Date: June 23, 2015 (*amended June 30, 2015, with link to IBC website and notice of approval timeline*)

To: UMass Community

From: Carol Bova, RN, PhD, Chair, IRB
Michael Centola, MHS, CIP, IRB Manager
Margaret Koziel, MD, Director of the Human Research Protection Program and Asst. Vice Provost for Clinical and Translational Science
Sassan Abdollahzadeh, PhD, Radiation Safety Committee
Thomas Greenough, MD, Chair, IBC
Samuel Varghese, PhD, Director, IBC and IACUC

RE: Change in the timing for the review of proposals involving biohazardous agents and/or radiation

Currently, investigators submitting proposals to the Institutional Review Board (IRB) involving the use of infectious agents, recombinant and synthetic nucleic acids or radiation are asked to obtain approval from the Institutional Biosafety Committee (IBC) or Radiation Safety Committee (RSC) before initiating research; concurrent submissions have been allowed. However, since review by these committees may result in significant changes to the protocol and consent, we are changing the timing of this review so that the IRB reviews the final protocol only after the IBC and/or RSC has approved the use of biohazardous agents and/or radiation for the proposed study and specified the language that must appear in the consent document. The goal is to reduce multiple reviews by the IRB and ultimately speed the time to initiation of research.

Effective September 1, 2015, submissions to the IRB that indicate the use of infectious agents, synthetic nucleic acids or radiation will be required to provide documentation that the protocol and consent has been reviewed and approved by IBC and/or RSC prior to IRB review. If this documentation is not included with the IRB submission, the investigator will be notified about missing information during the preapproval process. Review of the study by the IRB will not proceed until this documentation is provided.

Further details about the process for review and approval of clinical research by these committees may be found here:

- The IBC reviews research involving recombinant and synthetic nucleic acids (e.g. human gene transfer studies), infectious agents and toxins. It also reviews research involving the processing, and/or experimentation with human blood, secretions and/or tissues in clinical or basic research laboratories. In order to determine if your project needs IBC registration, please review the questionnaire at: IBC Registration Questionnaire for IRB Protocols (intranet only). For more information on submission deadlines, policies, guidelines and other resources, please visit: IBC Website (intranet only). IBC review and approval may take 4-8 weeks, so plan accordingly.

- The RSC reviews research with internally administered radioisotopes or external sources of ionizing radiation, which are experimental or protocol driven (i.e., would not normally be required by the subject's medical condition). For more information see http://inside.umassmed.edu/Radiation/Clinical-Trials/ (intranet only)