



OHSU Position Statement

Research Integrity Office

Mail code **L106-RI**
3181 S.W. Sam Jackson Park Road
Portland, Oregon 97239-3098
tel: 503 494-7887 | fax: 503 346-6808

Payment for Subject Injuries

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. This is because many third party payers will not pay for research or complications due to research since research is often a non-covered service under payers' policies, and Oregon law specifically excludes research complications from required coverage (ORS 743A.192). In addition, some research subjects are not insured. Where coverage exists (e.g., CMS generally covers clinical complications due to research), a patient would bear the financial burden of copayments, deductibles, and impact on life time limits. Moreover, our physicians are AMA members. The AMA Code of Medical Ethics 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 Medical Ethics, Opinion 8.0315.

For the reasons set forth above, OHSU will bill a company directly for research-related injuries caused by participation in the company's study. Third party payers will be notified of the services provided to address research-related injuries if required by the payer's rules, but OHSU will not seek payment from the third party payer or the research subject for research-related injuries.

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 may include the first letter of their first name, the first six letters of their last 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.