



STATEMENT OF PRACTICE

Ancillary Approval & Final IRBMED Approval

Effective: 07-31-2019

I. STATEMENT OF PRACTICE

IRBMED will issue a final approval letter once all applicable review units have completed their review and formally documented their approval.

Study activities may not take place until final IRBMED approval is processed. In rare cases, a study may require additional permissions after IRB approval, from other committees inside or outside U-M.

[Human Research Protections Program \(HRPP\)](#) website and [HRPP Operations Manual Part 2](#) list U-M research review units. Examples include but are not limited to:

- eResearch Core and Ancillary Committees such as the Protocol Review Committee (PRC), Research Pharmacy (IDS), and the Calendar Review & Analysis Office (CRAO)
- eResearch “parallel” ancillaries such as the MICHR IND/IDE Investigator Assistance Program (MIAP), Michigan Clinical Research Unit (MCRU), and Clinical Engineering (BEU)
- other research support units such as the Human Pluripotent Stem Cell Research Oversight Committee (HPSCRO) and the Medical School Human Data and Biospecimen Release Committee managed by the Data Office for Clinical & Translational Research (DOCTR).