

Division of Academic Affairs

Human Research Protection Program

Baystate Health & UMass Amherst IRB Collaboration Fact Sheet

Baystate and UMass Amherst have entered into an agreement that will allow single IRB review and oversight by the Baystate IRB for many of our collaborative research projects. It is our hope that eliminating the requirement for dual IRB review will facilitate collaboration and the ability of our researchers to move forward with their studies in a timelier manner. We provide this fact sheet to help researchers determine whether or not this agreement may extend to their projects and to provide basic information on requirements.

Eligible Research Studies: Collaborative human research studies where the source of the subjects, data, or specimens is Baystate. The research itself may occur at either or both campuses.

Constraints: Multi-institutional projects or projects where recruitment is from multiple sources may not be eligible. In these instances, please consult with the UMass Human Research Protection Office (HRPO) or the Baystate Human Research Protection Program (HRPP) so that the appropriate review mechanism can be identified. Research involving storage or use of human tissue or body fluids at the UMass campus must be conducted in labs cleared through EH&S Biosafety. Please contact Judy LaDuc for more information (577-7293). Research for which UMass study personnel may have a potential conflict of interest (COI) must be cleared through the UMass COI Committee. A COI screening tool is available on the [UMass website](#) to assist investigators in determining whether COI Committee review is necessary.

Registration: The research must be registered with the UMass Human Research Protection Office (HRPO) prior to application to the Baystate IRB so that there is an institutional record of the project. Registration forms are available on the [UMass website](#).

Electronic Signature: The electronic signature of a representative from the UMass HRPO must be obtained on the initial IRBNet application to the Baystate IRB. This will serve as the verification to Baystate that the project has been registered with the UMass HRPO.

Principal Investigator: A Baystate Principal Investigator must be named on the Baystate IRB application, while the grant or study-wide Principal Investigator may be from either UMass or Baystate.

Ethics Training and Research Personnel: Individuals who directly interact with subjects or their identifiable data must be listed on the application to the Baystate IRB and have current (within the past 3 years) Baystate training in the protection of human subjects (CITI or approved substitute). UMass personnel can identify Baystate as a secondary affiliation on the CITI website to gain access to the Baystate-required modules. There is overlap between the institutions requirements, the secondary affiliation feature “credits” the researcher for the modules already completed for UMass.

Access to Baystate Facilities and Records: Research personnel for UMass who will be assisting in the conduct of research at a Baystate facility can gain the necessary clearance and access to Baystate systems through the “Associates in Research” process. Associates in Research are processed through the Academic Affairs Allied Health Office. Please contact Kristi Gosselin for more information (794-4466).

Grant Application: When a project is federally funded, the grant application must be included in the submission to the Baystate IRB so that the IRB can fulfill its duty to verify that the research proposed to the IRB is consistent with the research as described to the grantor.

ClinicalTrials.Gov: When registration on ClinicalTrials.Gov is required, the study-wide Principal Investigator holds responsibility for ensuring that registration, interim updates, and reporting of results takes place. The Baystate IRB Application Part 1 contains information on the ICJME and FDA guidelines to help investigators determine whether or not their study must be registered.

Event Reporting: When UMass is the recipient of grant or other funds to support the project, both the Baystate IRB and the UMass HRPO must be informed of any unanticipated problems, noncompliance, or suspension or termination of the research. Baystate and UMass will collaborate on any required reporting to the grantor and applicable federal and state agencies.

Repositories: When data or specimens will be retained for future research projects at UMass the repository must be approved by the UMass IRB and documentation of the repository approval included in the Baystate application. Subjects should be consented separately for the banking of their specimens or data for future research; this should not be a condition of participation in the primary research project.

Policies: The policies and guidance documents of the Baystate HRPP must be adhered to including allowing access at reasonable times and with reasonable notice for routine and for-cause quality assurance monitoring. The policies of the Baystate HRPP can be accessed internally on [eWorkplace](#) or externally on [BaystateHealth.org](#).

Contact Information:

Baystate Health	University of Massachusetts Amherst
Karen Christianson Director: Human Research Protection Program Phone: (413)794-5714 Email: Karen.Christianson@baystatehealth.org	Margaret Burggren Associate Director: Office of Research Affairs Phone: (413)545-3428 Email: burggren@ora.umass.edu
Glenn Markenson, MD Institutional Official, Medical Director HRPP Phone: (413)794-3470 Email: Glenn.Markenson@baystatehealth.org	Vice Chancellor Michael F. Malone, PhD Institutional Official, VC for Research and Engagement Phone: (413) 545-5270 Email: vcre@umass.edu
Matthew Richardson, MD Chair: IRB #1 Phone: (413)794-9338 Email: Matthew.Richardson@baystatehealth.org	Priscilla Clarkson, PhD Chair: UMass Amherst IRB Phone: (413) 577-3902 Email: pclarkson@honors.umass.edu
Robert Baevsky, MD Chair: IRB #2 Phone: (413)794-4159 Email: Robert.Baevsky@baystatehealth.org	Judy LaDuc Manager: Biological Safety Services, EHS Phone: (413) 545-7293 Email: jladuc@ehs.umass.edu
HRPP/IRB Main Line: (413)794-4356	HRPO/IRB Main Office: (413) 545-3428
Associates in Research:	

<p>Kristi Gosselin Phone: (413)794-4466 Email: Kristi.Gosselin@baystatehealth.org</p>	
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