HOSPITAL FOR SPECIAL SURGERY
Institutional Review Board

To: Joseph Lane, M.D.
Cc: Arianna Gianakos, Research Fellow

From: Edward C. Jones, M.D., MA
Chairman, Institutional Review Board

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

Re: Research Request to Review Existing Medical Records **New Protocol** - Approval via Expedited Review – **Category #5** - Research involving materials, data, specimens, records, documents
Category #7 – Research on individual or group characteristics or behavior

Date: December 8, 2014

On **December 4, 2014** the Institutional Review Board (IRB) of Hospital for Special Surgery granted **approval, via expedited review,** of the project entitled:

IRB #14165

TITLE: ***Avascular Necrosis of the Hip.***

For the Period of: 12/4/14 – 12/3/15

Attached are copies of the date-stamped, IRB approved: *Informed Consent to Participate in Research Registry, Request for Waiver of HIPAA Authorization (partial), Past Medical History, HOOS Hip Survey, ROC: Patient Administered Questionnaire-Hip, Modified Harris Hip Score, HIP-QOL for Young Active Patients with Hip Problems, Appendix 1-Pain Questionnaire, Initial Visit Form, Follow-up Form,* Copies of the date-stamped forms must be used when obtaining written informed consent and authorization from research subjects and posting flyers/advertisements

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 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.