Valdosta State University

APPLICATION FOR USE OF HUMAN PARTICIPANTS IN RESEARCH

EXPEDITED APPLICATION

INSTRUCTIONS: Complete this form by checking all appropriate boxes. Attach all CITI training documents, and obtain all necessary 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:

E-mail:

Telephone:

Supervising Faculty:

Supervising Faculty Email:

Dissertation Research Member *(If applicable)*:

Minimum # of Participants:

Maximum # of Participants:

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 use of human participants.)

Researcher's Status:

- ☐ **FT/PT Faculty**
- ☐ **Adjunct Faculty**
- ☐ **Research Associate**
- ☐ **Administrator/Staff Member**
- ☐ **Graduate Student**
- ☐ **Undergraduate Student**
- ☐ ***Unaffiliated Investigator**

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

Co-investigator	Institutional Affiliation	Email Address	*IRB FWA #

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. Biosafety

(1) Does your research involve human blood, body fluids, cells, or tissue components? ☐ **YES** ☐ **NO**

(2) Does your research involve recombinant DNA or a biohazardous agent? ☐ **YES** ☐ **NO**

If you answered **YES** to the either question above – email (or mail) your IRB application to Meredith Lancaster, Associate Director of Environmental and Occupational Safety (mlancaster@valdosta.edu) for Biosafety review.

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7. EDUCATIONAL REQUIREMENTS: In accordance with federal regulations, the VSU IRB requires ***all responsible researchers, co-investigators, faculty advising student research, Dissertation Chair & Research Members, and unaffiliated investigators*** to complete the CITI educational program. Co-investigators from other institutions are not required to complete if they have a certificate of completion from their own federally assured IRB.

Please visit: http://www.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.)	Populations in Research Requiring Additional Considerations and/or Protections
☐ 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	Research and HIPAA Privacy Protections
☐ j. Individuals from whom information will be collected via Internet	Internet-Based Research
☐ k. Employees	Vulnerable Subjects - Research Involving Workers/Employees

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8. 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, please complete the CITI module "Conflicts of Interest in Research Involving Human Subjects" & complete the VSU Conflict of Interest form available at the website below. http://www.valdosta.edu/grants/forms.

9. 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:

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

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

"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 includes psychological, emotional, or behavioral risks to employability, economic well-being, social standing, and risk of civil criminal liability.

12. If the research project can be described by one or more of the categories listed below, please check all that apply:

☐ **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:
(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:
(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.

***Please provide complete answers for the questions listed below and submit question answers (13-21) as a separate document*.**

13. 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 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.

14. Informed Consent or Parental Permission/Child Assent: Describe how you will implement the informed consent process. 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 that 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. Please visit our website for information and examples of 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.

15. 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.

16. 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.

17. 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? 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.)

18. 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/unidentifiable 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.)

19. 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.)

20. Benefits: Describe benefits likely to accrue to the participant, or, if there is none likely, state such. Describe the benefits of the proposed research to science and/or society in realistic terms.

21. 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."

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 Supervising Faculty 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

Statement of Biosafety Officer: ***(if applicable – review question # 6)***

I certify that the Valdosta State University Committee on Biosafety has reviewed the proposed research project and has found it to be in compliance with the VSU Biosafety Manual, which outlines standards for conducting experiments with biohazardous agents.

SIGNATURE: _____ Date:

Bio-safety Officer