Valdosta State University Institutional Review Board

Protocol Modification and/or Continuation Review Request or Final Report Form

During the protocol approval period, any proposed protocol changes must be approved by the IRB before they are implemented. Even when no protocol modifications are anticipated, Federal regulations require the IRB to conduct continuation reviews no less frequently than annually. This form may be used to request a protocol modification during the approval period, to request a continuation review to extend the protocol approval period, to request a combination of these actions, or to provide a final report.

SECTION 1: PURPOSE OF REQUEST

- ☐ **Protocol Modification Request Only (Complete Sections 3 and 5)**
- ☐ **Continuation Review Request Only (Complete Sections 4, and 5)**
- ☐ **Combination Protocol Modification & Continuation Review Request (Complete Sections 3-5)**
- ☐ **Final Report (Complete Sections 4 and 5)**

SECTION 2: PROTOCOL INFORMATION (to be completed by the Office of Sponsored Programs & Research Administration)

Primary Investigator: **Department:**
E-mail: @valdosta.edu **Telephone:**

Project Title: **IRB Number:**

Original Approval Date:	**Review Type**	**Risk Determination**	**Approved Participants**
Last Approval Date:	☐ **Expedited**	☐ **Minimal**	**Minimum:**
Current Expiration:	☐ **Convened**	☐ **Greater than Minimal**	**Maximum:**

SECTION 3: PROPOSED PROTOCOL MODIFICATION(S)

If you are requesting approval of a Protocol Modification only or a combination Protocol Modification and Continuation Review Request, please complete this section. Attach a statement (maximum 2 pages) that addresses the following as appropriate:

A. Description of **CHANGES PROPOSED** (i.e., change in project title, responsible researcher, co-investigator(s), purpose of the study; duration of the study; participant population; location of the study, participant recruitment procedures; number of participants, including controls; costs and/or compensation to participants; voluntary participation; experimental procedures; alternate procedures; data to be collected; procedures for maintaining confidentiality; and/or consent procedures, including changes to the consent form)
B. Discussion of **UNANTICIPATED RISKS** or **NEW INFORMATION** that may affect the risk/benefit assessment, if applicable
C. Brief discussion of the **IMPLICATIONS OF THE PROPOSED CHANGES** on the likelihood of increased or decreased risks and/or benefits to the study participants
D. If recruitment materials and/or consent form(s) will be modified, please **attach** a copy of the new consent form(s) for IRB approval

SECTION 4: PROJECT STATUS REPORT

Total number of participants enrolled in the study to date:

Do you plan to enroll additional participants in this study? ☐ No ☐ Yes **If YES, how many more?**

Adult **Minor**

Number of participants withdrawn since initiation of the study?

Number of participants excluded by the researcher since initiation:

☐ **A.** ***Check here*** *if you have* ***not yet begun enrolling participants*** *in the study.* ***Answer Questions 1 and 2 below*** *only, and attach an explanation if you answer YES to either question. Attach unstamped copies of all recruitment posters and informed consent documents.*

☐ **B.** ***Check here*** *if the study is* ***currently open*** *to enrollment of new participants and/or* ***interaction or intervention with, or collection of private information about, participants is ongoing****.* ***Answer Questions 1 through 8 below.*** *If you answer YES to any question, attach an explanation and describe actions taken to reduce risks or discomforts to participants and/or to communicate new findings or knowledge to participants. Also, attach unstamped copies of all recruitment posters and informed consent documents.*

IF THE STUDY HAS BEEN PERMANENTLY CLOSED TO ENROLLMENT OF NEW PARTICIPANTS AND ALL RESEARCH-RELATED INTERACTIONS, INTERVENTIONS, AND/OR COLLECTION OF PRIVATE INFORMATION ARE COMPLETED, CHECK ONE OF THE THREE BOXES BELOW THAT DESCRIBES THE CURRENT STATUS OF THE STUDY:

☐ **C.** ***All data have been de-identified*** *(i.e., the researcher has destroyed any key or code list that links participants' identities to their private information and/or has stripped any identifiers from data collection instruments and/or the database).* ***Answer Questions 1 through 8 below.*** *This protocol is considered complete, regardless of whether or not data analysis is ongoing, and no further continuing review is required. This form serves as the researcher's final report. The researcher may use the data in the future for other research purposes without IRB exemption or approval.*

☐ **D.** ***Data analysis is ongoing*** *to answer this protocol's research question (i.e., findings have not yet been summarized and conclusions have not yet been drawn)* ***AND*** *participants'* ***private information remains identifiable*** *(i.e., the researcher still maintains a key or code list that links participants' identities to their private information or data collection instruments and/or the database still contain identifiers).* ***Answer Questions 1 through 8 below.*** *If you answer YES to any question, attach an explanation and, if applicable, describe actions taken to communicate new findings or knowledge to participants. This protocol remains subject to continuing review until data analysis to answer the research question is complete.*

☐ E. ***Data analysis is completed*** *(i.e., findings have been summarized and conclusions have been drawn)* ***BUT*** *participants'* ***private information remains identifiable*** *(i.e., the researcher still maintains a key or code list that links participants' identities to their private information or data collection instruments and/or the database still contain identifiers).* ***Answer Questions 1 through 9 below.*** *If you answer YES to any question, attach an explanation and, if applicable, describe actions taken to communicate new findings or knowledge to participants. This protocol is considered complete and no further continuing review is required. Use of the data for any future research purpose is subject to IRB oversight, and the researcher must submit an IRB application describing how the data will be used.*

SINCE THE IRB' MOST RECENT REVIEW OF THIS PROTOCOL…

1. Have there been any findings, publications, or other relevant information that relate to risks associated with the research? ☐ Yes ☐ No
2. Have the risks and/or benefits to the participants changed from those anticipated? ☐ Yes ☐ No
3. Did any participants withdraw from the study? ☐ Yes ☐ No
4. Did you exclude any individuals from the study? ☐ Yes ☐ No
5. Did any participants express discomfort or concerns or complain about the research? ☐ Yes ☐ No
6. Have any unanticipated problems or adverse events occurred? *(An unanticipated problem is any unexpected event related, or possibly related, to participation that suggests a great risk of harm than previously known or recognized. An adverse event in as unfavorable medical or psychological occurrence in the participant, such as a physical injury, a drug reaction, an abnormal laboratory finding, or a psychiatric episode.)* ☐ Yes ☐ No
7. Were any participants enrolled who did not give consent/permission/assent as required by the approved protocol? ☐ Yes ☐ No
8. Were there any instances in which documentation of consent/permission/assent was not obtained as required by the approved protocol? ☐ Yes ☐ No
9. Please provide an explanation of why the data cannot be de-identified at this time; when you expect to de-identify the data; and what security methods you have in place to ensure confidentiality of the identifiable data as long as it is on hand.

SECTION 5: CERTIFICATION

By typing my name below, I certify that I will continue to observe the ethical guidelines and regulations regarding the protection of human participants from research risks and will continue to adhere to the policies and procedures of the VSU IRB.
(Note: If applicable, the faculty advisor may also type his/her name and forward this request electronically.)

Responsible Researcher	Date	Faculty Advisor if Researcher is a Student	Date