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

Centers for Medicare & Medicade Services (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 and, in addition, OHSU has elected not to implement the provisions of the NCD due to the administrative difficulties of implementation. 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." (Letter from CMS, Office of Financial Management, April 13, 2004)

Some research subjects are not insured. All other third party payers at OHSU will not pay for research or complications due to research because research is a noncovered service. Therefore, these costs are not covered by the third party payer. OHSU then cannot bill for a service for which we have reason to believe is a noncovered service. By law that is considered fraud. In addition, our physicians are AMA members and, though not legally binding, 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).

OHSU believes that its 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 the NCD or insurance, OHSU will not allow its research participants to have their insurance charged for events caused by their participation in a company's study. This is because a patient would bear the financial burden of copayments, deductibles, and life time limits being affected.

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

Per the FDA Bioresearch Monitoring Guidelines For Clinical Investigators, it is the FDA's expectation that the causality for adverse experiences reported to the FDA on case report forms be determined by the site investigator. Therefore, OHSU relies on the determination of the causality of any injury to the subject be determined by the investigator in order to be 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 and 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 Investigator shall be resolved as described in Dispute Resolution, section <insert section> of the Agreement."

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