or image recordings made for research purposes.
4. Collection of biological specimens by non-invasive procedures routinely used in research. (See the federal guidelines for specifics.)
5. 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).
6. Moderate exercise by healthy volunteers.
7. Review of revised applications approved contingent on modifications.
8. Review of minor changes in approved applications.
9. Reactivation of inactive, previously approved research projects.

[NOTE: Some research in these categories may be exempt under the specifications in Part A (p.2). This listing refers only to research that is not exempt.]

The expedited review procedure may not be used where identification of subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects' financial standing, academic 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. Research topics which may place human subjects at risk include sensitive aspects of the subject's own behavior, such as illegal conduct, drug or alcohol use, sexual behavior, or violent behavior.

C. Research Requiring Full Review

All research not covered in the exempt or expedited categories must undergo a full review process. Also, any research that involves the use of deception or incomplete disclosure requires full review [voted by IRB 4/12/12].

Procedures for IRB Review of Research

Exempt Category: An application submitted under the exempt category may be reviewed by the IRB chair or by one or more experienced reviewers designated by the chair from among members of the IRB. If the review will be done by a single IRB member, that member may not be a member of the department which initiated the project, or have any other clear conflict of interest. Reviewers of applications for exemption may approve the exemption, require modifications in it (to secure approval), or request resubmission under a different category, but may not disapprove the research.

Department chairs or heads or their designees shall act as Human Subjects Reviewers for their departments. Department chairs shall ensure that Human Subjects Reviewers are familiar with these Assumption Guidelines for Review of Research Involving Human Subjects and with the relevant U.S. Department of Health and Human Services regulations. A Human Subjects Reviewer shall carry out a preliminary review of all research projects involving human subjects proposed by faculty, students, or staff within that department. S/he will then forward the application to the IRB along with a recommendation of the review category to be utilized: exempt, expedited, or full.

Expedited Review: Under an expedited review procedure, the review may be carried out by the IRB chair and one or more experienced reviewers designated by the chair from among members of the IRB. Reviewers of expedited applications may approve the research, require modifications in it (to secure approval), or request resubmission for a full review, but may not disapprove the research. Applications eligible for expedited review may be referred for full review at the discretion of the chair, or at the request of a committee member.

The IRB chair shall adopt a method for keeping all board members advised of research proposals which have been reviewed under the exempt or expedited procedures.

Full Review: Under a full review procedure, members of the board shall receive a copy of the application at least five working days before the board meets to review it. A majority of the board must be present at the meeting, including at least one member from outside the College and one member whose primary concerns are in nonscientific areas. The board may approve the research, require modifications (to secure approval), or disapprove the research. In order for the research to be approved, it shall receive the approval of the majority of those members present at the meeting, excluding any members with a conflict of interest (see p. 12).

The IRB shall notify investigators in writing of its decision to approve or disapprove any proposed research activity, or of modifications required to secure IRB approval of the research. The investigator must respond to the request for modification of a project proposal within three months, by sending a revised proposal to the IRB. If the investigator does not respond, the study

will be considered to be terminated without approval. If the IRB disapproves a research project, it shall include in its written notification a statement of the reasons for its decision and give the investigator an opportunity to respond in person or in writing.

Criteria for IRB Approval of Research

In order to approve research under either the expedited or the full review, the IRB shall determine that all of the following requirements are satisfied:

1. Risks to subjects are minimized.
2. Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and to the importance of the knowledge that may be reasonably expected to result.
3. Selection of subjects is equitable, considering the methodology, purpose and setting of the research.
4. As appropriate, and taking into account differences in research methodologies, informed consent will be sought from each prospective subject. Such consent may be written, but in some circumstances may be oral or may be waived under the stipulations of the regulations from the U.S. Department of Health and Human Services. Applicants may consult the federal regulations at: <http://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html#>
5. As appropriate, the research plan makes adequate provision for securing the data collected to ensure the safety of subjects.
6. As appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data. In particular, faculty supervisors are responsible to make student researchers aware of the possibility of accidental harm to research subjects, and of the necessity to keep all data anonymous.
7. When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects. In such cases the investigator and the IRB should consult the regulations of the U.S. Department of Health and Human Services and relevant professional guidelines.

Application Processes

Applicants are encouraged to consult with the IRB Chair while preparing applications.

All principal investigators and project personnel must complete an approved human subjects training every three years. The two currently approved trainings are the free online National Institute of Health's (NIH) Protecting Human Research Participants (<https://phrp.nihtraining.com/users/login.php>) and the online Collaborative Institutional Training Initiative (CITI) on Responsible Conduct of Research – Social and Behavioral Conduct of Research (<https://www.citiprogram.org/index.cfm?pageID=22>).

Application for Exemption from Review: An application for research to be certified as exempt shall include all of the following in one paper copy including signatures, and an electronic copy emailed to irb@assumption.edu:

- 1-10. IRB application face sheet: use form in Appendix A.

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11. Concise description of the study, written for non-specialists in the field, including:
 - a. Purpose: brief statement of purpose of the study.
 - b. Background: concise description of the prior research that led to the plan for this project.
12. Description of the research plan and methodology, with emphasis on purpose of the study, methods employed, and potential impacts on human participants.
13. Concise explanation of why the applicant sees the project as eligible for exemption, with specific reference to the criteria specified in these guidelines

Application for Expedited Review:

An application for expedited review of a research project shall include all of the following in one paper copy including signatures, and an electronic copy emailed to irb@assumption.edu:

- 1-10. IRB application face sheet: use form in Appendix A.
11. Concise description of the study, written for non-specialists in the field, including:
 - a. Purpose: brief statement of purpose of the study.
 - b. Background: concise description of the prior research that led to the plan for this project.
12. Research Methodology
 - a. Description of overall research plan and methodology: Provide a description of the intended procedures as they affect the participants. Include copies of any materials to be used in the research, including, but not limited to, surveys and questionnaires, audio-visual materials, and materials to be read to or by research subjects.
 - b. Description of subjects: source; method of recruitment (including specific criteria for inclusion and exclusion); total number. Any recruitment materials should be included in the application for review (e.g., scripts, emails, flyers, social media posts). Describe any material inducements, including extra credit, that will be offered to subjects in return for their participation. Such inducements also must be explained on the consent form.
13. Outline of potential benefits of this project: Describe the hoped-for benefits to society and to the participants. If there are no benefits to the participants this should be stated.
14. Outline of potential risks to subjects: Describe and assess any risks. If other methods of research present lesser risks, describe those, if any, that were considered and why they will not be used. In general, risks to participants must be minimized. Include how risks will be minimized, including, but not limited to, description of procedures for protecting the privacy of subjects and the confidentiality of data.
15. Informed Consent: Describe consent procedures to be followed, including how, where, and by whom informed consent will be obtained. Include a copy of the Informed Consent Form with the application. (See sample in Appendix B.)
16. Concise explanation of why the applicant sees the project as eligible for expedited review, with specific reference to the criteria specified in these guidelines.

Application for Full Review:

An application for full review of a research project shall include one paper copy with signatures, and an electronic copy emailed to irb@assumption.edu. Such application shall include all of the materials listed above for the expedited review (items 1 – 15) plus, for item 16, a concise explanation for why it should be subject to a full review.

Informed Consent

A. General Principles

The process of obtaining informed consent from those participating in a research project is central to the protection of human subjects of research. Investigators must provide potential subjects with reasonable information about the study, its procedures, benefits, risks, and alternatives, to enable him or her to make an intelligent decision about participation. The format of informed consent may vary according to the research methodology. In some circumstances, federal regulations allow for exceptions or alterations to the general requirements for written consent forms. In such cases, applicants and the IRB should consult those guidelines, and relevant professional guidelines. (<http://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html#>)

A written consent form is worded in the second person and written in a language which the prospective subject can be expected to understand. The consent form must not sound coercive. It must not include any language through which a subject is made to waive or appear to waive any legal rights or to release the College or its agents from liability for negligence.

A signed copy of all written consent forms should be placed in a research file. Participants must be given a copy of the consent form as well, though this need not be a signed copy.

B. Preparation of the Informed Consent Form

Each of the following points must be covered on all written consent forms unless the specific point is irrelevant to the project:

1. Purpose: The purpose of the study should be expressed in lay terms. It should be stated specifically that this is research.
2. Procedures: The subject must be told exactly what his/her participation will involve, with particular attention to the way it will be experienced by the subject. This should include length of time required, the number of times the subject will be contacted, the types of tests or procedures to be completed, and whether any videotaping or audiotaping will be included.
3. Benefits: Any benefits to the subject or to others which may reasonably be expected from the research should be described. Most often the expected benefit is the development of knowledge which it is hoped will be of value to other individuals at some time in the future. In some cases, however, there may be direct or indirect benefit to the individual participant. Both should be made clear.
4. Risks and inconveniences: Any reasonably foreseeable risks, discomforts, or inconveniences to the subject should be described. Participants should be informed of the availability of professional counseling in case they should experience discomfort due to the research.
5. Economic considerations: The financial consequences of participation or any material inducements offered in return for participation should be stated. Any conditions related to these (e.g., payment based on complete participation only) should be stated.
6. Confidentiality: Steps taken to assure confidentiality of records identifying the participant should be explained.
7. Anonymity: If the data is to be published or discussed in a public forum, potential

subjects must be informed. Procedures for ensuring the anonymity of data to be used in publications or any public forum should be explained.

8. Questions: Since potential subjects often need time to decide about participation, it is appropriate to encourage them to ask any questions about any part of the study that might be unclear to them. Also subjects should be assured that they may take as much time as necessary to think over the question of their participation. The consent form shall include telephone numbers and email addresses of the project supervisor and the IRB chair, so that a subject can ask further questions about the research or his/her rights as a research participant, or in the event of any research-related problem.
9. Freedom of choice to participate: Subjects should be informed that they are free to decide whether or not to participate, and free to discontinue participation in the study at any time without penalty or loss of benefits to which they are otherwise entitled. They should be assured that a decision not to participate will not adversely prejudice future interactions with the investigator(s) or the College. This is especially important when a dependent relationship exists between the investigator and the subject (e.g., faculty-student).
10. Signatures: Space is provided on the consent form for the signature of the subject or legal guardian. In the case of children, if the child is old enough to understand, the child is also invited to sign the form, in addition to the required signature of the parent or guardian. There is also space for the signature of the person who obtained the consent, and the dates of the signatures.

Special Categories of Human Subjects

Additional safeguards shall be provided for the following categories of human subjects who may be vulnerable to coercion or undue influence: children, prisoners, pregnant women, mentally disabled persons, physically disabled persons, or economically or educationally disadvantaged persons. Investigators who wish to include human subjects from these categories in their research shall design their research projects taking into consideration the federal regulations, and IRB reviewers shall consult those regulations in such cases.

(<http://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/#46.204>.)

Reconsideration Procedure

An investigator who disagrees with an IRB decision may request reconsideration by either appearing before the Board or by requesting an advisory review panel. This request must be made in writing within ten business days of the investigator's receipt of the Board's notification.

1. Investigator appears before the IRB

An investigator may ask to appear before the IRB to request that the Board reconsider a decision. This meeting must occur no later than the next regularly scheduled meeting of the IRB. Within ten business days of that meeting, the IRB will notify the investigator of its decision, and may affirm, modify or reverse its original decision. If the investigator is still dissatisfied, he or she may now have ten business days to request in writing to the Office of Academic Affairs formation of an advisory review panel.

2. Advisory Review Panel

An investigator may request reconsideration by the IRB based on the report of an advisory review panel.

- A. Composition of Advisory Review Panel: The advisory review panel must be formed within ten business days of the investigator's request for its formation. The panel shall consist of three persons, selected as follows:
 - i. One member chosen by the IRB chair; this person may not be a current member of the IRB.
 - ii. One member chosen by the principal investigator; this person may not be a member of the investigator's department and may not have had any direct involvement in the activities in question.
 - iii. One member chosen by the Office of the Vice-President for Academic Affairs; this person will serve as chair, may not be a current member of the IRB, may not be a member of the investigator's department, and may not have had any direct involvement in the activities in question.

- B. Procedures of Advisory Review Panel
 - i. Purpose: The Panel's purpose is not to substitute its own judgment for that of the members of the IRB on the merits of whether the research should be approved. Instead, the Panel will focus on procedural questions such as the following: Was all available information bearing on the proposed research sought out and considered? Was there adequate deliberation by the IRB of the information in light of relevant professional standards? Were the standards applied relevant to the scope and purpose of the IRB as defined in these guidelines, and to the criteria for IRB approval stated in the federal and/or these guidelines?
 - ii. Meeting: The members of the Advisory Review Panel will convene and hear statements from a representative of the IRB, the investigator, and other persons who might be called by the Panel, the IRB representative, or the investigator. The Panel may involve the College's general counsel or other legal assistance. The panel will meet in executive session to reach its decision. Within 30 calendar days of its formation, the panel will complete its investigation and transmit to the IRB chair and to the Office for Academic Affairs a written report of its findings and recommendations.

- C. IRB Reconsideration Based on Report of the Advisory Review Panel

The IRB will consider the Advisory Review Panel's report at a regular or special meeting held within 30 calendar days of the chair's receipt of the Panel's report. A majority of the IRB, including at least one member from outside the College and one member whose primary concerns are in nonscientific areas, must be present at this meeting. The investigator and members of the Advisory Review Panel may be present at this meeting. Statements may be made by all parties. Then the IRB will meet in executive session and, by a simple majority vote of members present, may affirm, modify, or reverse its original decision. The IRB is under no

obligation to accept the Panel's findings or recommendations.

Within five business days of that meeting, the IRB will provide written notice of its final decision to the investigator and to the appropriate department chair, the Office of the Vice-President for Academic Affairs, and members of the advisory review panel. This report will include a statement of the reasons for the Board's decision and a description of any action taken by the Board.

Procedure for Changing an Approved Research Project

To make substantive changes in an approved research project, the investigator should submit the revised plan with the requested changes highlighted, a revised informed consent form if needed, and a letter explaining the requested changes. The revision should be submitted in a signed paper copy and an electronic copy. Revised projects may usually be reviewed by expedited review. However, a full review may be required by the Board.

Reports of Adverse Events

Any adverse events involving human subjects in a research project must be reported to the IRB within 48 hours of the incident by the principal investigator or the faculty supervisor in the case of a student project. Adverse events include all unanticipated (not mentioned in the consent form or application) occurrences of physical or psychological harm and unexpected threats to privacy (e.g., lost records) or safety of subjects. Minor adverse consequences should be reported only if they were either unanticipated in the consent form or if the original application substantially underestimated their probability or magnitude.

Upon receipt of an adverse event report, the IRB will decide if further investigation of the event is required. In some cases, investigators may be required to discontinue a study pending the outcome of the IRB review. Where required by other agencies, investigators must fulfill additional obligations to report adverse events to funding agencies or other institutions.

Continuing Review of an Approved Research Project

Continuing review of IRB approved expedited and full review research projects is required on an annual basis. If IRB approval expires, all research activities must be immediately suspended until IRB approval is again secured. Principal investigators and faculty supervisors are responsible for monitoring when IRB approval of a research project expires and applying for continuing review (see Continuing Review Form in Appendix C). Continuing review applications are reviewed at the same level at which the research project was most recently approved. Continuing review of previously approved IRB research projects follows the procedures outlined above for submission and review of expedited and full applications.

Closeout of an Approved Research Project

Upon completion of an IRB approved expedited or full review research project, the principal investigator(s) must file a project closeout form (Appendix D) to end IRB oversight. An approved expedited or full research project is considered completed when data analysis is complete, when data analysis is ongoing with de-identified data (where any identifiers have been destroyed), when the principal investigator leaves the institution, or for other reasons. Once a project is closed out, principal investigators should retain completed informed consent forms for three years. It is expected that informed consent forms are stored securely.

IRB Records

The IRB chair shall supply documentation of all IRB activities to the Office of Academic Affairs at the end of each academic year. That office shall retain such records for a period of three years, or, in the case of approved projects, three years following completion of the research. Records shall include the following:

1. Complete copies of all research proposals received, together with the Board's action taken thereon.
2. For approved projects, progress reports submitted by investigators, and reports of injuries to subjects.
3. Summary account of IRB meetings which shall include: attendance at the meetings; actions taken by the IRB; the vote on these actions including the number of members voting for, against, and abstaining; and, where relevant, the basis for requiring changes in or disapproving research.
4. Copies of important correspondence between the IRB and investigators relevant to research applications and research in progress.

Membership of the IRB

The IRB chair and members are appointed by the Vice-President for Academic Affairs to two-year terms, on a staggered basis, so that only one-half of the members' terms expire in a given year. The Vice-President for Academic Affairs will solicit nominations from the faculty (self-nominations are allowed) for membership on the IRB and for IRB chair. The IRB chair is awarded a one course reduction each year. The IRB shall be comprised of at least five members, and must have an odd number of members. At least four members shall be from the Assumption faculty and one member from the community outside Assumption, having no connections to the College. There can be no more than one member from any single department. A majority of the board, or at least three members, should have some familiarity with social scientific or scientific research. One member at least should be a person whose primary concerns are in nonscientific areas. Members should represent a diversity of experience and background. When the IRB lacks the required expertise in a given field, it may avail itself of the expertise of consultants from within or outside of the College.

All IRB members must complete an approved human subjects training every three years. The two currently approved trainings are the free online National Institute of Health's (NIH) Protecting Human Research Participants (<https://phrp.nihtraining.com/users/login.php>) and the online Collaborative Institutional Training Initiative (CITI) on Responsible Conduct of Research – Social and Behavioral Conduct of Research (<https://www.citiprogram.org/index.cfm?pageID=22>).

A board member may be removed from service by the Vice-President for Academic Affairs, on the recommendation of the IRB.

Conflict of Interest

Under certain circumstances, for example if personal or professional relationships exist between an applicant and a member of the Board, the IRB chair may rule that there is a conflict of interest and/or a member of the Board may excuse themselves if they feel they have a conflict of interest. A board member with a conflict of interest may be a consultant to the board on the project, but may not vote on the project.

Procedures for Amendment of IRB Guidelines

These guidelines may be amended by a two-thirds vote of the Board. Amendments must be within the spirit of the regulations provided by the U.S. Department of Health and Human Services.

APPENDIX A: IRB Application

APPLICATION TO: **Institutional Review Board, Assumption College**
 FOR: **Approval of Research Involving Human Subjects**

Please complete all items on this face sheet, using "Not applicable" (N/A) when appropriate.

Application # _____
 (to be assigned by IRB)

Date:

1. Principal Investigator(s) and Project Personnel:

(Submit a copy of the NIH or CITI certificate of completion for each person listed in the table below)

Name	Title & Affiliation	Project Role	Date of Training Certificate

2. Title of project:

3. Cooperating institutions other than Assumption College:

4. Research subjects:

5. Funding source (proposed or actual):

6. Expected completion date:

7. Suggested review category (exempt, expedited, full):

8. Signature of Principal Investigator(s): _____

9. Signature of Faculty Supervisor: _____
 (If a student project)

10. Signature of Department Chair/Head or Program/Division Director:

Application For Approval Of Research Involving Human Subjects: Study Protocol

11. General Statement of the problem:

a. Purpose:

b. Background:

12. Research Methodology

a. Description of overall research plan and methodology:

b. Description of subjects:

13. Outline of potential benefit of this project:

14. Outline potential risks to subjects:

15. Explain the manner in which you will obtain informed consent:

16. Explain eligibility for exempt, expedited, or full review:

APPENDIX B: Sample Informed Consent Form

INFORMED CONSENT

CONSENT TO PARTICIPATE IN RESEARCH PROJECT ENTITLED: _____

Principal Investigator(s): _____

Participant's Name: _____

You are invited to take part in a research study examining the potential link between perceived stress and time management skills. You have been asked to be in this study because we are particularly interested in this link among college students.

Procedures: Your participation is completely voluntary. If you choose to participate in the study, you will be asked to complete two questionnaires. The first survey contains questions about the degree to which an individual experiences stress as well as the source(s) of the stress. The second questionnaire asks about the strategies one might use to manage short and long term demands and the ways in which resources such as time are allocated. Both surveys will take approximately 20 minutes to complete.

Benefits: This study may be of no direct benefit to you, but it will improve our knowledge of how efficient time management strategies may be related to reduced stress. The questionnaires may help you to be more aware of your stress and the way you manage your time. Some individuals have found that this increased insight has enabled them to work more efficiently.

Potential Risks: There are no inherent physical risks in the procedures themselves, and it is not anticipated that participants will experience risks in completing the questionnaire. Participants will not be exposed to any more risk of harm or discomfort than those ordinarily encountered in daily life. Occasionally, an individual may be more aware of ongoing stresses as a result of completing the questionnaire. If this is the case, you are free to discontinue completing the surveys at any time. In addition, information about supportive professional counseling services will be made available should you be interested.

Confidentiality: The information from the surveys will be used for research purposes only. Your survey will only include a participant ID number and not your name. Any records with your name, including this informed consent form, will be stored separately from your responses. All data collected in this study will be kept in a locked file cabinet. The researchers will keep your participation confidential - your name will not be used in any reports or publications of this study and only aggregated findings will be shared in presentations or publications of this study.

Freedom of Choice to Participate: You are free (1) to decide whether or not to participate, (2) to skip questions and (3) to withdraw from the study at any time. A decision not to participate will not adversely affect any interactions with the investigator or any representative/employee of Assumption College.

Questions: Before you sign this form, please ask any questions on any part of this study that is unclear to you. You may take as much time as necessary to think this over. At any point in the study, you may question the Principal Investigator about the study (include name, phone number, and email address) or the faculty advisor (include name, phone number, and email address). In addition, you are free to contact the Institutional Review Board Chair about any concerns (name, phone number, and email address of irb@assumption.edu).

Consent: This project has been explained to me to my satisfaction and in language I can understand, and I have received a copy of this consent form. I understand what my participation will involve and I agree to take part in this project under the terms of this agreement. I understand that I am not giving up my legal rights by signing this form.

Signature of Participant

Date

Printed Name of Participant

Signature of Investigator/Designee Obtaining Informed Consent

Date

APPENDIX C: Continuing Review Form

Assumption College
Institutional Review Board
Continuing Review Form

Date: _____

Application # _____
(as originally assigned by the IRB)

Original Approval Date: _____

Most Recent Review Date: _____

Title of Project: _____

1. What is the current research project status?

- Enrollment of participants is ongoing
- Enrollment of participants has ended, but data collection from participants is ongoing
- Enrollment of participants and data collection have ended, but data analysis continues
(If individual identifiers have been removed and destroyed, the research project IRB file may be closed – please file an IRB Close Out Form)
- Enrollment of participants, data collection, and data analysis have ended
(Please file an IRB Close Out Form)

2. Name and Title of Principal Investigator(s) and Project Personnel:

Name	Title & Affiliation	Project Role	Date of Training Certificate

Submit updated training certificates for any personnel whose certificates have expired since last IRB review.

Detail any changes to project personnel since last IRB review:

3. Is there any new and relevant information, published or unpublished, since the last IRB review, especially any information related to risks associated with this type of research?

4. Research Participants

Number already enrolled _____

Additional number anticipated to be enrolled _____

How many subjects discontinued their participation or withdrew from the study after the informed consent process? _____

If known, provide a summary of the reasons for withdrawal.

5. Detail any changes to the research protocol as most recently approved (including, but not limited to, changes in recruitment, informed consent procedure, and data collection procedures). Significant changes may require researchers to file an amendment for formal review.

6. Summarize any unanticipated problems related to the research project since the last IRB review and how they were addressed or resolved.

7. Summarize available information regarding any adverse events since the last IRB review and how they were addressed or resolved.

8. Summarize any complaints about the research project from research participants or others since the last IRB review.

9. Attach a copy of the latest version of the IRB approved application and sample informed consent form(s).

Signature of Principal Investigator(s): _____

Name of Faculty Supervisor: _____
(If a student project)

Signature of Faculty Supervisor: _____
(If a student project)

Signature of Department Chair/Head: _____

APPENDIX D: Closeout Form

Assumption College
Institutional Review Board
Closeout Form

Date: _____

 Application # _____
 (as originally assigned by the IRB)

Original Approval Date: _____

Most Recent Review Date: _____

Title of Project:

1. The research project IRB oversight can be closed out because:

- Enrollment of participants and data collection have ended, and data analysis continues, but individual identifiers have been removed and destroyed
- Enrollment of participants, data collection, and data analysis have ended
- Principal investigator(s) are no longer at Assumption
- Other, please describe:

2. Name and Title of Principal Investigator(s) and Project Personnel:

Name	Title & Affiliation	Project Role

3. Research Participants

Number enrolled over the course of the research project _____

4. Provide a summary of findings to date, including citations of any related published research.

Signature of Principal Investigator(s): _____

 Name of Faculty Supervisor: _____
 (If a student project)

 Signature of Faculty Supervisor: _____
 (If a student project)

Signature of Department Chair/Head: _____

APPENDIX E: Research Approved by Other IRBs

The General Guidelines at the beginning of this document state that, in the case of research that has already been approved by an IRB at another institution, the Assumption IRB has the discretion to accept or reject the approval of an outside IRB. On March 2, 2011 the Assumption IRB voted to adopt the practice that, upon the request of any member, the IRB will conduct a review of research already approved by the IRB of another institution.

This empowers any IRB member to positively assert a desire to protect Assumption students or other human subjects to a higher degree than that expressed by the other IRB or other IRB members. In this fashion, the default position is to provide the greatest degree of protection possible. This action obviates the need for a majority vote of the IRB to review research already approved by the IRB of another institution.

This Appendix was approved by Assumption College Provost Francis Lazarus on April 19, 2011.