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Scope: Medical Center Beckman Research Foundation

**Treatment of and
Financial Responsibility
for Research-Related
Injuries Policy**

I. PURPOSE / BACKGROUND

The purpose of this Treatment of and Financial Responsibility for Research-Related Injuries Policy (“Policy”) is to establish the treatment of research-related injuries requirements for City of Hope National Medical Center and City of Hope Medical Foundation (collectively, “COH”) that comply with federal and state laws and COH Institutional positions. It is also to detail the treatment COH will provide to research subjects as a result of a Research-Related Injury, and to define COH’s requirements for industry sponsors regarding payment for treatment of Research-Related Injuries.

Federal regulations require that for human subjects’ research involving more than minimal risk, prospective study subjects be provided with “an explanation as to whether any medical treatments will be provided if an injury occurs and if so, what they consist of, or where further information may be obtained.” (45 C.F.R. § 46.116(a)(6), 21 C.F.R. § 50.25(a)(6).) COH also follows the requirements of the Association for the Accreditation of Human Research Protection Programs (“AAHRPP”), including AAHRPP Elements I.8.A, I.8.B, and I.8.E.

This **process begins** when a Principal Investigator identifies a Research-Related Injury.

This **process ends** when Research Finance invoices the clinical trial sponsor for all fees corresponding to the Research-Related Injury.

II. POLICY

For Studies Sponsored/Funded by Industry:

- A. If a research subject suffers a Research-Related Injury, it is the policy of COH to provide Medical Treatment at no cost to the subject.
- B. Industry sponsors are required to reimburse COH for Diagnosis and Medical Treatment of Research-Related Injuries as set forth in the applicable contract for the underlying clinical trial.
- C. Reimbursement will include all Research-Related Injuries and diagnostic tests necessary to determine whether an injury or illness is or is not a Research-Related Injury. Reimbursement should take place within thirty (30) days and are not subject to refund.

III. PROCEDURE

RESPONSIBLE PERSON(S)/DEPT.	PROCEDURE
PI / Study Team Clinical Trials Support Services (CTSS) Patient Financial Services / Patient Billing Services Research Finance	A. Identifies the Research-Related Injury and notifies the IRB, Trial Sponsor, and Budgeting / Contracting Office (CTSS). B. Receives notification from PI / Study Team. C. Works with Patient Finance groups and the Study Team to establish items / services / procedures performed related to the injury. D. Receives notification from CTSS. E. Places a bill hold on all services occurring during the Research-Related Injury. F. Reviews items / services / procedures related to diagnosis and treatment of the Research-Related Injury with the PI. G. Provides Research Finance a list of scrubbed charges following PI review. H. Receives list of scrubbed charges from Patient Finance / Patient Billing. I. Confirms invoiceable fees to the sponsor with PI / Study Team. 1. Also confirms Time and Effort costs for the PI / Study Team. J. Invoices sponsor for all Research-Related Injury Charges.

Owner and Sponsor: Senior Vice President, Research Operations

References:

1. 21 CFR 50.25
2. 45 CFR 46.116
3. AAHRPP Elements I.8.A, I.8.B and I.8.E

Appendix One - Acronyms, Terms and Definitions Applicable to this Policy:

1. **City of Hope (“COH”)** – City of Hope National Medical Center (“COHNMC”), Beckman Research Institute (“BRI”) and City of Hope Medical Foundation (“COHMF”) collectively referred to as City of Hope (“COH”) for purposes of this policy.
2. **Community Practices** – Refers to the non-hospital practices operated by City of Hope Medical Foundation (“COHMF”).
3. **Diagnosis** – For the purposes of this Policy, “Diagnosis” of a Research-Related Injury means the tests/procedures required to identify if the injury is related to the research protocol, procedure or test article.
4. **Medical Center** – Refers to all facilities covered by City of Hope National Medical Center’s hospital license.
5. **Medical Treatment** – For purposes of this Policy, “Medical Treatment” means immediate life-sustaining or life-supporting medical care and all medical care for a Research-Related Injury that is provided at COH.
6. **PI** – Principal Investigator
7. **Research-Related Injury** – For purposes of this Policy, a “Research-Related Injury” means an injury that is Unanticipated, and occurs as a direct result of a research procedure arising from participation in a clinical trial.
8. **Unanticipated** – For purposes of this Policy, a Research-Related Injury is “Unanticipated” if it does not fit the definition of an adverse event, but which may, in the opinion of the investigator, involve risk to the subject, affect others in the research study, or significantly impact the integrity of research data.