Baystate Health | UMass Chan MEDICAL SCHOOL

Research Community Meeting – Monthly Education

March 19, 2025

- The history of human subjects research and foundations for regulations (Helsinki, Tuskegee, Nuremburg, etc.)

April 16, 2025

- Determining What Qualifies as Non-Human Subjects Research.

May 21, 2025

- Understanding the Regulatory Differences Between Exempt, Expedited, and Greater than Minimal Risk Research

June 18, 2025

- Single IRB-internal and external IRBs; use of commercial IRBs (CIRB, Advarra, WCG).

July 16, 2025

- Ethics training, CITI, and discussing the nature of ethics requirements vs. moral judgments in protection human research participants.

August 20, 2025

- Conducting participant-centered informed consent processes.

September 17, 2025

- Documenting Consent forms and procedures; documenting research enrollment—utilizing systems adequately (IRBNet; Florence; On-Core).

October 15, 2025

- Utilizing Baystate IRB forms, Baystate policies, and regulatory knowledge to prepare for submission to the IRB.

November 19, 2025

- Post IRB approval monitoring and auditing of research-Is it just the IRB?—Auditing requirements (electronic, in-person).

December 17, 2025

- Non-regulatory Reviews in your IRB submission —Why is the IRB asking for this information? Review Institutional and state policies.

January 21, 2026

- Research Administration Procedures at Baystate Health—departments and policies.

February 18, 2026

- Expanded Access