

For Internal IBC Use:

IBC Protocol #: _____
 Level of Review: _____
 Approval Category: _____
 Action: _____

IBC Registration Amendment and Report Application

U Mass Dartmouth (UMassD) requires all studies, regardless of approval category, to submit and obtain approval for amendments prior to the implementation of revisions. Any implementation of unapproved revisions constitute 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 ibc.research@umassd.edu.

Part A – General Information:

IBC Registration #:		Approval Date:	
Principal Investigator:		Expiration Date:	
Email Address:		Category:	
Department:		Sponsor(s):	
Location(s):		Grant #:	
Protocol Title:			

Part B – Amendment Information:

1. Study Status: *Select as appropriate.*

- Research related activities have not begun and no additional risks have been identified.
- Research related activities have been halted and/or additional risks have been identified.
- Research related activities involve data collection, or ongoing review of materials/specimens.
- Research related activities are limited to data analyses.

2. Reason for Amendment: *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 Title(s), Sponsor(s), or Cooperating Institution(s), and/or Location(s).
- Modify Classification, Materials, Risks, and/or Biohazards Management.
- Modify Research Protocol, Study Design, and/or Methodology.
- Report an Unanticipated Problem or Incident.
- Report Noncompliance/Violation/Deviation.
- Other: *Provide brief details.*

3. Provide a detailed explanation of the proposed amendment(s)/modification(s) or incident occurrence.

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 report to IBC within 5 business days constitutes noncompliance.* _____
- b. Type of UP:
 - Protocol Deviation/Violation
 - Incident 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 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 impact the biosafety level or risk group? No Yes
- g. Is the potential for the UP already identified in the protocol? No Yes
If no, revise application as appropriate.
- h. 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. How and why the investigator failed to follow protocol/procedure.
- c. Whether the noncompliance affected:
 - Risk to personnel or environment.
 - Integrity of data
- 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