**HOSPITAL FOR SPECIAL SURGERY**
**Institutional Review Board**

To: Steven Magid, M.D.
Cc: Sara Choi, Clinical Research Assistant

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

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

Research Project Involving Human Subjects – **New Protocol** - Approval via Expedited Review –**Expedited Category #5** – Research on data, document, materials, specimens **(form 4)**

Date: June 21, 2013

On **June 20, 2013** the Institutional Review Board (IRB) of Hospital for Special Surgery **approved,** via expedited review**,** your project entitled:

**IRB # 13098**

**Title/Description:** ***Retrospective Evaluation of all Patients who Developed Post-operative Delirium.***

**For the period of: 6/20/13 – 6/19/14**

Thank you.

# IRB SUBMISSION SHEET

MAY 13

NEW

Date: 06/19/13

Response to be returned to: Sara Choi

Interoffice Address: Blaine RH

Ext: 8993

IRB#: 13098

Submission of: Form 4

Name of person making submission: (PRINT)

Sara Choi

Email address: Choi s@hss.edu

Ext: 8993

## Check the document(s) submitted for IRB Review

***ALL applicable documents are required at time of submission***

**New Protocol**

☐ **Expedited Review (Original + 2 copies)**
☐ **Full Board Review (Original + 5 copies)**

☐ CRP Memo and Review Sheet
☐ IRB Application
☐ Informed Consent form
☐ Assent form (if applicable)
☐ Waiver of Informed Consent form
☐ Full Waiver of HIPAA
☐ Partial Waiver of HIPAA
☐ Financial Disclosure forms
☐ Questionnaires/Data collection forms
☐ Short Form consent (if applicable)
☐ Other _____
☐ **Missing document(s), include:**

_____

_____

**Continuing Review**

☐ **Expedited Review (Original + 2 copies)**
☐ **Full Board Review (Original + 5 copies)**

☐ Form 7 – Continuing Review Application
☐ Informed Consent form
☐ Assent form (if applicable)
☐ Waiver of Informed Consent form
☐ Full Waiver of HIPAA
☐ Partial Waiver of HIPAA
☐ Financial Disclosure forms
☐ Questionnaires/Data collection forms
☐ Short Form consent (if applicable)
☐ Other _____
☐ **Missing document(s), include:**

_____

_____

**Amendment (Original + 2 copies)**

☐ Cover memo & applicable documents attached

**Other**

☐ _____

**Adverse Event or Protocol Deviation**
**Original + 1copy**

☐ Cover sheet & applicable documents attached

IRB# 13098

## Review of the Medical Record for Research



Principal Investigator **Steven K. Magid, MD**

Co-Investigators **Sara Choi, Stephen Lyman PhD, Steven Magid MD, Lisa Mandl MD MPH, Michael Nurok MD, Ting-Jung Pan MPH, Mayu Sasaki MPH, Michael Urban MD PHD**

Condition/Procedure Intended for Study: **We propose the retrospective evaluation of all patients who developed post-operative delirium, as identified by ICD-9 codes and who were admitted between January 1st, 2008 and December 31st, 2012 for elective orthopedic surgery. We hope to identify risk factors for post-op delirium by identifying differences between patients who develop post-op delirium (cases) to those who do not (controls). By comparing the two groups, we can identify patients at risk for the condition and target potential risk-reduction strategies. We hypothesize that patients who develop post-operative delirium will have (1) different comorbidity profiles (e.g. age, narcotic dependence, psychiatric disease) upon admission to the hospital than controls, (2) distinct demographic, surgical, and medication use profiles compared to controls, and (3) be at increased risk of other post-operative adverse events compared to controls. The primary outcome of this study is the development of post-operative delirium.**

Estimated Number of Patients/Subjects: **Cases are patients with post-operative delirium, as identified by ICD-9 code (293.0, 293.9, 292.81, 780.09), and were admitted between January 1st, 2008 and December 31st, 2012. Controls will include all inpatients admitted between January 1st, 2008 to December 31st, 2012 and lack an ICD-9 code for delirium. Both groups will be 18 years of age or older. We estimate that there will be approximately 60,000 patients eligible for this study and that delirium will occur in 5% (3,000). We aim to identify independent risk factors that increase or decrease risk by a minimum of 5% (OR of 0.95 or 1.05). This sample size will provide over 80% power to detect effects this size.**

This form may be used only to apply for permission to review existent medical records and associated data (including images, lab values or reports) in order to conduct a review of a condition, treatment, surgical or other procedure, or other stated characteristic for research purposes.

This form may not be used if the investigator plans to interact (directly or through study staff) with the patient, including contacting the patient for purposes of follow-up or examination in order to conduct research. Contacting a patient/subject in pursuit of the stated research under this process would be considered a violation of IRB policy and Federal regulations regarding the protection of human subjects.

This form is also not to be used to access medical records to prepare a research protocol or for similar purposes preparatory to research.

Certifications:

- This study could not practicably be carried out without (i) the waiver of HIPAA authorization since patients are not scheduled to return for follow-up and (ii) access to and use of PHI[1] because identifiable information is needed in order to complete this study, after which PHI is no longer required.
- The use of PHI for this study poses minimal risk to the privacy of individuals.
    - All reasonable measures will be taken to protect the privacy of the PHI accessed and used for this study, and to prevent public disclosure of the identity of the patient and any information about

[1] Protected Health Information (as defined in the HIPAA Regulations and HSS's corresponding policies).

his/her diagnosis, treatment or condition. The physical medical record (including charts), if used, will be handled according to HSS's practices to maintain patient privacy.
    - The PHI accessed and used as part of this study will not be reused or disclosed to any persons other than those persons who are participating in the study as co-investigators.
- I will only access and use the minimum PHI necessary to carry out this study, and the identifiers will be deleted once the needed PHI has been collected for analysis. No PHI will be included in any work submitted for public disclosure (including any meeting, presentation, abstract or publication).
- I will ensure that personnel performing this study are qualified, appropriately trained, and will respect the privacy of the patients and adhere to the measures taken to maintain that privacy.
- **By this submission, I am applying for a waiver of documentation of informed consent according to 45 CFR § 46.117(c) and for a waiver of HIPAA authorization in accordance with 45 CFR § 164.512(i).**

**Signature of Principal Investigator** **Date**

6/13/13

**Approval Signature of Research Chief of Service** **Date**

6/18/13