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COMMITTEE FOR THE PROTECTION OF HUMAN SUBJECTS

Howard Hughes, PhD, Chair CPHS A
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Date: 05/09/13
Submission: Response to Previous IRB Notification
To: Sohail Mirza
Action: Response Approval
Department: Orthopaedics
Action Date: 05/07/13
From: The Committee for the Protection of Human Subjects
Expiration Date: 01/02/14
CPHS #: 23826
Review Type: Full Committee
Study: Advanced Surgery Center Patient Registry
Comments: Revision Approved:
- Change in name from the Advanced Surgery Center to The Dartmouth Center for Surgical Innovation Facility
- Study Plan v. 4/1/13
- Consent form v. 5/2/13, stamped with CPHS approval date 5/7/2013

The Committee for the Protection of Human Subjects (CPHS) has reviewed your response to the previous IRB notification regarding the above-referenced study. The CPHS now approves the revisions to this study as stated above. This approval is based on an appropriate risk/benefit ratio and a study design wherein risks have been minimized.

Please be reminded that informed consent is a process beginning with a description of the research and including an evaluation of comprehension by the researcher. Once the consent form has been signed, each participant should receive a copy. Assessment of each participant's consent by the researcher should continue throughout a research study.

Date Stamped CPHS Consent Form:

The CPHS "date stamps" final approved consent form(s). The stamped approved consent form accompanies this approval letter. Please photocopy and use only the CPHS date stamped consent form for this project.

Any revision to previously approved materials must be approved by the CPHS prior to initiation. Please use the Revisions or Addition Review form for this procedure.

Unanticipated problems involving risks to subjects or others as well as certain adverse drug events and medical device effects should be promptly reported to the CPHS. Please refer to the information and forms to make these reports on the CPHS web site at www.Dartmouth.edu/~cphs. In addition, please promptly report to the CPHS office any known instances of noncompliance and complaints made by subjects in connection with this study.

Based on the risks, this project requires Continuing Review by the CPHS on an annual basis.

If you have any questions, please direct them to CPHS.Tasks@Dartmouth.edu.

Sincerely,



Designee for Chair, CPHS "D"

cc: Judith Forman, MPH