

# STANFORD UNIVERSITY

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David D. Oakes, M.D.

CHAIR, PANEL ON MEDICAL HUMAN SUBJECTS

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## Certification of Human Subjects Approval

**Date:** July 19, 2007

**To:** **Dubin, Anne M. M.D.**, Department Of Pediatrics

David Rosenthal M.D., Debra Hanisch R.N., George Van Hare M.D.

**From:** David D. Oakes, M.D., Chair, Administrative Panel on Human Subjects in Medical Research

**Protocol Title:**

Efficacy of Biventricular Pacing in Pediatric Patients and Patients with congenital Heart Disease (eProtocol 10205)  
(Includes Informed Consent and Assent dated July 19, 2007) (Includes HIPAA Authorization)

**Protocol ID:** 98199

**IRB Number:** 4947 (Panel 6)

The IRB approved human subjects involvement in your research project on July 19, 2007. **Prior to subject recruitment and enrollment, if this is a Cancer-related research project, you must obtain approval from the Cancer Center Scientific Review Committee (SRC). If there is a contract involved, it must be signed prior to subject recruitment and enrollment.**

The expiration date of this approval is July 18, 2008. If this project is to continue beyond that date, you must submit an updated proposal in advance for the IRB's re-approval. If this proposal is used in conjunction with any other human experimentation it must be re-approved. Proposed changes to approved research must be reviewed and approved by the IRB. **No changes may be initiated without prior approval by the IRB, except where necessary to eliminate apparent immediate hazards to subjects. (Any such exceptions must be reported to the IRB within 10 working days.)** Unanticipated problems involving risks to participants or others and other events or information, as defined and listed in the IRB Report Form, must be submitted promptly to the IRB. See guidance entitled Events and Information that Require Prompt Reporting to the IRB, on the Research Compliance Office website at <http://humansubjects.stanford.edu>.

All continuing projects and activities must be reviewed and re-approved on or before the expiration date. The expiration date is the last day that research may be conducted unless the IRB has approved a renewal following continuing review. The approval period will be less than one year if so determined by the IRB based on the level of risk to subjects. It is the responsibility of the investigator to resubmit the project to the IRB for continuing review. The investigator is also responsible for reporting the completion of the protocol to the IRB within 30 days; at that time you should use the Final Report Form, found at <http://humansubjects.stanford.edu/research/documents/FinalReportForm.rtf>

Please remember that all data including all signed consent form documents must be retained for a minimum of three years past the completion of this research. Additional requirements may be imposed by your funding agency, your department, or other entities. (Policy on Retention of and Access to Research Data, Research Policy Handbook, [www.stanford.edu/dept/DoR/rph/2-10.html](http://www.stanford.edu/dept/DoR/rph/2-10.html)).

This institution is in compliance with requirements of protection of human subjects (45 CFR 46 and 21 CFR 56).



David D. Oakes, M.D., Chair

**Approval Period:** 7/19/2007 through 7/18/2008

**Review Type:** Expedited - NEW

**Funding:** - None

**Assurance Number** FWA00000933 (LPCH)

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