



UNIVERSITY OF
SOUTHERN MAINE

Office of
Research Integrity and Outreach

TO: Reid Plimpton
Sheila Nelson

FROM: Casey Webster

DATE: September 1, 2017

RE: MIYHS Confidentiality Agreement - IRB Requirement

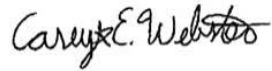
The purpose of this letter is to describe the procedure for the Office of Research Integrity and Outreach (ORIO) and Institutional Review Board (IRB) at the University of Southern Maine (USM) to follow in their review of research projects requesting Maine Integrated Youth Health Survey (MIYHS) data as required by the MIYHS Confidentiality Agreement.

1. Each community coalition (examples: Drug Free Community Grantees (DFCs), Maine Prevention Services grantees (MPS)) requesting MIYHS disaggregated data and/or protected health information (PHI) will complete a Determination of Research Involving Human Subjects form.
 - a. The Determination of Research Involving Human Subjects form can be found here: <http://usm.maine.edu/orio/hrpp-submission-requirements-and-application-forms>
2. The ORIO will review this submission and determine if the coalitions research meets the definition of “human subject research” under the U.S. Department of Health and Human Services Code of Federal Regulations for Protection of Human Subjects.
 - a. The ORIO will conduct this service **free of charge** to help foster academic and scientific efforts in the pursuit of knowledge.
3. If the ORIO determines the research does not meet the definition of “human subject research,” a determination letter will be sent to the coalition via email.
 - a. This determination letter will be provided to the MIYHS by the coalition to demonstrate that an IRB review and approval will not be required.
4. If the ORIO determines the research does meet the definition of “human subject research,” the ORIO will provide the coalition with instructions on how to submit a research protocol for review and approval by the USM IRB.
 - a. To cover reviewer time and administrative costs the coalition will pay the USM IRB based on the external review fee schedule with a 50% discount applied.
 - b. The external review fee schedule can be found here: <http://usm.maine.edu/orio/irb-external-reviews>

5. Once received, the coalition will provide the IRB approval letter to the MIYHS to demonstrate that an IRB has reviewed the research protocol and determined that the rights and welfare of the subjects of the research will be adequately protected and that the risks of disclosing identifying information are outweighed by the benefits of the project.

Thank you for your participation in this important and productive collaboration

Sincerely,

Handwritten signature of Casey E. Webster in cursive script.

Casey E. Webster, CIP, CIPP/US
Research Compliance Administrator
Office of Research Integrity and Outreach