STATEMENT OF PRACTICE
Flexibility Initiatives

Effective: 3 February 2020

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 IRBMED Staff.

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

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 trial" under the NIH Definition
- 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.

If a study also involves external site(s), the study team should check with outside contacts before agreeing to a U-M flexibility initiative.

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

- **U-M Exemption 5**: Research and demonstration projects sponsored by the State of Michigan
- **"No continuing review required" for ongoing studies** (without triggering additional "2018 Requirements" under the Common Rule) that do not include genetic analysis
- **24-month approval for Repository (REP) Applications** that are not intended to facilitate genetic analysis

Prior (retired) flexibility initiatives

- June 11, 2018 – January 20, 2019 : **Pilot** some of the 2018 Common Rule enhancements
- 2015 - June 10, 2018
    - U-M Exemption 2A
    - U-M Exemption 7

- Two-Year Approvals