

* 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

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## **New Human Subjects Regulations**

# What is *Broad Consent*

# and is UMMS using it?

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