Policy & Procedure Treatment and Compensation for Research-Related Injury	Document No.	HSPP 4.3
	Effective Date	August 31, 2023
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	Revision No.	1.0
	Approval: HSC 7-28-23 (Additional Approvals Pending)	

1.0 PURPOSE

This policy establishes the requirements for ensuring that subjects injured as a direct result of research participation are provided with medical care. The goal is to ensure that subjects are provided with an explanation as to what medical treatments and compensation are available if injury occurs, the terms under which compensation will be provided, where further information may be obtained, and care when injured.

2.0 REVISION HISTORY

Date	Rev. No.	Change	Reference Section(s)
10/16/08		New policy/procedure drafted	Not Applicable
07/2023	1.0	Updated	Most of doc

3.0 DEFINITIONS

Minimal risk is defined by the federal regulations as being "where the probability and magnitude of harm or discomfort anticipated in the proposed research are not greater, in and of themselves, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests". [45 CFR 46.102(i)]

Injury is a physical or psychological harm that generates medical costs and that is directly caused by the product or procedures required by the research study as described in the informed consent form. Injury specifically excludes the natural progression of an underlying or preexisting condition, unless the worsening condition is determined to be a direct result of the subject's participation in the research study described in the informed consent form.

Research subject or participant is a living individual about whom an investigator conducting research obtains: (1) data through intervention or interaction with the individual, or (2) identifiable private information. In clinical research, a subject is someone who becomes a participant in research, either as a recipient of the test article or as a control.

Reasonably Necessary Medical Care is the generally accepted standard of care for the injury in question as determined by and within the sole discretion of the University of California.

4.0 POLICY

The policy of LBNL is to ensure:

4.1 Full compliance with the University of California *Policy for Medical Treatment of Human Subjects for Injuries Resulting From Participation in Research*[1]

4.2 Potential participants in research involving more than minimal risk are provided with an explanation as to whether any compensation and any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained.

4.3 If the research is a drug or device clinical trial funded by a private industry sponsor and conducted according to the sponsor's protocol, the sponsor must assume the full treatment cost for any subject injury, even if the research was designed to benefit the subject directly[2].

4.4 Any injured participant is provided with any and all medical treatment reasonably necessary for any injury or illness which the subject has suffered as a direct result of participation.

4.5 That LBNL either pays for the care provided under 4.4 directly or reimburses the subject for the costs of care, except when the injury or illness is a consequence of a medical research procedure which is designed to benefit the subject directly.

5.0 PERSONS AFFECTED

5.1 All researchers participating in, conducting or with oversight over research projects involving human subjects.

5.2 Human Subjects Committee (HSC)

5.3 LBNL contracts and grants officers

5.4 Research participants (subjects)

5.5 LBNL Legal Counsel, Office of the Directorate (Risk Management)

6.0. RESPONSIBILITIES

6.1 **Researchers** shall comply with this policy. Investigators shall include the LBNL language from section 7.0 (below) in all consent forms for research involving more than minimal risk, and shall be familiar with LBNL procedures for obtaining medical care for injured research participants.

6.2 **HSC** shall ensure that all consent forms for research involving more than minimal risk include the University of California-approved language in section 7.1 (below) to describe compensation and/or medical treatments available if injury occurs.

6.3 **LBNL contracts and grants officers** shall implement agreements with private industry sponsors that address University of California policy requirements as outlined in 7.3, below.

6.4 **Research participants** shall provide documentation as outlined in 7.4, below, in support of any claim of injury or request for reimbursement.

6.5 **LBNL Office of Legal Counsel** shall provide risk management services, render timely review of claims submitted under 7.4, and ensure that compensation found appropriate is promptly paid by Lawrence Berkeley National Laboratory.

7.0 PROCEDURES

7.1 Research Requirements

a) **Consent forms** A statement regarding "Compensation for Injury" is a required element of informed consent for all research that presents more than minimal risk as determined by the LBNL HSC [45 CFR 46.116(a)(6)]. Investigators should explain in the consent form whether any compensation/medical treatments are available if injury occurs and, if so, describe the extent and nature of the compensation.

Standard statement for greater than minimal risk research. **The language in this statement may not be changed or modified without approval by Berkeley Lab legal.**

Should you be injured as a result of being in this study, if you are treated at Lawrence Berkeley National Lab (LBNL) there will be no cost to you. If treatment outside of LBNL is required, the costs of the treatment may be billed to you or your insurer just like other medical costs, and potentially reimbursed, depending on a number of factors. LBNL [and name of study sponsor may also be inserted here] does not normally provide any other form of compensation for injury. For more information about this, you may call the office of the Human Subjects Committee at (510) 486-6005 or contact harc@lbl.gov.

b) **Providing treatment for subjects injured on site**

i) In the case of serious injury or life-threatening emergency, immediately call extension 911 and follow their instructions.

ii) It is the preference of the Laboratory that non-emergency medical treatment available under this policy be provided at LBNL Health Services or at a University of California medical facility to the extent practicable.

iii) Between 7:30 AM and 3:30 PM Monday to Friday, minor first aid, medical evaluations and advice can be obtained at the on-site Health Services clinic, Building 26 (LBNL extension 6266).

iv) Further information on Health Services is available in the LBNL Health and Safety Manual, Chapter 3.

7.2 HSC Review

The HSC will make determinations for each study as to whether or not it meets the minimal risk standard. For studies that are determined to be of greater than minimal risk, the primary reviewer will review the consent form in detail to ensure that the approved language on compensation for injury is included.

7.3 Agreements with private industry sponsors

a. LBNL contracts and grants officers will review agreements with a private industry sponsor to determine if the Lab will be testing a drug or device according to the sponsor's protocol.

b. If so, the signatory contracts and grants officer will only negotiate and approve an agreement that makes explicit the sponsor's assumption of responsibility for reimbursing the Laboratory for the reasonable cost of medical treatment for injuries directly resulting from participation in the study.

c. Contracts and grants office will further note that it is not acceptable for such agreements to require billing of third party insurance companies in lieu of recovery of such costs from the sponsor, nor is it appropriate to accept provisions restricting participation of human subjects on the basis of medical insurance coverage status or on the subject's ability to pay. They will consult the *Requirements for Administration of Agreements with Private Sponsors for Drug and Device Testing Using Human Subjects*[2] if more detail is needed.

7.4 **Obtaining compensation for treatment**

a. Written notification of a potentially research-related injury is to be given to LBNL Legal Counsel at the address below[3] by the injured participant within a reasonable time after discovery. The notification should include:

   i. A description of the injury and the treatment received.

   ii. The name of the principal investigator conducting the study, the title of the study, and the date of participation.

   iii. A statement supporting the claim that the injury resulted directly from participation in the specified activity.

b. Any claim for reimbursement is to be supported by appropriate documentation, such as treatment records, invoices and proofs of payment.

7.5 Reviews of participant request for compensation

a. Any notification of a potentially research-related injury by the HSC office, any HSC member, research investigators or other should be forwarded to LBNL Legal Counsel with a notice to the HSC office.

b. Legal Counsel's office will notify the HSC upon receipt of any notification of a potentially research-related injury.

c. Requests for compensation will be reviewed promptly.

d. Legal Counsel will communicate with the subject as needed, including but not limited to requests for additional information and the decision on the request.

e. Legal Counsel will inform the HSC of the decision.

Regulations
45 CFR 46.102(i)
45 CFR 46.116(a)(6)
21 CFR 50.25(a)(6)

References

[1]UC-6 University of California Presidential Memorandum, "University Policy for Medical Treatment of Human Subjects for Injuries Resulting from Participation in Research", January 19, 1979.
https://www.ucop.edu/research-policy-analysis-coordination/resources-tools/contract-and-grant-manual/chapter18/chapter-18-300.html

[2]UC-11 University of California Presidential Memorandum, "Requirements for Administration of Agreements with Private Sponsors for Drug and Device Testing Using Human Subjects", February 3, 1995.
http://www.ucop.edu/research/policies/ucpols.html

[3]Address to which claims of compensation for research injury should be sent:

Office of Legal Counsel, LBNL Directorate
Attn.: Risk Management/Research Subject Injury
Lawrence Berkeley National Laboratory
1 Cyclotron Road, MS 50A4112
Berkeley, CA 94720

Fax: (510) 486-6498