



Policy Number: IL.03

Treating Injuries of Participants in Human Subjects Research

Adopted: 11/05

Revised: 03/2015

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Human Research Protection Program Policy

TREATING INJURIES OF PARTICIPANTS IN HUMAN SUBJECTS RESEARCH

POLICY

Researchers at the University of Cincinnati will assure that there are adequate resources to provide for ancillary care for injuries that may result from research, or for psychological or social interventions or counseling and other social support services.

SUBMISSION OF PROTOCOLS TO THE IRB

A researcher submitting a research protocol for approval by the Institutional Review Board (IRB) that has more than minimal risk to participants will include a statement detailing how participants will be treated for injuries that may result from the research. Examples of research related injuries include physical injury resulting from clinical research, breach of sensitive confidential information collected by the researcher, emotional or psychological distress, or business, social or employment repercussions. Generally, researchers depend on sponsors of the research to provide resources for such treatment. For research where there is no extramural sponsor or where the extramural sponsor does not provide funding for treating injuries resulting from research, the department or departments conducting the research will provide funding for treatment of participants who have research related injuries.

Each clinical trial agreement shall clearly describe the availability of medical care for research-related injuries, including whether such care will be provided, and, if so, who will provide such care and who will be responsible for the cost of such care.

Veteran's Affairs Medical Center (VAMC) investigators submitting a research protocol for approval by the IRB must include a statement detailing how participants will be treated for injuries that may result from the research. VAMC research is defined as that is conducted by VAMC investigators (serving on compensated, work without compensation (WOC), or Intergovernmental Personnel Agreement (IPA) appointments while on VAMC time, utilizing VAMC resources, and/or on VAMC property including space leased to, and used by, VAMC. The research may be funded by VAMC, by other sponsors, or be unfunded.



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Applicable Regulations, Documents:

- 45 CFR 46.111 (a) (1)
- 21 CFR 56.111 (a) (1)
- 38 CFR 17.85
- VHA Handbook 1200.5

Adoption Date:	Created by:	Date of Revision:	Revised By:	Summary of Revision:
11/2005	M. Belskis	05/2009	J. Gerlach	Revision made to require that informed consent include language explaining the VA's authority to provide medical treatment to research subjects injured by participation in a VA research project- minimal and more than minimal research.
		9/2014	A.Braggs-Brown	Revised to include AAHRPP recommendations
3/2015		3/2015	J. Strasser	Revisions for clarification

Date Adopted March 2015 **Signature** signed copy on file