



OREGON CLINICAL
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Research Institute

OCTRI Research Forum: Subject Injury Policy, Identification, and Reporting at OHSU

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Subject Injury Definition:

- A subject injury is an adverse experience:
 - arising directly from or contributed to by the research; and
 - not due to the subject's primary disease or other condition; and
 - would not have been expected from the standard treatment for the subject's condition using currently accepted therapies

Identifying A Subject Injury

- When the study team is notified of an adverse experience, it needs to be evaluated to determine if it is considered an injury
- The principal investigator is responsible for making the determination whether an injury has occurred

Subject Injury Identification Exercise

Is it subject injury?

- Clinical trial of investigational chemotherapy in cancer usually treated with tyrosine kinase inhibitor
 - Disease progression?
 - Anticipated side effect of research medication the same as tyrosine kinase inhibitor side effect?
 - Unanticipated side effect of research medication the same as tyrosine kinase inhibitor side effect?
 - Anticipated side effect of research medication different than expected tyrosine kinase side effect?
 - Unanticipated side effect of research medication different than expected tyrosine kinase side effect?

Exercise Answers

Clinical trial of investigational chemotherapy in cancer usually treated with tyrosine kinase inhibitor:

- Disease progression: **Not Subject Injury**
- Anticipated side effect of research medication the same as tyrosine kinase inhibitor side effect: **Not Subject Injury**
- Unanticipated side effect of research medication the same as tyrosine kinase inhibitor side effect: **Not Subject Injury**
- Anticipated side effect of research medication different than expected tyrosine kinase side effect: **Subject Injury**
- Unanticipated side effect of research medication different than expected tyrosine kinase side effect: **Subject Injury**

OHSU Subject Injury Position: Industry Sponsored Studies

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 bill subject injuries to subjects or their insurance

- Oregon law specifically excludes research complications from required coverage (ORS 743A.192)
- Where coverage exists, a patient should not bear the financial burden of copayments and deductibles
- Some research subjects are not insured

Policy: Billing Insurance Not Allowed for Industry Sponsored Studies

- Industry sponsors must pay ALL costs for evaluation and treatment resulting from subject injury. Subject's insurance cannot be billed:
 - Solely
 - First, with sponsor paying remainder
 - First, with sponsor paying if insurance doesn't cover
- Why:
 - The sponsor is benefiting from the study and the subjects should not be harmed financially for participating in the study
 - If insurance pays, it still generates co-pays/deductibles
 - Violates Medicare Secondary Payer rules
- Exceptions:
 - Marketed drugs/devices being used for their approved purposes
 - Category B devices (sometimes – check with your contract officer)
 - OHSU personnel caused the injury (OHSU pays for the injury)

OHSU Position on Limiting Liability to Subject Following Instructions

OHSU does not allow sponsors to require that subjects follow instructions in order to have the costs of research related injuries covered. This language appears exculpatory/asks subjects to waive their legal rights.

- **45 CFR 46.116 and 21 CFR 50.20** state: No informed consent, whether oral or written, may include any **exculpatory language** through which the subject or the representative is made to **waive or appear to waive any of the subject's legal rights, or releases** or appears to release the investigator, the sponsor, the institution or its agents **from liability for negligence**.

Subject Injury Coverage: Investigator-Initiated studies

- OHSU *may* cover the injury dependent upon various factors including
 - Oregon Tort Claims Act
 - OHSU's insurance
 - the role of OHSU personnel in causing the injury
- Studies funded through federal grants do not cover subject injuries

Subject Injury Consent Language

- Consent boilerplate liability language
 - Specifies what injuries are covered (just those caused by drug, or drug *and* procedures, or just procedures, etc. based on the study)
 - Intentionally doesn't detail who will pay for what injuries in what circumstances (e.g., OHSU for some/sponsor in others)
- Select the correct boilerplate consent language to ensure consent language will match the executed contract terms:
 - Funding type and type of study (device vs. drug) is important:
 - Category B device (device + procedures vs. study procedures only)
 - Approved drug with research-only procedures

Sponsors and Boilerplate Liability Language in Consent:

- Don't negotiate - Do not edit the boilerplate language without prior IRB approval.
- Do not insert unallowed limitations (exculpatory)
 - Cannot predicate payment for injury on following instructions
 - Can't include time limits for identification of the injury
- Inform sponsors that the boilerplate language is required
- Contact the IRB early if the sponsor has issues with using OHSU boilerplate language

Subject Injury Contract Language

- Cannot bill injuries to insurance
- Cannot include failure to follow instructions
- Injuries treated at other facilities: Can't limit reimbursement to only injuries treated at OHSU
- Reimbursement rates: Sometimes identified in the contract, OHSU bills the sponsor for injuries treated at OHSU at the DHHS negotiated research rate (does not apply to outside facilities)
- Can't exclude anticipated risks, e.g., risks noted in consent form or IB
- Attribution: The sponsor cannot control the determination of whether an adverse event is an injury (conflict of interest)
- Timelines for reporting can be included in contracts, but must begin upon OHSU becoming aware of the injury (e.g., no limit on the subject identifying the injury)

Reporting a Subject Injury – Industry Sponsored Research

- Sponsor:
 - Contact the sponsor immediately upon the PI determining a reportable injury has occurred
 - Even if all the information is not available, notify the sponsor an injury is suspected and complete information will be provided as it is available
 - Document that notification in writing (email or note to file)
- CRBO:
 - If there are any charges associated with evaluation and treatment of the injury, contact CRBO immediately to assist with directing charges to study account and providing sponsor with information about subject's Medicare status
- CTO-Contracting:
 - Contact if the sponsor refuses to pay for the injury
- Risk Management:
 - Contact if injury is potentially due to actions of OHSU personnel

Reporting a Subject Injury- Investigator Initiated Research

- Contact Risk Management if a subject is injured while participating in an investigator initiated clinical trial

Reporting a Subject Injury- All Injuries

- If patient harm from care not consistent with appropriate standard of care at OHSU (including medical errors, near misses, general safety issues), and occurred in the health system, file Patient Safety Intelligence report (PSI, <https://o2.ohsu.edu/healthcare/tools/patient-safety-intelligence.cfm>)
- If meets the criteria for Reportable New Information (RNI), report in eIRB

Subject Injury Reimbursement Processes

- Direct charges to the study account
 - Evaluation and treatment at OHSU: CRBO contacts PBS/UMG to direct charges
 - If evaluated and/or treated at outside facility: study team requests copy of bill from facility and sends it to Accounts Payable to pay the external facility from OGA study account
 - If subject paid for evaluation and/or treatment out of pocket: subject provides copy of bills to study team and study team sends a request to Accounts Payable to pay the subject from study account
- If the subject's insurance has been billed, the charges will be reversed/refunded and directed to the study account
- Once available, the study team provides itemized bill for the injury to the sponsor for payment

Sponsor Medicare Reporting Requirements (MMSEA)

- Section 111 of the Medicare, Medicaid, and SCHIP Extension Act of 2007 (MMSEA)
- Mandatory reporting requirements for sponsors when they pay for the injury of a Medicare beneficiary
- Study team should direct sponsor to contact CRBO for any information needed for MMSEA reporting
 - Refer all inquiries to CRBO

Resources

- Policies and Procedures
 - Links to all policies and procedures can be found on the **NEW!!!** Subject Injury Reporting Webpage <https://o2.ohsu.edu/clinical-research-services/subject-injury.cfm>
- Contact information
 - Billing questions: crbo@ohsu.edu
 - Contract questions: Kristen Baptiste, CTO Manager
 - Consent questions: Contact your IRB Specialist
 - RNI questions: Contact your IRB Specialist



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Thank You