

## **Why OHSU Does not Allow Billing of Research Related Injuries to Subjects or Their Third Party Payers**

OHSU believes that our research subjects should not bear the financial burden of participation in the development of products for companies. Therefore, even if the complications were covered by Medicare or private insurance, OHSU will not charge research participants' insurance for events caused by participation in a company's study. This is because a patient would bear the financial burden of copayments, deductibles, and impact on life time limits.

CMS covers clinical complications due to research when the study meets all criteria of the "Routine Costs in Clinical Trials" National Coverage Decision (NCD). However, not all studies meet the CMS NCD criteria. Furthermore, CMS has determined that a "clinical trial sponsor's agreement with trial participants that it will pay for medically necessary services related to injuries participants may receive as a result of participation in the trial constitutes a plan or policy of insurance under which payment can reasonably be expected to be made in the event such injury occurs...Therefore, Medicare will not make payment." (CMS, Office of Financial Management, April 13, 2004)

Some research subjects are not insured. Third party payers at OHSU will not pay for research or complications due to research because research is a noncovered service under those payers' policies, and Oregon law specifically excludes research complications from required coverage (OR SB 316). OHSU cannot bill for noncovered services, as to do so would be fraudulent. In addition, our physicians are AMA members. The AMA Code of Conduct explicitly states, "Physicians should ensure that protocols include provisions for the funding of subjects' medical care in the event of complications associated with the research" (AMA code of conduct, E-8.035).

## **Who Makes the Determination of Relationship of Injuries to Research Procedures and/or the Study Intervention**

In accordance with the FDA Bioresearch Monitoring Guidelines For Clinical Investigators, the causality for adverse experiences reported to the FDA on case report forms must be determined by the site investigator. This is also consistent with how the adverse experience is reported to the sponsor and subsequently the FDA in support of a marketing application for the product under investigation. OHSU in its standard contract language remains silent on this point, as it is implied per the regulatory responsibilities of a clinical investigator. Procedures for resolution of any disputes in this regard are outlined elsewhere in the contract. Should it be necessary to clarify this point further, the following may be added to the end of the agreement subject liability statement:

"Responsibility for determination of the relationship of adverse reactions to research procedures or study drugs or devices shall reside with the Principal Investigator. Sponsor disagreement with a determination by the Principal



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Investigator shall be resolved as described in Dispute Resolution, section <insert section> of the Agreement.”