Subject Injury Policy, Identification, and Reporting at OHSU

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Subject injuries are adverse reactions:
- Arising directly from or contributed to by the research
- That are not due to the subject’s primary disease or other condition
- That would not have been expected from the standard treatment using currently approved therapies for the subject’s condition
• **Industry sponsors** must pay any costs resulting from subject injury
  • The sponsor is benefiting from the study and the subjects should not be harmed financially for participating in the study
    – Subject’s insurance cannot be billed:
      • Solely, NOR
      • First with sponsor paying remainder, NOR
      • First with sponsor paying if insurance doesn’t cover
    – Why:
      • If insurance pays it still generates co-pays/deductibles and affects subject insurance maximums
      • Violates Medicare rules and other insurance policies
    – Exceptions:
      • Marketed drugs/devices for their approved purposes
      • Category B devices (sometimes)
      • OHSU personnel caused the injury (then OHSU pays for the injury)
• **Investigator-initiated** studies:
  – OHSU may cover the injury - Coverage of injury by OHSU dependent upon various factors, including the Oregon Tort Claims Act, OHSU’s insurance, and the role of OHSU personnel in causing the injury
  – Federal grants do not cover subject injuries
Subject Injury Consent Form Language

• Need to specify what injuries the subject is not responsible for (drug vs. drug and procedures vs. just procedures, etc. based on the study)
• The entire injury needs to be paid for (no billing to insurance first)
• CF should not discuss who will pay for what injuries in what circumstances (e.g., OHSU for certain circumstances and sponsor in others)
• Can’t place limitations on the subject (exculpatory)
  – Cannot predicate payment for injury upon following instructions
  – Can’t include time limits
• Template language required – see IRB website
  – Know what the sponsor will cover so that the consent matches the contract
    • Category B device
    • Approved drug with research procedures
  – Be clear with sponsors that the template language is required
  – Contact the IRB if the sponsor refuses to use OHSU template language
Subject Injury Issues in Contracts

- Consent issues:
  - No billing injuries to insurance
  - 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 rate (does not apply to outside facilities)

- Can’t agree to 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
Identifying A Subject Injury

• When the study team is notified of adverse experiences, they need to be evaluated to determine if they are considered injuries
• The principal investigator is responsible for making the determination of whether an injury has occurred
• Definition
  – Adverse reactions:
    • Arising directly from or contributed to by the research
    • That are not due to the subject’s primary disease
    • That would not have been expected from the standard treatment using currently approved therapies for the subject’s condition

• Is it subject injury?: Clinical trial of investigational chemotherapy in cancer usually treated with tyrosine kinase inhibitor
  – Disease progression?
  – 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?
Clinical trial of investigational chemotherapy in cancer usually treated with tyrosine kinase inhibitor:

- Disease progression: Not an SI
- Side effect of research medication the same as tyrosine kinase inhibitor side effect: Not an SI
- Anticipated side effect of research medication different than expected tyrosine kinase side effect: SI
- Unanticipated side effect of research medication different than expected tyrosine kinase side effect: SI
• **Industry-sponsored**
  
  — Sponsor
    
    • Contact the sponsor immediately upon the PI determining an injury has occurred
    
    • May not have all the information but 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:
    
    • Contact CRBO immediately to assist with directing charges appropriately to study account and providing sponsor with information about subject’s Medicare status
  
  — PBS/UMG: Provides detailed charge information for study team to provide to sponsor
  
  — CTO-Contracting: Contact if the sponsor refuses to pay for the injury or if you know that OHSU is at fault (will involve Legal and/or Risk Management as appropriate)

• **Investigator-initiated**: Contact Risk Management

• **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
• Direct charges to the study account
  – If injury treated at OHSU: CRBO contacts PBS to direct charges
  – In injury treated at outside facility: Study team requests copy of bill and sends it to Accounts Payable to pay the external facility from study account
  – If subject paid for 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
• Section 111 of the Medicare, Medicaid, and SCHIP Extension Act of 2007 (MMSEA)

• Added mandatory reporting requirements to sponsors when they pay for the injury of a Medicare beneficiary

• CRBO informs the sponsor if the subject is a Medicare beneficiary and provides the information needed by the sponsor for reporting

• Sponsor inquiries related to MMSEA:
  – Do not release lists of SSNs of any subject to the sponsor
  – Refer the sponsor to CRBO
• Policies and Procedures
  – Subject injury reporting procedure: [https://o2.ohsu.edu/integrity-department/forms-and-policies/upload/Research-Subject-Injury-Reporting.pdf](https://o2.ohsu.edu/integrity-department/forms-and-policies/upload/Research-Subject-Injury-Reporting.pdf)
  – RNI policy (HRP-801 Prompt Reporting Requirements under Investigator Guidance): [http://www.ohsu.edu/xd/about/services/integrity/policies/all-irb-documents.cfm](http://www.ohsu.edu/xd/about/services/integrity/policies/all-irb-documents.cfm)

• Contact information
  – Billing questions: crbo@ohsu.edu
  – Contract questions: Jaci Brown, Manager, CTO
  – Consent questions: Contact your IRB analyst
  – RNI questions: Contact your IRB analyst