NEW PRODUCT TRIAL FORM
Instructions

This form must be completed prior to start of trial usage of any FDA approved product in the Cleveland Clinic (CC) Operating Rooms.

1. Submissions may be initiated by nurse, physician, vendor or Supply Chain Management (SCM) analyst that would like to trial a product in the CC Operating Rooms prior to a new product committee submission. A CC Physician or Nurse* is required to champion each product. The product Champion (or designee) will be responsible to track product usage and collect data.

2. A copy of this form can be obtained from OR Nurse Managers or Supply Chain Management.

3. Trial Initiator (nurse, physician, vendor or SCM) to complete form and obtain Physician/Nurse* Champion and Department/Institute Chairman signature. (SCM initiated-Analyst and Director signature as noted below)

4. Email scanned form to ORNewProductSubmission@ccf.org or fax attention ORNP to 216-448-8085

5. SCM will provide a completed, signed form to: Physician/Nurse Champion, Vendor Representative, Regional Hospital OR Manager or Main Campus Department Nurse Manager responsible for this product.

6. Vendor Representative must provide the completed approval form to each OR Manager or Department Nurse Manager and the OR team in OR case prior to trialing any product.

7. Product must be provided at no charge to CC unless other arrangements have been made through SCM. Free product is never charged to CC patients or their insurance.

8. To facilitate tracking of product utilization, vendor item and/or Mfg number should be entered into Op Time each time the product is trialed.

9. Data collected will be provided to Supply Chain Management if product is to be presented to a new products committee.

10. If OR New Products Committee reviews a product and requests a trial, similar information will accompany the conditional approval letter and serve the same purpose as the product trial form. The data collected during the trial will be presented at the assigned Committee follow up meeting. A Lawson number may be assigned to these conditionally approved products.

New Product Trial Flow

*Nursing related products
NEW PRODUCT TRIAL FORM

Date: ________________________________
Requesting Physician/Nurse/SCM Champion: ________________________________
Surgical Department or Institute: ________________________________
Hospital: ________________________________

What are the product attributes that exist which makes an evaluation desired? ______________

For what purpose/procedures would it be used? ________________________________

What do you do for those issues now? ________________________________

VENDOR PRODUCT INFORMATION

Product(s): ________________________________
Vendor name: ________________________________
Vendor representative: ________________________________
Vendor phone number and email: ________________________________
Vendor item and/or Mfg.#: ________________________________
Quantity of free product to be provided: ________________________________

Is there capital required for this trial? □ YES □ NO
If yes, how will it be provided? ________________________________

Is there any training required to use this product? □ YES □ NO
If yes who will provided it? ________________________________

TRIAL INFORMATION

Trial estimated start date: ________________________________
Trial length: ________________________________
Trial conditions (limited number of devices, procedure type, specialty, locations or physicians):
________________________________________________________________________

Trial data to be collected: ______________________________________________________
________________________________________________________________________

Method (i.e. questionnaire, email survey, utilization): __________________________________
________________________________________________________________________

Requesting Physician/Nurse Champion:
OR
(Please Print)

Requesting Supply Chain Analyst:
(Supply Chain Initiated Only)
(Please Print)

Signature: ___________________________ Employee Number: ___________ Date _____

Department/Institute Chairman:
OR
(Please Print)

Supply Chain Director:
(Supply Chain Initiated Only)
(Please Print)

Signature: ___________________________ Employee Number: ___________ Date _____

Supply Chain Management Approval:
(Please Print)

Signature: ___________________________ Employee Number: ___________ Date _____