Valdosta State University

APPLICATION FOR USE OF HUMAN PARTICIPANTS IN RESEARCH

EXEMPT APPLICATION

INSTRUCTIONS: Complete all required information, and check appropriate boxes. Attach all CITI training documents, answers to questions 12–15, and obtain all required signatures before submitting to the Office of Sponsored Programs & Research Administration.

Project Title:

Project Dates: to
MM/DD/YYYY MM/DD/YYYY

Responsible Researcher:
Mailing Address:
Department:
Email:
Telephone:

Minimum # of Participants:
Maximum # of Participants:
External Funding: ☐ **Yes** ☐ **No**
If Yes, Sponsor:
(Note: If research will be externally funded, include a copy of the proposal or award that describes use of human participants.)

Supervising Faculty:
Supervising Faculty Email:
VSU Status:
☐**FT/PT Faculty**
☐**Adjunct Faculty**
☐**Research Associate**
☐**Administrator/Staff Member**
☐**Graduate Student**
☐**Doctoral Dissertation**
☐**Master's Thesis**
☐**Undergraduate Student**
☐**Senior Project**
☐***Unaffiliated Investigator**

Co-Investigator	Institutional Affiliation	Email Address	*IRB FWA #

Note: Unaffiliated Investigators must fill out the last column **IRB FWA #** and complete the **Unaffiliated Agreement** form at the link below:
http://www.valdosta.edu/academics/graduate-school/research/office-of-sponsored-programs-research-administration/institutional-review-board-irb-for-the-protection-of-human-research-participants.php

1. ☐ **YES** ☐ **NO** **Does your proposed study (a) meet the Valdosta State University Institutional Review Board definition of research (as cited below) or (b) does it involve a condition for IRB oversight as listed below?**

VSU IRB Definition of Research: Valdosta State University describes research as a systematic investigation, including research development, testing and evaluation designed to develop or contribute to generalizable knowledge.

Conditions: The following conditions may not meet the definition of "research" as provided above, but will cause your research to be subject to IRB oversight:

- Intent to produce results that will be submitted for peer-reviewed publication or presentation
- Include minors (e.g. those under the age of 18)
- Target potentially vulnerable individuals
- May place pregnant women and/or fetuses at risk of physical harm
- Deal with a topic of sensitive nature in a way which anonymity cannot be sustained
- Involve any activity that places the participants at more than minimal risk (see Question 9 for definition of "minimal risk")

2. ☐ **YES** ☐ **NO** **Are the human participants in your study living individuals?**

3. ☐ **YES** ☐ **NO** **Are you collecting information about deceased persons that may put third parties (i.e., surviving spouses and/or living descendants) at more than minimal risk of harm?**

4. ☐ **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 of venipuncture)
"Interaction" includes communication or interpersonal contact between the investigator and participant (e.g. surveying or interviewing)

5. ☐ **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. Identifiable means that the identity of the participant maybe ascertained by the investigator.

Note: If you have questions as to whether your research requires IRB oversight, additional information is available at our website.
http://www.valdosta.edu/academics/graduate-school/research/office-of-sponsored-programs-research-administration/institutional-review-board-irb-for-the-protection-of-human-research-participants.php

6. 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 the CITI educational program. Co-investigators from other institutions are not required to complete this if they have a certificate of completion from their own federally assured IRB.
Please visit: http://ww.citiprogram.org to complete all of the following mandatory trainings:

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

Additional modules may be required for specific types of research. Please check all that apply and complete the corresponding modules:

Study population targets	Additional CITI Modules Required
☐ a. Minors (under the age of 18)	Research with Children
☐ b. Public School Children	Research in Public Elementary and Secondary Schools
☐ c. Pregnant Women	Vulnerable Subjects
☐ d. Prisoners	Research with Prisoners
☐ e. Potentially vulnerable individuals (those whose consent maybe compromised due to socio-economic, educational or linguistic disadvantage.)	Research with Protected Populations
☐ f. Individuals in foreign countries	International Research
☐ 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
☐ j. Individuals from whom information will be collected via Internet	Internet Research
☐ k. VSU Employees	Workers as Research Subjects

7. ☐ YES ☐ NO ***Does the primary researcher, co-investigator, or any other key person, have a potential or actual significant financial conflict of interest in performance of the research?*** **If YES, it is required that the researcher completes the CITI module "Conflicts of Interest in Research Involving Human Subjects" and complete the VSU Conflict of Interest form available at:** http://www.valdosta.edu/grants/forms

8. As a researcher you are expected to follow VSU's code of ethics. Will there be an additional code of ethics followed?
Include organization's name & Web address:

9. Name and location of external organization(s) providing research participants (attach letter(s) of cooperation)

10. ☐ YES ☐ NO ☐ UNCERTAIN **Does the study present more than minimal risk to the participants?**
"Minimal Risk" means that the risk 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 includes psychological, emotional, or behavioral risks to employability, economic well-being, social standing, and risk of civil criminal liability.

11. Federal Regulations permit the exemption of some types of research from IRB Committee review.
NOTE: Studies involving *fetuses, pregnant women, children, or prisoners* are not eligible for exemption.

☐ **Category 1:** Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) 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: (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation. **Note: This category of exemption is not applicable to research involving minors (45 CFR 46.401 b).**

☐ **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** if: (i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) federal statute(s) require(s) 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 subjects cannot be identified, directly or through identifiers linked to the subjects.

☐ **Category 5:** Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine: (i) Public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.

☐ **Category 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.

Please answer each question below (12-15) in 1-3 paragraphs - answers to be submitted as a separate document.

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

13. Describe how the participants and/or data will be collected. Attach copies of posters, brochures, flyers, and/or signed letters of cooperation. Briefly describe the consent process utilized for this research.

14. Describe the research methodology. Attach all questionnaires, assessments, and/or focus group questions. If questionnaires or assessments will be developed during the research project please indicate the general nature of the questions in an attachment.

15. Describe how you will insure the privacy of participants and the confidentiality of the information about them, including how and by whom the date will be collected, managed, stored accessed, rendered anonymous, and destroyed**.**

CERTIFICATIONS AND REQUIRED SIGNATURES

Note: Applications without all required signatures will be not be reviewed.

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 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, and (d) maintain documentation of consent and research data and reports for a minimum of three 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/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.

SIGNATURE: _____ **Date:** _____

Supervising Faculty