New Human Subjects Regulations

Exemptions & Waivers

09.03.2018

MANDATORY IRB REVIEW

- At UMMS human subjects research that fits one or more exemption categories has always required – and will continue to require – prior IRB review and approval.
- This is already in compliance with the new requirement that only an IRB issue exemptions that require "limited review." (See **KEY DEFINITIONS**)

APPROVAL PERIOD

- Exempt research at UMMS already has no expiration date.
- Research that has been deemed exempt will receive an annual reminder notification of the investigator's obligations until the PI submits a study closure to the IRB.
- The PI must submit a Modification to close exempt research.
- The PI must obtain prior IRB review and approval when changes involve HIPAA, risks, the exemption category, or the scope of the research.

NEW EXEMPTION CATEGORIES AFTER NEW RULE TAKES EFFECT JANUARY 21, 2019

- Additional types of research will qualify for exemption, most notably:
    - Uses of secondary data and biospecimens that are already subject to HIPAA (**at UMMS use is contingent on additional Federal guidance**)
    - Research involving benign behavioral interventions with adults
    - Research that only includes interactions involving educational tests, survey procedures, interview procedures, or observation of public behavior, even if identifiers are recorded and disclosure may pose a confidentiality risk to research participants
- Investigators will still be expected to obtain informed consent for prospective data collection.

UMMS Institutional Review Board
Phone: 508-856-4261
E-mail: irb@umassmed.edu
https://www.umassmed.edu/ccts/irb/

University of Massachusetts Medical School
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BENIGN BEHAVIORAL INTERVENTION WITH ADULTS

- This is a new exemption category.
- The exemption is only permitted with adults.
- A benign behavioral intervention is brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing.
- Medical tests, procedures, and devices (e.g., EEG recording) are excluded.
- Research participants must be prospectively informed if they will be unaware of or misled regarding the nature or purposes of the research.

CHANGES TO CRITERIA FOR WAIVER OF INFORMED CONSENT

- If the waiver of consent involves identifiable private information or identifiable biospecimens, investigators must justify why the research could not practicably be carried out without using the information or biospecimens in an identifiable format.
- FDA now permits a waiver of informed consent for clinical investigations involving no more than minimal risk that previously were ineligible. This is independent of the New Rule.
- All waivers of informed consent require prior IRB review and approval.
- Waiver requests must be requested through the Consent Process section of the Investigator Study Plan either as a part of a new study or as a Modification to an existing study.