

* 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.

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|  |  | **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.

* **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.

UMMS Institutional Review Board

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## **New Human Subjects Regulations**

# Annual Reminder of Investigator Obligations

09.03.2018



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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/* |
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| **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/* |

 