STATEMENT OF PRACTICE
Flexibility Initiative:
Two-Year Approvals

Effective: ***May 1, 2015***

Note: IRB applications granted a two-year approval may not be used to support proposals or future awards involving federal funding.

I. STATEMENT OF PRACTICE

Under the current federal regulations for human research, studies are required to undergo continuing review of the research at least annually, depending on the degree of risk to the subjects. Many research studies under the oversight of IRBMED pose no more than minimal risk to the subjects. Thus, it is unlikely that IRB determinations about potential benefits, informed consent, or risks to subjects would be affected by new information gathered from the research or from other sources if the approval period were lengthened beyond one year.

To exercise existing flexibility in the application of federal regulations to non-federally funded studies, IRBMED will undertake a flexibility initiative by issuing *two year* approval periods for certain types of studies. The longer approval period will eliminate the need for principal investigators to submit scheduled continuing reviews (SCRs) on an annual basis.

II. PROCESS

To qualify for two-year approval studies must

- pose **no more than minimal risk** to subjects

AND

- Must *not* include any of the following:
    - Federal funding or federal training grants (direct or prime sponsorship)
    - FDA regulated components
    - Sponsor or other contractual restrictions
    - Clinical research interventions (including behavioral interventions)
    - Prisoners as subjects
    - Receipt of an NIH issued Certificate of Confidentiality to protect identifiable research data

New or renewing applications meeting the criteria cited above will be reviewed by the IRBMED to determine that subject protections comply with federal regulations. If appropriate protections are in place, and there are no additional extenuating circumstances, IRBMED may issue a two year approval. All other regulatory requirements, including amendments, adverse event, and ORIO reporting, remain unchanged.

Examples of qualifying research may include, but are not necessarily limited to, the following:

- Secondary use of identifiable data/specimens (both prospective and retrospective), not otherwise exempt
- Survey, focus group, or interview projects not otherwise exempt

III. RESOURCES

- U-M HRPP Policy Innovation & Demonstration Initiative http://research-compliance.umich.edu/hrpp-innovation-demonstration-initiative
- U-M HRPP: Exemption Category 7 http://www.hrpp.umich.edu/initiative/Exemption7.pdf
- 45 CFR 46.101(b)(4): http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.101(b)