New policies and/or revisions to approved Michigan State University (MSU) Human Research Protection Program (HRPP) Manual policies and procedures can be recommended by any member of the MSU research community including Institutional Review Boards (IRB), the Office of the Vice President for Research and Graduate Studies, MSU faculty, staff, students, or external members of HRPP advisory committees. Recommendations for new HRPP policies and/or revisions to approved MSU HRPP policies should be submitted to the HRPP director. The Institutional Official (IO) must approve the new or revised policies, with the exception of non-substantial revisions which may be approved by the assistant vice president (AVP) for the Office of Regulatory Affairs (ORA).

New Policies
The HRPP director drafts the new policy into MSU HRPP format or delegates as appropriate. The HRPP director may seek additional consultation, advice, and/or review from others as appropriate (e.g., legal counsel, IRB chairs, IRB members, IRB staff, advisory committees, researchers, ORA staff, AVP ORA). The HRPP director, in consultation with ORA and/or Office of the General Counsel (OGC), determines if the recommended policy follows all applicable regulations and laws, is necessary to protect human subjects, is redundant or complementary to existing policies, conflicts with existing policies, or is otherwise appropriate.

The HRPP director shall submit the draft policy to the AVP ORA. The AVP ORA may provide comments to the HRPP director or may submit the draft policy to the IO for approval. The IO may approve the policy, not approve the policy, or may request advice and consultation on the recommendation. Some sources for advice and consultation may include the Council of Research Deans, the University Graduate Council, other standing or ad hoc committees and/or individuals as appropriate.

Revisions to Existing Policies
The HRPP director reviews recommended revisions to existing policies and, in consultation with the ORA and/or OGC, determines whether revisions are substantial (e.g., major policy changes). If the revisions are substantial they are processed in the same manner as new policies. If the revisions are non-substantial (e.g., updates to IRB procedures that do not substantially affect human research subjects, investigators, or
IRB members) the HRPP director submits the revised policy to the AVP ORA for approval.

**Implementation**
Once the policy is approved, the HRPP director will develop implementation procedures or delegate as appropriate. Implementation procedures will include processes for communication and dissemination. The HRPP director may consult with the ORA education coordinator and others as needed.

Implementation must include publication, posting, or other means to provide easy accessibility for IRB staff, IRB members, researchers, and the MSU community. At a minimum, the new and/or revised policy will be posted to the HRPP Manual on the [MSU HRPP website](http://example.com), which is accessible to all individuals. A notice will also be posted on the human research website to alert all individuals of the update to the HRPP Manual.

Other mechanisms of communication to be used will be dependent upon factors such as the nature of the new policy or revision, the stakeholders impacted, and whether the new policy or revision was substantial or non-substantial. Communication mechanisms may include, but are not limited to:

- Memos or emails to affected individuals
- Memos or emails to deans, directors, and chairs
- Targeted educational sessions
- Information provided at other regularly occurring meetings, such as the Council of Research Deans, the University Graduate Council, or the Sponsored Programs Outreach and University Training
- Educational handouts or materials made available through the human research website
- Creation or updates to online tutorials
- Creation or updates to frequently asked questions available on the human research website
- New webpage on the human research website