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: MM/DD/YYYY **to** 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:

Dissertation Research Member ***(If applicable):***

Researcher's Status:

- ☐ **FT/PT Faculty**
- ☐ **Adjunct Faculty**
- ☐ **Research Associate**
- ☐ **Administrator/Staff Member**
- ☐ **Graduate Student**
- ☐ **Undergraduate Student**
- ☐ ***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 meet the Valdosta State University Institutional Review Board definition of research and/or does it involve a condition for IRB oversight as stated below?**

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

The following **conditions** may not meet the definition of "research" as provided; however, may 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 10 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.

6. EDUCATIONAL REQUIREMENTS: In accordance with federal regulations, the VSU IRB requires all responsible researchers, co-investigators, faculty advising student research, Dissertation committee members, and unaffiliated investigators to complete the CITI educational program.
Please visit: http://ww.citiprogram.org to complete the *IRB Basic* course.

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. Does the primary researcher, co-investigator, or other key person, have a potential or actual financial conflict of interest in performance of the research? ☐ YES ☐ NO
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 permission/cooperation)

10. Does the study present more than minimal risk to the participants? ☐ YES ☐ NO ☐ UNCERTAIN
"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. From the categories listed below – select the category that describes your research study. Note: Studies involving *fetuses, pregnant women, 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**. 45 CFR 46.104(b)(2), does not permit involving children (under 18) in survey or interview procedures, per subpart D.**

☐ **Category 2: This exemption is not applicable to research involving minors.**
Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), **survey procedures, **interview procedures*, or observation of public behavior (including visual or auditory recording) if the following criteria is met:
(i) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects; IRB conducts a limited IRB review to make the determination required by §46.111(a)(7).
Note: **VSU's IRB** interprets this category to include – but not limited to, non-invasive experimental research studies on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior.
45 CFR 46.104(b)(2), for research involving survey or interview procedures or observation of public behavior, does not apply to research with children, subpart D, except for research involving observations of public behavior when the investigator(s) do not participate in the activities being observed.

☐ **Category 3: This exemption is not applicable to research involving minors.**
(i) Research involving benign behavioral interventions (BBI) in conjunction with the collection of information from an **adult** subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and the following criteria is met: The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects; IRB conducts a limited IRB review to make the determination required by §46.111(a)(7).
(ii) Benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing.
(iii) If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research. (45 CFR 46.104 (d)(3)(i)).

☐ **Category 4:** Secondary research for which consent is not required: Use of identifiable information or identifiable biospecimen that have been or will be collected for some other 'primary' or 'initial' activity, if at least **ONE** of the following criteria is met:
(i) The identifiable private information or identifiable biospecimen **MUST** be publicly available;
(ii) Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects;
(iii) The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of "health care operations" or "research" as those terms are defined at 45 CFR 164.501 or for "public health activities and purposes" as described under 45 CFR 164.512(b); or
(iv) The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 *et seq.*

☐ **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. **Must be posted on a publicly accessible Federal Web site or in such other manner as the department or agency head may determine a list of the research and demonstration projects that the Federal department or agency conducts or supports under this provision. The research or demonstration project must be published on this list prior to commencing the research involving human subjects.**

☐ **Category 6:** This category may not be applied to research involving the ingestion of alcohol. 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.

■ **Category 7:** Storage or maintenance for secondary research for which broad consent is required §46.111. *This category does not apply to research currently conducted at VSU. If you feel as though your research falls under this category, please contact the IRB Administrator.*
■ **Category 8:** Secondary research for which broad consent is required. §46.116. *This category does not apply to research currently conducted at VSU. If you feel as though your research falls under this category, please contact the IRB Administrator.*

***Please provide complete answers for the questions listed below and submit Q&A's (12-15) 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 required signatures will 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