New Human Subjects Regulations

What is *Broad Consent* and is UMMS using it?

01.24.2018

- Two new exemption categories in the New Rule pertain to broad consent.
    - The term *broad consent* applies to identifiable private information or identifiable biospecimens that already exist for non-research purposes (e.g., clinical data, leftover pathology specimens).
    - Individuals are asked to consent to the storage, maintenance, or use of this identifiable private information or identifiable biospecimens for research purposes.
- UMMS does not have a process to seek broad consent from all patients.
- Broad consent requires an infrastructure to track patient responses and any changes over time. There are no plans at this time to build this infrastructure at UMMS.
- IRBs are prohibited from granting waivers of informed consent that override a patient's decision to refuse broad consent.
- The IRB is still able to review and approve research involving existing data or biospecimens.

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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