Valdosta State University

APPLICATION FOR USE OF HUMAN PARTICIPANTS IN RESEARCH

(NOTE: This is not a fillable form; it is intended for printing and completion by hand.)

INSTRUCTIONS: Print this form, check all appropriate boxes, answer all questions completely, include all attachments, read certification statement, and sign. Submit package to the Office of Grants & Contracts. ***(NOTE: Incomplete applications will be returned unreviewed.)***

FOR IRB USE ONLY: **IRB -** _____ **-** _____
Received: _____ Reviewed: _____
Exemption: ☐ Yes ☐ No Category(ies): _____
Reviewer Signature: _____
Expedited: ☐ Yes ☐ No Category(ies): _____

Project Title: _____

Responsible Researcher: _____

Department: _____

E-mail: _____ **Telephone:** _____

Mailing Address *(if Student):*

_____
_____

Project Dates: From ___/___/___ To: ___/___/___
MM DD YY MM DD YY

Minimum # of Participants (including controls): _____
Maximum # of Participants (including controls): _____

External Funding: ☐ Yes ☐ No
***If YES,* Sponsor:** _____

(Note: If the research is or will be externally funded, include a copy of the portion of the proposal or award that describes the use of human participants with your application.)

VSU Status:
☐ General Faculty
☐ Adjunct Faculty
☐ Research Associate
☐ Administrator/Staff Member
☐ Graduate Student
☐ Undergraduate Student
☐ Other: _____

If you are a VSU student, please indicate the academic purpose of the proposed research:
☐ Doctoral Dissertation
☐ Master's Thesis
☐ Undergraduate/Honors Senior Project
☐ Other: _____

(Note: If your research is subject to oversight by another institution's IRB (i.e., the research is intended to satisfy degree requirements at another institution), please consult with the IRB Administrator by calling 229-259-5045.

Co-Investigator Name(s)	Institutional Affiliation*	E-mail Address	IRB FWA Number

*****If not affiliated with Valdosta State University. If any Co-Investigator is not affiliated with an institution that has a federally-assured IRB, he/she will be required to complete IRB training and execute an "Unaffiliated Investigator Agreement" with the VSU IRB.*

Applicability of IRB Oversight of Student-Conducted Projects:

Most student-conducted **class assignments** that involve observing, surveying, interviewing, or otherwise interacting with other individuals do not constitute "research" as defined by the VSU IRB and are not are not subject to IRB oversight. Specifically, the following types of student projects that do not require IRB oversight include those that:

- Are conducted solely within the confines of the classroom or within a departmental research participant pool if they:
  -- are a general requirement of a course,
  -- have the sole purpose of developing the student's research skills, and
  -- will be overseen by a faculty member; or
- Are conducted outside the classroom and outside departmental research participant pools, provided they do not involve minors, do not target vulnerable adult populations, do not pose a risk of physical harm to pregnant women and fetuses, do not deal with a topic of sensitive or personal nature unless data are collected anonymously, and do not involve any type of activity that places the participants at more than minimal risk. ("Minimal risk" is defined in Question 9 of this application form.)

Other student-conducted research activities that are not subject to IRB overview as independent research protocols include those that:

- Are part of a larger research project that has current Valdosta State University IRB approval, and the approved protocol includes student engagement in the specific activities; or
- Are part of a larger research project that has current approval of a federally assured IRB at another institution.

If you are a student conducting a class project that fits the above description and your instructor concurs, your project is not subject to IRB oversight and no application is required.

1. ☐ YES ☐ NO Does your proposed study meet the Valdosta State University Institutional Review Board definition of *research* as described below?

All research involving human participants conducted by Valdosta State University faculty, staff, and students and staff is subject to IRB review. **The Valdosta State University IRB defines "research" as a *systematic* investigation, including research development, testing and evaluation, designed to develop or contribute to *generalizable knowledge.***

Some student-conducted studies that may not meet the definition of "research" provided above but involve human participants are subject to IRB oversight if they:

- Are undertaken with the intent to produce results that will be submitted for peer-reviewed publication or presentation;
- Include minors (e.g., persons under the age of 18);
- Target potentially vulnerable individuals (e.g., those whose capacity to freely give consent may be compromised because of socio-economic, educational, or linguistic disadvantage; cognitive impairment; advanced age; or terminal illness)
- May place pregnant women and/or fetuses at risk of physical harm;
- Deal with a topic of a sensitive or personal nature in a way in which anonymity cannot be sustained and the examination or reporting of participant responses or behavior may be potentially stigmatizing or may place the participant at more than minimal risk physically, psychologically, socially, or economically or for civil or criminal liability;
- Involvesany other type of activity that places the participants at more than minimal risk, considering both the probability and the magnitude of harm. (See Question 9 for a full definition of "minimal risk.")

2. ☐ YES ☐ NO Are the human participants in your study *living* individuals or are you are collecting information about deceased persons that may put third parties (i.e., surviving spouses and/or living descendents) at more than minimal risk of harm? ("Minimal risk" is defined in Question 9 of this application form.)

*If you answered NO to Question 1 **or** 2, stop here; no review is required, submitting this form is not necessary. If you answered YES to **both** questions, continue.*

3. ☐ YES ☐ NO Will you obtain data through *intervention* or *interaction* with living or third party individuals?

"Intervention" includes both physical procedures by which data are gathered (*e.g.,* measurement of heart rate or venipuncture) and manipulations of the participant or the participant's environment that are performed for research purposes. "Interaction" includes communication or interpersonal contact between the investigator and participant (*e.g.,* surveying or interviewing).

4. ☐ YES ☐ NO Will you obtain *identifiable private information* about these individuals?

'Private information' includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, or information provided for specific purposes which the individual can reasonably expect will not be made public (*e.g.,* a medical record or student record). 'Identifiable' means that the identity of the participant may be ascertained by the investigator or associated with the information (*e.g.,* by name, code number, pattern of answers, etc.).

*If you answered NO to Questions 3 **and** 4, stop here. No review is required, and it is not necessary to submit this form. If you answered YES to **either** question, continue.*

EDUCATIONAL REQUIREMENTS: In accordance with federal regulations, the VSU IRB requires all responsible researchers, co-investigators, key personnel, including unaffiliated investigators, and faculty advising student researchers to complete an educational program. Co-investigators from other institutions are not required to complete the VSU educational program if they have a current certificate of training from their own federally assured IRB. Key personnel are those individuals who will play a role in designing, conducting, and/or reporting on the research. Unaffiliated investigators are those individuals not affiliated with VSU or another institution or organization that has a federally assured IRB. Educational requirements must be met before the IRB will review your research protocol for either exemption or approval. The IRB strongly recommends that the required CITI educational program be completed ***before*** you finalize your research protocol, as it may provide information on research design and considerations that will enhance protections for your research participants.

VSU's educational program is available on-line at <http://www.citiprogram.org>. **All responsible researchers, VSU co-investigators, key personnel, unaffiliated investigators, and faculty advisors must successfully complete, at a minimum, the following CITI modules:**

1. Introduction
2. History and Ethical Principles–SBR
3. Defining Research with Human Subjects–SBR
4. The Regulations and the Social and Behavioral Sciences–SBR
5. Basic Institutional Review Board (IRB) Regulations and Review Process
6. Assessing Risk in Social and Behavioral Sciences–SBR
7. Informed Consent–SBR
8. Privacy and Confidentiality–SBR
9. Valdosta State University Module

Additional modules may be required for specific types of research, as indicated in Question 5.

5. Characteristics of the Target Population *(check all that apply and complete the CITI modules indicated*):

(Note: Characteristics are not mutually exclusive. For example, if your are proposing research involving children in public schools, both the "Research with Children – SBR" and "Research in Public Elementary and Secondary Schools – SBR" modules are required.)

Study population targets…	**Additional CITI Modules Required**
☐ a. Minors (individuals under 18 years of age); **Age(s):** _____	Research with Children – SBR
☐ b. Public school (PK-12) children; **Grade Level(s):** _____	Research in Public Elementary and Secondary Schools – SBR
☐ c. Pregnant women or fetuses	Vulnerable Subjects - Research Involving Pregnant Women and Fetuses in Utero
☐ d. Prisoners (adults or juveniles involuntarily confined or detained in a penal institution, detained in other facilities which provide alternatives to criminal prosecution or prison, or individuals detained pending arraignment, trial, or sentencing)	Research with Prisoners – SBR
☐ e. Potentially vulnerable individuals (e.g., those whose capacity to freely give consent may be compromised because of socio-economic, educational, or linguistic disadvantage; cognitive impairment; advanced age; or terminal illness)	Research with Protected Populations – Vulnerable Subjects: An Overview
☐ f. Individuals in foreign countries	International Research – SBR
☐ g. Individuals from different cultures or individuals from a particular racial/ethnic group	Group Harms: Research with Culturally or Medically Vulnerable Groups
☐ h. Individuals about whom data will be collected from records (e.g., educational, health, or employment records)	Records-Based Research
☐ i. Individuals from or about whom Private Health Information (PHI) subject to HIPAA compliance will be collected	HIPAA and Human Subjects Research
☐ j. Individuals from whom information will be collected via the Internet	Internet Research – SBR
☐ k. VSU employees	Workers as Research Subjects—A Vulnerable Population

6. Does the Primary Researcher, any Co-Investigator, or any other key person have a potential or actual significant financial conflict of interest in performance of the research?

☐ **Yes** ☐ **No** **If YES,** ***complete*** *CITI module " Conflicts of Interest in Research Involving Human Subjects"* ***AND complete and attach*** *a VSU Conflict of Interest form (available at <http://www.valdosta.edu/grants/forms>).*

A "conflict of interest" may arise when a key member of the research team has the opportunity to influence the research in ways that could lead to personal gain or advantage of any kind and possibly impact the rights and welfare of participants involved in the research. A "significant financial conflict of interest" is defined as income or equity interests over $10,000 per year or 5 percent or greater ownership in a company with interests related to research results by the researcher or his/her spouse and/or dependent children. For details, see the VSU policy on Conflict of Interest at <http://www. valdosta.edu/grants/coi.shtml>.

When you have completed all required CITI modules, print a copy of your training certificate and *attach* it to this application. You may reprint your certificate at any time from the CITI website at <http://www.citiprogram.org>.

7. Will you be observing a disciplinary Code of Ethics in the conduct of the research?

☐ **Yes** ☐ **No** If **YES**, organization's name: _____

Web Address: _____

8. Name and location of external organization(s) providing research participants (***attach*** letter[s] of cooperation):

_____

_____

_____

9. ☐ **YES** ☐ **NO** ☐ **UNCERTAIN** **Does the study present *more than minimal risk* to the participants?**

'Minimal risk' means that the risks of harm or discomfort anticipated in the proposed research are not greater, considering probability and magnitude, than those ordinarily encountered in daily life or during performance of routine physical or psychological examinations or tests. Note that the concept of risk goes beyond physical risk and includes psychological, emotional, or behavioral risk as well as risks to employability, economic well being, social standing, and risks of civil and criminal liability.

If NO, continue. If YES or UNCERTAIN, your protocol cannot be exempted from IRB review; skip to Question 15.

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10. Federal regulations (available at <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm>) permit the **exemption** of some types of research from IRB review.

If your research can be described by one or more of the categories listed below, check the appropriate box(es).
*(**NOTE:** Studies involving fetuses, pregnant women, human* in vitro *fertilization, or prisoners are not eligible for exemption.)*

☐ **Category 1** - Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as: (a) research on regular and special education instructional strategies; or (b) research on the effectiveness of, or the comparison among, instructional techniques, curricula, or classroom management methods.

☐ **Category 2** - Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior, unless: (a) information obtained is recorded in such a manner that the human participants can be identified, directly or through identifiers linked to the participants; and (b) any disclosure of the human participants' responses outside the research could reasonably place the participants at risk of criminal or civil liability or be damaging to the participants' financial standing, employability, or reputation.

*(**Note:** Exemption for survey and interview procedures does not apply to research involving children. Exemption for observation of public behavior does not apply to research involving children except when the investigator does not participate in the activities being observed.)*

☐ **Category 3** - Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under Category 2 above if: (a) the human participants are elected or appointed public officials or candidates for public office; or (b) federal statute requires without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

☐ **Category 4** - Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that participants cannot be identified, directly or through identifiers linked to the participants.

☐ **Category 5** - Research and demonstration projects that are mandated by federal statute and are designed to study, evaluate, or otherwise examine: (a) public benefit or service programs; (b) procedures for obtaining benefits or services under those programs; (c) possible changes in or alternatives to these programs or procedures; or (d) possible changes in methods or levels of payment for benefits or services under those programs, unless there is a specific requirement for IRB review in the statute and provided the project does not involve significant physical invasions or intrusion upon the privacy of the participants. *(Note: This category is not applicable to evaluation public programs financed by state or local government or a non-profit organization.)*

☐ **Category 6** - Taste and food quality evaluation and consumer acceptance studies: (a) if wholesome foods without additives are consumed; or (b) 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.

*If you checked at least one of the Exemption Categories above, please **attach** word processed answers to Questions 11-14 to this application (Do not substitute your proposal or grant scope of work for your answers to the questions.) Indicate the question number and provide a succinct response which addresses all of the points in the question. Suggested length of each answer is no more than ½ page single spaced. If you did not check at least one of the Exemption Categories above, your research is not exempt from IRB review; please skip to Question 15.*

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11. In lay terms, what are the objectives of the proposed research?

12. Describe the strategies, including compensation, you will employ to recruit participants and/or access data about them. ***Attach*** final copies of all posters, brochures, flyers, and/or advertisements that will be used in participant recruitment. If you are recruiting participants through another organization, describe how the process will work and ***attach*** a letter of cooperation signed by the chief executive or operational officer of that organization. Briefly describe the consent process you will employ.

(NOTE: For exempt research, the VSU IRB recommends against using a written consent form that requires the participant's signature if the consent form is the only document that identifies the participant. A consent statement may be added to written surveys or a consent script may be used in interview or focus group sessions. If the researcher wishes to document consent with participant signatures on a consent form, then an explanation of how the signed consent forms will be collected separately from any written data collected so that there can be no physical linking of the two.)

13. Using lay terminology, briefly describe the research methodology. ***Attach*** final copies of all test instruments, questionnaires, assessments, focus group questions, etc. to be used. If questionnaires or assessments will be developed during the research project (e.g., survey questions will be developed following focus group sessions), or if open-ended interviewing techniques will be used, indicate the general nature of the questions. Note that the IRB may require a later protocol modification to incorporate final data collection instruments and/or strategies into the approved protocol.

14. Describe how you will insure the privacy of participants and the confidentiality of the information about them, including how and by whom the data will be collected, managed, stored, accessed, rendered anonymous, disposed of, and/or destroyed.

When you have completed Questions 11-14, skip to Question 26.

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*If your research is NOT exempt from IRB review, please **attach** word processed answers to Questions 15-24 to this application. (Do not substitute your proposal or grant scope of work for your answers to the questions.) Indicate the question number and provide a succinct response which addresses all the points in the question.*

15. Objectives and Significance: In lay terms, what are the objectives and significance of the proposed research project involving human participants?

16. Selection of Participants and Voluntariness: Describe (a) the participant population and any special characteristics of participants, (b) methods for selecting participants, and (c) procedures for assuring that their participation is voluntary. If English is not the first language of the participants, describe how language barriers will be overcome. As appropriate, provide translated documents. If utilizing data about human participants, describe the strategies you will employ to access data about the participants. **Attach** copies of flyers, posters, and/or letters that will be used to recruit participants, if applicable. *(Note: All attachments must be in final form; drafts are unacceptable.)*

17. Informed Consent or Parental Permission/Child Assent: Describe how you will implement the informed consent process. This should be a description about how you will communicate with the participants to ensure continued voluntary participation throughout the study. If English is not the participants' first language, describe how you will communicate with the participants and how you will provide an understandable written consent document. **Attach** a copy of the written informed consent and/or parental permission and child assent documents and/or provide any verbal or written explanation which will be given to the participant in lieu of a written informed consent document. If the consent process will be implemented in a foreign language, provide the foreign language script and documents as well as English versions. Unless dictated by the nature of the research and/or specific research methodologies employed in some types of social science research, the written consent form must comply with the format requirements specified in the IRB's Model Informed Consent Form or Parental Permission Form. If appropriate, a Child Assent Form written at an age-appropriate level should also be developed. If waiver of informed consent, a modification to the elements of consent, or waiver of documentation of informed consent is being requested, submit a Request for Waiver of Informed Consent or Waiver of Documentation of Consent as an attachment to this application. *(Note: All attachments must be in final form; drafts are unacceptable.)*

18. Compensation: If participants will receive payment, extra-credit points, or any other form of compensation or special consideration for participation, state the form, amount, and conditions for award. Explain alternate activities and compensation that will be available to persons who elect to not participate in the research, if applicable.

19. Deception: If participants will be deceived or misled or if information is withheld from participants, identify the information involved, justify the deception, and describe the debriefing plan, if applicable. If deception will not be used, indicate such.

20. Research Protocol: In lay terms, describe the specific procedures that relate to the participants' participation. What will the participants do and/or what will be done to them? Describe data collection activities, including any plans to audio-tape, video-tape, or photograph participants. If applicable, address how any communication barriers will be overcome during conduct of the research. Provide enough detail so that a lay reader will understand exactly what is going to occur in the study. **Attach** copies of all test instruments, questionnaires, and other data collection instruments that will be used. Describe how interviewers or data collectors will be trained. If appropriate, describe arrangements for referral of participants to support services or assistance that may be needed as a result of their participation in the research (e.g., referral for psychological counseling, medical treatment, etc.) If the research protocol has been or will be submitted to an external sponsor, **attach** a copy of the technical portion of the proposal. *(Note: All attachments must be in final form; drafts are unacceptable.)*

21. Privacy and Confidentiality: Explain if the participants will be identified and/or if their participation in the study might reasonably place them at risk for criminal or civil liability, or be damaging to their financial standing, employability, insurability, or reputation or be stigmatizing. Describe the protections that will be implemented to reduce risks related to invasion of privacy and/or breach of confidentiality, including data collection, manipulation, and reporting methods and plans for long-term protection, including any methods to render the data anonymous and/or disposal or destruction of participants' data or records. (Note: Federal IRB regulations require the retention of records for three years after completion of the final report. Research sponsors or the institution may impose longer retention period that must be observed by the researcher.)

22. Risks: Describe all potential risks to the participants in the study, including potential physical, psychological, social, and/or economic harms. Discuss potential risks in relation to their probability and magnitude of harm. Explain the precautions that will be taken to minimize those risks. (Note: Rarely does participation in a research project carry no risk; the more appropriate statement is that risks are minimal or that there are no known risks associated with the research procedures.)

23. Benefits: Describe benefits likely to accrue to the participant, or, if there are none likely, state such. Describe the benefits of the proposed research to science and/or society in realistic terms. (For example, one study will likely not identify the root cause of poor reading comprehension of sixth graders, but it *may* contribute to the body of knowledge regarding reading comprehension of middle school children or it *may* lead to a change of practice in the classroom.)

24. Prior Research: If you have conducted prior research that bears on the risk-benefit ratio of this proposed study, please provide a brief summary of the methods and results. If you have not conducted such prior research, answer "Not Applicable."

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25. Federal regulations (45CFR46.110) permit the **expedited review** of some types of research. A protocol that qualifies for expedited review will be assigned immediately to a review team or to the IRB chair for review. The team and/or the chair have the authority to approve the protocol without a full board review. However, the review team has the option of referring the protocol for convened review at the next regularly scheduled IRB meeting if additional input is desired. The IRB also reserves the right to rescind the review team/chair's approval if any member has concerns about the protocol that have not been addressed.

If the research project can be described by one or more of the categories listed below, please check the applicable box(es). (Note that, if a waiver of informed consent or any elements of informed consent is being requested, the research does not qualify for expedited review.)

☐ **Category 1** - Clinical studies of drugs and medical devices only when
- (a) the research is on drugs for which an investigational new drug application (21 CFR 312) is not required or
- (b) the research is on medical devices for which
  - (i) an investigational device exemption application (21 CFR 812) is not required or
  - (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

☐ **Category 2 -** Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture from
- (a) healthy, non-pregnant adults who weigh at least 110 pounds for whom
  - (i) the amounts drawn do not exceed 550 ml in an 8 week period and
  - (ii) collection does not occur more frequently than 2 times per week or
- (b) other adults and children, for whom, considering the age, weight, and health of the participants, and the collection procedures,
  - (i) the amount of blood to be collected does not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and
  - (ii) collection does not occur more frequently than 2 times per week.

(NOTE: Children are defined as "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.")

☐ **Category 3 -** Prospective collection of biological specimens for research purposes by noninvasive means, including, but not limited to:
- (a) hair and nail clippings, in a non-disfiguring manner;
- (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction;
- (c) permanent teeth if routine patient care indicates a need for extraction;
- (d) excreta and external secretions (including sweat);
- (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue;
- (f) placenta removed at delivery;
- (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor;
- (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques;
- (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; and
- (j) sputum collected after saline mist nebulization.

☐ **Category 4 -** Collection of data through non-invasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Such procedures include, but are not limited to:
- (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the participant or an invasion of the participant's privacy;
- (b) weighing or testing sensory acuity;
- (c) magnetic resonance imaging;
- (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; and
- (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

(NOTE: Where medical devices are employed, they must be cleared/approved for marketing.)

☐ **Category 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).

☐ **Category 6 -** Collection of data from voice, video, digital, or image recordings made for research purposes.

☐ **Category 7 -** 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) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

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26. CERTIFICATIONS AND REQUIRED SIGNATURES

(Note: Applications without all required signatures will be returned by the IRB unreviewed.)

Statement of Responsible Researcher:

I certify that I have completed required training regarding human participant research ethics and am familiar with the ethical guidelines and regulations regarding the protection of human participants from research risks. I will adhere to the policies and procedures of the Valdosta State University Institutional Review Board (IRB). I will ensure that all research staff working on the proposed project who will have direct and substantive involvement in proposing, performing, reviewing, or reporting this research (including students fulfilling these roles) will complete IRB required training. I agree to obtain and document the informed consent of participants in this project as required by the IRB. I understand that potential research participants under the age of 18 may not participate without the permission of a parent or legal guardian, and in addition to parental permission, minors must assent to participate. I will not initiate this research project until I receive written exemption or approval from the IRB. I will not involve any participant in the research until I have obtained and documented his/her informed consent as required by the IRB.

I agree to (a) report to the IRB any unanticipated problems or adverse events which become apparent during the course or as a result of the research and the actions taken as a result; (b) cooperate with the IRB in the continuing review of this project; (c) obtain prior approval from the IRB before amending or altering the scope of the project or the research protocol or implementing changes in the approved consent form; and (d) maintain documentation of consent and research data and reports for a minimum of three (3) years and in accordance with approved data retention and procedures and confidentiality requirements after completion of the final report or longer if required by the sponsor or the institution. I understand that my department chair/unit director/cognizant administrator (or faculty advisor if I am a student) will receive a copy of my IRB exemption or approval report.

SIGNATURE: _____ Date: _____
Responsible Researcher

Statement of Faculty Advisor if Responsible Researcher is a Student:

I certify that I am familiar with the ethical guidelines and regulations regarding the protection of human participants from research risks and have completed training required by the VSU IRB. I agree to provide guidance and oversight as necessary to the above named student regarding the conduct of his/her research. I will ensure the student's timely requests for protocol modifications and/or continuing reviews, compliance with the ethical conduct of human participant research, and the submission of the final report. I understand that an IRB protocol cannot be closed until final report is submitted, and I agree that, if the student fails to complete a final report, I will be responsible for timely completion and submission of the report. I understand that a copy of the IRB's exemption or approval report for this protocol will be provided to my department chair/cognizant administrator.

SIGNATURE: _____ Date: _____
Faculty Advisor

Please remember to attach your CITI training certificate, answers to applicable questions, copies of recruitment materials, letters of permission if you are recruiting participants through another organization, the informed consent scripts and/or documents you intend to use, and the data collection instruments you plan to use. If your research is or will be externally funded, please also include a copy of the portion of the proposal or award that describes the use of human participants.

Please do not start your research project without a formal exemption or approval notification from the IRB.

For additional information or assistance, please contact the IRB at irb@valdosta.edu or 229-259-5045.