

July 11, 2014

Michael P. Savage, M.D.  
Medicine/Cardiology

Dear Dr. Savage:

The Institutional Review Board (IRB) has reviewed the involvement of humans as research subjects in your study entitled:

**“Treatment of Restenosis in Saphenous Vein Grafts with Angiography” (Departmental) 45 CFR 46.110 (5-retrospective record/chart/database review; IDs required) Control #14D.320**

In accordance with Federal-Wide Assurance #00002109 to the U.S. Department of Health and Human Services, this study was administratively approved for one year on 07/10/14. Board #153 was notified at the 07/10/14 meeting.

**EXPEDITED/NEW ( X )****REVIEW**

**PURSUANT TO TITLE 45 CODE OF FEDERAL REGULATIONS PART 46.116(d), THE IRB HAS GRANTED A WAIVER OF INFORMED CONSENT.**

This approval expires 07/09/15 one year from the original approval date of the study, unless suspended or terminated earlier by action of the IRB. Prior to the expiration date, an OSA-9 must be submitted to the IRB summarizing progress on the study during that period.

Any injury and/or unanticipated problem involving risks to the human research subjects not included in the written consent form must be reported promptly to the IRB using Form OSA-10 ON-SITE or OSA-10 OFF-SITE. This report should describe the event, evaluate its probable relationship to the experimental treatment received by the subject, and summarize the resulting outcome of the event.

Any proposed change in the protocol or in the written consent form must be submitted to the IRB for review and approval using Form OSA-12 before the proposed change can be implemented.

**This approval verifies that the IRB operates in accordance with applicable federal, local and institutional regulations that govern IRB operations.**

Sincerely yours,

Walter Kraft, M.D.  
Associate Director  
Office of Human Research

/mrt





**WAIVER OF AUTHORIZATION FOR USE /DISCLOSURE OF PROTECTED HEALTH INFORMATION (PHI) FOR HUMAN SUBJECTS RESEARCH**

Please present this letter and your IRB approval letter to the appropriate personnel when requesting protected health information (PHI) from databases outside your own practice.

**Approval Date:** 07/10/14

**Principal Investigator:** Michael  
Savage, M.D.

**Control:** #14D.320

**Study Title:** 'Treatment of restenosis in saphenous vein grafts with angiography'  
(Departmental) 45 CFR 46.110 (5-retro record/chart/database review;  
IDs required)

☒ **EXPEDITED** Review

☐ **Exempt**

The requested waiver of authorization satisfies the criteria set forth in 45 CFR 164.512(i)(1)(i):

- ☒ The use or disclosure of PHI involves no more than minimal risk to the privacy of individuals, based on, at least the presence of the following elements:
- ☒ An adequate plan to protect the identifiers from improper use and disclosure;
- ☒ An adequate plan to destroy the identifiers at the earliest opportunity consistent with the conduct of the research, unless there is a health or research justification for regaining the identifiers or such retention is otherwise required by law;
- ☒ Adequate verbal/written assurances that the protected health information will not be reused or disclosed to any other person or entity, except as required by law, for the authorized oversight of the research study, or for other research for which the use or disclosure of PHI would be otherwise permitted.
- ☒ The research could not be practicably conducted without the waiver of authorization.
- ☒ The research could not be practicably conducted without access to and use of the PHI.

**This waiver applies to the following "minimum necessary" PHI:**

*Patient name, medical record number, medical testing: cardiac cath results, images from cardiac cath; medical history including medical and surgical history to look for comorbid conditions that could affect atrial fibrillation*

**Signature**

**July 11, 2014**

**Date**

J. Bruce Smith, M.D., CIP  
Director  
Division of Human Subjects Protection

Kyle Conner, MA, CIP  
Associate Director  
Division of Human Subjects Protection

Walter Kraft, M.D.  
Associate Director  
Office of Human Research

