

## **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, 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 generally covers clinical complications due to research, but some research subjects are not insured. Further, third party payers will not pay for research or complications due to research because research is a non-covered service under those payers' policies, and Oregon law specifically excludes research complications from required coverage (OR SB 316). 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 Investigator shall be resolved as described in Dispute Resolution, section <insert section> of the Agreement."

## **What Information Will OHSU Provide to Facilitate Compliance with Section 111 of the Medicare, Medicaid, and SCHIP Extension Act of 2007**

In accordance with MMSEA Section 111, and upon request of the Responsible Reporting Entity (RRE - study sponsor), OHSU will provide the necessary identifying information for any injured party who is a Medicare beneficiary and for whom a determination has been made that a payment will be, or has been, made by the RRE on behalf of the injured party. Such identifying information will include name, date of birth, gender, and either the Medicare Health Insurance



Claim Number (HICN) or Social Security Number (SSN) of the injured party. ([See CMS MMSEA Section 111 Mandatory Insurer Reporting Quick Reference Guide](#)). Any subsequent reporting requirements will be the sole responsibility of the RRE. This information can be specified in the agreement with the study sponsor. However, since release of this information is pursuant to payment for treatment of an injury, specific language describing its release is not required and shall not be described in the study informed consent or research authorization.