New Human Subjects Regulations

Annual Reminder of Investigator Obligations

09.03.2018

- **HRP-800 INVESTIGATOR GUIDANCE: Investigator Obligations** outlines all investigator obligations. (https://www.umassmed.edu/ccts/irb/investigator-guidance/)
- The following table outlines the requirements for Approval, Modification, Continuing Review, and Closure according to whether research is Exempt, Expedited, or reviewed by the Full Committee.

		Requires prior IRB review and approval?	Requires prior IRB review and approval of Modifications?*	Requires Continuing Review?	Requires Closure?
Category of Review	**Exempt**	Yes	Yes – if the changes involve HIPAA, risks, exemption category, or scope of research	No	Yes – submit Modification
	Expedited	Yes	Yes – all changes	Yes – has one-year or three-year approval period	Yes – submit final Continuing Review
	Committee	Yes	Yes – all changes	Yes – has maximum one-year approval period	Yes – submit final Continuing Review

*Changes to eliminate immediate apparent hazards to research participants are permitted and must then be reported promptly to the IRB.

- All approved research – including exempt research – will receive an annual notification of investigator obligations until the PI submits a study closure.
- For Expedited and Full Committee studies, the annual notification is in addition to the first and second continuing review reminders, which are issued as a courtesy in the months prior to expiration.
- Exempt and Full Committee approval periods are unchanged: Exempt approvals never expire; Full Committee approvals do not exceed one-year.
- New Expedited research approved under the new regulations is eligible for a three-year approval period, unless it is FDA-regulated or funded or supported by the Department of Justice.

UMMS Institutional Review Board
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University of Massachusetts Medical School
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Annual Reminder for Exempt Research
This is an annual reminder that you are required to conduct the research in accordance with the Investigator's Manual. Your obligations include, but are not limited to: *•Obtaining prior IRB review and approval for all Modifications that involve HIPAA or that potentially change the risks, exemption category, or scope of the research;* *•Maintaining a current list of CITI-trained Active Study Staff in eIRB;* *•Adhering to Prompt Reporting Requirements;* *•Updating conflict of interest declarations; and* *•Closing the study via Modification.* *https://www.umassmed.edu/ccts/irb/investigator-manual/*
Annual Reminder for Expedited and Full Committee Research
This is an annual reminder that you are required to conduct the research in accordance with the Investigator's Manual. Your obligations include, but are not limited to: *•Obtaining prior IRB review and approval for all Modifications;* *•Maintaining a current list of CITI-trained Active Study Staff in eIRB;* *•Adhering to Prompt Reporting Requirements;* *•Updating conflict of interest declarations; and* *•Closing the study via Continuing Review.* *If your research expires this year, you may receive additional reminder notifications related to the Continuing Review.* *https://www.umassmed.edu/ccts/irb/investigator-manual/*