



Committee for the Protection  
of Human Subjects

7000 Fannin Street, Suite 1870  
Houston, Texas 77030

**NOTICE OF APPROVAL TO IMPLEMENT REQUESTED CHANGES**

**HSC-MS-23-0471** - Does prophylactic placement of mesh during loop ileostomy closure prevent parastomal hernias?

PI: Dr. Amit Agarwal

Reference Number: 246403

**PROVISIONS:** Unless otherwise noted, this approval relates to the research to be conducted under the above referenced title and/or to any associated materials considered at this meeting, e.g. study documents, informed consent, etc.

APPROVED: By Expedited Review and Approval

CHANGE APPROVED: Added Connie Klein as Nurse/Study Contact

CHANGE APPROVED: Added Angielyn Rivera as Study Coordinator/Study Contact

APPROVAL DATE: 05/25/2023



CHAIRPERSON: Rebecca Lunstroth, JD

Upon receipt of this letter, and subject to any provisions noted above, you may now implement the changes approved at this meeting.

**CHANGES:** The principal investigator (PI) must receive approval from the CPHS before initiating any changes, including those required by the sponsor, which would affect human subjects, e.g. changes in methods or procedures, numbers or kinds of human subjects, or revisions to the informed consent document or procedures. The addition of co-investigators must also receive approval from the CPHS. ALL PROTOCOL REVISIONS MUST BE SUBMITTED TO THE SPONSOR OF THE RESEARCH.

**INFORMED CONSENT:** Informed consent must be obtained by the PI or designee(s), using the format and procedures approved by the CPHS. The PI is responsible to instruct the designee in the methods approved by the CPHS for the consent process. The individual obtaining informed consent must also sign the consent document. **Please note that if revisions to the informed consent form were made and approved, then old blank copies of the ICF MUST be destroyed. Only copies of the appropriately dated, stamped**

**approved informed consent form can be used when obtaining consent.**

**UNANTICIPATED RISK OR HARM, OR ADVERSE DRUG REACTIONS:** The PI will immediately inform the CPHS of any unanticipated problems involving risks to subjects or others, of any serious harm to subjects, and of any adverse drug reactions.

**RECORDS:** The PI will maintain adequate records, including signed consent documents if required, in a manner that ensures subject confidentiality.