UMass | Dartmouth
Institutional Review Board (IRB)

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

IRB Closure Report Form

U Mass Dartmouth (UMD) requires studies of all approval categories (Exempt, Expedited, or requiring Full Board Review), to submit a closure report form once all study related procedures and data analyses have been completed.

Instructions:
1. Ensure to provide complete information for every item (*Note: blank or incomplete items may delay the form processing*).
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 Address:		**Grant #:**	
Location(s): *Physical or virtual*			
Protocol Title:			

Part B – Closure Information:

1. Study Status: *Confirm the study status.*
☐ **Closed to enrollment: all research related activities, long term follow up, and data analyses have been completed.**

2. Reason for Closure: *Select as appropriate.*
☐ **Study Completed** ☐ **PI left University** ☐ **Student left University** ☐ **Closed by Sponsor**
☐ **Lack or Loss of Funding** ☐ **Other:**

3. Were there any changes in relevant literature or any new scientific information that would've impacted the study design, study procedures, or risk level to participants which not reported to the IRB? ☐**No** ☐ **Yes**
If yes, summarize literature findings or new information in sufficient detail.

4. Were there any interim findings associated with this study? ☐**No** ☐ **Yes**
If yes, summarize any preliminary findings resulting from the research in sufficient detail.

5. Have there been, or will there be any new publications resulting from this study? ☐**No** ☐ **Yes**
If yes, list each publication and provide a copy in PDF format.

6. Summarize the overall study conduct and detail measures taken to prevent potential risks to participants.

7. Was there a data monitoring plan, committee, or board? ☐**No** ☐ **Yes**
If yes, summarize how monitoring compliance was upheld and any relevant documents.

8. Was there an annual progress report required by the funding agency? ☐No ☐ Yes
If yes, provide report and any relevant documents.

9. 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*

Part C – Participant Information:

1. Target Enrollment (Total # of participants IRB approved to enroll): _____
2. Number of Participants Enrolled to Date: _____
3. Number of Participants Enrolled since last approval: _____
4. Number of Participants Anticipated to be enrolled in the next approval period: ☐No ☐ Yes
5. Does this study involve screening/assessment procedures to determine participant eligibility?
If yes, provide Accrual Information:

a. Target Accrual (Total # of participants IRB approved to accrue): _____
b. Number of Participants Accrued to Date: _____
c. Number of Participants Accrued since last approval: _____
d. Number of Participants Anticipated to the accrued in the next approval period: _____

6. How many participants remain on study? *If greater than 0, submit continuing review.*
7. How many participants are considered off study? *Must equal the sum of all below.*

a. How many have completed participation?
b. How many have withdrawn of their own initiative? *If any, explain why.*
c. How many have been removed by the PI? (*ex: failed screening, erroneously enrolled*)
d. How many have been lost to follow up?
e. How many have died while on-study? *If any, clarify if related to study participation.* ☐No ☐ Yes

8. Does this study have one or more components, or subset of the overall study population?
If yes, identify component/subset and provide enrollment numbers.

9. Have any participant complaints been received? ☐No ☐ Yes
If yes, clarify complaint and resolution.

10. Have any participants experienced any harm as a part of enrollment? ☐No ☐ Yes
If yes, clarify harm and resolution.

11. Did all participants receive a copy of the consent form? ☐No ☐ Yes
If no, clarify why and address noncompliance.

12. Where are signed consent forms stored? *Identify Physical Location.*
a. If not stored, was a waiver of the documentation of consent granted? ☐No ☐ Yes
If no waiver of documentation granted, clarify why not obtained, and address noncompliance.

13. Was informed consent obtained from all participants? ☐No ☐ Yes
a. If no, was a waiver of informed consent granted? ☐No ☐ Yes
If no waiver of consent granted and no informed consent obtained, clarify why not obtained, and address noncompliance.

14. Were there any problems encountered in obtaining informed consent? ☐No ☐ Yes
If yes, clarify problem and resolution.

15. Were there been any unanticipated problems? ☐No ☐ Yes
If yes, summarize details, clarify when submitted to the IRB, and overall outcome.

16. Has the IRB approved any amendments to this study within the past year? ☐No ☐ Yes
17. Has the submission been modified without an IRB amendment approval? ☐No ☐ Yes
If yes, select category, explain what was modified, and address noncompliance in question 9:
☐ *Protocol/Application, Study Design, or Target Enrollment* _____
☐ *Consent Forms* _____
☐ *Participant Facing Materials (Questionnaires/Surveys/Recruitment)* _____
☐ *New Investigators* _____
☐ *New Sponsors* _____

Part D - Investigator Assurance:

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

_____ _____
Signature of Principal Investigator **Date**