SUNY Upstate Medical University Institutional Review Board

**Case Reports Using Existing Data - Author Worksheet**

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|---|---|
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| Title: Hyperammonemia-induced encephalopathy: A rare devastating complication of bariatric surgery. | |

The SUNY Upstate IRB does not require review of case reports that do not meet the definition of human subject research. Information gathered for the a priori intent to conduct research is considered research and such studies must be submitted to the IRB for review. Use this form to help determine whether submission to the IRB is required.

| | TRUE | FALSE |
|---|---|---|
| The case report includes three records or less (if more than three, call the IRB office). | ☒ | ☐ |
| Nothing was done to the patient(s) with prior research intent. | ☒ | ☐ |
| The case report does not contain elements of a systematic investigation (e.g. statistical methods, qualitative research, structured interviews, etc.). | ☒ | ☐ |
| The case report describes an interesting treatment, presentation, or outcome. | ☒ | ☐ |
| The published article will not contain and identifiable information[1], or authorization[2] has been obtained. | ☒ | ☐ |

**SUBMISSION IS NOT REQUIRED IF:** All of the questions are answered "TRUE".

- You must read and agree to the statement of assurance.
- Print a copy of this checklist, sign, and date.
- Save a copy for your records.

**SUBMISSION IS REQUIRED IF:** Any of the questions are "FALSE".

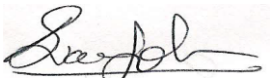
- Submit a new study application to the IRB.

**Statement of Assurance**

I agree to the following:

- I will take specific measures to protect the confidentiality of information obtained retrospectively about existing data studied in this review.
- I will record data in such a way that individuals will not be identifiable in any public communication unless specific permission, documented in writing, to do so is granted by the individual(s) involved.
- I will submit a separate new study application, as required by the IRB, if further studies involving human subjects are desired in this project.

I accept and agree to the terms set forth as it pertains to this checklist.

Savio John, MD ___  01/20/2015 ____

Printed Name Signature Date

[1] Direct identifiers such as names, social security numbers, addresses, and telephone numbers, or any of the 18 protected health information identifiers noted in the HIPAA regulations.

[2] Signed authorization to disclose this information should be obtained from the individual(s) whose information is being disclosed. If the patient is deceased, authorization should be obtained from the next of kin or personal representative of the estate.