Department of Veterans Affairs **VHA DIRECTIVE 2004-064**
Veterans Health Administration
Washington, DC 20420 **November 12, 2004**

USE OF NON-CONTRACT IMPLANTABLE PACEMAKERS AND IMPLANTABLE DEFIBRILLATORS IN VA APPROVED RESEARCH

1. PURPOSE: This Veterans Health Administration (VHA) Directive provides policy for use of implantable pacemakers and implantable defibrillators that are not covered by the current national contract for research purposes.

2. BACKGROUND

a. In December 2003, Prosthetic and Sensory Aids Service entered into a contract with Medtronic, Inc. and Guidant Corporation to provide all implantable pacemakers and implantable defibrillators used by VHA.

b. Prior to the commencement of this contract with Medtronic, Inc. and Guidant Corporation, there were a number of active research protocols that involved the use of implantable pacemakers or implantable defibrillators manufactured by companies not holding a contract with VHA. These research protocols seek to answer clinically important questions that are relevant to the care of veterans.

c. It has also been recognized that the use of non-contract devices in approved Department of Veterans Affairs (VA) research protocols may be based on compelling clinical need.

d. **Definitions**

(1) **Device.** For the purposes of this directive a device is an implantable pacemaker (generator and lead[s]), an implantable defibrillator (generator and lead[s]) or a cardiac resynchronization therapy system (generator and lead[s]).

(2) **Sponsor.** This term refers to the entity (company, association, government agency - Federal, state, local) that is supporting the research.

(3) **VA-approved Research.** This is research that is approved by the VHA Research and Development (R&D) Committee, the Institutional Review Board (IRB) (if human subjects research), conducted at VA institutions, uses VA resources or is conducted by VA employees (compensated or Work Without Compensation [WOC]) while on their VA tour of duty.

3. POLICY: It is VHA policy that only implantable pacemakers, implantable defibrillators, and resynchronization therapy systems that are supplied through a current contract entered into by Prosthetic and Sensory Aids Service are used.

4. ACTION

a. **Facility Director.** The facility Director is responsible for:

(1) Ensuring that only devices that are covered by the current contract are used unless:

(a) R&D Committee approval of the protocol using a non-contract device predates this Directive.

(b) A waiver to use a non-contract device has been approved by VA Central Office. To use off-contract devices within a VA-approved research protocol, a waiver must be obtained from VA Central Office prior to initiation of the protocol.

(2) Approving all requests for waiver prior to the request being forwarded to VA Central Office.

b. **Principal Investigators (PI).** The PI is responsible for:

(1) Obtaining a waiver for use of a non-contract device prior to entering into any agreements to use such a device.

(a) A waiver must be obtained if a VA-approved research protocol requires use of non-contract devices. The PI must receive approval from both the IRB and the R&D Committee and submit documentation of this approval to VA Central Office prior to receiving final approval of a waiver.

(b) A waiver request should include the following:

1. Rationale for using a non-contract device including a discussion on:

a. How the use of both a non-contract device and contract devise would affect study design, outcome measures, power effect, sample size and endpoints of the study, and

b. How the outcome of the research may impact current policy and recommendations for future treatment with the waived device.

2. Additional risks and/or benefits to the research subject.

3. The number of devices that will be used and the sample size.

4. Location where the research will take place.

5. The costs of the device including all hardware required for implantation.

a. The sponsor of the research must cover the costs of all non-Food and Drug Administration (FDA)-approved devices if the cost is not covered by other entities (e.g., the Center for Medicare and Medicaid Services [CMS] or other non-VA protocol sponsor).

b. If VHA is to be responsible for the costs, these costs must be confirmed in writing by Prosthetics and Sensory Aids Service (P&SAS).

c. An agreement with the sponsor to cover research-related injuries, if the device is not approved for that indication by the FDA.

(c) Additional documentation needed includes:

1. IRB approval,

2. R&D Committee approval, and

3. An abstract for the research protocol.

(d) Once approved and signed by the facility director, the request for waiver is submitted to the Chief Research and Development Officer (CRADO), VA Central Office.

(e) If the device is approved by the FDA and is being used for an approved indication, the use must follow all applicable standard clinical guidelines.

(f) If the device has not been approved by the FDA or the device is being used for a non-approved indication, then the research must be conducted under applicable FDA regulations (see 21 CFR 50, 54, 56, 812, and 814).

(2) Ensuring that the protocol submitted to the R&D Committee details the number of implantable devices to be used, and any costs above the costs for a similar implantable device covered by the existing contract.

(3) Ensuring that the information applicable to FDA's Investigational Device Exemptions regulations is submitted to both the IRB and R&D Committee.

NOTE: *If the protocol is to be conducted at multiple VA sites, the waiver request for all sites may be incorporated into one submission package. Each VA site must receive and submit documentation of IRB and R&D Committee approval.*

c. **Associate Chief of Staff (ACOS) for Research and Development (R&D).** The ACOS for R&D must ensure that for all protocols receiving a waiver to use non-contract devices, the following is completed in writing:

(1) If the total device cost exceeds the cost of a comparable contract device, arrangements have been made to cover the additional costs.

(2) The number of devices to be used is included in the contract with the sponsor.

(3) For all studies initiated prior to the date of this Directive, the cost of the implantable devices must be assessed, and appended to the existing contracts. ***NOTE:*** *This does not require*

a waiver be obtained for those protocols that pre-date this Directive per paragraph 4a(1)(a) of this Directive.

d. **Chief Research and Development Officer (CRADO).** Is responsible for reviewing the request and forwarding it with a recommendation to the Chief Consultant, P&SAS Strategic Healthcare Group, through the National Program Director for Cardiology for concurrence.

e. **National Program Director for Cardiology.** The National Program Director for Cardiology reviews the request and the recommendation of the CRADO, concurs with the recommendation, and makes further recommendation or non-concurs with the CRADO's recommendation; regardless, the request is then forwarded to the Chief Consultant, P&SAS Strategic Healthcare Group.

f. **Chief Consultant, P&SAS Strategic Healthcare Group.** The Chief Consultant, P&SAS Strategic Healthcare Group reviews the request and the recommendations of the CRADO and the National Program Director for Cardiology, makes the final decision, and notifies the medical center Director regarding the decision.

5. REFERENCES

a. Title 21 CFR 50, 54, 56, 812, and 814.

b. Prosthetics and Sensory Aids Service contract number V797P-9113 (Guidant) and V797P-9114 (Medtronic).

6. FOLLOW-UP RESPONSIBILITY: The Office of Research and Development (12) is responsible for the contents of this VHA Directive. For questions related to this Directive call (202) 254-0183.

7. RECISSIONS: None. This VHA Directive expires November 30, 2009.

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