ST. JOHN HOSPITAL & MEDICAL CENTER

Institutional Review Board
19251 Mack Avenue, Suite 340
Grosse Pointe Woods MI 48236
FWA: 00003217

DATE:	March 8, 2018
TO:	Sunetris Fluellen, MD
FROM:	St. John Hospital and Medical Center IRB
STUDY TITLE:	[1165375-2] Skin Closure with Tissue Adhesives vs. Subcuticular Suture after Robotic Urogynecologic Procedures
IRB REFERENCE #:	1165375
SUBMISSION TYPE:	Response/Follow-Up
ACTION:	**APPROVED**
APPROVAL DATE:	January 18, 2018
EXPIRATION DATE:	January 17, 2019
REVIEW TYPE:	Expedited Review
PROJECT STATUS:	Active

This research presents Minimal Risk.
Based on the risks, this project requires Continuing Review by this office on an annual basis. Please use the appropriate renewal forms for this procedure.

The St. John Hospital and Medical Center IRB has APPROVED your submission. This approval is based on an appropriate risk/benefit ratio and a study design wherein the risks have been minimized. All research must be conducted in accordance with this approved submission.

Your protocol, #1165375 was APPROVED along with the following documents:

- Application Form - A1 rev 10-4-17 rev KH 10-5-17 rev KH 10-6-17 rev 10-17-17 sms 10-18-17 sf 1-31-18 rev KH 1-31-18 rev KH 2-1-18 rev KH 2-15-18.pdf (UPDATED: 02/15/2018)
- Application Form - A-2 Form rev 10-4-17 rev KH 10-5-17 rev 10-17-17 rev 12-1-17 4 rev 1-26-18.pdf (UPDATED: 02/1/2018)
- Consent Form - Fluellen informed consent rev KH 10-17-17 sms 10-18-17 rev KH 1-26-18.doc (UPDATED: 02/1/2018)
- Data Collection - Fluellen data collection form rev KH 10-5-17 rev KH 10-6-17 rev KH 10-9-17 rev KH 10-17-17 sms 10-18-17 rev KH 10-24-17 rev KH 1-26-18 rev SF 1-31-18.doc (UPDATED: 02/1/2018)
- Letter - IRB response memo 1-31-18 rev 2-1-18.doc (UPDATED: 02/1/2018)
- Protocol - IRB Protocol (GluevsSubQ) rev KH 2-15-18 rev 3-8-18 marked copy.docx (UPDATED: 03/8/2018)
- Protocol - IRB Protocol (GluevsSubQ) rev KH 2-15-18 rev 3-8-18 clean copy.docx (UPDATED: 03/8/2018)
- Training/Certification - citiCompletionReport6809768.pdf (UPDATED: 12/7/2017)

- Training/Certification - Lori Neil.pdf (UPDATED: 12/1/2017)
- Training/Certification - Tamika Smith.pdf (UPDATED: 12/1/2017)
- Data Collection - Fluellen data collection form rev KH 10-5-17 rev KH 10-6-17 rev KH 10-9-17 rev KH 10-17-17 sms 10-18-17 rev KH 10-24-17.doc (UPDATED: 12/1/2017)
- Other - Note to file from Karen Hagglund.docx (UPDATED: 12/1/2017)
- Application Form - 201712041204.pdf (UPDATED: 12/4/2017)

Please remember that informed consent is a process beginning with a description of the study and insurance of participant understanding followed by a signed consent form. Informed consent must continue throughout the study via a dialogue between the researcher and research participant. Federal regulations require each participant receive a copy of the signed consent document.

Please be advised, while the IRB has approved your research project under the federal regulations for the protection of human subjects, you are still required by the institution to obtain approval from the appropriate department heads as applicable for the conduct of your research (e.g., Finance, Patient Accounts, Legal, Pharmacy, Laboratory, etc.) before you begin your study. A copy of this approval should be forwarded to the IRB for the project records.

As part of the Institutional Review Board requirements, which are mandated by the FDA and OHRP, you are required to report back to the IRB in the event of any of the following: significant adverse reactions, changes to the previously approved materials, non-compliance issues or complaints regarding the study, major protocol deviations, and termination of the study. Please note that any revision to previously approved materials must be approved by this office prior to initiation. Please use the appropriate revision forms for this procedure.

Please note that all research records must be retained for a minimum of three years following the final closure of the study.

If you have any questions, please contact Lisa Miller at (313) 343-7224 or lisa.miller4@ascension.org. Please include your study title and reference number in all correspondence with this office.

St. John Hospital and Medical Center's Institutional Review Board is in full compliance with Good Clinical Practices as defined under the U.S. Food and Drug Administration (FDA) regulations and the International Conference on Harmonisation (ICH-GCP) Guidelines, as adopted by the FDA.

Sincerely,

Robert B. Dunne, MD, Chairperson
Institutional Review Board
St. John Hospital and Medical Center