

DEPARTMENT: INSTITUTIONAL REVIEW BOARD
POLICY NUMBER: 031
SECTION: GENERAL IRB POLICIES
REVIEW RESPONSIBILITY: IRB
EFFECTIVE DATE: AUGUST 13, 2003
REVISION DATE:
LAW IMPLEMENTED: 45 CFR 46.116

SUBJECT: Compensation or Medical Treatment If Injury Occurs

1. If applicable, all subjects must be provided an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained.
2. For commercially sponsored studies, the Informed Consent document must contain one of the following three choices and the following paragraph (given the provisions of the agreement with the sponsor), unless specifically waived by the IRB:
 - a) Any costs for the treatment of research related adverse events will be paid for or reimbursed by the sponsor (Note: This is the preferred language).
 - b) Any costs for the treatment of research related adverse events will be charged to you or your insurance carrier. However, if for any reason these costs are not covered by insurance, they will be paid for or reimbursed by the sponsor. (Note: Use of this option requires that it matches the agreement to be approved by the Office of Research).
 - c) Any costs for the treatment of research related adverse events will be charged to you or your insurance carrier. However, if for any reason these costs are not covered by insurance, they will be your responsibility. (Note: Use of this option requires that it matches agreement to be approved by the Office of Research).