

**INSTITUTIONAL RESEARCH BOARD (IRB) ADHOC COMMITTEE
REPORT – April 12, 2012**

Members of the Institutional Research Board (IRB) Subcommittee were asked to review and provide a recommendation regarding the HOP draft of 10.10 Research Involving Human Subjects.

Ad Hoc Comments:

The proposed HOP draft of 10.10 Research Involving Human Subjects appears to provide an overly restrictive interpretation of Federal policy regarding human subjects. Most of the interpretations seem to involve administrative compliance issues.

The Research Involving Human Subjects policy should consider separating out natural science human subject issues from similar issues for the social sciences. The policy should better reflect the differences between the two approaches relative to scientific research and participation of human subjects.

Section VIII, B 2, needs clarifying language relative to nonexempt Human Subjects and provide a reference to relevant document requiring this.

Section VIII, B 3, needs to describe why the IRB conducts post-approval monitoring of Research involving Human Subjects to ensure that research is being conducted as approved by the IRB....

Section IX, B 5, should say if necessary in order to determine that the risk/benefit ratio is acceptable and reference relevant Federal guidelines.

Section IX, B 7, should delineate who is an appropriate UTSA official. Additionally, discuss why an appropriate official can decide against allowing an IRB-approved activity to move forward. Language and rationale needs to be adjusted prior to final approval.

Recommendation:

After reviewing the proposed HOP draft of 10.10 Research Involving Human Subjects, the IRB Ad Hoc Committee recommended approval of the policy with minor adjustments.