# Policy Brief

Last Revised: 11/11/2025

# 7.71 Billing Coverage for Uninsured and/or Injured Research Subjects

**Administering Department:** Research Compliance and Regulatory Affairs (RCRA)

## Scope:

### Summary

Emory University is committed to protecting the rights and welfare of individuals who participate in clinical research. Participation in clinical trials is essential to advancing science but may expose research subjects to financial burdens if they lack adequate insurance coverage or experience illness or injury related to study participation.

Policy 7.71 establishes institutional requirements for how routine clinical trial costs and research-related injury costs are billed and covered. The policy clarifies sponsor responsibilities, institutional billing practices, and protections for uninsured or under-insured research subjects. Its purpose is to ensure that subjects are not unfairly burdened with costs that should appropriately be covered by sponsors or institutional mechanisms, while maintaining compliance with applicable laws, regulations, and contractual obligations.

### Applicability

This policy applies to all clinical trials conducted at Emory University, including those sponsored by industry, federal agencies, foundations, or internal funding sources.

## Compliance with the Policy

All Emory clinical trials must comply with this policy and with applicable federal regulations, institutional billing practices, and contractual requirements. The Institutional Review Board (IRB) is responsible for ensuring that informed consent documents accurately describe subject costs and injury coverage. Emory will not agree to contract terms or consent language that contradict this policy or shift inappropriate financial responsibility to research subjects.

The Principal Investigator is responsible for ensuring compliance with this policy, including obtaining appropriate approvals and adhering to approved billing and injury coverage provisions.

Key compliance expectations include:

- Alignment between the Clinical Trial Agreement (CTA) and the Informed Consent Form (ICF).
- Oversight by the Institutional Review Board (IRB) to ensure subject cost language is accurate and non-exculpatory.

- Coordination with Research Compliance & Regulatory Affairs (RCRA) and the Office of General Counsel when contractual billing or waiver provisions are proposed.
- Assurance that subjects are not charged for costs the sponsor has agreed to pay or for costs not disclosed in the IRB-approved ICF.

## Noncompliance with the Policy

Failure to comply with this policy may result in corrective actions, including contract revision, suspension of research activities, loss of funding opportunities, or other institutional actions consistent with Emory policies and applicable regulations.