IRB Application Face Sheet

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 # _____ **Date: _____**
(to be assigned by IRB)

1. **Principal Investigator(s) and Project Personnel:**
   (Submit a copy of an approved ethics training certificate of completion for each person listed in the table below)

   From the Guidelines: 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, investigators and project personnel should consult with the IRB chair, who provides approval and access to the training as needed on a case-by-case basis. For investigators or 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.

Name	Title & Affiliation	Project Role	Date of Training Certificate

The principal investigator is the researcher, so this is the applicant's name, and anyone who is also doing the research with them. Student researchers should include the name of their faculty advisor(s) in the table.

2. **Title of project:**

3. **Cooperating institutions other than Assumption University:** If there are institutional partners, they should be listed here and there should be some evidence to demonstrate their cooperation. For example, if working with a school, an email or letter of support from the principal.
4. **Research subjects:** As a part of this, include the expected number of cases that will be included in the research. For example, the number of people who will be surveyed or the number of people who will be interviewed.

5. **Funding source** (proposed or actual):

6. **Expected completion date:**

7. **Suggested review category (exempt, expedited, limited, full):** As with all of these sections, refer to the Assumption University IRB Guidelines for guidance on completing this section. This can be found on pages 5-11 of the guidelines. For additional assistance beyond that which is provided by the guidelines, refer to the exempt, expedited and full flowcharts.

8. **Signature of Principal Investigator(s): _____**

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

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

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

_____

For example, if research is being done by someone in Student Affairs, the Vice-President of Student Affairs would review and sign.

Application For Approval Of Research Involving Human Subjects: Study Protocol

11. General Statement of the problem:

a. Purpose:

From the guidelines: brief statement of purpose of the study.

Typically, this is one to two paragraphs.

b. Background:

From the guidelines: concise description of the prior research that led to the plan for this project.

The purpose of this section is for the committee to see that the researcher(s) knows enough about past research to be able to determine that this proposed research project addresses a previously unanswered and important question, and is therefore not an unnecessary use of participants' time. This should typically be just a few paragraphs written for someone who is not a specialist in this particular field. It should not just a copy and paste of an existing literature review. If you include any in text citations, at the end of this section include the full citations of those works. Any sentences that include phrases similar to "research has found" should include citations of that research.

12. Research Methodology

a. Description of overall research plan and methodology:

From the guidelines: 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.

This needs to be a detailed account of what the researcher proposes to actually do, from start to finish. This includes, at a minimum, how participants will be recruited, what participants will be told and what they will be participating in, what measures will be taken/data will be collected, and how long participation is expected to take.

If the following are a part of the proposed project, they should be submitted as a part of the application (typically as an appendix) for IRB review:

- Questionnaires or surveys (for validated or copyrighted scales or questionnaires, include relevant citations). Each should be a separate, labeled appendix to make it easier for IRB reviewers to cross-reference and review.

- Image or videos to be viewed by participants (if needed, can be shared by internet links)
- Vignettes to be read by or two participants
- Interview questions or topics

If the researcher needs permission from someone to conduct the research or approach participants, there needs to be documentation of that permission. For example, if proposing to interview police officers in one town, an email or letter giving permission from the Chief of Police would be appropriate.

If participants are going to be offered extra credit for participating in the research, the class professor(s) must also offer an alternate extra credit assignment for those who do not want to participate in the research. Researchers also need to include how participation will be tracked and shared so extra credit can be awarded.

If participants are to be recruited through SONA systems, please see the Guidelines for some helpful wording suggestions. If participants are to be prescreened in SONA using a prescreening question or two, those questions need to be submitted for review.

If participants will be photographed or filmed and the researcher would like to use those images in future papers or presentations, participants need to sign a release giving the researcher permission to do so.

d. Description of subjects:

From the guidelines: 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, which will be offered to subjects in return for their participation. Such inducements also must be explained on the consent form.

This needs to be a detailed description of how subjects will be selected (including inclusion and exclusion criteria), including where they will be selected or sampled from, how many, and any payment or incentives that may be given for participation. Recruitment emails, recruitment scripts, social media postings, portal announcements, posters, flyers, and any other recruitment materials should be submitted for review.

13. Outline of potential benefit of this project:

From the guidelines: 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 potential risks to subjects:

From the guidelines: 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.

This is typically where to detail how data and other project materials (such as informed consent forms) are being safeguarded, including where and how they are being stored (for example, in a locked cabinet in the researcher's office with informed consent forms stored separately from completed questionnaires or on a password protected device that remains in the control of the researcher), when and how it will be deleted or destroyed.

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

From the guidelines: 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.

If the informed consent is written and in person, provide two copies of the informed consent forms – one for the participant to keep for their records and one for the researcher's records. Both should be signed by the researcher and the participant.

16. Concise explanation of why the applicant sees the project as qualifying for exempt, expedited, limited or full review, with specific reference to the criteria for the relevant category specified in the Assumption University IRB guidelines.

This should be detailed and matched to the research project. For example, it is not appropriate to say the application should be expedited because it meets requirements 1, 2, and 4. Instead, the response should include what those are and how this particular application meets those criteria.

From the guidelines: For exempt research using Exemption 4, include justification as to why the procedures qualify as "benign behavioral intervention." See pages 13-14 in the guidelines for assistance.

From the guidelines: For exempt research using Exemption 8, this portion of the application must address that the scope of the research is covered under Broad Consent.

Sample Informed Consent Form

This is a **sample** informed consent form. For an IRB application, either this form should be modified to the proposed project or an alternate version that includes the same information can be created. This example is based off of a study on stress and time management that used an in person informed consent process and collected data through questionnaires administered in person. Therefore, much of the language below may not apply to other research projects and designs. Important information for IRB applications containing the potential for commercial profit, clinical applications for participants, and the use of biospecimen or individually-identifiable data, although not relevant to the stress and time management study detailed below are highlighted in red.

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 take part in a research study. Your participation is completely voluntary. 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.

2. Purpose, Duration and Procedures: You are invited to take part in a research study examining the potential link between perceived stress and time management skills. You have been asked to be in this study because we are particularly interested in this link among college students. If you choose to participate in the study, you will be asked to complete two questionnaires. The first survey contains questions about the degree to which an individual experiences stress as well as the source(s) of the stress. The second questionnaire asks about the strategies one might use to manage short and long term demands and the ways in which resources such as time are allocated. Both surveys will take approximately 20 minutes to complete.

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. Occasionally, an individual may be more aware of ongoing stresses as a result of completing the questionnaire. If this is the case, you are free to discontinue completing the surveys at any time. In addition, information about supportive professional counseling services will be made available should you be interested.

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

5. Appropriate Alternative Procedures or Courses of Treatment: You are free to not participate in this research. As the research does not involve treatment, there are no 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. All data collected in this study will be kept in a locked file cabinet. The researchers will keep your participation confidential - your name will not be used in any reports or publications of this study and only aggregated findings will be shared in presentations or publications of this study.

Freedom of Choice to Participate: You are free (1) to decide whether or not to participate, (2) to skip questions and (3) to withdraw from the study at any time. A decision not to participate will not adversely affect any interactions with the investigator or any representative/employee of Assumption 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: As relevant for specific categories of research, before the following "Questions" and "Consent" information, applicants may need to provide Notices to participants, including the following: (1) notice of possible commercial profit; (2) notice about whether clinically relevant results will be returned to the subjects; (3) notice about whether research activities will or might include whole genome sequencing. If not relevant, delete this section).

(NOTE TO INVESTIGATORS: for Broad Consent for Research with Biospecimens or Individually Identifiable Data, additional elements must be included in the Broad Consent/Informed Consent Form to cover secondary research using the same set of data or biospecimens collected in the current research. See pages 17-18 of the guidelines for these additional required elements. If not relevant, 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. I also certify that I am 18 years of age or older.

Signature of Participant	Date
Printed Name of Participant	
Signature of Investigator/Designee Obtaining Informed Consent	Date