HOSPITAL FOR SPECIAL SURGERY

NOTIFICATION OF CONTINUING REVIEW APPROVAL

To: Christina Esposito, Ph.D.

From: Edward C. Jones, M.D., MA, Chairperson, Institutional Review Board
Rosemarie Gagliardi, Executive Director, Clinical Research Administration

Charles Castel, M.A, IRB Administrator

Re: Study #2016-0076-CR2
2018 Review for 2016-0076
Review pre-operative and post-operative images (radiographs, CT, MRI,EOS) (Old IRB #13094)
#5: This research involves materials (data, documents, records, or specimens) that have been collected or will be collected solely for non-research purposes

Date: 6/4/2018

On 6/4/2018 the Institutional Review Board (IRB) of Hospital for Special Surgery granted **approval for continuation of one year** for your Expedited Application reference above.

For the period: 6/20/2018 to 6/19/2019

Inclusive dates of chart review: June 2013 - June 1, 2018 for 1000 subjects

1. A copy of the watermark dated 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,

Hospital for Special Surgery
Institutional Review Board
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