HOSPITAL FOR SPECIAL SURGERY
Institutional Review Board

To: Stavros G. Memtsoudis, M.D., Ph.D.

From: Edward C. Jones, MD, MA
Chairperson, Institutional Review Board

Tzipora Kuba, Ph.D.
Director, Clinical Research Administration

Re: Research Project Involving Human Subjects – New Protocol - Approval via Expedited Review: Category #4 – Collection of data through non-invasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical Devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device and not generally eligible for expedited review, including studies of cleared medical devices for new indications.)

Date: June 29, 2009

On **June 10, 2009** the Institutional Review Board (IRB) of Hospital for Special Surgery **approved,** via expedited review, your project entitled:

IRB #: 29051

Protocol Title: Non-invasive Tissue Perfusion Monitor: A Pilot Study for the Detection of Hypoperfusion during Complex Spine Surgery.

For the Period of: 6/10/09 – 6/9/10

1. Attached are the **date-stamped** copies of the **IRB-approved:** *HIPAA Compliant Informed Consent.*
Copies of the date-stamped forms must be used when obtaining written informed consent and authorization and questionnaires from research subjects.

2. Please note that it is the responsibility of the principal investigator to send signed copies of the research consent form and research authorization form, with the subject's hospital identification number and other required information, to the Hospital's Medical Records Department for filing if the subject is an inpatient. If the subject is an outpatient,

a copy of the signed consent form and research authorization form must be kept in the office/study chart.

3. Research investigators shall ensure that each person signing the research consent form receives a copy of the signed form.

4. The research investigators are advised to maintain a confidential listing of subjects in the research study, as well as the signed research consent form and research authorization form for their own records.

5. The research investigators are responsible for **immediately** reporting directly to the Chairman of the Institutional Review Board, any injuries or adverse events to human subjects participating in the research project, or any unanticipated problems which involve risk to the human subjects.

6. No Resident or Fellow can be listed as a Principal Investigator on any research protocols.

7. The Principal Investigators are responsible for notifying the IRB, in writing, of any changes to this original approved protocol, consent form, and any additions or deletions to the original list of investigators on the protocol. Changes in the above referenced research project cannot be initiated without prior IRB approval.

8. In the event that your research deals with existing pathological or diagnostic tissue specimens, you must comply with Medical Staff Rules and Regulations.

Thank you.