University Hospitals
Cleveland Medical Center

Operative Services Research Fact Sheet

Patient Name: _____ MRN: _____

Planned Surgery Date: _____ MD on case: _____

Name of Study: _____

Name of Device: _____

IDE Number: _____ Current IRB Approval Date: _____

Research contact: _____ Contact phone / pager: _____

Is study device/product to be supplied to the OR by the research staff? Yes / No

Is this device/product FDA approved for the intended use? Yes / No

Note: If the above answer is "no" there must be an IDE number assigned to device. The IDE number is required to assure the correct CDM.

Have manufacturer's instructions for use been supplied to the OR staff? Yes / No

If the device is to be processed within operative services, have the manufacturers instructions for decontamination and sterilization been supplied to the OR staff? Yes / No / NA

Electrical checks completed? Yes / No / NA

Is vendor/rep scheduled in VCS system? Yes / No / NA

Purpose/brief description of study:

_____

_____

Special instructions:

_____

_____

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OR nursing responsibilities *(Please check when completed):*

- ☐ Verify signed consent for the study with research staff. Document "IRB consent signed" in the additional consents section of the Picis "Time Out" screen.
- ☐ Review any specific needs in the OR (i.e., additional equipment, supplies, etc.) with the investigator for the study and/or the research staff.
- ☐ Investigational item(s) must be entered in SUNRISE as a generic implant / supply unless already in the system with a given Oracle number. The OR informatics/OR Billing Team will document in the notes for that item the word "research" in the billing comments section.
- ☐ Review data/information to be returned to the principal investigator/research nurse/coordinator at the conclusion of the procedure (if applicable).
- ☐ Include all study information in hand-off report.
- ☐ Place completed form in the patient chart.

Signature OR Nurse: _____

Reminder of Surgeon responsibility:

- ☐ The surgeon must include a statement in the operative note that indicates the following 3 items:

  a) "patient is enrolled in research study",

  b) "Study name", and

  c) "has received (device name)".

Note: in order for correct coding to occur on the patient claim, the word "**research**" and the study name must be included in MD documentation. If this wording is not present, the claim will not bill and the physician will be requested to amend the original documentation.

Email / scan completed form to Lisa Prentice, Janet DallaRiva, Marianne Fiala, researchbiller@uhhospitals.org, and the following specific O.R. staff:

Mather OR: Christina McKenzie (NM), Caitlyn Unger (ANM), Melysa Ford (ANM), Mary Ann Domanovic (SCN), Daria Mercurio (Surgical Coordinator), Tonya Lloyd (Surgical Coordinator), Barb Rosplock (HN), Brooke Beringuel (HN Pre/Post), Jennifer McIntire (AHN Pre/Post).
MOSC/Humphrey OR: Erinta Betarello-Hemerka (Manager OR Support Services), Cindy Juris (Surgical Coordinator).
Prentiss OR: Cheryl Hoover (NM OR), Tara Gawloski (HN Pre/Post), Susan Shea (Surgical Coordinator), Miranda Jeffries (Operations and Core Supervisor).