



*Human Subjects*  
**Institutional Review Board**



Changes to the Code of Federal Regulations for Human Subjects Research are scheduled to take effect on **January 19, 2018**, despite a proposed one-year delay that is under review by the Federal Office of Management and Budget. The IRB will be providing detailed updates, training, and revised templates starting in earnest in December.

**What do you need to do right now?**

- a. **Watch for messages from the IRB:** <https://www.umassmed.edu/ccts/irb/>. We recommend that you refresh your login page for eIRB, which now provides a link to the News and Announcements section of the IRB homepage for easy access to periodic updates: <https://eresearch.umassmed.edu/OVPR/>
- b. **Continue to submit to the IRB as you normally would.**
  - i. Studies approved before January 19, 2018, will largely stay under today's "pre-2018" regulations and standard operating procedures.
  - ii. All human subjects research – including research that fits one or more of the exemption categories – and all Modifications to human subjects research will continue to require prior IRB review and approval, in accordance with *HRP-800 INVESTIGATOR GUIDANCE: Investigator Obligations* (<https://www.umassmed.edu/ccts/irb/investigator-guidance/>).
- c. **When you need a form or template, download from the IRB website instead of recycling earlier versions.** Changes are coming soon to the consent form template and the study plan instructions.
- d. **Take note of the expiration dates indicated in your approval letters and create a reminder system to ensure timely submission of continuing reviews and study closures.** Starting January 19, 2018, all new non-exempt minimal risk research will have a one-year or three-year approval period. All research – including exempt research – will

receive annual reminders of investigator obligations, including the obligation to submit research closures to the IRB.

**We look forward to working with you as we transition to the new regulations.**

**Sincerely,**

**IRB**