Application/Research Protocol Review Form for Research Involving Human Participants
Institutional Review Board (IRB)

Contact Information: The Office of Research and Sponsored Programs (Billy C. Black Building, Room 389) 229.500.2032
NOTE: ***The IRB Committee does not meet in the summer (May – July); as a result, reviewing of protocols will be delayed.***

Part 1: Administrative Information

1.1 Proposed Start and End Dates of the Study (mm/yyyy): _____ to _____

1.2 Title of Protocol:

1.3 Contact Information:

Principal Investigator (PI): (In regard to student researchers, the Principal Investigator of the project will be the faculty mentor/advisor or thesis committee chair. Student researchers will be considered Co-PIs and listed under key personnel.)

Name: _____
Email Address: _____
College/Division: _____
Department/Unit: _____
Role in Research: _____
Human Subjects Training Certificate: ☐ **CITI** ☐ **NIH** ☐ **Other** (please list) _____

Key Personnel/ Co-PIs:

Name:	Email:	Phone/Ext:	Human Subjects Training Certificate:	Role in Research:
			Choose an item.	
			Choose an item.	
			Choose an item.	
			Choose an item.	

1.4 Source of Funding: Choose an item.

Name of External Funding Agency:

Sponsor's Project ID Number:

Part 2: Proposed Review Category

Please select the proposed review category. **If an exempt review is chosen, please complete the *Exemption Self-Assessment* section. If full board or expedited review is chosen, please move on to Part 3: Study Design, Methods, and Procedures.**

☐ **Full Board Review:** For research that has potentially more than minimal risks and/or the use of vulnerable populations.
☐ **Expedited Review:** For certain kinds of research that involves no more than minimal risks to human research subjects.
☐ **Exempt Review:** For research activities that fall under one or more of the exemption categories specified by the federal regulations. Ultimately the ASU IRB is responsible for deciding if research qualifies for exemption; however, use the following self-assessment to see if your project qualifies as exempt:

Exemption Self-Assessment

Please select all the categories that apply to your research protocol from the list below.

1) ☐ Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as: regular and special education instructional strategies, or effectiveness or comparison of instructional techniques, curricula, or classroom management methods.

2) ☐ Research involving one or more of the following:

i. Educational tests (cognitive, diagnostic, aptitude, achievement):
   a. If the information is recorded in a manner that individuals cannot be identified (directly or through identifiers linked to the individual), OR
   b. If the information may be recorded in a manner that individuals can be identified (directly or through identifiers linked to the individual), but disclosure of the information could NOT reasonably place the participants at risk of criminal or civil liability or be damaging to their financial standing, employability, or reputation.*****

ii. Survey or interview procedures (this exemption category does not apply to research activities with minors/children):
   a. If the information is recorded in a manner that individuals cannot be identified (directly or through identifiers linked to the individual), OR
   b. If the information may be recorded in a manner that individuals can be identified (directly or through identifiers linked to the individual), but disclosure of the information could NOT reasonably place the participants at risk of criminal or civil liability or be damaging to their financial standing, employability, or reputation.*****

i. Observation of public behavior:
   For minors/children: Observation of public behavior of minors is eligible for exemption only if the researcher does not participate in the activities being observed.
   For non-minors: Generally considered exempt from IRB review as follows:
   a. If the information is recorded in a manner that individuals cannot be identified (directly or through identifiers linked to the individual), OR
   b. If the information may be recorded in a manner that individuals can be identified (directly or through identifiers linked to the individual), but disclosure of the information could NOT reasonably place the participants at risk of criminal or civil liability or be damaging to their financial standing, employability, or reputation.*****

*****Risks of criminal or civil liability or of damage to financial standing, employability, or reputation can be dependent on the context of the research and are determined by the IRB staff based on experience, past precedent and benchmarked best practices. The IRB staff welcomes the input of investigators in determining the possibility of such risks, but if there is reasonable doubt about whether or not criteria b. applies, **the research is not exempt.**

Note: Exemption category #2 does not apply to research with children, unless the research is exclusively limited to activities described in 2.i (educational tests) and/or 2.iii (observation of public behavior and the investigators do not participate in or manipulate the activities being observed).

3) ☐ Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior, but is not eligible for the above exemption (2), can be exempted if the research participants are elected or appointed public officials or candidates for public office, or federal statute requires that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

4) ☐ Research involving the collection or study of existing (i.e., existing before the request for exemption is submitted to ORIA to determine whether the research is exempt) data, documents, records, pathological specimens, or diagnostic specimens:

i. If these sources are publicly available; OR
ii. If the sources are not publicly available, but the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

5) ☐ Research and demonstration projects that are conducted by or subject to the approval of federal department or agency heads, and are designed to study, evaluate, or otherwise examine public benefit or service programs, procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs.

6) ☐ Taste and food quality evaluation and consumer acceptance studies:

i. If wholesome foods without additives are consumed, OR

ii. If a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

Part 3: Project Overview:

3.1 Type of project/study: Please select ALL of the categories of work that apply to this proposed project.

☐ Active Collection of New Data
☐ Active Collection and Use of Human Biological Materials or Physiological Data
☐ Use of Physiological or Biomedical Devices, or Drugs, Biologics, or Chemicals
☐ Use of Existing Data
☐ Use of Existing Human Biological Materials

3.2 Data collection will involve the use of (check all that apply):

☐ Surveys/Questionnaires
☐ Internet/ Electronic
☐ Audio/Video/Photos
☐ Interview/Observation
☐ Private Records or Files
☐ Educational Tests (cognitive diagnostic, aptitude, etc.)
☐ Physical/Physiological Measures or Specimens
☐ Other (Specify):

3.3 Please provide an abstract of the study in lay terminology, including the purpose, research questions, hypothesis to be evaluated, and expected/possible outcomes. (400 word maximum)

3.4 Please describe briefly how this study will contribute to existing knowledge in the field.

3.5 Clearly state all of the objectives, goals, or aims of this project.

3.6 How will the results of this project be used? (check all that apply):

☐ Presentation
☐ Publication
☐ Thesis
☐ Dissertation
☐ Other (Specify):_____

3.7 List all locations where data collection will take place. (School systems, organizations, businesses, buildings, and room numbers, servers for web surveys, etc.) Be as specific as possible. Upload permission documentation in IRBNet, if applicable.

Part 4: Participants, Recruitment, and Compensation

4.1 Please select all the categories of participants that will be included in your study.

☐ASU Employees
☐ASU Students
☐Children Under 18
☐Cognitively Impaired Persons
☐Healthy Adult Volunteers
☐Pregnant or Nursing Women
☐Prisoners or Individuals under Detention
☐Persons Unable to Read, Speak, or Understand English
☐Persons with Limited Literacy
☐Persons with Specific Health Conditions
☐Persons in Foreign Countries
☐Other Category of Participants Not Listed (Specify):_____

4.2 Provide details concerning the participant population you have chosen for this project (e.g., age, gender, race, etc.).

4.3 Describe why this participant population is appropriate for inclusion in this research.

4.4 What is the minimum number of participants you will need to validate this study? _____

4.5 Is there a limit on the number of participants you will recruit? ☐No ☐Yes – the number is _____

4.6 Is there a limit on the number of participants you will include in the study? ☐No ☐Yes – the number is _____

4.7 Please select all of the tools that you plan to use to recruit your participants (a copy must be uploaded in IRBNet):

☐Email
☐Face to face communication
☐Flyers
☐Notices
☐Mailers (U.S. Postal)
☐Online advertisements
☐Presentation at meetings
☐TV, radio, print advertisements
☐Use of internet social media or online networking sites
☐Other (specify):_____

4.8 Describe, step-by-step, all procedures you will use to recruit participants.

4.9 Will participants be compensated for their participation?

☐**No compensation will be given**
☐**Yes, compensation will be given (specify) _____**

Part 5: Consent and Project Methodology

5.1 Will you document written informed consent?

☐Yes

☐No, I am seeking a waiver of documentation of written informed consent.

5.2 Will you obtain written assent for children and individual under 18?

☐Not applicable to this project

☐Yes

☐No, I am seeking a waiver of documentation of written assent.

5.3 Will you obtain written parental or guardian permission for children and individuals under 18?

☐Not applicable to this project

☐Yes

☐No, I am seeking a waiver of documentation of parental or guardian permission.

5.4 Describe, step-by-step, all procedures and methods that will be used to consent participants. If seeking a waiver of consent, please describe the conditions under which the waiver will be used and how participant consent will be determined.

5.5 Describe the procedures you will use in order to address your research purpose. Provide a step-by-step description of how you will carry out this research project.

5.6 Please provide an estimate of the time commitment from each participant of the study.

Part 6: Risk and Benefits

6.1 From the list below, please select ALL of the potential risks that are involved in your study.

☐Use of deceptive techniques (be sure to upload a debriefing form/script)

☐Use of private records (such as educational or medical records)

☐Manipulation of psychological or social state such as sensory deprivation, social isolation, psychological stress

☐Probing for personal or sensitive information in surveys or interviews (e.g.: private behaviors, employer assessments)

☐Presentation of materials which some participants may consider sensitive, offensive, threatening or degrading

☐Possible invasion of privacy of subject or subject's family

☐Social or economic risk (reputational, cultural, employability, etc.)

☐Identification of child, spousal, or elder abuse

☐Identification of illegal activity

☐Risk of injury or bodily harm

☐Breach of confidentiality

☐Other risks **(specify)** _____

6.2 List and describe the nature and degree of the risks or harms selected above. All of the risks/harms must be disclosed in the consent form. If you are using deception in this study, please justify the use of deception and be sure to upload a copy of the debriefing form you plan to use.

6.3 Identify and describe all precautions that will be taken to minimize or reduce the risks or harms list in 6.2 above in order to protect the welfare of participants. Include a description of how you will handle an adverse or unexpected outcome that could be potentially harmful (e.g., suicidal ideation). If the study will include protected populations, identify each group and provide an explanatory paragraph for each group. Please upload a copy of any emergency plans/procedures and medical referral lists, as needed.

6.4 If using the internet to collect data, what confidentiality or security precautions are in place to protect (or not collect) identifiable data? Include precautions used during both the collection and transfer of data. (These are likely on the server's website.)

6.5 List all realistic direct benefits participants can expect by participating in this specific study. (Do not include "compensation" listed in #4.10)

6.6 List all realistic benefits for the general population that may be generated from this study.

Part 7: Privacy, Confidentiality and Protection of the Data

7.1 Will data be collected as anonymous? ("Anonymous" means that you will **not** collect any identifiable data.)

☐Yes
☐No

7.2 Will data be collected as confidential? ("Confidential" means that you will collect and protect identifiable data)

☐Yes
☐No

7.3 Which identifiers listed below will you or any member of your research team collect or have access to? Select all that apply.

☐Name
☐Date of birth
☐Mailing or email address
☐Phone or fax numbers
☐Social Security number
☐Medical records
☐License, certificate or Vehicle ID
☐IP address
☐Biometric identifiers
☐Photos/images/audio recording
☐Signatures, handwriting samples
☐Any unique identifier not mentioned above (specify):_____

7.4 If data are collected as confidential, will the participants' data be coded or linked to identifying information?

☐No
☐Yes, describe how the data will be linked: _____

7.5 Justify your need to code participants' data or link the data with identifying information.

7.6 Where will the code list be stored? (Building, room number, location, etc…)

7.7 Will data collected as "confidential" be recorded and analyzed as "anonymous"?
(If you will maintain identifiable data, protections should have been described in #15.)
☐Yes
☐No

7.8 Describe how and where the data will be stored (e.g., hard copy, audio cassette, electronic data, etc.), and how the location where data are stored will be secured in your absence. For electronic data, describe security. If applicable, state specifically where any IRB-approved and participant-signed consent documents will be kept [on campus] for 3 years after the study ends.

7.9 Who will have access to participants' data? (The faculty advisor should have full access and be able to produce the data in the case of federal or institutional audit.)

7.10 What is the latest date that confidential data will be retained? _____
☐Check here if only anonymous data will be retained.

7.11 How will the confidential data be destroyed? (NOTE: Data recorded and analyzed as "anonymous" may be retained indefinitely.)

Part 7: Financial Conflict of Interest

Albany State University policy on Financial Conflicts of Interest Related to Research requires that **personnel conducting funded research** involving human participants at ASU to disclose known significant financial interests that would reasonably appear to be affected by the research project and that if the interest is deemed to constitute a conflict of interest with the proposed research, the conflict be managed prior to their engagement in the research with human participants.

7.1 Do any members of the research team or any of their immediate family members have any financial interest in the sponsor of this research and/or in the results of this research?
☐Yes (complete a complete and upload a financial conflict of interest form)
☐No

Part 8: Assurances

8.1 Principal Investigator(s) Assurances:

NOTE: In regards to student researchers, the Principal Investigator of the project will be the faculty advisor. The student will input the advisor's name in IRBNet as the Principal Investigator and will share the project with named person in IRBNet by giving them full access.

1. I certify that all information provided in this application is complete and correct.
2. I understand that, as Principal Investigator, I have ultimate responsibility for the conduct of this study, the ethical performance of this project, the protection of the rights and welfare of human subjects, and strict adherence to any stipulations imposed by ASU IRB.
3. I certify that all individuals involved with the conduct of this project are qualified to carry out their specified roles and responsibilities and are in compliance with ASU policies regarding the collection and analysis of research data.
4. I agree to comply with all ASU policies and procedures, as well as with all applicable federal, state, and local laws regarding the protection of human subjects, including, but not limited to the following:
    a. Conducting the project by qualified personnel according to the approved protocol
    b. Implementing no changes in the approval protocol or consent form without prior approval from the ASU IRB
    c. Obtaining the legally effective informed consent from each participant or their legally responsible representative prior to their participation in the project using only the currently approved consent form
    d. Promptly reporting significant adverse events and/or effects to the ASU IRB in writing within 5 working days of the occurrence.
5. If I will be unavailable to direct this research personally, I will arrange for a co-investigator to assume responsibility in my absence. This person has been named as co-investigator in this application, or I will advise the ASU IRB, in writing, in advance of such arrangements.
6. I agree to conduct this study only during the period approved the ASU IRB. (one year of approval date)
7. I will prepare and submit a renewal request and supply all supporting documents to the ASU IRB before the approval period has expired if it is necessary to continue the research project beyond the time period approved by ASU IRB.
8. I will prepare and submit a final report upon completion of this research project.

☐By checking this box I indicate that I have read, understand, and agree to conduct this research project in accordance with the assurances listed above.

Printed Name of Student Investigator	**Printed Name of Principal Investigator**

8.2 Faculty Advisor/Sponsor's Assurances

1. I certify that the project will be performed by qualified personnel according to the approved protocol using conventional or experimental methodology.
2. I agree to meet with the investigator on a regular basis to monitor study progress.
3. Should problems arise during the course of the study, I agree to be available, personally to supervise the investigator in solving them.
4. I assure that the investigator will promptly report significant adverse events and/or effects to the ASU IRB in writing within 5 working days of the occurrence. If I will be unavailable, I will arrange for an alternate faculty/sponsor to assume responsibility during my absence, and I will advise the ASU IRB in writing of such arrangements. If the investigator is unable to fulfill requirements for submission of renewal, modifications or the final report, I will assume that responsibility.
5. I have read the protocol submitted for this project for content, clarity, and methodology.

By providing my electronic signature IRBNet.org concerning this protocol, I certify that the student or guest investigator is knowledgeable about the regulations and policies governing research with human subject and has sufficient training and experience to conduct this particular study in accord with the approved protocol.

Printed Name of Research Advisor/Sponsor

8.3 Department Chair's or Dean's Assurance

By my signature electronic signature within IRBBet.org concerning this protocol, I certify that this research promotes compliance with Federal and State regulations, sponsor, and Institutional policies and procedures regarding the safety and welfare of human participants involved in research studies within the department. I have reviewed and approve this IRB application. I also assure the soundness of the research design, scientific and scholarly merit in relation to the department capacities and adequate staff and resources to conduct the study. I will cooperate with the administration in the application and enforcement of all ASU policies and procedures, as well as all applicable federal, state, and local laws regarding the protection and ethical treatment of human participants by researchers in my department/college. I also attest that the Principal Investigator will be allowed the time required to complete the research as described.

_____

Printed Name of Chair or Dean

Reminder Check List

All IRB protocols must include the following items (these items must be uploaded in IRBNet as separate documents):

☐Research Protocol Review/ Application Form (All sections completed)

☐Consent Form or Informational letter and any Releases (audio, video, or photo) that the participant will sign

☐Reference List

☐Copy of Human Subjects Training Certification(s)

☐If data is collected either from sites other than Albany State University or in cooperation with other academic institutions, hospitals or private research organizations, either a permission letter from the site(s)/ program director(s) or a letter of IRB approval from each entity is required prior to initiating the project.

☐If e-mails, flyers, advertisements, generalized announcements or scripts, etc., are used to recruit participants.

☐If data collection sheets, surveys, tests, other recording instruments, interview scripts, etc. will be used for data collection. Be sure to upload them in the order in which they are listed in #13c.

☐If you will be using a debriefing form or include emergency plans/procedures and medical referral lists. (A referral list may be attached to the consent document).

☐Written evidence of approval from either an academic chair/supervisor or IRB of the foreign institution if data is collected at or in collaboration with an institution outside the United States.