UMass | Dartmouth
Institutional Review Board (IRB)

For Internal IRB Use:
IRB Protocol #: _____
Level of Review: _____
Approval Category: _____
Action: _____

IRB Amendment and Report Form

U Mass Dartmouth (UMD) requires studies of all approval categories (*Exempt, Expedited, or requiring Full Board Review*) to obtain approval from the IRB for amendments prior to implementation and to report instances of Unanticipated Problems (UP) and noncompliance (violations or deviations) to the IRB. Failure to report a UP or noncompliance, or any implementation of an unapproved amendment constitutes noncompliance.

Instructions:
1. Ensure to provide complete information for every item (*Note: blank or incomplete items may delay the form processing and approval*).
2. For more information and to submit completed forms, please email Stephanie Peña at irb.research@umassd.edu.

Part A – General Information:

IRB Protocol #:		**Approval Date:**	
Principal Investigator:		**Expiration Date:**	
Academic Title:		**Category:**	
Department:		**Sponsor(s):**	
Email:		**Grant #:**	
Location(s): *Physical or virtual*			
Protocol Title:			

Part B – Amendment Information:

1. Study Status: *Select as appropriate.*
☐**Open to enrollment, no participants have been enrolled, and no additional risks have been identified.**
☐**Open to enrollment, involves data collection, or ongoing review of records/specimens.**
☐**Closed to enrollment, ongoing review of data/records/specimens.**
☐**Closed to enrollment, active only for long term follow up of participants.**
☐**Closed to enrollment, research related activities are limited to data analysis.**

2. Reason for Submission: *Select as appropriate.*
☐**Change Principal Investigator.** *Must provide a letter of acknowledgment from previous PI or Department Chair.*
☐**Modify Personnel.** *Add/Remove Co-Investigator(s) and/or Student Investigator(s).*
☐**Modify Study Title.**
☐**Modify Research Protocol, Study Design, and/or Methodology.**
☐**Modify Informed Consent Process.**
☐**Modify Study Measures (Instruments, Surveys, or Questionnaires).**
☐**Modify Other Participant Facing Materials (Recruitment Materials, Emails, or Consent Forms).**
☐**Modify Target Enrollment.**
☐**Modify Cooperating Institutions/Sites.**
☐**Report an Unanticipated Problem.**
☐**Report Noncompliance/Violation/Deviation).**
☐**Other:** *Provide details in Q.3.*

3. Provide a detailed explanation of the proposed amendment(s)/modification(s) or of the report included. *Ensure to provide the clean and corresponding tracked changes version of all revised approved documents.*

4. Does this submission include a report of an Unanticipated Problem (UP)? ☐**No** ☐ **Yes**

If yes, provide:

a. Date of UP: *Note: Failure to notify the IRB within 5 business days constitutes noncompliance.* _____

b. Type of UP:
☐ Protocol Deviation/Violation ☐ Adverse Event ☐ Participant Complaint
☐ Breach of Confidentiality ☐ Data Safety Monitoring Report ☐ Other: _____

c. Location of UP Occurrence: ☐ At UMD ☐ Other: _____

d. Did the problem involve a UMD PI or study personnel? ☐**No** ☐ **Yes**

e. Is the problem unexpected and related to the study design, procedures, measures, protocols, etc.? ☐**No** ☐ **Yes**
If yes, address the potential for the UP to recur and clarify if study design/procedures/measures/protocol should be revised.

f. Does the UP place the participant(s) at an increased risk (psychological, physical, economical)? ☐**No** ☐ **Yes**
If yes, provide the notification which will be issued to previously enrolled participants for IRB review/approval.

g. Is the potential for the UP already identified in the consent/authorization forms? ☐**No** ☐ **Yes**
***If no, revise consent/authorization forms to include possible risks (Note: enrolled** participants td be re-consented/notified).*

h. If there is a monitoring entity, has a determination of risk and relatedness been made? ☐**No** ☐ **Yes**
If no, notify monitoring entity and provide relevant documentation.

i. Describe the corrective measures taken to address the UP and additional measures to prevent the recurrence of the UP(s).

5. Does this submission include a report of Noncompliance? ☑**No** ☐ **Yes**

If yes, provide:

a. A description of the noncompliance (violation or deviation).

b. Details on how and why the investigator failed to follow IRB protocol/procedure.

c. Clarification on whether the noncompliance affected:
- Risk/benefit ratio to participants.
- Integrity of data.
- Participant's willingness to participate.

d. A description of the corrective measures that will be taken to prevent the recurrence of the noncompliance(s).
Specify what steps will be taken by the investigator to avoid similar problems in the future.

Part C - Investigator Assurance:

☐ I attest the information provided is accurate and complete to the best of my knowledge.

_____ _____
Signature of Principal Investigator **Date**