

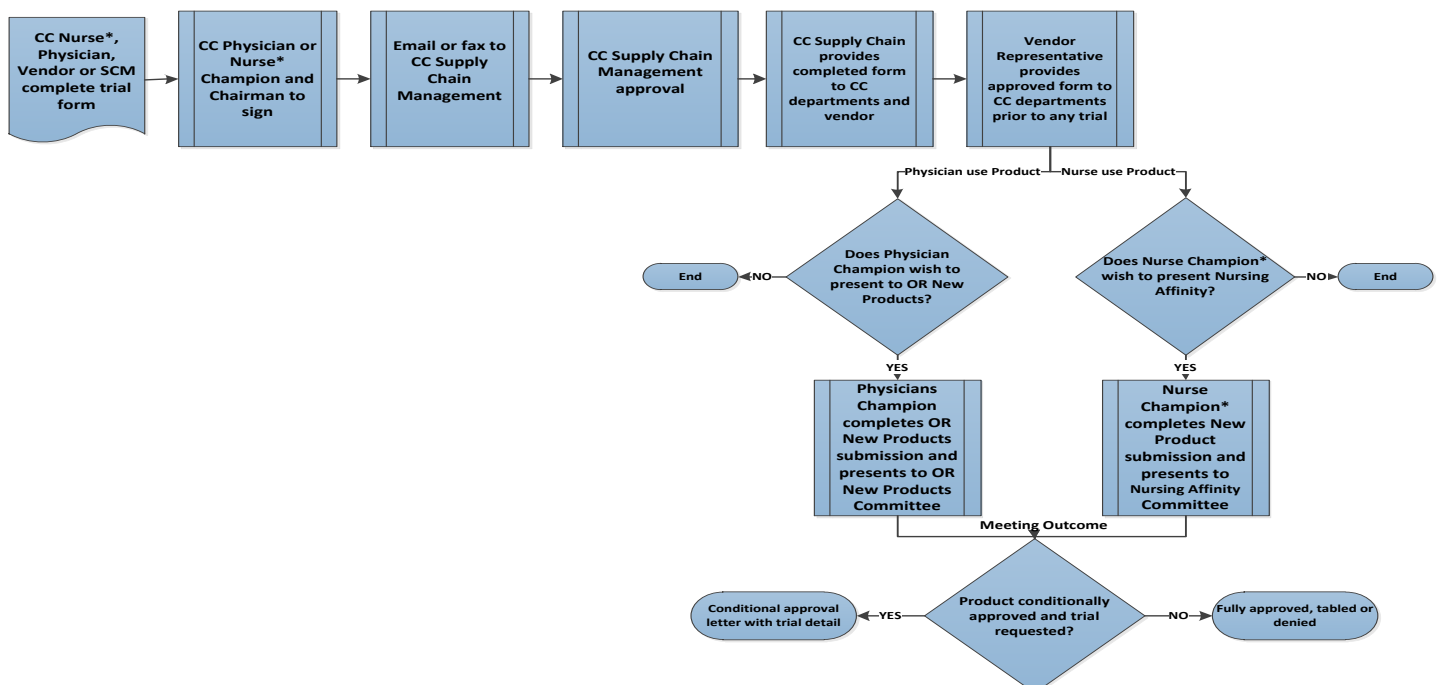
NEW PRODUCT TRIAL FORM Instructions

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** _____