Beth Israel Deaconess Medical Center

Committee on Clinical Investigations
Beth Israel Deaconess Medical Center
330 Brookline Ave.
Boston, MA 02215

Continuing Review: Notification of IRB Approval

IRB Protocol #: 2009P000134
Principal Investigator: Arun Ramappa
Protocol Title: The effect of insurance status on the delivery of upper extremity surgical care
Funding: None
Review Type: Expedited
IRB Approval Date: 10/18/2018
Expiration Date: 10/17/2019
Notification Date: 10/18/2018

This certifies that the action on the research study referenced was reviewed by the Committee on Clinical Investigations (CCI), the appropriately authorized Institutional Review Board (IRB) and Privacy Board appointed to review research involving human subjects. This action was reviewed via Expedited review.

This study approved for continuation for a period of one year with waiver of informed consent and authorization under expedited category #8. Study Status; Data Analysis Only.

Acknowledge receipt of Research Staffing Form dated 8/14/18.

PLEASE NOTE:

As Principal Investigator, you are responsible for ensuring that this project is conducted in compliance with all applicable Federal, State and Local Laws and regulations, BIDMC institutional policies, and requirements of the CCI IRB, which include, but are not limited to, the following:

1. No changes will be made to the IRB-approved research protocol without first submitting a request to the CCI IRB and receiving the IRB's approval. The only exception to this requirement to obtain prior approval is when it is necessary to eliminate an apparent immediate hazard to subjects (45 CFR 46.103(b)(4)). Changes made to eliminate apparent hazards to subjects must be reported to the IRB as a deviation.

2. Using the IRB-approved consent process(es), PI and research staff will obtain and document informed consent (unless waived) and HIPAA research authorization (when applicable) from participants or their legally authorized representative (LAR) prior to the participant's involvement in the research. Refer to CCI Consent Guidance on the portal: (**https://portal.bidmc.org/Research/Human-Subjects/CCI/CCIIRBFrms/InfoCnstnAuth.aspx**) For most recent IRB-approved consent form(s) download and/or print for each participant to be consented from the following link: **https://research.bidmc.harvard.edu/CTPro/ProtocolList.aspx**

3. Submission of any and all reportable events including adverse events, protocol deviations and new information consistent with the CCI policy on unanticipated problems (Section XII, XIII of the CCI Policy and Procedure Manual). Refer to CCI Post Approval Reporting Guidance on the portal: (**https://portal.bidmc.org/Research/Human-Subjects/CCI/CCIIRBFrms/ReportableEvent.aspx**)

4. Informing all investigators and research staff listed on the study of protocol modifications and unanticipated problems, including adverse event(s), involving risks to subjects or others.

5. Obtain Continuing Review and approval of ongoing research at the interval determined by the IRB (at least annually) to avoid expiration of IRB approval and cessation of all research activities. PI will submit a final CCI Progress Report to the IRB and other required reports to sponsors or funding/regulatory agencies, as applicable, when all research activities have ended. **https://portal.bidmc.org/Research/Human-Subjects/CCI/CCIIRBFrms/ContRvwnTermFrm.aspx**

6. Investigators and research staff are responsible for informing the IRB whenever there is a change to the information contained in the initial COI disclosure if a) he/she has acquired new financial interest(s) related to the study protocol and/or b) any of their previously reported financial interests related to the study protocol have changed. (Section VII, C.5 of the CCI Policy and Procedure Manual)

If there are any questions you may contact the Committee on Clinical Investigations (CCI) at 617-975-8511.

cc: Katiri Wagner-Nunes