

Informed Consent/Subject Injury Update

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Key Issue

- Inconsistent language
 - Subject injury
 - Subject costs
- Goal
 - Develop policy regarding subject injury
 - Improve template language
 - Subject injury
 - Study related costs

Subject Injury

- **Policy IC 709: Treatment and Cost of Research Related Injury**
 - **Medicare Secondary Payor Rule**
 - Centers for Medicare and Medicaid Services (CMS) has taken a position that a promise to pay for Subject Injury Costs in a contract (even conditional payment), of itself, is sufficient to be considered a liability insurance policy or plan such that Medicare would not be the primary payor (Medicare Secondary Payor (MSP) provisions).
 - As a result, CMS requires that if a Sponsor chooses to pay Subject Injury Costs for subjects covered by Medicare, then the Sponsor must be treated as the primary payor for those costs. The MSP provisions require that Medicare is the secondary payor. The same principles apply to Medicaid, the payor of last resort.

Funding source dictates who pays for Subject Injury

- Government, philanthropic, foundation, Jefferson-sponsored:
 - Jefferson will offer treatment for a research-related injury or illness, but neither Sponsor nor Jefferson will pay for Subject Injury Costs.
- Commercially-sponsored research
 - Although not legally required to pay for subject injury costs, Jefferson requires that commercial sponsors pay for these costs.
 - Terms are negotiated as part of the clinical trial agreement.

Commercially Sponsored Clinical Research Study

- Clinical Trial Agreement Language:
 - Policy IC 709: Treatment and Cost of Research Related Injury
 - Section 5.3.1
- Informed Consent Form: OHR-8
 - Option 1: For all Commercially Sponsored Research.
 - There is a possibility that you could have research-related injury, which is an illness or an injury that is directly caused by the study drug(s)/device or a study procedure. If you have a research-related injury, reasonable and necessary medical care will be available to you. The cost of care for the research-related injury will be paid by the sponsor of the study.

Government, Philanthropic, Jefferson-sponsored Clinical research Studies

- **Clinical Trial Agreement Language:**
 - Policy IC 709: Treatment and Cost of Research Related Injury
 - Section 5.4
- **Informed Consent Form: OHR-8**
 - Option 2: For all Government, Philanthropic, or Jefferson Sponsored Research.
 - There is a possibility that you could have research-related injury, which is an illness or an injury that is directly caused by the study drug(s)/device or a study procedure. If you have a research-related injury, we will offer you reasonable and necessary care to treat injuries directly resulting from taking part in this research. Neither Jefferson nor the study will pay for costs associated with treatment of research-related injury or illness. These costs may be billed to your insurance. In addition, you will be responsible for any deductibles and co-payments required under your health plan and for any claims ultimately denied by your health plan. There are no plans for Jefferson to pay you or give you other compensation for the injury. If you think you have been injured as a result of taking part in this research study, tell the research personnel as soon as possible. Please see the contact information in this consent form

Research Costs

- The section of the ICF that identifies costs the subject may be responsible as a result of their participation in the research study
- Issue: High variability in language from study to study
 - Creates confusion among study staff and research subjects
- Solution: Created template language in the OHR-8 for study teams to use that:
 - More clearly spells out if there is a possibility for insurance to be billed, potential out of pocket costs
 - Also clearly identifies if any payments are due to the subjects'

****Must be consistent with the study budget and contract****

Option 1: For studies with no billable activity (i.e. the sponsor pays for everything)

1. Insurance costs→ There will be no study related items or services billed to you or your insurance company.
2. Underlying/ “hidden” costs→ You may be responsible for other costs. There is no plan to pay you for lost wages, lost time from work, personal discomfort, or for injuries or problems related to your underlying medical condition(s).
3. Billing issues→ If you receive a bill that you think is wrong, please contact the research personnel.
4. Payment Section:→Will align with final budget/contract if payment available or you will be responsible to pay for your travel to and from the study site and other out-of-pocket expenses such as parking.

Option 2: For studies with billable activity and the sponsor is **NOT** paying for everything

1. Items for Free→ The study drug or device will be provided to you free of charge.
2. Paid for by sponsor→ There may be items or services performed during your participation in this study that will be paid for by the sponsor.
3. Insurance costs→ There may be costs to you for taking part in the study. Some of the procedures and services performed in the study are part of the regular treatment for your condition. These would be performed even if you were not enrolled in the study. The costs for these procedures and services will be billed to your insurance. Additional items may also be billed to your insurance while you are taking part in the study. These items may include administration of the study drug, as well as procedures and services to prevent, diagnose or treat potential complications arising from your participation in the study.
4. Patient responsibility→ You will be responsible for any costs your insurance does not cover. You will be responsible for insurance co-pays and deductibles.
5. Underlying/ “hidden” costs→ There is no plan to pay you for lost wages, lost time from work, personal discomfort, or for injuries or problems related to your underlying medical condition(s).
6. Billing Issues→ If you receive a bill that you think is wrong, please contact the research personnel.
7. Payment section→ Will align with final budget/contract if payment available or you will be responsible to pay for your travel to and from the study site and other out-of-pocket expenses such as parking.
8. Patient guidance for insurance coverage→ You should talk to your insurance carrier to find out what costs you will need to pay before taking part in this study. If you are a Medicare beneficiary and have opted for a Medicare Advantage plan to manage your health care needs, your out-of-pocket expenses may increase while you are on this study. Depending on your insurance carrier, some of the costs not covered by your insurance may be sizeable.

Take-Away

- During IRB review if the ICF language for subject injury or research costs is unclear or inconsistent with Jefferson policy, please ask study staff to coordinate with JCRI business operations



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Philadelphia University +
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