Department of Veterans Affairs
Veterans Health Administration
Washington, DC 20420

VHA DIRECTIVE 2001-071

November 23, 2001

REHABILITATION RESEARCH AND DEVELOPMENT SERVICE DATA SAFETY MONITORING BOARD

1. PURPOSE: This Veterans Health Administration (VHA) Directive establishes the Data Safety Monitoring Board (DSMB) as a resource, ensuring human subjects' protection.

2. BACKGROUND: The VHA Rehabilitation Research and Development (RR&D) Service DSMB is being established to serve as a review panel to address issues pertaining to the protection of subjects participating in human research programs and projects that involve one or more than one Department of Veterans Affairs (VA) medical center. This is a new mechanism to provide advice to the Director of RR&D on questions or concerns pertaining to human subjects' protections. The panel will oversee projects funded by the Office of Research and Development (ORD), RR&D Service.

3. POLICY: It is VHA policy that ORD establish a Data Safety Monitoring Board (DSMB) to serve as a review panel to address issues pertaining to the protection of subjects participating in human research programs and projects that involve more than one Department of Veterans Affairs' medical center.

4. ACTION

a. Composition

(1) The Director, RR&D Service, appoints the DSMB members. The chair, members, and any ad hoc representatives added, if their special expertise is needed, must possess and maintain valid human subjects' protection education certification.

(2) The Director, RR&D Service, appoints the Chair, DSMB, whose term is not to exceed 3 years.

b. Scope of Function

(1) The DSMB is to function administratively as an extension of the Office of RR&D Service. It primarily acts as an oversight board to review data and concerns raised during the conduct of VA multi-center clinical trials. As needed, the DSMB may act as a resource to the Director on single site clinical trials or other human studies issues.

(2) The DSMB is to review adverse responses to treatments and any human subject concerns raised to the Director, RR&D. The DSMB will apply Federal principles and regulatory requirements associated with research involving human subjects in making its determinations.

(3) The DSMB must report human subjects' protections review findings to the Office of the Director of RR&D Service. The DSMB must also provide recommendations to local Research

Service Offices, Research and Development (R&D) Committees; Initial Review Board Sub-committees; and Principal Investigators; as follow-up to their inquiries, and as directed by the Director, RR&D Service.

c. Frequency of Meetings. The DSMB must convene biannually on a regular schedule, or more often, if necessary. The DSMB may convene by telephone conference calls or meetings, as necessary and appropriate, to address human subjects' protections issues.

d. Dissemination of Review Determinations. The DSMB must provide the Office of the Director, RR&D Service, with written reports of human subjects' protections review determinations and recommendations for action. Each clinical trial funded by RR&D is to be informed of DSMB procedures.

5. REFERENCES: None.

6. FOLLOW-UP RESPONSIBILITY: ORD's RR&D Service (122) is responsible for the contents of this Directive. ***NOTE:*** *VA RR&D-funded research programs and projects may be directed to the following email address: dsmb@vard.org, or telephone number (202) 408-3686. Contact information also may be found at the following web site: http://www.va.gov/resdev.*

7. RESCISSIONS. None. This VHA Directive Expires November 30, 2006.

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