Guidance and Procedure: Treatment and Compensation for Research Related Injuries

Introduction

For studies that involve more than minimal risk, Federal regulations require that informed consent documents contain information regarding the availability of compensation and medical treatment if a research related injury occurs, to include the types of compensation and treatment available and sources of additional information. University of Florida investigators and the IRBs share responsibility for complying with University of Florida policies, guidance, and procedures relating to treatment and compensation for research related injuries.

University of Florida Subject Injury Guidance and Procedure

For research related injuries, as determined below, an injured participant will receive professional services for their research related injury. The University of Florida has a strong preference that those services be provided by a University of Florida Health Science Center healthcare provider whenever possible. These healthcare providers include physicians, physician assistants, nurse practitioners, dentists, and psychologists.

The University of Florida's obligation is subject to the following conditions:

- The injury must be a direct result of participation in the specified research study.
- The participant must notify the University of Florida within a reasonable time after the injury is discovered.
- Any claim for reimbursement must be accompanied by appropriate documentation.

Standard Wording Required in University of Florida Informed Consent Documents

The University of Florida treatment and compensation statement is a required element of the consent form for greater than minimal risk research. The wording of the University of Florida diagnosis, treatment and compensation for research related injury statement was formulated with the intent of adhering to the requirements of federal regulations and University of Florida policy.

University of Florida investigators must use the following compensation for research related injury statement when drafting the informed consent document:

What if you are injured because of the research study?

It is important that you promptly tell any member of the research team if you experience an injury or have questions about any discomforts that you experience while participating in this study. If you are injured, you will be treated or referred for treatment.

If you are injured as a result of being in this study, the costs of the diagnosis and/or treatment may be covered by the University of Florida or the study sponsor or billed to you or your insurer just like other medical costs, depending on a number of factors, such as if the injury was the result of the study intervention, or the way in which the study was conducted. The University of Florida and the study sponsor do not normally provide any other form of compensation for injury. The Principal Investigator and others involved in this study may be University of Florida employees. As employees of the University, they are protected under state law, which limits financial recovery for negligence.

Clinical Trial Agreements with Industry Sponsors

The negotiated clinical trial agreement language specifies under what conditions and through which process an industry sponsor has an obligation to pay for the costs related to the diagnosis and treatment of any research related injuries. This language does not belong in the consent form.

For industry sponsor-initiated studies that involve more than minimal risk, the University of Florida Human Research Protection Program Policy HRP-010 governs and requires that sponsors assume responsibility for the reasonable costs of medical diagnosis and treatment for injuries resulting from the participation in research.

Please contact the UF Research Division of Sponsored Programs for additional information about clinical trial agreements: ufawards@ufl.edu

Working with Industry Sponsors

Requests from Industry Sponsors to Change or Alter Standard Wording:

Sponsors sometimes request changes to the University of Florida (UF) standard wording . UF's standard wording was adopted after significant benchmarking of peer institutions and input from multiple stakeholders including UF's General Counsel, Division of Sponsored Programs, Clinical Research Hub, and Human Research Protection Program (HRPP). As a matter of course, given the amount of time and effort it took to develop and adopt this standard wording, UF will not consider modifications to the standard wording. If a sponsor/entity believes there is a compelling and justifiable reason for a change, the UF PI may submit a request to modify the language by filling out this form (https://research.ufl.edu/wp-content/uploads/injury-template-modification-request.docx) and emailing it to operations@research.ufl.edu. It should be noted that requesting a modification will delay the approval process because the following stakeholders must review and approve the change, in sequence:

- Division of Sponsored Programs: responsible for verifying the modification is consistent with the clinical trial agreement.
- Clinical Research Hub: responsible for verifying treatment terms are consistent with UF's intended involvement by UF physicians (if applicable).
- General Counsel: responsible for considering institutional issues and engaging other UF stakeholders if issues are identified.

UF's HRPP office will only process the request if the form is properly filled out, including providing a compelling justification. Requests can be denied for a variety of reasons including failure to provide a compelling justification, inconsistency with the clinical trial agreement, etc. Once all three offices have reviewed the request, UF HRPP will return the completed form to the recipients indicated on the form. The requested change is only considered approved if **all** three units approve the change (i.e. the request is denied if any of the three units do not approve it).

Regulations and References

DHHS Regulation:

- Elements of Informed Consent: 45 CFR 46.116(b)(6)(7)

FDA Regulation:

- Elements of Informed Consent: 21 CFR 50.25(a)(6)(7)

Reference:

- University of Florida Human Research Protection Program Policy: HRP-010