STATEMENT OF PRACTICE

The University of Michigan maintains a federalwide assurance (FWA00004969) with the Department of Health and Human Services (HHS) in which it pledges to comply with federal regulations for all federally supported research and also to follow the ethical principles of the Belmont Report (National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research). This commitment allows the IRB flexibility in its application of federal regulations to studies that are not federally funded or FDA regulated. While continuing to apply the highest ethical standards for the protection of human subjects, this initiative will decrease the administrative burden on investigators and IRB MED Staff.

The webpage HRPP Flexibility Initiatives also provides information about current and historical flexibility initiatives and demonstration projects.

Flexibility initiative criteria and examples

To qualify for any flexibility initiative, a study must pose no more than minimal risk to subjects and may not include any of the following:

- Federal funding or federal training grants (direct or prime sponsorship)
- FDA regulated components
- Sponsor or other contractual restrictions (including ICH-GCP E6 compliance)
- Clinical interventions (including clinical behavioral interventions)
- Prisoners as subjects
- Receipt of a Certificate of Confidentiality to protect identifiable research data

Studies intended to support proposals or future awards for federal funding usually should not use “flexibility initiatives,” out of an ‘abundance of caution.’ However, former federal funding is not a barrier to flexibility initiatives for an ongoing study.

Flexibility initiatives at IRB MED include, but are not necessarily limited to:

Starting June 11, 2018: Pilot some of the 2018 Common Rule enhancements

- Implement new and updated exemption categories (except 7 and 8);
- Remove the requirement for continuing review when ongoing study activity is limited to data analysis and/or accessing follow-up clinical data.
- Remove the requirement for continuing review for new studies eligible for expedited review.

2015 - June 10, 2018

- U-M Exemption 2A
- U-M Exemption 7
- Two-Year Approvals