

**INSTITUTIONAL REVIEW BOARD
THE UNIVERSITY OF MONTANA-MISSOULA**

OVERSIGHT OR VERIFICATION

POLICY: In certain cases the UM IRB may institute continuous oversight on projects in order to monitor reporting of changes in research and to ensure prompt reporting of unanticipated problems.

PROCEDURES:

1. The UM IRB may institute a plan for continuing oversight of certain human subject research projects in which:
 - a. There are extraordinary risks to the subjects;
 - b. Verification is needed from sources other than the investigators that no material changes have occurred in the approved protocol; or
 - c. There are indications that the investigators are not promptly reporting changes in research activity.

2. Oversight may be provided by a subcommittee of the UM IRB or by a designated individual or group, who are not part of the UM IRB.

APPROVED: 
Chair, UM IRB

DATE: 11/12/03