

**Institutional Review Board
Assumption University**

**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 University Institutional Review Board (IRB): 1) the research is sponsored by Assumption University; 2) the research is conducted by or under the direction of faculty and staff of Assumption University, or students under the direction of faculty or staff of the University, even if the research is conducted off campus; 3) the research is conducted on the premises of Assumption University.

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: 1) the cover sheet included in Appendix A, 2) the full protocol that was approved by the outside IRB, and 3) a copy of the outside IRB approval. The protocol will be read by the IRB Chair or designated committee member. 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 University.

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#> and 2018 revisions to the Common Rule: <https://www.hhs.gov/ohrp/regulations-and-policy/regulations/finalized-revisions-common-rule/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.

Under the 2018 revisions, the following activities are deemed NOT to be research:

- Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of

information, that focus directly on the specific individuals about whom the information is collected.

- Public health surveillance activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority. Such activities are limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance (including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products). Such activities include those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters).
- Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes.
- Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions.

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.

Clinical trial - the revised Common Rule revises the term *clinical trial* to mean a research study in which one or more human subjects are prospectively assigned* to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes. Note: This may mean that many studies previously considered behavioral (e.g., assigning two groups of participants to a positive psychology exercise to evaluate effects on well-being) may now be considered a clinical trial. Research considered to be a clinical trial and receiving federal funding are subject to the reporting guidelines for such. See: <https://clinicaltrials.gov>

* Refers to a pre-defined process (e.g., randomization) specified in an approved protocol that stipulates the assignment of research subjects (individually or in clusters) to one or more arms (e.g., intervention, placebo, or other control) of a clinical trial.

The following questions should be used to determine whether a study meets the NIH clinical trial definition:

- Does the study involve human participants?
- Are the participants prospectively assigned to an intervention?
- Is the study designed to evaluate the effect of the intervention on the participants?
- Is the effect being evaluated a health-related biomedical or behavioral outcome?

If the answers are all “yes,” the study is a clinical trial.

If any answers are “no,” the study is not a clinical trial

NOTE: This may mean that many studies previously considered behavioral (e.g., assigning two

groups of participants to a positive psychology exercise to evaluate effects on well-being) may now be considered a clinical trial. Research considered to be a clinical trial **and receiving federal funding** are subject to the reporting guidelines for such, including the posting of the initial informed consent form for the research study. See: <https://clinicaltrials.gov/>.

Human Subjects

(1) Human subject means a living individual about whom an investigator (whether professional or student) conducting research:

(i) Obtains data information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or

(ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

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, in recognition that coercion or undue influence refers to the ability to make an informed decision about participating in research, such as individuals with impaired decision-making capacity. 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.>)

Note: Adopting a suggestion from NPRM public comments and the Secretary's Advisory Committee on Human Research Protections (SACHRP), the Revised Common Rule no longer includes pregnant women or handicapped and physically disabled individuals as examples of populations that are potentially vulnerable to coercion or undue influence. The Revised Common Rule uses the term "individuals with impaired decision-making ability" to replace the term "mentally disabled persons." The Rule's preamble states that the possibility of coercion or undue influence could affect the ability to make an informed decision about participating in research. Therefore, the vulnerability of the subjects in research studies should be considered as a function of the possibility of coercion or undue influence. The preamble states that this type of vulnerability alone should be the IRB focus of concern in determinations about vulnerable populations. The preamble also notes that the assessment of the equitable selection of subjects (46.111[a][3]) should include factors like societal marginalization or discrimination. Likewise, the preamble discusses that the criterion at 46.111(a)(1) includes risks that some might term "vulnerabilities," which are not covered by the regulatory term.

Categories of Research

Persons intending to carry out research involving human subjects will submit to the IRB an application under one of the following four 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.

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.

The list of exempt research below reflects the 2018 revisions to the Common Rule.

Exempt are research activities in which the only involvement of human subjects will be in one or more of the following categories.

1. EXEMPT CATEGORY 1: Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as:
 - research on regular and special education instructional strategies, or
 - research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

Note: this research must not be likely to have adverse impacts on either the students learning their required educational content, or the assessment of educators who provide instruction.

2. EXEMPT CATEGORY 2: Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior, as long as one of the following criteria are met:
 - Information obtained is not identifiable.
 - Disclosure outside of the research would not put subjects at risk of harm, including possible harm to “educational advancement.”
 - Information obtained can be identifiable, but an IRB has done a limited IRB review in keeping with 46.11(a)(7) of the Revised Common Rule which relates to there being adequate provisions for protecting privacy and maintaining confidentiality.

This category may include visual or auditory recordings as research methods.

Surveys cannot be combined or paired with collection of biospecimens or interventions, as those additional activities would disqualify the research from this category.

When the research includes children, Category 2 does not allow: Surveys, interviews, or the investigator participating in the activities being observed. Public behavioral observation without intervention is permitted with children.

3. EXEMPT CATEGORY THREE: Benign behavioral interventions in conjunction with the collection of information from adult subjects.

This is a new category in the Revised Common Rule. This exemption is only for

benign behavioral research with adults and is not applicable to children.

An example provided is having participants solve puzzles under various noise conditions.

Benign behavioral interventions are defined as “brief in duration, harmless, painless, and not physically invasive, not likely to have significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing.”

Exemption is permitted if the data are recorded in such a way that the identity of the subjects cannot be readily ascertained either directly or indirectly or if the subjects’ identities can be ascertained, a disclosure of responses outside the research setting would not reasonably place the subjects at risk of harm.

Alternatively, if the subjects’ identities can readily be ascertained and if a disclosure of the subjects’ responses has potential to harm subjects, the exemption is permitted if the IRB conducts a limited review and determines that there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of the data.

Research using deception is not eligible for exemption in this category unless the subjects prospectively agree that they will be unaware of or misled regarding the nature and purpose of the research.

4. EXEMPT CATEGORY FOUR: Secondary research for which consent is not required.

This exemption covers secondary research uses of identifiable private information or identifiable biospecimens.

Some new provisions have been added to Exemption 4 so that more research can be exempt. In the pre-2018 Common Rule, there are two provisions for when Exemption 4 can be used: (1) when the identifiable materials are publicly available, or (2) when the information is recorded by the investigator in a nonidentifiable manner. The revised Common Rule retains these two provisions, and it also adds two new ones:

- When the investigator’s secondary use of the identifiable private information is regulated under HIPAA as “healthcare operations,” “research,” or “public health.” Note that HIPAA does not apply to biospecimens, so this provision applies only to the secondary use of identifiable private health information (which can include information obtained from biospecimens).
- When the secondary research is conducted by or on behalf of a federal department or agency, using data collected or generated by the government for non-research purposes, and the information is subject to federal privacy standards and other requirements specified in the exemption.

It is important to note that data do not need to be existing (“on the shelf”) at the time of the research study, as was previously required by the pre-2018 rule. The

data can be collected prospectively and still be used for exempt research under Category 4 in the Revised Common Rule.

NOTE: If an investigator records information about individuals in a nonidentifiable manner, the investigator must not attempt to re-identify or contact the research subjects.

5. EXEMPT CATEGORY FIVE: Research and demonstration projects that are conducted or supported by a federal department or agency.

The Revised Common Rule revised this category to allow research supported by a federal agency (not just conducted) to:

- Qualify for this exemption.
- Provide examples of the types of public benefit and service programs covered by the exemption.
- Clarify the federal components for which the exempt research is subject to approval (for example, delegated subordinate agencies).

Exemption 5 has been expanded to cover more research than it does under the pre-2018 Common Rule. In the pre-2018 Common Rule, Exemption 5 applies to research that is designed to study, evaluate, improve, or otherwise examine public benefit or public service programs, if the research is conducted by a federal department or agency. This has been expanded to include research that is also supported by a federal department or agency (for example, through a grant of funding). There is also a new requirement for the federal entity conducting or sponsoring the research to publish a publicly available list of the projects that are covered by this exemption before the research begins.

6. EXEMPT CATEGORY SIX: Taste and food quality evaluation and consumer acceptance studies.
7. EXEMPT CATEGORY SEVEN: Storage or maintenance for secondary use for which broad consent is required.

This is a new exempt category.

This category is for the storage of identifiable biospecimens and identifiable private information, prior to secondary analysis.

Secondary research refers to research with materials originally obtained for non-research purposes or for research other than the current research proposal. The exemption can only be used when there is broad consent from the subjects for the storage, maintenance, and secondary research use of their identifiable materials.

The use of exemption 7 in the revised Common Rule requires the IRB to conduct a limited review of specific requirements that pertain to the use of the exemption. The IRB is not asked to conduct a standard IRB review using all the

criteria at 46.111. For Exemption 7, the IRB review is limited to the determinations described in 46.111(a)(8), which pertain to protections for privacy and confidentiality and broad consent.

8. EXEMPT CATEGORY EIGHT: Secondary research for which broad consent is required.

Exemption 8 is a new exemption in the revised Common Rule that covers the secondary research use of identifiable private information or identifiable biospecimens originally obtained for non-research purposes or for research other than the current proposal. There are four requirements that must be satisfied to use exemption 8:

1. broad consent must be obtained from the subjects for the secondary research use of their identifiable materials,
2. documentation or waiver of documentation of informed consent must be obtained,
3. an IRB must conduct a limited review to make certain determinations relating to privacy and confidentiality protections and broad consent, and
4. investigators cannot include the return of individual research results to subjects in the study plan. Note that this requirement does not limit an investigator's ability to abide by any other legal requirement to return individual research results.

The use of Exemption 8 in the revised Common Rule requires the IRB to conduct a limited review of specific requirements that pertain to the use of the exemption. The IRB is not asked to conduct a standard IRB review. For Exemption 8, the IRB conducts a limited review to determine whether the following criteria are met:

There are adequate privacy and confidentiality protections as required

and

The research to be conducted is within the scope of the broad consent.

Category 8 also requires that the investigator does not include returning individual research results to subjects as part of the study plan; however, the exemption does not prevent investigators from returning results if required by law.

Research Qualifying for Limited IRB Review

Limited IRB review is a process that is required only for certain exemptions. In limited IRB review, the IRB must determine that certain conditions, which are specified in the regulations below, are met. Limited IRB review may be done via the expedited review mechanism, that is, by the Chair or an experienced IRB member designated by the Chair (although it can also be conducted by the full IRB). Continuing review is not required.

There are **four exemptions that may require limited IRB review**: Exemptions 2, 3, 7, and 8.

- **Exemption 2** is for research that only includes interactions involving educational tests, survey or interview procedures, or observation of public behavior if at least one of the three provisions included in this exemption is met. Limited IRB review is required only if the third provision of the exemption is being used—that the information obtained is recorded by the investigator such that the identity of the subjects can readily be ascertained either directly or through identifiers. For this provision of Exemption 2, the limited IRB review serves to determine that adequate provisions are in place to protect the privacy of subjects and maintain confidentiality of the data.
- **Exemption 3** is for research involving benign behavioral interventions in conjunction with specified data collection methods if the criteria listed in one of three possible provisions are met. Limited IRB review is required only if the third provision of the exemption is being used—that the information obtained is recorded by the investigator such that the identity of the subject can readily be ascertained either directly or through identifiers. For this provision of Exemption 3, the limited IRB review serves to determine that adequate provisions are in place to protect the privacy of subjects and maintain confidentiality of the data.
- **Exemption 7** is for the storage and maintenance of identifiable private information or identifiable biospecimens for potential secondary research use, for which broad consent is required. This exemption requires limited IRB review to determine that the requirements for broad consent are met; that broad consent is appropriately documented or documentation of broad consent is appropriately waived; and that there are adequate provisions in place to protect the privacy of subjects and maintain confidentiality of the data, if there will be a change made for research purposes in the way the identifiable private information or identifiable biospecimens are stored or maintained.
- **Exemption 8** is for secondary research involving identifiable private information or identifiable biospecimens, for which broad consent is required. This exemption requires an IRB to determine through limited review that there are adequate provisions in place to protect the privacy of subjects and maintain confidentiality of the data, and that the research to be conducted is within the scope of the obtained broad consent.

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, 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. 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.

Research Qualifying for 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.

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

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 University 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. If the research is not approved by a majority of the board, it will be considered 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.

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.

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, 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 research investigators and project personnel must complete an approved human subjects training every three years. Beginning September 1, 2020, Assumption University's approved training is the Protecting Human Research Participants (PHRP) online training (<https://phrptraining.com>). In order to access this training, applicants should consult with the IRB chair, who provides approval and access to the training as needed on a case-by-case basis. For research applicants and other project personnel who may have personal-, department- or institution-subscriptions to the online Collaborative Institutional Training Initiative (CITI) website, a certificate showing completion of the Responsible Conduct of Research – Social and Behavioral Conduct of Research training program also serves as an approved human subjects training through Assumption University. Previous ethics certifications provided through the free online FHI360 Research Ethics Training Curriculum also serve as an approved human subjects training through Assumption University, as long as the certificate was issued within three years of the IRB research application date.

Beginning September 1, 2020, only electronic applications of research should be submitted to the IRB, emailed to irb@assumption.edu. Before September 1, 2020, both paper and electronic copies were required. In order to authenticate signatures of applicants, the application face sheet (form in Appendix A for exempt, expedited and full applications and form in Appendix F for External IRB for Cooperative Research), should be submitted in one of the following approved ways:

1. As a PDF with electronic signatures provided using DocuSign.
2. As a scanned PDF or Word document with handwritten signatures.
3. As a scanned PDF or Word document with images of handwritten signatures inserted.

External IRB for Cooperative Research

Starting in 2020, all institutions involved in cooperative research, if located in the United States, must rely on only a single IRB for review of research, except for:

- 1) Cooperative research for which more than a single IRB is legally necessary.
- 2) OR Research conducted where a federal department or agency determines that the use of a single IRB is not appropriate.

Before 2020, individual researchers may choose to rely on a single IRB for a review. To do so, the principal investigator should submit: 1) the cover sheet included in Appendix F and available on the IRB website, 2) the full protocol that was approved by the outside IRB, and 3) a copy of the outside IRB approval. The protocol will be read by the IRB Chair or designated committee member. Assumption IRB has the discretion to accept or reject the approval of an outside IRB in lieu of an Assumption review process.

Application for Exemption from Review: An application for research to be certified as exempt shall include all of the following in one electronic copy, including signatures, 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. 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. If using Exemption 4, justification why the procedures qualify as “benign behavioral intervention.” “Benign behavioral intervention” is described as behavioral (not biomedical) interventions in conjunction with collecting information from an adult subject through oral or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and certain conditions are met. The new exemption is for the research activities that pose little risk to subjects.

The regulations also add that benign behavioral interventions are:

- Brief in duration
- Painless
- Harmless
- Not physically invasive
- Not likely to have a significant adverse lasting effect on the subjects
- The investigator has no reason to think the subjects will find the interventions offensive or embarrassing

The following are examples of benign behavioral interventions: having the subjects play an online game; solve puzzles under various noise conditions; comparing test performance of test takers in quiet or noisy surroundings; or decide how to allocate a nominal amount of received cash between themselves and someone else.

Application for Limited Review:

The Revised Common Rule stipulates a new form of application, one for “limited IRB review.”

Limited IRB review is a process that is required only for certain exemptions. In limited IRB review, the IRB must determine that certain conditions, which are specified in the regulations, are met. Limited IRB review may be done via the expedited review mechanism, that is, by the Chair or an experienced IRB member designated by the Chair (although it can also be conducted by the full IRB). Continuing review is not required.

There are **four exemptions that may require limited IRB review**: Exemptions 2, 3, 7, and 8, which require that the application address that adequate provisions are in place to protect the privacy of subjects and maintain confidentiality of the data, and where relevant, that (for Category 8) that the scope of the research is covered under Broad Consent. The application should include all materials listed for exempt review plus (14) procedures for protecting identity and risks and (15) where, applicable, Broad Consent Form (see Appendix C).

Application for Expedited Review:

An application for expedited review of a research project shall include all of the following in one electronic copy, including signatures, 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 electronic copy, including signatures, emailed to irb@assumption.edu. Such application shall include all of the materials listed above for the expedited review (items 1 – 16) plus, for item 17, a concise explanation for why it should be subject to a full review.

Informed Consent

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 University 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.

Screening: According to Revised Common Rule, investigators may request in the protocol to screen, recruit, or determine eligibility of potential subjects without informed consent or applying for an informed consent waiver if said screening is obtained through oral or written communication with the subject or legally authorized representative, or by accessing records or stored biospecimens.

Waivers: According to the Revised Common Rule, obtaining the subject's signature can be waived if: a) subjects are members of a distinct community in which signing forms is not the norm, b) research involves no more than minimal risk, and c) an alternative method for documenting consent is used.

Electronic signatures: Electronic signatures (as common in online studies) are permissible.

Preparation of the Informed Consent Form

- In addition to the points below, the Revised Common Rule states the following principles:
 - The consent form should be as brief as possible (to maximize subject reading and retaining all of the relevant information).
 - It should start with a section on "KEY INFORMATION" that includes five elements. Key Information must receive priority by appearing at the beginning of the consent form and be presented first in the consent discussion. According to the Revised Common Rule's preamble, a brief description of five elements at the beginning of the consent form, and informed consent process, would encompass the required key information.

These five elements include:

1. The fact that consent is being sought for research and that participation is **voluntary**;
 2. The **purposes** of the research, **expected duration** of the prospective subject's participation, and **procedures** to be followed in the research;
 3. The **reasonably foreseeable risks or discomforts** to the prospective subject;
 4. The **benefits** to the prospective subject or others that may reasonably be expected from the research;
 5. **Appropriate alternative procedures or courses of treatment**, if any, that might be advantageous to the prospective subject.
- In addition, consent forms will need to say either that information or biospecimens collected for the research might be stripped of identifiers and used in other research in the future, or that this will not happen.
 - There are three new additional elements of informed consent. Note that these are additional elements; they may not be relevant to all studies, in which case they wouldn't need to be included. These new additional elements are all notices. One is a notice about possible commercial profit, the second is a notice about whether clinically relevant research results will be returned to the subjects, and the third is a notice about whether

research activities will or might include whole genome sequencing.

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 University. 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.

Broad Consent for Research with Biospecimens or Individually Identifiable Data

Broad consent affords researchers the opportunity to ask participants to an informed consent form which covers both the subject of the investigator's current research as well as future unspecified research using the same set of data or biospecimens. Broad consent contains the typical Informed Consent information and adds the following elements to cover secondary research:

1. If the biospecimens may be used for commercial profit, the consent must inform the subject of that potential use and must disclose whether the subject will or will not share in any commercial profit.
2. If the possible research will (if known) or might include whole genome sequencing, that information must be disclosed.
3. The consent must explain the types of research that may be conducted with identifiable private information or identifiable biospecimens.
4. The consent must inform a subject if identifiable private information or identifiable biospecimens might be shared with other researchers or institutions and should include an explanation of the types of institutions or investigators that might conduct research with such information or biospecimens.
5. If personally identifiable data or biospecimens will be stored, the consent must describe both the period of time allowed for storage and maintenance (even if indefinite) and the time period that such information or biospecimens may be used for research purposes (even if indefinite).
6. Unless the subject or legally authorized representative will be provided details about specific research studies, the broad consent must include a statement that the subject or the legally authorized representative will not be informed of the details of any specific research studies that might be conducted using the subject's identifiable private information or identifiable biospecimens. This includes the purposes of the research and that the subject might have chosen not to consent to some of those specific research studies.
7. Unless it is known that clinically relevant research results will be disclosed to the subject in all circumstances, the consent must include a statement that such results may not be disclosed to the subject.
8. The consent must contain an explanation of whom to contact with questions about the subject's rights about storage and use of the subject's identifiable private information or identifiable biospecimens, and whom to contact in the event of a research-related harm.

As part of the review for Broad Consent, the IRB committee will:

- 1) Review the appropriateness of the process proposed for obtaining broad consent.
- 2) Ensure that the required elements of broad consent were appropriately included in the broad consent form (or process if broad consent is to be obtained orally).
- 3) Determine that consent is appropriately documented or that a waiver of documentation is appropriate.
- 4) If a change is made for research purposes in the way that identifiable private information or identifiable biospecimens are stored or maintained, the IRB must determine that adequate provisions are in place to protect the privacy of subjects and to maintain the confidentiality of the data.

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 University'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 University 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 electronic copy, emailed to irb@assumption.edu. 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 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 D). 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.

The Revised Common Rule states that continuing review is no longer mandated for expedited

applications or full applications where research has progressed to the point that the only remaining activities are: a) data analysis, including analysis of identifiable private information and/or biospecimens, and/or b) accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care.

In addition, continuing review is not required for research reviewed in accordance with limited IRB review.

Investigators are not required to provide annual confirmation to their IRB that the research is ongoing and that no changes have been made that would constitute a required ongoing review.

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 E) 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 University. 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 University.

All IRB members must complete an approved human subjects training every three years. Beginning September 1, 2020, Assumption University's approved training is the Protecting Human Research Participants (PHRP) online training (<https://phrptraining.com>). In order to access this training, IRB members should consult with the IRB chair, who provides approval and access to the training as needed on a case-by-case basis. For internal or external IRB members who may have personal-, department- or institution- subscriptions to the online Collaborative Institutional Training Initiative (CITI) website, a certificate showing completion of the Responsible Conduct of Research – Social and Behavioral Conduct of Research training program also serves as an approved human subjects training through Assumption University. Previous ethics certifications provided through the free online FHI360 Research Ethics Training Curriculum also serve as an approved human subjects training through Assumption University, as long as the certificate was issued within three years of the IRB research application date.

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.

Guidelines for Compensating Research Participation

OVERVIEW

Researchers at Assumption University often conduct research projects that involve the use of Human Subjects. Payments to Human Subjects may be paid in the form of cash, gift cards/certificates, or check depending on the circumstances of the study and the dollar amounts involved. The Institutional Review Board reviews and approves proposed incentives (payments), as part of the protocol review process, for anyone participating in human subject research. Verification of IRB approval for the payment or incentive amount and process can be provided by either the researcher or the IRB Administrator. U.S. Tax and Immigration laws dictate that the University and its employees comply with certain rules and regulations pertaining to processing compensation for participants in Human Subject studies. To ensure compliance with these

regulations, the procedures outlined in this policy must be followed. Failure to comply with these procedures may result in a violation of Federal Law.

Payment for participation in research may not be offered to the subject as a means of undue influence, where it might cause someone to assume risks they would not otherwise assume. Rather, it should be a form of recognition for the investment of the subject's time, loss of wages, or other inconvenience incurred.

HUMAN SUBJECT PAYMENTS IN NON-CONFIDENTIAL STUDIES

Cash or Gift Card/Certificate Payments

Payments to Human Subjects may be processed in the form of cash or gift cards/certificates if the total payment to each Human Subject during the course of the study does not exceed \$600 for the calendar year. If gift cards/certificates are used as the payment mechanism, it is imperative that all gift cards/certificates are distributed during the course of the study since it is unlikely the merchant will redeem those that are not used. The principal investigators conducting the study must maintain a schedule of the payments issued, including name, address (if available), signature of recipient (if obtainable), amount paid to each individual, and date.

Payments

Human Subject payments must be issued in the form of a check by processing a Vendor Payment Voucher Form and W9 Form when total payments to a Human Subject during the course of the study are equal to or greater than \$600 for the calendar year.

In acknowledgement that participants may participate in multiple studies in a given year supervised by different principal investigators, participants should be paid by check if the participant payment exceeds \$100.

HUMAN SUBJECT PAYMENTS IN CONFIDENTIAL STUDIES

In certain circumstances, research studies are performed in which the privacy of the Human Subjects must be protected and the confidentiality of the data must be maintained. If the research study has been determined to be confidential, the procedures for obtaining the funds for payment are the same as those described above.

Cash or Gift Card/Certificate Payments Cash or gift card/certificate payments may be processed for up to \$600 to any one Human Subject in a calendar year for confidential studies.

Use the procedure for Human Subject Payments in Non-Confidential Studies with the following exceptions:

- Because the study is confidential, it is not necessary to identify the Human Subject as described above for non-confidential studies; however, an identifying code must be assigned to each Human Subject being paid.
- A listing of these codes, along with the dollar amounts paid to each must be kept by the principal investigator.
- A cross-reference of the coded identification, including the Human Subject name, amount received, and date, must be maintained on file by the Principal Investigator for a period of three (3) years following the submission of the final financial report, unless the terms of the award provide for a different period.

- This information is required to be available upon the request of internal auditors, Grants and Contracts auditors, and the Internal Revenue Service (IRS).

Total payments to any one Human Subject during the course of a study totaling \$600 or more in a calendar year must be processed through the Accounts Payable for payment to be issued in the form of a check. Information required for these payments include the Human Subject's name, address, and SSN. This information will be reported to the IRS, and Form 1099-MISC, Miscellaneous Income, will be sent to the payee at the end of the calendar year in which the payment(s) were made.

Payments

Human Subject payments must be issued in the form of a check by processing a Vendor Payment Voucher Form and W9 Form when total payments to a Human Subject during the course of the study are equal to or greater than \$600 for the calendar year.

In acknowledgement that participants may participate in multiple studies in a given year supervised by different principal investigators, participants should be paid by check if the participant payment exceeds \$100.

Since completing a W-9 and processing it through the Accounts Payable office means that study participation will be revealed to multiple people not involved in the research team and having been trained in research ethics, all informed consent forms for studies using this method of payment must clearly delineate these exceptions to confidentiality.

HUMAN SUBJECT PAYMENTS TAXATION

In order to fulfill the University's tax reporting responsibilities with the IRS, the University is required to obtain the Human Subject's SSN if he/she will be paid \$600 or more in a calendar year and report these payments on Form 1099-MISC, Miscellaneous Income. The University is not required to report payments that total less than \$600. Human Subjects are required to report all income received as a study participant on his/her individual income tax return, regardless of the dollar amount. Human Subjects should consult with his/her individual tax advisor regarding reporting requirements for these payments. Payments made to Human Subjects who are also employees of the University are subject to the procedures detailed in this policy unless the relationship of an employer/employee exists within the study. In such rare cases, the payment is reported on Form W-2, Wage and Tax Statement.

Only an approved study under the IRB would be allowed an exemption to the gift card policy. The exemption to the General expense policy is being made due to the confidentiality of these studies. Each fall, along with the listing of Department chairs, the administrative assistant to the Provost (currently Lorrie McCarty) will include in the listing the name of the chair of the IRB and send this listing to the Accounts payable office.

The chair of the IRB must be one of the approvers of the gift card purchase request. The explanation of the expense must include "for IRB research." Principal investigators using gift cards should obtain from the IRB the approved form Institutional Review Board Gift Card Approval (form in Appendix H), complete it, obtain the current IRB Chair's signature. This form should be submitted to the purchasing official (e.g., department chair, Provost's Office, depending on the source of funds) and also kept with the research records.

Assumption University Misconduct in Research Policy

Introduction

Assumption University, through its commitment to academic excellence and ethical leadership, strives to promote a climate of honesty in research. The University has established a policy on misconduct in research applicable to all research at the institution.

It is the responsibility of deans, department chairpersons, program directors, faculty advisers, and individual investigators to familiarize themselves with IRB policies and procedures including the Misconduct in Research Policy. The University regards any infringement of these policies and procedures as a serious breach of professional standards. The University's willingness to defend researchers in litigation depends on strict adherence to policies and procedures regarding IRB approval. Interpretation of applicability of IRB rules and regulations are solely the legal right and responsibility of the IRB. General policy questions regarding human subjects research should be directed to the attention of the IRB Chair (Angela Kaufman-Parks; 508-767-7357; irb@assumption.edu or am.kaufman@assumption.edu)

General Elements

For the purposes of IRB policy, research misconduct means knowing and willful non-compliance with requirements of the conduct of research involving human subjects.

Examples of research misconduct *might* include any of the following:

- failing to seek IRB approval before beginning research with human subjects, whether knowingly or inadvertently
- failing to seek renewal of IRB approval following the lapse of such approval
- failing to report adverse events with human subjects
- modifying a research protocol without consulting IRB
- failing to adequately report risks to human subjects
- failing to secure and properly document informed consent

While considering possible cases of misconduct in research, the University will:

- Establish a Review and Investigation Team consisting of the IRB Chair and at least one other faculty member appointed by the Provost.
- Take all reasonable and practical steps to ensure the cooperation of respondents and other institutional members with research misconduct proceedings, including, but not limited to, their providing information, research records, and evidence;
- Carry inquiries and investigations through to completion and to pursue diligently all significant issues;
- Notify the U.S. Department of Health and Human Services, Office of Research Integrity (ORI) in advance if the University plans to close a case at the Inquiry, Investigation, or Appeal stage on the basis that the respondent has admitted guilt, a settlement with the respondent has been reached, or for any other reason, except the closing of a case at the

inquiry stage on the basis that an investigation is not warranted or a finding of no misconduct at the investigation stage;

- Retain and secure all records of research misconduct proceedings, including the inquiry report, final documents produced in the course of preparing the inquiry report, and documentation of decisions, findings and sanctions, if any;
- Abide by the following time limits:
 - Complete the inquiry within 60 calendar days of its initiation unless circumstances clearly warrant a longer period. If the inquiry takes longer than 60 days to complete, the inquiry record must include documentation of the reasons for exceeding the 60-day period
 - Within 30 days of finding that an investigation is warranted, provide ORI with the written finding by the responsible institutional official and a copy of the inquiry report
 - Begin the investigation within 30 days after determining that an investigation is warranted
 - Complete all aspects of an investigation within 120 days of beginning it, including conducting the investigation, preparing the report of findings, providing the draft final report for comment, and sending the final report to ORI.
 - Six-year limitation on allegations from the date an allegation is received
- Provide written notice to the respondent(s), consistent with and within the time limits:
 - At the time of or before beginning an inquiry, the IRB will make a good faith effort to notify in writing the presumed respondent, if any;
 - If the inquiry subsequently identifies additional respondents, the IRB will notify them;
 - The IRB will notify the respondent whether the inquiry found that an investigation is warranted. The notice will include a copy of the inquiry report and include a copy of or refer to this part and the University's policies and procedures;
 - The IRB will notify the respondent in writing of the allegations within a reasonable amount of time after determining that an investigation is warranted, but before the investigation begins;
 - The IRB will give the respondent written notice of any new allegations of research misconduct within a reasonable amount of time of deciding to pursue allegations not addressed during the inquiry or in the initial notice of investigation;
 - The IRB will provide written notice to ORI of any decision to open an investigation on or before the date on which the investigation begins.
- Provide opportunity for the respondent to provide written comments on the IRB's draft inquiry and investigation reports.
- Consider and address the comments before issuing the final reports.
- Specify and implement appropriate interim institutional actions to protect public health, Federal funds and equipment, and the integrity of the research process.
- Notify ORI of any facts that may be relevant to protect public health, Federal funds and equipment, and the integrity of the supported research process.

Inquiry Stage

The University and the IRB recognize that honest errors are an inevitable part of the research process. To distinguish instances of knowing and willful research misconduct from "honest" errors,

simple carelessness, and minor infractions, the IRB will conduct an Inquiry, according to the following procedures.

This review is performed when concerns regarding compliance, protocol adherence, or subject safety are brought to the attention of the IRB in any form of communication. This review may take place on-site or on the Assumption University campus, at the discretion of the IRB, and may include review of:

- Protocol file/regulatory documentation
- IRB Documentation
- Consent/Assent Forms
- Individual Participant Records. A random sample to determine if:
 - The participants met the inclusion/exclusion criteria for the study.
 - Study related procedures are performed according to the protocol.
 - Study related procedures are scheduled and performed per the study timeline.
 - Data is recorded and stored securely as described in the Consent Form.

Documents that may be selected for review include, but are not limited to:

- Regulatory submissions and associated IRB correspondence
- Changes in the protocol and associated IRB correspondence
- Review of any lapses in IRB approvals
- Review of eligibility criteria
- Review of all informed consents
- Review of subject accrual and recruitment practices
- Review of data collection tools and procedures
- Review of adverse event reporting (including timeliness of reports to the IRB, Sponsor and other regulatory agency).
- Review of protocol deviations (including timeliness of reports to the IRB, Sponsor and other regulatory bodies)
- Review of continuing review reports

An Inquiry is conducted by the IRB Chair and at least one IRB board member. In the case of a for-cause audit, the IRB may request a 100% audit of study participant's records and/or collected data. Draft Inquiry Reports are presented to the entire IRB Board at the next scheduled IRB Meeting and to respondent (s) for review and comments. Inquiry Reports contain the following elements:

- The name and position of the respondent;
- A description of the allegations of research misconduct; the nature of support, including, for example, grant numbers, grant applications, contracts, and publications listing support;
- The basis for recommending that the alleged actions do or do not warrant an investigation; and
- Any comments on the report by the respondent or the complainant.

Final Inquiry Reports are completed within 60 calendar days of initiation of the Inquiry. If an Investigation is warranted the next stage is initiated.

Investigation Stage

During this stage, the IRB will:

- Notify ORI on or before date investigation is to begin
- Provide additional sequestration as needed to conduct the research misconduct proceeding
- Request extension of the investigation if warranted
- Use diligent efforts to ensure that the investigation is thorough and sufficiently documented and includes examination of all research records and evidence relevant to reaching a decision on the merits of the allegations.
- Conduct required interviews, transcribed or recorded.
- Pursue diligently all significant issues and leads discovered that are determined relevant to the investigation
- Produce a Draft Investigation Report and distribute to respondent (s) for review and comment.
- Produce an Investigation Report that includes:
 - Description of the nature of the allegations of research misconduct
 - Description and documentation of support (e.g., grant numbers, grant applications, contracts, and publications listing support)
 - Specification of charges (e.g., description of the specific allegations of research misconduct for consideration in the investigation)
 - Copy of the institutional policies and procedures under which the investigation was conducted
 - Identification and summary of the research records and evidence reviewed, and identify any evidence taken into custody but not reviewed
 - Statement of findings: For each separate allegation of research misconduct identified during the investigation, provide a finding as to whether research misconduct did or did not occur, and if so
 - Identify whether the research misconduct was falsification, fabrication, or plagiarism, and if it was intentional, knowing, or in reckless disregard;
 - Summarize the facts and the analysis which support the conclusion and consider the merits of any reasonable explanation by the respondent;
 - Identify the specific support;
 - Identify whether any publications need correction or retraction;
 - Identify the person(s) responsible for the misconduct; and
 - List any current support or known applications or proposals for support that the respondent has pending with other Federal and non-Federal agencies
 - Comments made by the respondent and complainant on the draft investigation report.

Subsequently, notification of observations of noncompliance will be sent to the PI with a detailed explanation of the basis for the findings.

Actions will not be taken by the IRB against any investigator or project without providing the investigator (according to general policies) an opportunity to provide information in writing that might mitigate or refute an adverse finding.

Requirements for findings of research misconduct include:

- Significant departure from accepted practices of the relevant research community, and
- Misconduct committed intentionally, knowingly, or recklessly, and
- Proven by a preponderance of evidence

Sanctions Stage

All instances of human subject non-compliance will be reported to appropriate University officials, and may be reported to OHRP, according to stated Federal reporting requirements and guidelines (http://www.hhs.gov/ohrp/policy/incidreport_ohrp.html).

University faculty, staff, and students who are found to be in violation of IRB policies and/or Research Misconduct may be subject to sanctions relating to their participation in research involving human subjects. Depending on the severity of the violation, sanctions may involve a written warning, temporary suspension of the research, termination of the research, or the permanent destruction of collected research data. Actions taken by the IRB and the University also will be subject to Federal reporting guidelines.

Post Proceedings Stage

The IRB will maintain records of research misconduct proceedings in a secure manner for seven years after completion of the proceeding or the completion of any Federal Agency proceeding involving the research misconduct allegation, whichever is later.

SONA Systems

The Psychology Department has recently begun using a participant pool model through SONA Systems: A Cloud-Based Subject Pool Software for Universities. To expose students in introductory research classes to a variety of example psychological research experiments, students in Statistics and Research Methods register on SONA Systems and complete several experiments run by either Assumption faculty members or student groups collecting data in partial fulfillment of the Psychology capstone course Research Seminar. All students have the option of declining such participation and instead completing short written reviews of experimental studies selected by the faculty.

Any research study using SONA to recruit participants must state in the informed consent form that said participation is completely voluntary and that students may opt for the written assignment to fulfill this research credit as an alternative.

The SONA systems allows for principal investigators to ask prescreening questions which then filter the experiments that particular participants are shown as options. (For instance, an investigator may be recruiting only female participants and can set the prescreening question such that only female students are shown their experiment as an option).

In conjunction with the SONA administrator, these prescreening questions are now preceded by a brief informed consent outlining that they may opt out of answering any such questions, that their answers are only available to the on-campus SONA administrator and SONA Systems, and that they are free to contact the IRB chairperson with any concerns.

To help facilitate your participation in psychological research this semester, we would like you to complete the following questionnaire. The questionnaire presents a series of questions, which may range from basic demographic information such as age and gender, to health-related information, to measures of personal experiences and attitudes. The primary purpose of this questionnaire is to help the system determine which research studies you may be eligible to participate in. The questionnaire is intended to take less than 30 minutes to finish. To the best of our understanding, none of these questions are likely to elicit discomfort or put you at risk in any way.

All of your responses will remain confidential. Your responses will only be associated with the random Participant ID# assigned to you by SONA. Your name is linked to your ID in a separate file that only the SONA administrator (a faculty member in the department) and the SONA company can access.

If you are uncomfortable answering any of these questions, you may check the box that reads "prefer not to provide an answer." In order to successfully complete the questionnaire, you must either provide an answer or check this box for each question.

Your interactions with the Psychology Department will not be affected should you choose to skip questions; you may skip questions and still complete the research participation option of your course. However, keep in mind that the more questions you answer, the more studies for which you will likely be eligible during the semester.

You must complete all sections in one sitting, as the system will not allow you to resume your work at another time. While you are participating, your responses will be stored in a temporary holding area as you move through the sections, but they will not be permanently saved until you complete all sections and you are given a chance to review your responses.

If at any time you wish to have your pre-test answers removed from the system, you may contact the SONA pool administrator to do so.

By clicking on the button below to begin the pre-test, you are providing consent for the psychology department to collect information from you. Your consent indicates that you have read, understood, and agreed to these terms. Finally, if you are not yet 18-years-old, you must have a parent or guardian sign a separate permission form before you may proceed to complete this questionnaire. Your instructor will be able to provide you with this form.

All investigators interested in using the prescreening must submit prescreening questions as part of the IRB protocol for review by the IRB committee to be evaluated for psychological risk or threats to confidentiality.

Here we provide some standard language that researchers can use in their IRB applications if they so wish.

“Participants for the study will be recruited through the Psychology department’s SONA system. Students in General Psychology, Statistics, and Research Methods courses are required to explore contemporary psychology research either by participating in research studies on campus or by completing brief writing assignments about contemporary research studies selected by the psychology faculty. Students on the SONA system may also participate in studies for extra credit in their psychology courses (faculty members have been informed that they must offer an alternative extra credit assignment for those who do not wish to participate in research).”

Note: if researchers wish to also recruit participants through word of mouth or other methods, these methods should also be described in the protocol.

Underage University Participants

Some University freshmen have not yet turned 18. If 17-year-old participants wish to participate in research on campus, their parents must complete a parental assent form (see Appendix G). If underage freshmen are enrolled in one of the courses requiring research participation (unlikely, since these are courses largely taken by sophomores and juniors) and do not have their parents complete a parental assent form, they will be required to opt for the alternate credit option. If data are mistakenly collected from such participants by researchers, their data should be discarded from analysis.

APPENDIX A: IRB Application

APPLICATION TO: Institutional Review Board, Assumption University

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 _____ Date
IRB)

Principal Investigator(s) and Project Personnel:

(Submit a copy of the ethical training certificate of completion for each person listed in the table below)

Name	Title & Affiliation	Project Role	Date of Training Certificate

- 1. Title of project:**
- 2. Cooperating institutions other than Assumption University:**
- 3. Research subjects:**
- 4. Funding source** (proposed or actual):
- 5. Expected completion date:**
- 6. Suggested review category** (exempt, limited, expedited, full):
- 7. If exempt, indicate which exempt category (1-8):**
- 8. If limited, indicate which exempt category (2, 3, 7, or 8):**
- 9. Signature of Principal Investigator(s):** _____
- 10. Signature of Faculty Supervisor:** _____
(If a student project)
- 11. 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, limited, expedited, or full review, including a thorough accounting of why your procedures count as “benign behavioral interventions” if you believe your protocol meets criteria for Exemption Category 4:

APPENDIX B: Sample Informed Consent Form

INFORMED CONSENT

CONSENT TO PARTICIPATE IN RESEARCH PROJECT ENTITLED: _____

Principal Investigator(s): _____

Participant's Name: _____

KEY INFORMATION:

1. Consent and Voluntary Nature of Research: You are invited to give your consent to participate in a research study. Your participation is completely voluntary.
2. Purpose, Duration, and Procedures: The purpose of this research is to examine the potential link between perceived stress and time management skills. If you choose to participate in the study, you will be asked to complete two questionnaires. The first questionnaire 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.
3. Reasonably Foreseeable Risks and Discomforts: There are no inherent physical risks in the procedures themselves, and it is not anticipated that you will experience risks in completing the questionnaire. You will not be exposed to any more risk of harm or discomfort than those ordinarily encountered in daily life. It is possible that you may become more aware of ongoing stresses as a result of completing the questionnaire. If this is the case and you find it uncomfortable, 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.
4. Reasonably Foreseeable 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 people have found that this increased insight has enabled them to work more efficiently.
5. Alternative Procedures or Courses of Treatment: You are free to not participate in this research. As the research does not involve treatment, there are not alternative courses of treatment other than not participating.

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 in a

loc. All paper records collected in this study will be kept in a locked file cabinet, and all data will be stored without your identity in a password-protected computer. The researchers will keep your participation confidential - your name will not be used in any reports or publications of this study and only summary findings will be shared in presentations or publications of this study. The data will be kept for three years following publication and then destroyed.

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 University.

Future Research: Information collected for this project will not be stripped of identifiers and used in other research in the future.

(NOTE TO INVESTIGATORS: If there is any chance that the data will be used for possible commercial profit, that clinically relevant research results will be returned to the subjects, or that research activities will or might include whole genome sequencing, you must provide details of these facts in the Informed Consent Form. Otherwise, delete this section).

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: Sample Broad Informed Consent Form

BROAD INFORMED CONSENT FOR FUTURE USE OF INFORMATION OR
BIOSPECIMENS

FOR PROJECT ENTITLED:

Principal Investigator(s): _____

Participant's Name: _____

KEY INFORMATION:

1. Consent and Voluntary Nature of Research: You are invited to give your consent for your personal information or biospecimens to be used in research studies in the future, something called "broad consent." Your consent is completely voluntary. You can choose to participate in the original research study without giving this broad consent for future use of your data.
2. Purpose, Duration, and Procedures: You are being asked by an Assumption University researcher to provide broad consent for the storage, maintenance, and secondary research use of your identifiable private information and/or your identifiable biospecimens. For you to be able to decide whether you want to participate, you should understand what type(s) of research may be performed, as well as the possible risks and benefits in order to make an informed decision. This process is known as informed consent. This form describes the purpose, procedures, possible benefits, and risks of storage, maintenance, and secondary research use of your identifiable private information / biospecimens. It also explains how your personal information and/or biospecimens will be used and protected. Once you have read this form and your questions about the storage, maintenance, and secondary research use of your identifiable private information and/or biospecimens are answered, you will be asked to provide broad consent. You should receive a copy of this document to take with you.
3. Reasonably Foreseeable Risks and Discomforts: 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. It is possible that you may become more aware of ongoing stresses as a result of completing the questionnaire. If this is the case and you find it uncomfortable, 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.
4. Reasonably Foreseeable 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 people have found that this increased

insight has enabled them to work more efficiently.

5. Alternative Procedures or Courses of Treatment: You are free to not participate in this research. As the research does not involve treatment, there are not alternative courses of treatment other than not participating. You are also free to participate in the original research study without consenting to future use of your data.

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 paper records collected in this study will be kept in a locked file cabinet, and all data will be stored without your identity in a password-protected computer. The researchers will keep your participation confidential - your name will not be used in any reports or publications of this study and only summary findings will be shared in presentations or publications of this study. The data will be kept for three years following publication and then destroyed.

Explanation of Type(s) of Specified Future Research

[Use this section to describe either a particular type of specified research or a wider scope of research to be performed in the future. This section must include sufficient information to allow a reasonable person to know what types of research the broad consent would permit and the types of research to be conducted.]

Description of Identifiable Private Information/Biospecimens

[Use this section to describe the identifiable private information/biospecimens to be stored, maintained, and used in secondary research. Indicate whether or not the information/biospecimens will be shared with other researchers and what the nature of the secondary institutions and investigations will be.]

Length of Storage

Your identifiable private information/biospecimens will be stored and maintained for a duration of... [State if the private information/biospecimens will be stored and maintained indefinitely]

Your identifiable private information/biospecimens may be used for research purposes for a duration of... [State if the private information/biospecimens will be used for research purposes indefinitely]

Disclosure of Secondary Research Studies

You will be provided the purpose of and/or details about specific studies that may be conducted using your identifiable private information/biospecimens.

OR

You will not be provided the purpose of and/or details about specific studies that may be conducted using your identifiable personal information/biospecimens. Secondary research may include studies that you would have chosen not to consent to.

Disclosure of Clinically Relevant Research Results

You will be provided clinically relevant research results. [Indicate under what conditions results will be provided or if results will be provided in all circumstances]

OR

You will not be provided with any research results, including individual research results.

Where applicable:

Identifiable or de-identified biospecimens may be used for commercial profit. [Indicate whether or not the profit will be shared with the participant]

Research with biospecimens will or might include whole genome or exome sequencing.

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 University.

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 D: Continuing Review Form

Assumption University
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 E: Closeout Form

Assumption University
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 F: External IRB Approval Form

Institutional Review Board (IRB) Authorization Agreement

If you would like to request that an external IRB stand as the IRB of record for your protocol, please: 1) complete and submit the below; 2) submit an Assumption University protocol cover sheet; 3) submit the external protocol; and 4) submit the external approval letter.

Name of Research Project:

Name of Principal Investigator:

Name of Local (Assumption) Co-Investigator (if different from above):

Sponsor or Funding Agency:

Protocol Approval # (at IRB of record):

Institution or Organization Providing IRB Review (This is the IRB you would like to serve as the IRB of record):

Name of External IRB of Record:

IRB Registration #:

Federalwide Assurance (FWA)#, if any:

Institution Relying on the Designated IRB (Institution B):

Name: Assumption University (Assumption Coll IRB #1; IORG0001567)

IRB Registration #: IRB00002024

The review performed by the designated IRB will meet the human subject protection requirements of Institution B's OHRP-approved FWA. The IRB at Institution/Organization A will follow written procedures for reporting its findings and actions to appropriate officials at Institution B. Relevant minutes of IRB meetings will be made available to Institution B upon request. Institution B remains responsible for ensuring compliance with the IRB's determinations and with the Terms of its OHRP-approved FWA. This document must be kept on file by both parties and provided to OHRP upon request.

Appendix G: Under 18 Parental Assent Form

EXPERIMENTAL PERMISSION FORM FOR STUDENTS UNDER 18 YEARS OF AGE

Guidelines established by the US Department of Health and Human Services prohibit the use of children who are under the age of 18 as participants in Human Subjects Research unless permission is granted by their parents or guardians.

_____ is presently enrolled in a psychology course
(Name of Student)

that either 1) has a research requirement which can be fulfilled either by participating in psychological research studies or by writing a paper on psychological research, or 2) offers extra credit for participating in psychological research studies or writing a paper on psychological research.

The Department of Psychology at Assumption University believes that participation in psychological research provides students with a positive educational benefit because they experience how psychological studies are conducted and learn about the vast array of research topics being investigated by members of the department. This experience allows students to better understand and evaluate research presented in the context of their courses.

Participation in experiments is on a completely voluntary basis. For each experiment in which your child is involved, they will be asked to review and sign a detailed informed consent form. By signing the present form, you grant permission for your child to sign the informed consent forms provided to them at each experiment even though s/he is not yet 18. Ultimately, of course, your child would be the one to decide whether or not to participate in any study for which s/he signs up; your signing this form simply grants them permission to sign up for studies and participate in them should they wish to do so.

If you do not wish to grant your child permission to participate in the research studies offered through the department, their course performance will not be negatively affected. They will still be able to complete the written assignment alternative to fulfill the research requirement and/or extra credit opportunities.

If you have any questions, please contact the Institutional Review Board Administrator at Assumption, Dr. Angela Kaufman-Parks at (508) 767-7357 or am.kaufman@assumption.edu.

I give permission for _____ to serve in research
(Name of Student)

projects approved and monitored by the Institutional Review Board and the Psychology Department of Assumption University.

Date

Signature of Parent of Guardian

Please return this completed form to the SONA Pool Administrator, Dr. Leamarie Gordon, at Department of Psychology - 500 Salisbury St. Worcester, MA 01609, or via email at lt.gordon@assumption.edu.

Examples of Research Studies Recently Conducted in the Psychology Department

Memory for Scenes – Primary Investigator: Dr. Leamarie Gordon

In this study, participants complete a brief mindfulness meditation exercise, and/or play Sudoku, along with watching a video of a burglary. They then listen to an audio narrative of the video. Finally, they take a memory test on the video.

Card Game Study – Primary Investigator: Dr. Karen Lionello-DeNolf

In this study, participants work with a partner on a card-game task and complete a questionnaire. This game may be played using physical cards that are placed on a table or using a computer program. Regardless of whether the game is played on the tabletop or the computer, the game procedures will be the same. In addition, even though participants play the game with a partner, they will not be able to see their partner during the game because they will be separated by room divider (i.e., participants will be able to see which card their partner plays on each trial, but they will not see their partner's face). In addition, the research session will be videotaped so that we can verify the accuracy of data collection. This experiment will take approximately 30 minutes to complete.

The Association of Anxiety, Depression, Anger, and Alcohol Misuse in Young Adults – Primary investigator: Dr. Len Doerfler

If you choose to participate in the study, you will be asked to complete a brief demographic questionnaire and 6 validated psychological tests. These psychological tests will ask you about your experiences of anxiety, depression, anger, and problematic alcohol use. The psychological tests that you will complete do not ask you to provide your name or other information that could identify you or anyone else who participates in this study. It will take about an hour to complete all the psychological tests.

Video Ratings: A Pilot Study – Primary Investigator: Dr. Maria Parmley

You are invited to take part in a research study to determine the ways in which people respond to various video clips. We will use results from the present study to further develop a research project that examines the relationship between emotion, cognition, and well-being. If you choose to participate in the study, you will be asked to watch a video clip and read some statements and then answer some questions about your reactions to the video. You will be asked to rate how the video makes you feel. You will also be asked to rate how positive and aroused each video made you feel.

Appendix H: Gift Card Approval Form

Institutional Review Board (IRB) Gift Card Approval

If you are purchasing gift cards for an IRB-approved research study (see policy below), please fill out the bolded items and obtain the signature of the current IRB chair. Submit this form to the person approving the purchase (e.g., Provost's Office, department chair) and keep a copy for your records.

Title of Research Project:

Name of Principal Investigator:

Sponsor or Funding Agency:

Protocol Approval #:

Signature of IRB CHAIR:

_____ **Date:**

Signature of Principal Investigator:

_____ **Date:**

Guidelines for Compensating Research Participation

OVERVIEW

Researchers at Assumption University often conducts research projects that involve the use of Human Subjects. Payments to Human Subjects may be paid in the form of cash, gift cards/certificates, or check depending on the circumstances of the study and the dollar amounts involved. The Institutional Review Board reviews and approves proposed incentives (payments), as part of the protocol review process, for anyone participating in human subject research.

Verification of IRB approval for the payment or incentive amount and process can be provided by either the researcher or the IRB Administrator. U.S. Tax and Immigration laws dictate that the University and its employees comply with certain rules and regulations pertaining to processing compensation for participants in Human Subject studies. To ensure compliance with these regulations, the procedures outlined in this policy must be followed. Failure to comply with these procedures may result in a violation of Federal Law.

Payment for participation in research may not be offered to the subject as a means of undue influence, where it might cause someone to assume risks they would not otherwise assume. Rather, it should be a form of recognition for the investment of the subject's time, loss of wages, or other inconvenience incurred.

HUMAN SUBJECT PAYMENTS IN NON-CONFIDENTIAL STUDIES

Cash or Gift Card/Certificate Payments

Payments to Human Subjects may be processed in the form of cash or gift cards/certificates if the total payment to each Human Subject during the course of the study does not exceed \$600 for the calendar year. If gift cards/certificates are used as the payment mechanism, it is imperative that all gift cards/certificates are distributed during the course of the study since it is unlikely the merchant will redeem those that are not used. The principal investigators conducting the study must maintain a schedule of the payments issued, including name, address (if available), signature of recipient (if obtainable), amount paid to each individual, and date.

Payments

Human Subject payments must be issued in the form of a check by processing a Vendor Payment Voucher Form and W9 Form when total payments to a Human Subject during the course of the study are equal to or greater than \$600 for the calendar year.

In acknowledgement that participants may participate in multiple studies in a given year supervised by different principal investigators, participants should be paid by check if the participant payment exceeds \$100.

HUMAN SUBJECT PAYMENTS IN CONFIDENTIAL STUDIES

In certain circumstances, research studies are performed in which the privacy of the Human Subjects must be protected and the confidentiality of the data must be maintained. If the research study has been determined to be confidential, the procedures for obtaining the funds for payment are the same as those described above.

Cash or Gift Card/Certificate Payments Cash or gift card/certificate payments may be processed for up to \$600 to any one Human Subject in a calendar year for confidential studies.

Use the procedure for Human Subject Payments in Non-Confidential Studies with the following exceptions:

- Because the study is confidential, it is not necessary to identify the Human Subject as described above for non-confidential studies; however an identifying code must be assigned to each Human Subject being paid.
- A listing of these codes, along with the dollar amounts paid to each must be kept by the principal investigator.
- A cross-reference of the coded identification, including the Human Subject name, amount received, and date, must be maintained on file by the Principal Investigator for a period of three (3) years following the submission of the final financial report, unless the terms of the award provide for a different period.
- This information is required to be available upon the request of internal auditors, Grants and Contracts auditors, and the Internal Revenue Service (IRS).

Total payments to any one Human Subject during the course of a study totaling \$600 or more in a calendar year must be processed through the Accounts Payable for payment to be issued in the form of a check. Information required for these payments include the Human Subject's name, address, and SSN. This information will be reported to the IRS, and Form 1099-MISC, Miscellaneous Income, will be sent to the payee at the end of the calendar year in which the payment(s) were made.

In acknowledgement that participants may participate in multiple studies in a given year supervised by different principal investigators, participants should be paid by check if the participant payment exceeds \$100.

Since completing a W-9 and processing it through the Accounts Payable office means that study participation will be revealed to multiple people not involved in the research team and having been trained in research ethics, all informed consent forms for studies using this method of payment must clearly delineate these exceptions to confidentiality.

HUMAN SUBJECT PAYMENTS TAXATION

In order to fulfill the University's tax reporting responsibilities with the IRS, the University is required to obtain the Human Subject's SSN if he/she will be paid \$600 or more in a calendar year and report these payments on Form 1099-MISC, Miscellaneous Income. The University is not required to report payments that total less than \$600. Human Subjects are required to report all income received as a study participant on his/her individual income tax return, regardless of the dollar amount. Human Subjects should consult with his/her individual tax advisor regarding reporting requirements for these payments. Payments made to Human Subjects who are also employees of the University are subject to the procedures detailed in this policy unless the relationship of an employer/employee exists within the study. In such rare cases, the payment is reported on Form W-2, Wage and Tax Statement.