1. APPLICATION INSTRUCTIONS
	1. Review the IRB application checklist
	2. Complete each section of this document.
	3. Email the completed application, with the following supporting documents as an appendix to IRB@sienaheights.edu. **ONLY USE YOUR SHU EMAIL (or academic email if not a SHU student/faculty). ALL SUPPORTING DOCUMENTS MUST BE COPY/PASTED OR INSERTED INTO THE APPENDIX FIELD AT THE END OF THE APPLICATION….ONLY 1 DOCUMENT SHOULD BE SUBMITTED.**
		1. Consent forms, permission letters, recruitment materials
		2. Surveys, Questionnaires, Interview Questions, Focus Group Questions
		3. Certificate/Evidence of completion of Protecting Human Research Participant training
		4. Please use subject line to identify what you are sending: Application version 1, etc.
	4. Save document: IRB\_Last name, first initial\_date
	5. If you plan to use a specific Siena Heights University department or population for your study, you will need to obtain permission from the appropriate department chair/director/dean/coach/etc. Submit documentation of permission (email or letter) to the IRB in the appendix of your application. Check the appropriate box on the application.
	6. Once received, the IRB processes applications at a first-come, first-served basis. Applications Review Periods: Fall and Winter semesters from the first day of classes of the semester-last day of classes of the semester.
	7. Preliminary review may take 2-4 weeks.
	8. Most applications will require revisions.
	9. The entire process length will vary and is greatly affected by the length of time it takes for revisions to be completed and submitted.

Note: Applications and supporting documents with the following problems will be returned immediately for revisions:

1. Grammar, spelling, or punctuation errors
2. Lack of professionalism
3. Lack of consistency or clarity
4. Incomplete applications
5. Plagiarism

*\*\*Failure to minimize these errors* ***will*** *cause delays in your processing time\*\**

1. **BASIC PROTOCOL INFORMATION**

|  |
| --- |
| **1. STUDY/THESIS/DISSERTATION TITLE** |
| Title: |

|  |
| --- |
| **2. INVESTIGATOR AND PROTOCOL INFORMATION** |
| Principal Investigator (**FACULTY**): |
| Professional Title: |
| School/Department: |
| Phone: | SHU E-mail: |
|  |
| Student/Secondary Researcher: |
| Professional title (students use ‘student’): |
| Phone: | SHU E-mail: |
| **Check all that apply:** |
| Undergraduate Student |  |  | Staff |  |  |
| Graduate Student |  |  | Other  |
| Faculty |  |  |  |
| **This research is for:** |
| Class Project |  |  | Master’s Thesis |
| Faculty Research |  |  | Doctoral Dissertation |  |
| Staff Research |  |  | Other |

|  |
| --- |
| **3. USE OF Siena Heights University PARTICIPANTS** |
| **Do you intend to use SHU students, staff, or faculty as participants or Data Sources?****NO (Proceed to Funding Source #4****Yes (Complete the section immediately below):** |
| **# of Participants/Data Sets:** | **Department Source:** |
| **Class(es)/Year(s):** | **Department Chair:** |
| **Obtaining permission to utilize SHU participants (check the appropriate box below)** |
| **DEPARTMENT(S) and/or GROUP(S):** If you are including faculty, students, or stafffrom multiple departments or groups (i.e. all sophomores or SHU Online), the IRB will need approval from the appropriate Dean/Administrator. |
| I have obtained permission from ALL of the appropriate Dean/Department Chair/Administrator/Coach and have included the necessary documentation to this Application (in Appendix) |

|  |
| --- |
| **4. FUNDING SOURCE** |
| **Is your research funded?**No (proceed to Study Dates) |
|  |  | Yes (complete the section immediately below) |
| **Grant Name/Funding Source/Number:** |
| **Funding Period (Month/Year):** |

|  |
| --- |
| **5. STUDY DATES** |
| **When do you plan to perform your study?***(Approximate dates for collection/ analysis):***Start** (*Month/Year*): **Finish** (*Month/Year*): |

|  |
| --- |
| **6. COMPLETION OF REQUIRED HUMAN RESEARCH PARTICIPANT PROTECTION TRAINING** |
| **List Course Name(s):** |
| **Date(s) of Completion:** |
| **Evidence of completion included in Appendix** |

1. **OTHER STUDY MATERIALS AND CONSIDERATIONS**

☐

☐

|  |
| --- |
| **7. STUDY MATERIALS LIST** |
| **Please indicate whether your proposed study will include any of the following:** |
| **Recording/photography of participants (voice, video, or images)?** | Yes | No |
| **Participant compensation (gift cards, meals, extra credit, etc.)?** | * Yes
 | * No
 |
| **Advertising for participants (flyers, TV/Radio advertisements)?** | * Yes
 | * No
 |
| **More than minimal physical/psychological stress?** | * Yes
 | * No
 |
| **Confidential data collection (participant identities not known)** | * Yes
 | * No
 |
| **Archival data collection (data previously collected for another purpose)?** | * Yes
 | * No
 |
| **More than minimal risk? \*** | * Yes
 | * No
 |
| **Consumption of food or drink?** | * Yes
 | * No
 |
| **Protected health information?** | * Yes
 | * No
 |
| **Pilot study procedures (which will be published/included in data analysis?** | * Yes
 | * No
 |
| ***\*Note:*** *Minimal risk is defined as “the probability and magnitude of harm or discomfort anticipate in the research are not greater in and of themselves than those ordinarily encountered in everyday life or during the performance of routine physical or physiological examinations or tests”. [45 CFR 46.102(i)].* |  |

|  |
| --- |
| **8.PURPOSE** |
| **Write an original, brief, non-technical description of the purpose of your research.** Include in your description your research hypothesis/question, a narrative that explains the major constructs of your study, and how the data will advance your research hypothesis or question. This section should be easy to read for someone not familiar with your academic discipline (a course requirement is NOT a purpose): |

1. **PARTICIPANT INCLUSION/EXCLUSION CRITERIA**

|  |
| --- |
| **9.STUDY POPULATION** |
| **Provide the inclusion criteria for the participant population** (*example: gender, age range, ethnic background, health status, occupation, employer, etc.*) |
| **Provide a rationale for selecting the above population** (*example: Why will this specific population enable you to answer your research questions*) |
| **Will your participant population be divided into different groups (**example: experimental and control groups)?* No
* Yes (***Describe the groups and explain how groups will be selected/assigned, include maximum number of participants you plan to enroll for each participant population and justify the sample size*** *(you will not be approved to enroll a number greater than the number*

*listed. If at a later time it becomes apparent that you need to increase your sample size- submit a request to Change Protocol and wait for approval to procede):* |
| **Are you related to any of your participants?*** No
* Yes (*Explain*):

☐ |
| **Indicate who will be excluded from your study population** *(example: persons under 18 years of age):* |
| **If applicable, provide rationale for involving any special populations** *(example: children, ethnic groups, individuals with impaired decisions-making ability or low socio-economic status, or prisoners):* |

|  |
| --- |
| **10.TYPES OF PARTICIPANTS** |
| **Who will be the focus of your study?** *(check all that apply)* |
| * Typical Participants (Age 18-65)
 | * Pregnant Women
 |
| * Minors (under age 18)
 | * Individual with cognitive impairment or developmental delays
 |
| * Over Age 65
 | * Individuals with physical impairment
 |
| * College/University Students
 | * Participants Incapable of Giving Consent
 |
| * Active-Duty/Military Personnel
 | * Prisoners of Institutional Individuals
 |
| * Discharged/Retired Military Personnel
 | * Special Ethnic/Racial Group(s)
 |
| * Inpatients
 | * Other potentially elevated risk populations
 |
| * Outpatients
 | * Participant(s) related to the researcher
 |
| * Patient Controls
 |  |
| **ANSWER THE FOLOWING QUESTION ONLY IF YOU ARE CONDUCTING A PROTOCOL WITH NIH, FEDERAL, OR STATE FUNDING:***Researchers sometimes believe their particular project is not appropriate for certain types of participants. These may include, for example, women, minorities, and children. If you believe your project should not include one or more of these groups, please provide your justification for their exclusion. Your justification will be reviewed**according to the applicable NIH, federal, or state guidelines:* |

1. **RECRUTMENT OF PARTICIPANTS**

|  |
| --- |
| **11. CONTACTING PARTICIPANTS/SAMPLING PROCEDURE** |
| **Describe in detail how you will contact participants regarding this study** *(include the method(s) used-email, phone call, social media, snowball sampling, in-person, etc.)***:** |
| **Describe in detail your sampling method (***Random sampling, systematic sampling, convenience sampling, cluster sampling, stratified sampling***):** |

|  |
| --- |
| **12. SUBMISSION OF RECRUITMENT MATERIALS** |
| **Submit a copy of all recruitment letters, scripts, emails, flyers, advertisements, or social media posts you plan to use to recruit participant for you study in the appendix.**. |
| **Check the appropriate box:** |
| * N/A (I am not using recruitment materials).
 |
| * All of the necessary recruitment materials will be submitted with my application.
 |
| **If you plan to provide documents in a language other than English:** |
| * I will submit a translated copy of my recruitment materials along with English version
 |

|  |
| --- |
| **13. LOCATION OF RECRUITMENT:** |
| **Describe the location, setting, and timing of recruitment:** |

|  |
| --- |
| **14. SCREENING PROCEDURES** |
| **Describe any procedures you will use to ensure that your participants meet your study criteria** *(example: a screening survey or verbal confirmation to verify that participants are 18 or older):* |

|  |
| --- |
| **15. CONFLICTS OF INTEREST** |
| Conflicts of interest are “situations in which financial or other personal considerations may compromise, or have the appearance of compromising, an investigator’s judgement in conducting or reporting research” AAMS, 1990. |
| **Do you have a position of academic or professional authority over the participants** *(example: You are the participants’ teacher, principal, supervisor, or district/school administrator.)?** No
* Yes *(Explain what safeguards are in place to reduce the likelihood of compromising the integrity of the research-addressing the conflicts in the consent process and/or emphasizing the pre-existing relationship will not be impacted by participation in the research.):*
 |
| **Do you have any financial or personal conflicts of interest to disclose** *(example: Do you or an immediate family member receive income or other payments, own investments in, or have a relationship with a non-profit organization that could benefit from this research)?** No
* Yes *(State the funding source/financial conflict ant then explain what safeguards are in place to reduce the likelihood of compromising the integrity of the research):*
 |

1. **RESEARCH PROCEDURES**

|  |
| --- |
| **16. PROCEDURES** |
| **Write an original, non-technical, step-by-step description of what your participants will be asked to do during your study and data collection process.** If you have multiple participant groups (ex: parents, teachers, and students) or control and experimental groups, please specify which group you are asking to complete which task(s). |
| **Step/Task/Procedure** | **Time to complete Procedure** *(Approximate)* | **Participant Group(s)***(All, Group A, Group B, Control Group, Experimental Group, etc.)* |
| **1.** |  |  |
| **2.** |  |  |
| **3.** |  |  |
| **4.** |  |  |
| **5.** |  |  |
| **6.** |  |  |
| **7.** |  |  |
| **8.** |  |  |
| **9.** |  |  |
| **10.** |  |  |
| **Note:** *For complex study designs, additional diagrams, timelines, or figures may be submitted separately in the appendix.* |

|  |
| --- |
| **17. SUBMISSION OF DATA COLLECTION INSTRUMENTS/MATERIALS** |
| **Submit a copy of all instruments, surveys, interviews questions, outlines, observation checklists,****prompts, etc.** that you plan to use to collect data for your study in your appendix separate at the end of your application. Pdfs are ONLY acceptable for proprietary instruments (insert Pdf). |
| Check the appropriate box: |
| * All of the necessary data collection instruments will be submitted with my application.
 |
| * My study strictly uses archival data, so data collection instruments are not applicable
 |
| **If you plan to provide documents in a language other than English** |
| * I will submit a translated copy of my study instrument(s) along with the English version(s).
 |

|  |
| --- |
| **18. STUDY LOCATION** |
| **Please state the actual location(s)/site(s) in which the study will be conducted.** Be specific (*include city, state, school/district, clinic, etc.)*: |
| ***Note:*** *Investigators must submit documentation of permission from some research sites to the IRB prior to receiving approval. If your study involves K-12 public schools, district-level approval is acceptable as opposed to submitting separate permission documentation from each school. If your study involves colleges or universities, hospitals, or prisons, you may also need to seek IRB approval from those institutions. You may seek permission prior to submitting your IRB application; however, do not begin**recruiting participants. If you find that you need a conditional approval letter from the IRB to obtain permission, the IRB will provide one once you have completed all requested revisions.* |

1. **DATA ANALYSIS**

|  |
| --- |
| **19. ANALYSIS METHODS** |
| **Describe how the data will be analyzed (include plan, be specific. For example, what statistical test(s) will be utilized: t-test, ANOVA, etc.)** |
| **Describe plans (if any) for dissemination of results that include data.** |

1. **PARENTAL/GAURDIAN CONENT**

|  |
| --- |
| **20. PARENTAL/GAURDIAN CONENT REQUIREMENTS** |
| **Does your study require parental/guardian consent?** *(If your participants are under 18, parental/guardian consent is required in most cases.)** No **(Proceed to Child Assent)**
* Yes (Answer the following question)
 |
| **Does your study entail greater than minimal risk without the potential for benefits to the participant?*** No
* Yes (consent of both parents in required, provide documentation in Appendix)
 |
| **CHILD ASSENT** |
| **Is assent required for your study?** *(Assent is required unless the child is not capable of assenting due to age, psychological state, or sedation OR the research holds out the prospect of a direct benefit that is only available within the context of the research.)** No **(Proceed to Consent Procedures)**
* Yes
 |

1. **PROCESS OF OBTAINING INFORMED CONSENT**

|  |
| --- |
| **21. CONSENT PROCEDURES** |
| **Describe in detail *how and when* you will provide the participants with consent (OR assent/parental consent information if applicable)** *(e.g., as an attachment to your recruitment email, as the first page participants see after clicking on the survey link, etc.):* |
| **Describe in detail *how and when* consent forms will be signed and returned to you** *(e.g., participants will type their names and the date on the consent form before completing the online survey, participants will sign and return the consent forms when you meet for their interview, etc.):* |
| **Submit a copy of all informed consent (OR Assent) documents in your Appendix.** (Informed consent template is available on the SHU IRB Website).* All of the necessary consent/assent documents will be submitted in my appendix. *(if any documents are submitted in a language other than English a translated copy must be included)*
* My study strictly uses archival data, so consent documents are not required.
 |

1. **WAIVER OF INFORMED CONSENT OR MODIFICATION OF REQUIRED ELEMENTS IN THE INFORMED CONSENT PROCESS**

|  |
| --- |
| **22. WAIVER OF INFORMED CONSENT, ELEMENTS OR MODIFICATION OF ELEMENTS****IN MOST CASES THIS SECTION DOES NOT APPLY TO UNDERGRADUATE STUDENT RESEARCH****(check no and skip to #23)** |
| **Does your study qualify for a waiver of informed consent or modification of required elements in the informed consent process?*** **No, I will not request a waiver of consent or assent (Skip to 23)**
* **Yes (review the following questions…Please indicate why you are requesting a waiver of consent Check the appropriate option below:**
 |
| **Does the research pose no more than minimal risk to participants** *(example: no more risk than that of everyday activities)*?* No, *the study is greater than minimal risk.*
* Yes, *the study is minimal risk.*
 |
| **Will the waiver have no adverse effects on participant rights and welfare?*** *No, the waiver will have adverse effects on participant rights and welfare.*
* *Yes, the waiver will not adversely affect participant rights and welfare.*
 |
| **Would the research be impracticable without the waiver?*** No, *there are other ways of performing the research without the waiver.*
* *Yes, not having a waiver would make the study unrealistic.* Explain:
 |
| **Will participant debriefing occur** *(i.e., Will the true purpose and/or deceptive procedures used in the study be reported to participants at a later date?)?** No, *participants will not be debriefed.*
* Yes, *participants will be debriefed.*
 |
| ***Note:*** *A waiver or modification of some or all of the required elements of informed consent is sometimes used in research involving deception or archival data.* |
| * **No, I will not request a waiver of signed consent (Skip to 23)**
* **Yes (review the following questions…Please indicate why you are requesting a waiver of consent Check the appropriate option below:**
 |
| **Would a signed consent form be the only record linking the participant to the research?*** No, *there are other records/study questions linking the participants to the study.*
* Yes, *only the signed form would link the participant to the study.*
 |
| **Does a breach of confidentiality constitute the principal risk to participants?*** No, *there are other risks involved greater than a breach of confidentiality.*
* Yes*, the main risk is a breach of confidentiality.*
 |
| **Does the research pose no more than minimal risk to participants** *(i.e., no more risk than that of everyday activities)?** No*, the study is greater than minimal risk.*
* Yes*, the study is minimal risk.*
 |
| **Does the research include any activities that would require signed consent in a non- research context (***e.g., liability waivers)?** No, *there are not any study related activities that would normally require signed consent*
* Yes, *there are study related activities that would normally require signed consent*
 |

|  |
| --- |
| **If your reason does not appear as an option, please explain here:** |
| **Are the subjects or their legally authorized representatives (LARs) members of a distinct cultural group or community in which signing forms is not the norm?*** No, *the subjects/their LARs are not members of a distinct cultural group or community in which signing forms is not the norm.*

Yes, *the subjects/their LARs are members of a distinct cultural group or community in whichsigning**forms is not the norm, and there is an appropriate alternative mechanism for documenting that informed consent was obtained.* |
| **Will you provide the participants with a written statement about the research** (*i.e., an information sheet that contains all of the elements of an informed consent form but without the signature lines)*?* No, *participants will not receive written information about the research.*
* Yes, *participants will receive written information about the research.*
 |
| ***Note:*** *A waiver of signed consent is sometimes used in anonymous surveys or research involving secondary data. This does not eliminate the need for a consent document, but it eliminates the need to obtain participant signatures* |

1. **USE OF DECEPTION**

|  |
| --- |
| **23. DECEPTION** |
| **Are there any aspects of the study kept secret from the participants** *(e.g., the full purpose of the study, assignment or use of experimental/control groups, etc.)?** No
* Yes *(Describe the deception involved and the debriefing procedures.):*
 |
| **Is deception used in the study procedures?*** No
* Yes *(Describe the deception involved and the debriefing procedures.):*
 |

1. **PARTICIPANT PRIVACY, DATA SECURITY, & MEDIA USE**

|  |
| --- |
| **24. PRIVACY** |
| Describe the steps you will take to protect theprivacy of your participants (e.g., maintain private interview, scrub IP addresses? |
| ***Note:*** *Privacy refers to persons and their interest in controlling access to their information.* |

|  |
| --- |
| **25. DATA SECURITY** |
| **How will you keep your data secure** *(i.e., password-locked computer, locked desk, locked filing cabinet, etc.)?* |
| **Who will have access to the data** *(i.e., the researcher and faculty mentor/chair, only the researcher, etc.)?* |
| **Will you destroy the data once the three-year retention period required by federal regulations expires?*** No
* Yes *(Explain how the data will be destroyed.):*
 |
| ***Note****: All research-related data must be stored for a minimum of three years after the end date of the study, as required by federal regulations.* |

|  |
| --- |
| **26. ARCHIVAL DATA (SECONDARY DATA)** |
| **Is all or part of the data archival** (*i.e., previously collected for another purpose)?** No *(Proceed to Non-Archival Data #27)*
* Yes *(Answer the questions below.)*
 |
| **Is the archival data publicly accessible?*** No (*Explain how you will obtain access to this data.):*
* Yes *(Indicate where the data is accessible from, i.e., a website, etc.):*
 |

|  |
| --- |
| **Will you receive the raw data stripped of identifying information** (*e.g., names, addresses, phone numbers, email addresses, IP addresses, social security numbers, medical records, birth dates, etc.)?** No (*Describe what data will remain identifiable and why this information will not be removed.):*
* Yes *(Describe who will link and/or strip the data—this person should have regular access to the data and should be a neutral party not involved in the study.):*
 |
| **Can the names or identities of the participants be deduced from the raw data?*** No *(Place your initials in the box: I will not attempt to deduce the identity of the participants in this study.):*

***□*** Yes *(Describe):* |

|  |
| --- |
| **Please provide the list of data fields you intend to use for your analysis and/or provide the original instruments used in the study:**I have added my instrument to appendix |
| ***Note:*** *If the archival data is not publicly available, submit proof of permission to access the data (i.e., school district letter or email). If you will receive data stripped of identifiers, this must be stated in the proof of permission letter or email.* |

|  |
| --- |
| **27. NON-ARCHIVAL DATA (PRIMARY DATA)** |
| If you are using non-archival data, will the data be anonymous to you (*i.e., Raw data does not contain identifying information and cannot be linked to an individual/organization by use**of pseudonyms, codes, or other means.)?* Note: For studies involving audio/video recording or photography, select “No”* N/A: I will only use archival data. (*Skip to Media*.)
* YES: My data will contain identifiers. (Complete the “No” section below.)
* NO: My data will not contain identifiers.
 |
| **\*\*COMPLETE THIS SECTION IF YOU ANSWERED “YES” TO QUESTION 27\*\*** |
| **Can participant names be deduced from the raw data?*** No
* Yes (*Describe*):
 |
| **Will a person be able to identify a subject based on other information in the raw data** *(i.e., title, position, sex, etc.)*?* No
* Yes *(Describe):*
 |
| **Describe the process you will use to ensure the confidentiality of the participants during data collection and in any publication(s)** *(i.e., You may be able to link individuals/organizations to identifiable data; however, you will use pseudonyms or a coding system to conceal their identities.):* |
| **Do you plan to maintain a list or codebook linking pseudonyms or codes to participant identities?*** No *(Justify):*
 |
| * **Yes (Please describe where this list/codebook will be stored and who will have access to the list/codebook. Explicitly state that the list will not be stored with the data):**
 |

|  |
| --- |
| **28. MEDIA USE** |
| **Will your participants be audio recorded?** | * No ☐Yes
 |
| **Will your participants be video recorded?** | * No ☐ Yes
 |
| **Will your participants be photographed?** | * No ☐Yes
 |
| **\*\*COMPLETE THIS SECTION IF YOU ANSWERED “YES” TO ANY MEDIA USE\*\*** |
| **Include information regarding how participant data will be withdrawn if he or she chooses to leave the study\*** |
| **Will your participants be audio recorded, video recorded, or photographed without their knowledge? \*\**** No
* Yes (*Describe the deception and debriefing procedures*):
 |
| **Describe the process you will use to collect the data to ensure that it is anonymous:** |
| **Place your initials on the line:** I will not attempt to deduce the identity of the participants inthis study: |
| ***Note****: If you plan to use participant data (i.e., photos, recordings, videos, drawings) for presentations**beyond data analysis for the research study (e.g., classroom presentations, library archive, or conference presentations) you will need to provide a materials release form to the participant* |

1. **PARTICIPANT COMPENSATION**

|  |
| --- |
| **29. COMPENSATION** |
| **Will participants be compensated (e.g., gift cards, raffle entry, reimbursement, food)?*** No (*Proceed to Risks*)
* Yes (*Describe*):
 |
| **Will compensation be pro-rated if the participant does not complete all aspects of the study?*** No
* Yes (*Describe*.):
 |
| ***Note:*** *Certain states outlaw the use of lotteries, raffles, or drawings as a means of compensating research participants. Research compensation exceeding $600 per participant within a one-year period is considered income and will need to be filed on the participant’s income tax returns. If your study is grant funded, Liberty University’s Business Office policies might affect how you compensate participants. Contact the IRB for additional information.* |

1. **PARTICIPANT RISKS AND BENEFITS**

|  |
| --- |
| **30. RISKS** |
| **Describe the risks to participants and any steps that will be taken to minimize those risks.** (*Risks can be physical, psychological, economic, social, or legal. If the only potential risk is a breach in confidentiality if the data is lost or stolen, state that here*): |
| **Will alternative procedures or treatments that might be advantageous to the participants be made available?*** No
* Yes (*Describe*):
 |
| **ANSWER THE FOLLOWING QUESTION ONLY IF YOUR STUDY IS CONSIDERED GREATER THAN MINIMAL RISK:** |
| **Describe provisions for ensuring necessary medical or professional intervention in the event of adverse effects to the participants** (e*.g., proximity of the research location to medical facilities or your ability to provide counseling referrals in the event of emotional distress*): |

|  |
| --- |
| **31. BENEFITS** |
| **Describe the possible direct benefits to the participants.** (*If participants are not expected toreceive direct benefits, please state “No direct benefits.” Completing a survey or participating in an interview will not typically result in direct benefits to participants*.):Click or tap here to enter text. |
| **Describe any possible benefits to society:** |
| **Evaluate the risk-benefit ratio.** (*Explain why you believe this study is worth doing, even with**any identified risks*): |

1. **ASSURANCE DOCUMENT FOR HUMAN SUBJECTS RESEARCH**

|  |
| --- |
| **3. ASSURANCE DOCUMENT** |
| *Please read the following document carefully. Indicate your acceptance of the specified conditions by typing your initials below.* |

The research described in this application involves the use of human subjects. As the Principal Investigator of this project, I hereby attest that I have carefully reviewed and understand the University’s policy regarding research with human subjects and I agree to comply fully with each of the conditions listed below. I further understand that any violation of these conditions by myself or co- investigator(s) constitutes sufficient grounds for the IRB to deny/revoke this application and/or to terminate the research project.

I agree:

* + To insure that all subjects are told they are participating in a research study and that such participation is voluntarily.
	+ That all subjects are fully informed of the principal investigator’s identity and affiliation, the risks and benefits of participation, their rights as subjects, and contact information to obtain more information about the research.
	+ That the proposed research conforms to the criteria in 45 Code of Federal Regulations 46.117(c) regarding informed consent, including whether a *signed* informed consent must be obtained for the purposes of this research.
	+ That, generally, subjects will not be deceived about the purposes or methods of this research during the execution of the study. In rare instances when deception is employed, it willstrictly adhere to the limited conditions described in the research protocol and approved by the Institutional Review Board (IRB).
	+ To report to the IRB any unanticipated effects on subjects which become apparent during the course of, or as a result of, any research activities.
	+ To obtain prior approval from the IRB before amending or altering the scope of this project.
	+ To maintain all documentation as required by institutional policy and to cooperate with members of the IRB charged with the continuing review of this project.
	+ To safeguard the confidentiality of research subjects and the data collected when the approved level of research requires it.

***I hereby attest that every reasonable effort has been made to abide by the ethical guidelines set forth by the governing organization of my academic discipline and the institutional guidelines of Siena Heights University for the use of human subjects in research. I will exercise every reasonable effort to safeguard the rights and welfare of all subjects in this research project. I agree to comply with all of the conditions specified above.***

**P.I. Initials Date**

**S.I. Initials Date**

**Submit Appendix in ONE document**

**Provide the Appendix Table of Contents below:**