

TREATMENT OF RESEARCH-RELATED INJURIES

1. PURPOSE

VA medical facilities must have a manner in which the facility is able to provide care for research participants, veteran and non-veteran, who sustain research-related injuries.

2. POLICY

a) VA medical facilities, including joint VA-DoD Federal health care centers, must provide necessary medical treatment (i.e., not just emergency treatment) to a research subject injured as a result of participation in a research study approved by a VA R&D Committee and conducted under the supervision of one or more VA employees (38 CFR 17.85). This requirement does not apply to:

1. Treatment for injuries due to non-compliance by a subject with study procedures; or
2. Research conducted for VA under a contract with an individual or a non-VA institution.

b) Care for VA research subjects under this section must be provided in VA medical facilities, except in the following situations:

1. If VA medical facilities are not capable of furnishing economical care or are not capable of furnishing the care or services required, VA medical facility Directors must contract for the needed care;
2. If inpatient care must be provided to a non-Veteran under this section, VA medical facility Directors may contract for such care; or
3. If a research subject needs treatment in a medical emergency for a condition covered by this section, VA medical facility Directors must provide reasonable reimbursement for the emergency treatment in a non-VA facility.

3. RESPONSIBILITIES

- a. **Principal Investigator (PI):** Report the research-related injury to the ACOS/Research promptly.
- b. **Associate Chief of Staff/Research (ACOS/R):** Assemble information regarding the injury, including the applicability of this policy. Convey this information to the MCD.
- c. **Medical Center Director (MCD):** Contract for needed care if facility is not capable of furnishing the care needed/not able to furnish the needed care economically. If emergency care outside of VA is required, the MCD must provide reasonable reimbursement to the non-VA facility.

4. PROCEDURES

- a. Treatment of the subject's injury is the first priority.
- b. PI will contact the ACOS/R directly, or via the HRPP staff, to report an event that appears to be a research-related injury which requires treatment.
- c. The ACOS/R will assemble pertinent information regarding the injury, including how the event meets the criteria of the policy stated above. The ACOS/R may consult with the PI, other clinicians, and IRB members as needed.

- d. The ACOS/R will convey this information to the MCD.
- e. For injuries which require use of resources outside of VA, the MCD will provide reasonable reimbursement for the emergency treatment in a non-VA facility.

REFERENCES

VHA Directive 1200.05 (01/07/2019)