UMass | Dartmouth
Institutional Review Board (IRB)

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

IRB Continuing Review Application

UMass Dartmouth (UMD) requires studies of all approval categories (Exempt, Expedited, or requiring Full Board Review), to submit a continuing review application one-year post approval. Alternatively, completed or inactive studies must submit a closure report form.

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 Address:		**Grant #:**	
Location(s): *Physical or Virtual*			
Protocol Title:			
Abbreviated Title:			

Part B – Continuing Review 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 data/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 analyses.**

2. Have there been any changes in the relevant literature or any new scientific information (such as newly identified risks for the type of study, measures used, treatment, or alternative approaches) that would impact the study design, study procedures, safety or risk level to participants? ☐**No** ☐ **Yes**
If yes, summarize literature findings or new information in sufficient detail.

3. Have there been any interim findings associated with this study? ☐**No** ☐ **Yes**
If yes, summarize findings in sufficient detail.

4. 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.

5. Is there a data monitoring plan, committee, or board? ☐**No** ☐ **Yes**
If yes, provide summary to report how monitoring compliance was upheld and any relevant documents.

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

7. 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 – 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: _____
5. Does this study involve screening/assessment procedures to determine participant eligibility? ☐No ☐ Yes

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? _____
7. How many participants are considered off study? *Must equal the sum of all the 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.*

8. Does this study have one or more components, or subset of the overall study population? ☐No ☐ Yes

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 signature was 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 consent was not obtained, and address noncompliance.

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

15. Have there been any unanticipated problem since the last approval? ☐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 Q.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.
☐ I agree to submit an amendment if there are changes that alter the approved protocol, before implementing changes.
☐ I agree to conduct this study in accordance with the *UMD IRB User Guide*, relevant UMD policies, and all Federal, State and Local regulations.

_____ _____
Signature of Principal Investigator **Date**

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F – Personnel and Training: *Please include all personnel to be involved in the research.*

Name of the Personnel:	**Role in the Project:** (*Title and job on project*)	**Experience and Relevant Details:**	**Training:** (*Provide certificates)*
			☐ Responsible Conduct for Research. ☐ Social & Behavior Research Investigators. ☐ Biomedical Research Investigators. ☐ Data or Specimens Only Research. ☐ Good Clinical Practice.
			☐ Responsible Conduct for Research. ☐ Social & Behavior Research Investigators. ☐ Biomedical Research Investigators. ☐ Data or Specimens Only Research. ☐ Good Clinical Practice.
			☐ Responsible Conduct for Research. ☐ Social & Behavior Research Investigators. ☐ Biomedical Research Investigators. ☐ Data or Specimens Only Research. ☐ Good Clinical Practice.
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