Published on *UCSF Institutional Review Board* (http://irb.ucsf.edu)

Treatment and Compensation for Injury

Federal Regulations and UC Policy

Both OHRP [1] and FDA [2] require that if research-related injury is possible in research that is more than minimal risk [3], the consent form must include an explanation of whatever voluntary compensation and treatment will be provided.

Below is the University of California's (UC) policy on treatment and compensation for injury. [4]

1. The University of California will provide to any injured subject any and all medical treatment reasonably necessary for any injury or illness which a human subject suffers as a direct result of participation in an authorized University activity covered by University policy on the protection of human subjects in research, or reimburse the subject for the costs of such treatment, except when the injury or illness is a consequence of a medical research procedure which is designed to benefit the subject directly.

2. The obligation of the University undertaken in paragraph 1 shall be subject to the following

conditions:

a. It must be demonstrated that the injury resulted directly from participation in the specified activity.

b. Written notification of any such injury is to be given to the University by the human subject within a reasonable time after discovery.

c. Any claim for reimbursement is to be supported by appropriate documentation.

3. It is the preference of the University that the medical treatment available under this policy be provided at a University of California medical facility.

4. Chancellors and other chief administrators, as appropriate, shall designate an individual or office as a contact for inquiries about implementation of this policy.

Standard Consent Form Wording

The UCSF IRB, in consultation with campus Legal Counsel, formulated a standard statement to describe the UC policy. An alternate version of the statement, to be used when a sponsoring company or another institution with a similar policy is involved, was also formulated.

UCSF wording

The IRB requires that one of the following be used on all consent forms for studies involving more than minimal risk:

Treatment and Compensation for Injury Statement (standard)

Treatment and Compensation for Injury: If you are injured as a result of being in this study, the University of California will provide necessary medical treatment. The costs of the treatment may be billed to you or your insurer just like any other medical costs, or covered by the University of California or the study sponsor *[sponsor name]*, depending on a number of factors. The University and the study sponsor do not normally provide any other form of compensation for injury. For further information about this, you may call the office of the Institutional Review Board at 415- 476-1814. *[NOTE:This statement must be used without changes[5] unless the Sponsor requests MMSEA 111 Language (see next entry below). See theIRB website[5] and notes section at the end of this sample form for standard wording for the SFVAMC and for other comments].*

Treatment and Compensation for Injury Statement (with MMSEA 111 Language- Only if Sponsor requests MMSEA 111 Language)

Treatment and Compensation for Injury: If you are injured as a result of being in this study, the University of California will provide necessary medical treatment. The costs of the treatment may be billed to you or your insurer just like any other medical costs, or covered by the University of California or the study sponsor *[sponsor name]*, depending on a number of factors. If the study sponsor covers these costs they will need to know some information about

you like your name, date of birth, and Medicare Health Insurance Claim Number, or, if you do not have one, your Social Security Number. This information will be used to check to see if you receive Medicare, and, if you do, report the payment they make to Medicare. The study sponsor will not use this information for any other purpose. The University and the study sponsor do not normally provide any other form of compensation for injury. For further information about this, you may call the office of the Institutional Review Board at 415- 476-1814.

The references to the sponsor's provision of compensation should be inserted only if they accurately reflect the sponsor's policy. If there is a distinctly different policy (e.g., the sponsor will cover the costs of research-related injuries, or the sponsor has no provision whatsoever for compensation) this may be stated in a brief but separate paragraph following the UCSF statement. See below for more info on this wording and industry sponsors.

SFVAMC wording

Biomedical studies involving real, foreseeable risk of harm must include a statement regarding treatment and compensation in case of injury. Use the following paragraph without changes:

If you are experiencing a medical emergency, please call 9-1-1. If you incur an injury or illness as a result of being in this study, the Department of Veterans Affairs (VA) will ensure that treatment is made available at a VA medical facility or non-VA facility, as appropriate. If you were following study instructions, the costs of such treatment will be covered by the VA or the study sponsor (if applicable). If you were NOT following study instructions, the costs of such treatment may be covered by the VA or the study sponsor (if applicable), or may be billed to you or your insurer just like any other medical costs, depending on a number of factors. The VA and a study sponsor do not normally provide any other form of compensation for injury or illness. For further information about this, call the study team at the number(s) provided.

Industry Sponsors' Wording

Sponsoring companies often request that their own wording be used for the treatment and compensation for injury policy statement or that minor changes be made in the UC statement. These requests **cannot** be honored. The wording of the statement was formulated with the advice of legal counsel with the intent of adhering to the requirements of the federal regulation, and conveying the basic, necessary information to the subject.

Industry sponsors have three ? and only three ? options regarding provisions for treatment and compensation for injury in the consent form:

1. The sponsor may include its name in the UCSF statement as written above.
2. The sponsor may remain silent on this point, in which case all reference to the sponsor should be omitted from the above statement.
3. A brief paragraph (one or two sentences) may be added below and separate from the UCSF statement to explain the sponsor's policy. However, any description of the sponsor's policy must state what the sponsor will cover, not what it will not cover. As a

further limitation, the sponsor's statement may not make reference to third party carriers, government programs or lost wages.

No other changes may be made to the UCSF statement.

The IRB office is not in the position to negotiate indemnification agreements. This occurs through the Industry Contracts Division of the Office of Innovation, Technology and Alliances [6] as part of the initial clinical research contract negotiations.

Implementation, Reporting and Questions

There are two major aspects of the UC policy: (1) treatment for injury and (2) compensation for injury. These two must be clearly distinguished in considering the University policy and the UCSF statement regarding that policy.

Appropriate treatment should be available to any subject injured as a result of participating in a research project. Treatment should be considered an ethical obligation rather than any admission of liability. Consent forms should indicate within the Risks section the nature of available treatment for any possible serious side effects.

Reporting: All reports of possible injury must be reported immediately to the IRB and to Clinical Research Risk Management [7] using standard UCSF Adverse Event [8] or [8] Protocol Violation/Incident Reporting [9] forms. Minor incidents of anticipated side effects may be reported at the time of continuing review or at termination of the study if it is not to be continued.

Questions: Contact the office of Clinical Research Risk Management [7] at 415-476-4171 with questions about whether any serious adverse event, illness or other medical concern is potentially compensable under the University policy, or with questions about the process for filing a research-related injury claim.

Page last updated:
Feb 6, 2019

Links
[1] http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.116
[2] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=50.25
[3] http://irb.ucsf.edu/levels-review
[4] http://irb.ucsf.edu/#
[5] http://hrpp.ucsf.edu/node/866
[6] https://ita.ucsf.edu/
[7] https://rmis.ucsf.edu/clinical-research-risk-management
[8] http://irb.ucsf.edu/adverse-event
[9] http://irb.ucsf.edu/protocol-violation-or-incident