MEMORANDUM OF UNDERSTANDING
BETWEEN
Bridgewater State University
AND
Massachusetts Maritime Academy

This MEMORANDUM OF UNDERSTANDING is hereby made and entered into between Bridgewater State University, 131 Summer Street, Bridgewater, MA 02325, hereinafter referred to as “BSU,” and Massachusetts Maritime Academy, 101 Academy Drive, Buzzards Bay, MA 02532 hereinafter referred to as “MMA” and collectively referred to as the “Parties.”

I. PURPOSE

This document formalizes a relationship between BSU and MMA in preparation of MMA utilizing the Institutional Review Board (IRB) at BSU including assisting MMA in the development of an independent IRB at MMA. It is expected that MMA will require the review of approximately five (5) applications per year during the life of this agreement. No compensation is expected within this level of assistance. This document will clarify roles and responsibilities of the Parties. This document must be kept on file by both parties.

II. STATEMENT OF WORK

A. BSU SHALL:
   a. Provide access to all IRB template applications, amendments and extensions, consent templates and other forms through a password protected, secure URL on the BSU webserver.
   b. Enable access to any human subjects training that BSU would require for IRB approval of studies by MMA investigators.
   c. Liaison with MMA’s Marlene Clapp, or designee, for the instruction of proper use of the forms.
   d. Review completed applications, amendments and extensions on behalf of MMA to ascertain IRB approval.
   e. Review documentation submitted for studies regarding any adverse events or violations.
   f. Communicate with MMA’s designee on the status of the applications.
   g. Provide minutes of IRB meetings upon request.
   h. Consult with MMA on the development of MMA’s institutional IRB.
   i. Maintain required IRB records pursuant to applicable federal, state, and local regulations.
   j. Notify MMA of any changes to the BSU procedures that would affect MMA in relation to this agreement.

B. MMA SHALL:
   a. IRB designee will share password protected URL with only colleagues within MMA.
   b. Instruct faculty and staff of MMA in the proper completion of all IRB forms, including any documentation requested.
   c. Ensure investigators are qualified to conduct the research and have completed required trainings in human subject protections. MMA will provide BSU documentation of researcher training at the time of IRB application submission.
   d. Review submitted application forms and consult with applicant for any needed corrections.
e. Submit completed applications, amendments and extensions to BSU/IRB in a timely manner.

f. Instruct faculty and staff of the need for approval before research can commence.

g. Instruct faculty and staff on the need to submit documentation for study modifications, continuing review, and adverse events or violations. MMA will promptly report changes to the research activity and ensure changes are not initiated prior to IRB approval of said changes except when necessary to eliminate immediate hazards to the subject(s).

h. Cooperate with BSU’s IRB regarding the investigation of any serious or continuing noncompliance or unanticipated problems involving risk to human subjects.

i. MMA shall ensure a process exists by which research participants can submit complaints about the study. MMA will notify BSU promptly of any complaints or injury that occur during research approved by BSU.

j. Counsel MMA applicants on IRB protocol in order to comply with procedures regarding full Board review.

k. MMA will perform investigator conflict of interest analysis under its relevant policies. Any applicable conflict of interest and associated management plan shall be communicated to the BSU IRB.

l. MMA will ensure MMA investigators compliance with protocol, IRB determinations, and applicable federal and state regulations and sponsor requirements.

m. MMA will be required to present to BSU a report detailing any adverse event or misconduct associated with any study which is represented under a BSU IRB.

n. MMA may disapprove any study approved by BSU’s IRB, in such cases, a notification to BSU would be appropriate.

C. BOTH PARTIES SHALL:

a. The parties agree to an open and equal exchange of ideas and knowledge for the purposes of developing an Institutional Review Board at MMA within three years.

b. Both parties agree to treat information exchanged pertaining to the review and continuing oversight of human subject research as confidential (Confidential Information). No party shall disclose Confidential Information received pursuant to this Agreement to any individual or other entity without prior written approval of the other party. Notwithstanding the foregoing, nothing in this Agreement shall be construed to restrict a party from disclosing Confidential Information as required by law, subpoena, court order, or other governmental order or request. This section shall survive the termination of this Agreement.

III. PARTICIPATION IN SIMILAR ACTIVITIES:

This instrument does not restrict MMA from entering a similar agreement with other public or private agencies, individuals, or organizations for the purpose of IRB review of research protocols. It does, however, restrict MMA from accepting IRB protocols from external applicants that would require a “pass-through” to BSU’s IRB.

IV. HOLD HARMLESS:

MMA is responsible to ensure compliance with the determinations of BSU’s IRB to safeguard the rights and welfare of research subjects.

A. MMA shall hold BSU’s IRB, its officers, directors, employees, and agents, harmless from any liability or loss resulting from the negligent acts or omissions of MMA, its agents or employees
pertaining to the activities to be carried out pursuant to the obligations of this Agreement; provided, however, that MMA shall not hold BSU’s IRB harmless from claims arising out of the negligence or willful malfeasance of BSU’s IRB, its officers, agents, or employees, or any person or entity not subject to MMA’s supervision or control.

B. BSU shall hold MMA, its officers, directors, employees, and agents harmless from any liability or loss resulting from judgments or claims against them arising out of the activities to be carried out pursuant to the obligations of this Agreement; provided, however, that the following are excluded from BSU IRB’s obligation to hold harmless: 1) the negligent failure of MMA to substantially comply with any applicable governmental requirements; or 2) the negligence or willful malfeasance by an, officer, agent, or employee of MMA.

V. GENERAL TERMS AND CONDITIONS:

The term of this Agreement shall commence upon execution of this Agreement by both parties, and shall continue until August 31, 2019, or until such time as either party gives written notice of termination, whichever comes first. This agreement shall be reviewed and modified as needed each academic year during the three-year term of the initiative.

The parties specifically recognize that 45 CFR 46.109(e) requires that, “An IRB shall conduct continuing review of research . . . not less than once per year, and shall have authority to observe or have a third party observe the consent process and the research.” Therefore, termination of this Agreement shall not affect BSU IRB’s obligations of continuing review for studies approved hereunder.

This agreement may not be assigned or transferred by either party without prior written consent of the other party.

VI. PRINCIPAL CONTACTS:

The principal contacts for this agreement are:

**Bridgewater State University**
Frederick W. Clark, Jr., President
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**Massachusetts Maritime Academy**
Rear Admiral Francis X. McDonald, President
101 Academy Drive
Massachusetts Maritime Academy
Buzzard’s Bay, MA 02532
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VI. AUTHORIZED REPRESENTATIVES

By signature below, the authorized representative of each institution signifies agreement to this Memorandum of Understanding. The signatures below also indicate that these are the authorized representatives for each organization.

On behalf of Bridgewater State University:

[Signature]
Frederick W. Clark Jr., President

Date: 8-21-18

On behalf of Massachusetts Maritime Academy:

[Signature]
Francis X. McDonald, President

Date: 8-14-18