Attachment A

UNIVERSITY HOSPITAL
Newark, New Jersey

New Clinical Product Request Form

New, Replacement, or For Product/Medical Equipment Evaluation

INSTRUCTIONS:

1. Requestor please complete this form and obtain Vendor Product Information from the vendor representative. Specifically, product, pricing, regulatory, and safety information:

2. Requestor, please initial the Conflict of Interest Statement

3. Attach any other supplemental information as needed.

Section A. To be filled out by the Requestor

Date Requested:	

1. **Physician Stakeholder:**		
(Name of Requesting Physician)	Department	Physician's Email
Stakeholder's Phone:	Pager -	Mobile Phone -
2. **Name & title of person completing this form:**		

3. Manufacturer:	
4. Name of New Product or Device:	
5. Product Number (if known):	
6. Sales Representative (name/phone/email)	
7. New Technology ☐ **or upgrade/replacement** ☐	
8. New procedure/technique ☐ Yes ☐ No	
9. What types of Procedure(s) will this product be used?	
10. How will the product improve clinical patient outcomes? (Please explain)	Patient/staff safety ☐ Pain ☐ Blood Loss ☐ Infection ☐ Wound Healing ☐ OR-time ☐ ICU-time ☐ Recovery time ☐ Length of stay ☐ Readmissions ☐ Re-Ops ☐ Staffing ☐ Cost/Procedure ☐ Other
11. Identify Evidence Based Practice literature in support of this product/clinical outcomes?	☐ Yes ☐ No (If yes, attach to form)
12. List all disposables or other device/instruments needed.	☐ None ☐ Unknown ☐ N/A
13. Anticipated annual volume of cases/procedures.	☐ ☐ Unknown ☐ N/A
14. How does the anticipated annual volume of cases or procedures differ from current?	☐ Same ☐ Higher ☐ Lower ☐ New Market
15. Does this new product have FDA Approval?	☐ Yes ☐ No ☐ Unknown ☐ N/A
16. Will this product require an initial evaluation?	☐ Yes ☐ No ☐ Unknown ☐ N/A

17. Is this new product part of a manufacturer's clinical trial? **If yes, does this product have an Investigational Device Exemption and/or Humanitarian Device Exemption (IDE/HDE)?**	☐ Yes ☐ No ☐ Yes ☐ No
18. Is this new product part of an IRB research study? **If yes, has there been a Medicare cost analysis? (Please attach to request form)** **Will Medicare reimburse?**	☐ Yes ☐ No ☐ Yes ☐ No ☐ Yes ☐ No ☐ Unknown
a. If yes, provide: Name of principal investigator and phone #:	Name: Phone:
19. Will there be additional implementation costs i.e. installation, education, &/or space?	☐ Yes ☐ No ☐ Unknown
a. If yes, please explain:	

20. How did you become aware of this product? (Mark <u>all</u> that are applicable)

☐ **Prior experience w/product** ☐ **Trade Show** ☐ **Sales Rep visit to department**
☐ **Surgeon's Request** ☐ **Publication** ☐ **Other (please specify) _____**

Section B. Conflict of Interest Statement

Departments/Physicians requesting products for inclusion to the item formulary must complete this Conflict of Interest Statement. This information is shared with the Executive Value Analysis Committee members and is considered when discussing your request. A potential conflict of interest issue does not disqualify someone from requesting a product. The Executive Value Analysis Committee recognizes many departments and members of the medical staff have relationships with manufacturing companies. Physicians with expertise in an area have often received research grants or other support from companies; however, the Executive Value Analysis Committee feels it is important to disclose these relationships.

20. Have you previously, are you currently, or are you planning on conducting research with his product? ☐ Yes ☐ No If Yes, what are the funding sources for this research?
21. Are you currently or have you in the past two years received funding, grants or contracts for research or is such funding pending from the manufacturer of this product? ☐ Yes ☐ No
22. Are you or have you in the last two years been employed as a consultant for the manufacturer of this product? ☐ Yes ☐ No
23. Do you have current or pending personal investments or other financial interests in this product or its manufacturer and/or vendor? ☐ Yes ☐ No
24. If you answered "Yes" to any of the above questions, please elaborate:

Note:	The requested product will be reviewed for item formulary inclusion on the basis of its clinical, functional, cost/utilization and education/compliance merits. Requests will not be denied solely on the basis of financial disclosure or potential conflict of interest information provided by the requestor(s).

25. Requestor's Initials confirming the Conflict of Interest responses above: _____

Requestor Signature: _____ **Date:** _____

Department Head: _____ **Date:** _____

Committee's Decision: Date _____ ☐ **Approved** ☐ **Denied** ☐ **Pending**

a. If "Pending," what action(s) are required prior to making a Final Decision? ***(Attach documentation and committee minutes as needed)***

Additional Review, if applicable: Date _____ ☐ **Approved** ☐ **Denied**

Product Evaluation Requested:

Evaluation Time period: _____

Designated Evaluation Department: _____

Education required: YES_____ NO _____

Medical Equipment Evaluation Agreement Required: YES_____ NO _____

Executive Value Analysis Committee Decision:

Date _____ ☐ **Approved** ☐ **Denied**