New Human Subjects Regulations

Expedited Review

09.03.2018

- Once the New Rule takes effect January 21, 2019, some research that previously qualified for expedited review will now qualify for exemption including:
  - Research involving benign behavioral interventions with adults
  - Research listed below provided the IRB conducts a "limited review" to ensure there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of the data:
    - Uses of secondary data and biospecimens that are subject to HIPAA (**at UMMS use is contingent on additional Federal guidance**)
    - 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
- Designated reviewers must document their rationale if they determine that research appearing on the expedited review list is greater than minimal risk (and thus requires Committee review).
- US Department of Health of Human Services is now required to review the list of expedited categories every 8 years and to amend the list if needed following consultation with agencies and an opportunity for public comment.
- At UMMS 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.
  - The new regulations continue to hold UMMS responsible for all research that the institution conducts.
  - A three-year approval period reduces burden on investigators, while allowing UMMS to maintain oversight of non-exempt research and the capability to generate reporting metrics required by accrediting bodies and funding agencies.
  - In the future, UMMS may consider extending the approval period or removing expiration dates entirely for minimal risk research.

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

University of Massachusetts Medical School
UMASS