Indiana University
Office of Clinical Research

Policy on Conditional Payment Language and Research-Related Injury (RRI) in Industry-Sponsored Clinical Trials

Payment Responsibility

For studies involving more than minimal risk, the Office of Clinical Research (OCR) expects Industry Sponsors to cover reasonable medical costs for diagnosing and treating research-related injuries or illnesses (RRI) for all participants, regardless of their insurance. Limited exceptions are specified below. Non-industry sponsored studies may bill patients or their insurance for these RRI costs, but duplicate payment is always prohibited.

Prohibiting Conditional Language

Statements suggesting a Sponsor's obligation depends on a participant's insured status or denial of payment by the primary insurer are considered conditional payment language. This language is prohibited for the following reasons:

- **Medicare Secondary Payer (MSP) Act Compliance** When a Sponsor agrees to pay for RRI, it creates liability coverage under 42 CFR § 411.50. As a result, Medicare is the secondary payer and cannot be billed first. Billing Medicare before the Sponsor or limiting Sponsor responsibility for Medicare beneficiaries violates MSP regulations.
- **Equity Among Participants** Billing private insurance before Medicare or vice versa is not allowed, as it results in unequal treatment. Medicare mandates that beneficiaries in clinical trials must receive, at no cost, any items or services provided free to non-Medicare participants. Sponsors cannot pay for subject injury costs only for uninsured participants.

Institutional Standard Language

Institutional standard language is provided below. The Clinical Trial Agreement (CTA) and Informed Consent Form (ICF) must align and be unambiguous. If the language is inconsistent, one of the documents should be modified appropriately to reflect the agreement of the parties.

CTA:

The Sponsor shall reimburse the Institution for the reasonable and necessary medical costs to diagnose and treat any injury or illness directly resulting from participation in the study. This includes injury or illness caused by the investigational product as well as any protocol related procedures subject only to the following standard exclusions.

- *The injury directly results from the Institution's or Principal Investigator's (PI's) failure to materially comply with the protocol or applicable laws.*
- *The injury directly results from the negligence or more culpable act of the Institution or PI.*
- *The injury results from the participant's primary disease or any concurrent disease not caused or exacerbated by the administration of the study drug or device in accordance with the protocol.*
- *The injury directly results from the participant's failure to follow the protocol or instructions provided by the PI.*

ICF:

The Sponsor has agreed to pay for all medical costs necessary for the diagnosis and treatment of any illness or injury resulting from your participation in this study, unless any of the following are true:

- *The injury happened because the Institution or Principal Investigator (PI) did not follow the study plan.*
- *The injury happened because the Institution or PI was careless or acted wrongly.*
- *The injury is from your main illness or another health issue that was not caused or made worse by the study drug or device when used as directed in the study.*
- *The injury happened because you did not follow the study instructions or the PI's directions.*

If there are medical expenses related to an illness or injury that are determined to be unrelated to your study participation or will not be paid by the Sponsor because of the limitations listed here, those costs will be your responsibility or that of your insurance. Signing this form won't take away any of your legal rights if you are injured.

Note: Where appropriate, an additional statement regarding Medicare reporting requirements may be added. Example:

To pay medical expenses, the sponsor will need to know some information about you like your name, date of birth, and Medicare Beneficiary Identifier (MBI). This is because the sponsor must check to see if you receive Medicare and if you do, report the payment it makes to Medicare.

Exceptions

For industry-sponsored studies, when sponsor has assumed payment responsibility, it may be limited only by the following standard exclusions:

- The injury directly results from the Institution's or Principal Investigator's (PI's) failure to materially comply with the protocol or applicable laws.
- The injury directly results from the negligence or more culpable act of the Institution or PI.
- The injury results from the participant's primary disease or any concurrent disease not caused or exacerbated by the administration of the study drug or device in accordance with the protocol.
- The injury directly results from the participant's failure to follow the protocol or instructions provided by the PI.

Reimbursement Rates

When the sponsor agrees to pay research-related injury costs, they must cover all reasonable and necessary expenses without limiting payment to Medicare rates or other set amounts. Participants may receive care at their chosen facilities, and all costs—plus overhead—will be handled accordingly. See above for preferred wording.

Unacceptable Language

Unacceptable language includes any provision that:

- Makes Sponsor payment contingent on denial (partial or full) by the participant's insurer.
- Requires the site to bill the participant's insurance first, with Sponsor covering only the remainder.
- Attempts to differentiate Sponsor's payment obligation by participant, carving out or establishing different payment scenarios for the uninsured, privately insured, or Medicare/Medicaid beneficiaries.
- States or implies that the participant (or their insurer) may be responsible for any portion of RRI treatment costs, except for standard exclusions noted below.

Conclusion

In the event of an inconsistency between an executed contract and signed informed consent, the following rules apply:

- The subject should not be required to pay for any costs that were not listed as being the subject's responsibility in the informed consent; and
- The subject should not be charged for any cost that the Sponsor agreed to pay because this may result in inadvertent double-billing.

Questions regarding this policy may be directed to the OCR Financial Compliance Team at ocrfin@iu.edu.