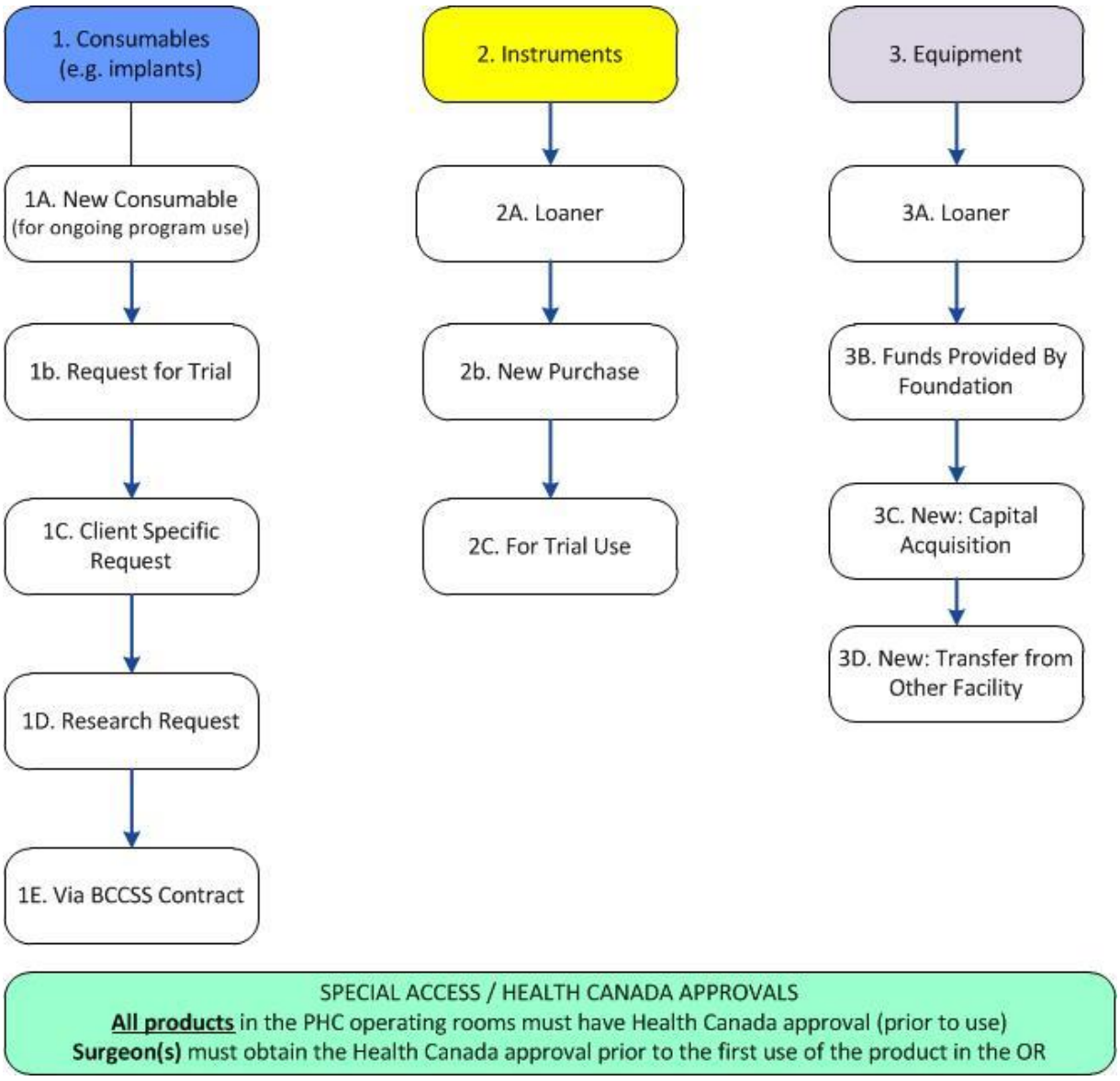
B-00-11-10014

Introduction of / Ordering of New Consumables, Instruments & Equipment by Surgical Program

Flowchart



BACKGROUND

Whenever a new product – consumable, instrument or equipment – is being introduced for use at PHC, whether it is for ongoing use or one time use or for trial evaluation, it is critical that all parties affected by the new product are informed. This can include Program Administration staff, Medical Staff,

Operating Room staff (including the OR CNL, the OR educator's, RN's, LPN's, Anesthetic Assistants), Medical Device Reprocessing (MDRD) and the OR Supply & Equipment Manager.

This allows for transparency in the process to ensure that:

- all members of the Surgical Program are made aware of requests being made,
- the program budget is not impacted disproportionately for one surgeon/group over another (without awareness of same) and,
- education can be planned for and provided to affected staff members in a pro-active fashion
- Departments can plan for capacity to accommodate roll-out

"Criteria" Checklist

The following criteria should be considered when new products are being proposed for use:

- Is there financial and resource viability to support the request?
- What are the impacts to the OR?
  - Practice changes?
  - Policy and procedure changes?
- OH&S impacts?
- Infection Control impacts?
- Is multi-disciplinary implementation expected?
- Is MDRD able to reprocess and meet clinical expectations for demand? (e.g. if only option is ETO it could be a problem)

All new requests must be made through the office of the OR Supply & Equipment Manager. Once all the required forms have been completed and approvals secured, the item will be ordered accordingly by appropriate personnel (i.e. MDRD, OR Supply & Equipment Manager).

Role of BCCSS

The completion of on-line forms serve to ensure that BCCSS has been involved in the Provincial approval process of obtaining new products (as required) and that all items appearing on a given site can in fact be tracked. Tracking supports patient safety for identifying product recalls, ECRI alerts and back orders requiring substitution.

Upon completion of required forms they are forwarded to BCCSS. It is the responsibility of BCCSS to:

1. Ensure that Health Canada approval for use is in place – if not, the surgeon will be notified that this approval must be obtained and that surgery cannot be booked nor can the product be brought in until documented evidence of same is provided.
2. Ensure that if there is an existing contract for use of the product in place that there are no conflicts with the new request.
3. Confirm pricing agreements and terms for purchase (including support and warranty)

It is BCCSS policy that all products arriving onto a hospital site must have a Purchase Order (PO) number assigned to it (even if the product is a "no charge" product).

Role of OR Supply & Equipment Manager

Ordering of all products is the responsibility of MDRD, upon receipt of applicable forms and required approvals.

To facilitate the actual purchase, it is the role of the OR Supply & Equipment Manager to:

- Ensure product is approved for use by BCCSS

- Ensure that each item has a PeopleSoft number & ORMIS assigned to it.
- Determine whether placement of the item will be in the warehouse or will be by direct purchase (along with establishment of re-order levels).
- Provides transparency / awareness to the service-specific OR CNL
- Ensure MDRD is alerted if reprocessing is required
- Provide PDF literature when available
- Co-ordinates the education / in-service required for the various disciplines in collaboration with OR Educator.
- Facilitate the completion of all items identified on the flow diagram "PHC CONSUMABLE ADDITION OR DELETING PRODUCT"
    - This document reflects all the additional work that needs to be carried out behind the scenes to ensure that all new products are integrated fully into regional and / or PHC systems such as ORMIS, regional data warehouse, etc.
- Review complete budgetary quotation

Visitor / Vendor Guidelines

As indicated in policy 34-900 Visitor's Policy, Section 3.5:

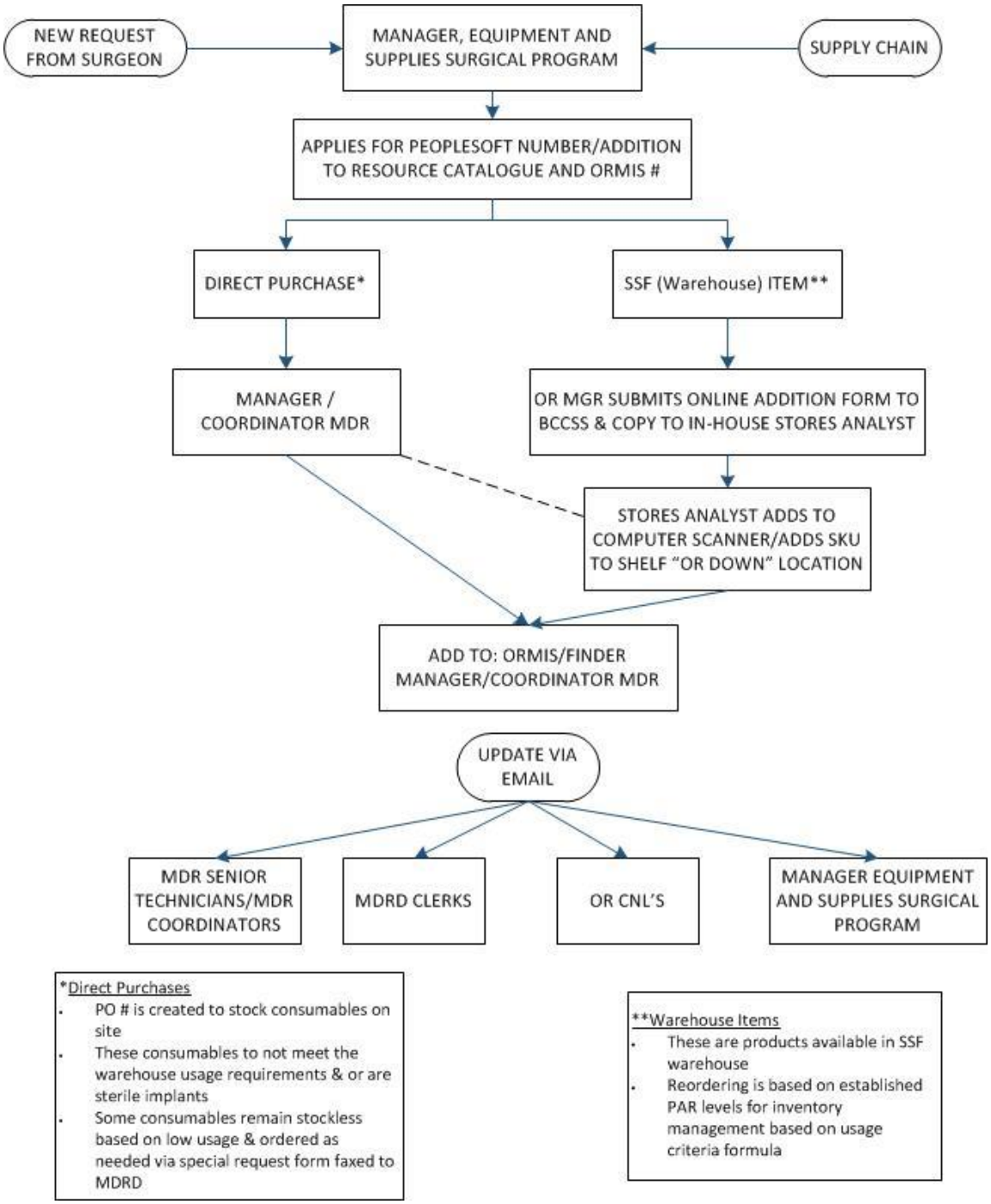
- All vendor representatives who have obtained prior permission from authorized individuals (Manager OR Equipment and Supply or Patient Care Manager) are allowed in the OR. Specific vendor only guidelines are as follows:
    - Attendance must be at the request of the surgeon and for technical assistance for **new** equipment or supplies only
    - Sponsor (Surgeon or CNL/CNE) must meet rep at OR reception and accompany to OR
    - No sales calls are permitted while in the OR
    - All vendors must register at OR reception
    - All vendors must remain in the OR
    - Vendors will have no contact with patients
    - Vendors may not have access to the OR lounge when in OR as a visitor

Orders to purchase (consumables, instruments or equipment) will not be initiated upon request of the vendor. All requests (and required approvals) must come directly from the surgeon (a conversation between surgeon and vendor rep does not constitute "surgeon" approval).

Costs incurred for products (consumables, instruments or equipment) that are brought into PHC facilities by a vendor will not be covered by PHC if the Purchase Order was not initiated prior to the arrival of the product.

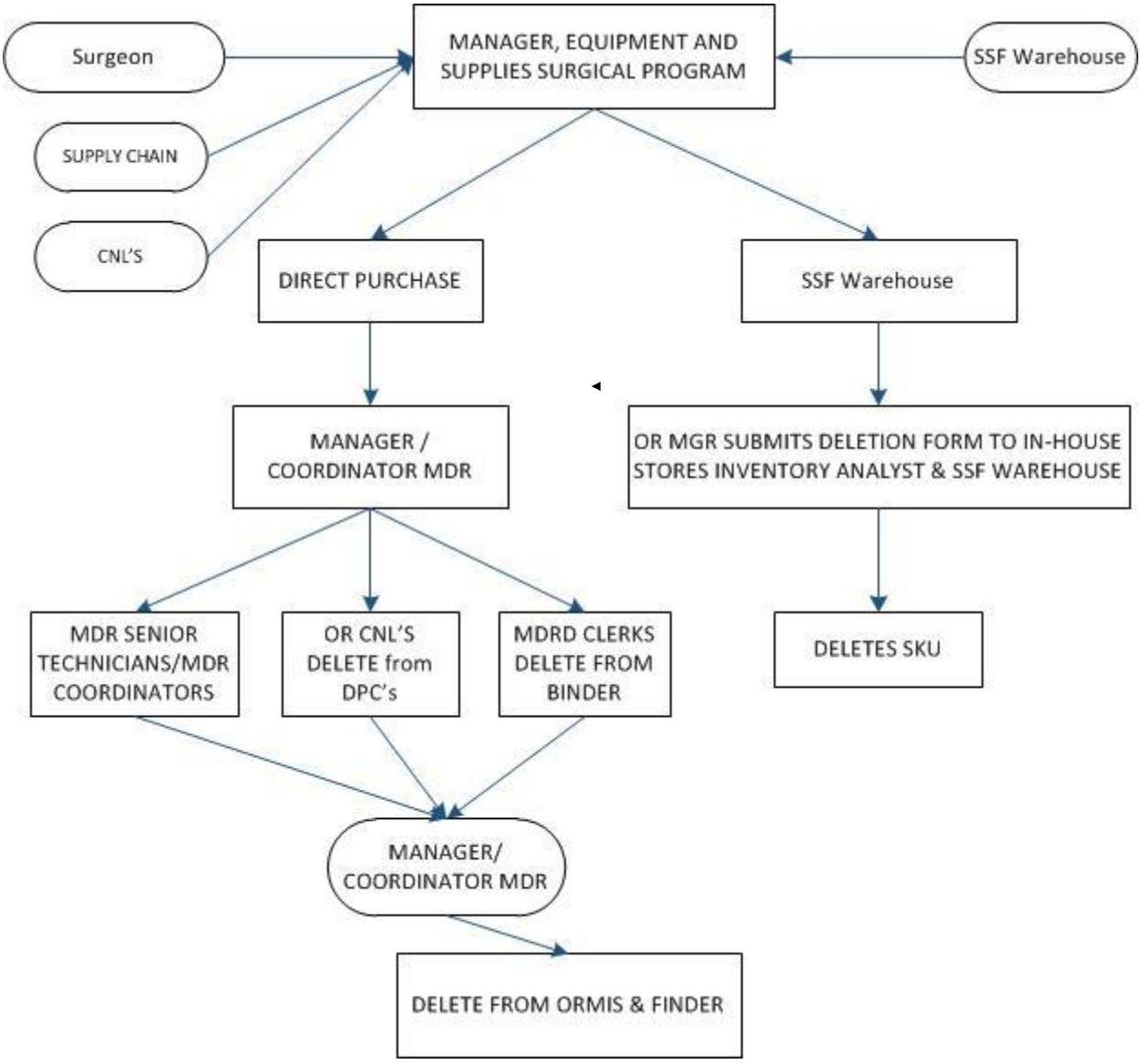
PHC CONSUMABLE ADDITION

- **NEW REQUEST**
- **SUB OR CHANGE**



NEXT Page (see DELETING PRODUCT)

DELETING PRODUCT



INTRODUCTION OF CONSUMABLES

1A. Consumable New – Ongoing Program Use

FORM TO BE COMPLETED:

- PHC Surgical Program Request Form
- BCCSS Request for New Product approval on-line form

FORM COMPLETION INITIATED BY:

- Surgeon
- Supply & Equipment Manager Surgical Program

APPROVAL MECHANISM:

- The Surgeon must complete and sign the form indicated above as well as obtain the signed approval of his/her Department Head and provide copy to Manager of Supplies and Equipment
- The request will be discussed with the Surgical Program Director and/or Business Director before ordering takes place

PROCESS & ISSUES:

- Upon receiving Program Approval, the Supply and Equipment Manager Surgical program completed the on-line "Product Request Form" and submits via the Product Investigation Center. BCCSS PIC submission is to ensure there are no contract violations with the use of the new consumable and Health Canada approvals are in place.
- BCCSS updates Supply and Equipment Manager via product investigation center
- Supply and Equipment Manager will facilitate procurement of the new consumable and the OR nursing education in collaboration with the OR Educator
- The surgeon must identify at the time of the request if NEW instrumentation will be required (and approval for the same will also be required by the Surgical Program).
- The Supply and Equipment Manager facilitates the addition to MDRD inventory

1B. Consumable – Request for Trial

FORM TO BE COMPLETED:

- PHC Surgical Program Request Form
- BCCSS Request for New Product approval on-line form

FORM COMPLETION INITIATED BY:

- Surgeon
- Supply & Equipment Manager Surgical Program

APPROVAL MECHANISM

- The Surgeon must complete and sign the form indicated above as well as obtain the signed approval of his/her Department Head and provide copy to Manager of Supplies and Equipment
- The request will be discussed will be discussed with the Surgical Program Director and/or Business Director before ordering takes place

PROCESS & ISSUES:

- The request to trial a product can come from the surgeon and /or BCCSS in the event of an RFP
- If the request is from the surgeon the intent is to evaluate the product before deciding if it should be brought in-house for on-going use
- At the time of the request by the surgeon, the surgeon should indicate length of trial and how many and what type of cases will be included in the product trial. Trial products should be negotiated an no charge by the surgeon and or Supply and Equipment Manager
- At the time of request the PHC Surgical Program Request Form is completed by the surgeon and forwarded to Supply and Equipment Manager.
- Supply and Equipment Manager will complete the BCCSS product request form for trial use and submit to BCCSS@ scm_cs@hssbc.ca.
- If at the end of the trial it is determined by the surgeon to continue to use the product on an on-going basis, the process steps in 1A " New Consumable for Ongoing use" must be followed

1C. Consumable – Client Specific Request

FORM TO BE COMPLETED

- Request to order non-standard implants, loaner instrumentation or loaner equipment for surgery

FORM COMPLETION INITIATED BY:

- Surgeon

APPROVAL MECHANISM

- The Surgeon must complete and sign the form indicated above as well as obtain the signed approval of his/her Department Head and fax to MDRD
- If the product is being used for the FIRST time in PHC , the request must be made through the office of the Supply and Equipment Manager
- Once the BCCSS process has been completed and approved, the Supply and Equipment Manager will contact the appropriate MDRD resource to issue the purchase order
- Subsequent client requests for the use of the approved product can be forwarded directly to MDRD after the Request to Order Non-Standard Implants, Loaner Instrumentation or Loaner Equipment for Surgery is completed and signed by Department Head

PROCESS & ISSUES

- The consumable /implant is often requested for one patient by one surgeon
- Every time the consumable is used for subsequent patients; this process must be followed
- To ensure that all affected parties are aware of client-specific requests, it is the responsibility of MDRD to inform the Supply and Equipment Manager so that the required education to introduce new products to the nursing staff is arranged and vendor support in the OR if necessary
- All Education provided by Vendors is coordinated by the Supply and Equipment Manager , based on items that have been approved for use by Surgical Program

1D. Consumable – Research Request

FORM TO BE COMPLETED

- No form required

- All research must be approved by the Surgical Program (i.e. Department Head of surgeon conducting the research) and the Program Director, Surgical Program
- All research must have UBC and PHC Certificate of Final Ethics Approval. This approval must be forwarded to the Surgical Program Supply and Equipment Manager Surgical
- All research requests do require a special purchase order (PO) number in order that the product (consumables) can be brought on-site
- This PO will be generated by the Surgical Program Supply and Equipment Manager
- The UBC PHC REB# will be quoted on the PO
- It is assumed that the Health Canada approvals have been obtained as part of the approved research proposal

PROCESS & ISSUES:

- Office of the Supply and Equipment Manager should be given copies of all the approvals once the Surgical Program has signed off on the same.

1E. Consumable – BCCSS Contract Award

FORM TO BE COMPLETED

- No form required

APPROVAL MECHANSISM:

- Often new consumable that have been introduced are a result of contract awards by BCCSS to vendor/s and /or through the Request for Proposal Process (RFP)
- Participation in the RFP process is generally decided by the Program Director, Surgical Program and/or appropriate senior executive pending scope of initiative
- It is common practice that the service/s affected by the contract and / or RFP have involvement in the process at the physician and / or administrative staff level
- In addition, the Supply and Equipment Manager is a member of VCHA SPEC (Surgical Product Evaluation Committee) a regional committee of RSEC (Regional Surgical Executive Committee)and the VCHA BCCSS CSC (Customer Service Committee)
- SPEC's mandate includes establishment of product specifications, evaluation of product performance(including clinical trials), recommendation for preferred products and utilization standards and integration of all recommendations into an implementation plan, all of which is taken to the health authority and BCCSS Management Boards for approval
- The Supply and Equipment Manager also collaborates with the PHC Director, Clinical Products & Standardization to identify BCCSS initiatives, such as Health Pro, that may impact any/all surgical programs. For any Health Pro contracts that involves OR clinical components, the Supply and Equipment Manager is informed of same
- The Supply and Equipment Manager will facilitate contract implementation for PHC Operating Rooms (e.g. Drape and Packs, Sutures, Endo-mechanical devices)

PROCESS & ISSUES

- The Supply and Equipment Manager will ensure that Surgical Program is aware of all activity (pending contracts, RFP's) that may affect the Program/practice change (as long as she/he is aware of same)

- The Supply and Equipment Manager will ensure the OR Educators, appropriate OR- CNL & OR nursing staff are advised of any new consumable that are introduced to PHC as a result of a contract award

INTRODUCTION OF NEW INSTRUMENTS

2A. Instruments – Loaner

FORM TO BE COMPLETED:

- Request to order non-standard implants, loaner instrumentation or loaner equipment for surgery

FORM COMPLETION INITIATED BY:

- Surgeon
- It is the responsibility of the surgeon (surgeon office) to obtain a written, itemized quote from the vendor as to:
  - Any costs (freight, late return charges, rental fee, etc.) that will be incurred by the Surgical Program when borrowing the equipment
  - Price quote on the consumable that will be used (if consumable is not already approved for use in PHC)
  - Indication (by vendor) that the program will/will not be responsible for payment of any damages incurred with the use of instrument and the amount

APPROVAL MECHANISM:

- The surgeon must complete an sign the form indicated above, obtain his/her Department Head approval (signature) and forward to MDRD
  - If the instrument has never been used before in PHC, the request must go through the office of the OR Equipment and Supply Manager
  - Subsequent requests for usage can go directly to MDRD
- If cost are to be incurred with the loaner equipment, the request must be approved by the Business Director, Surgical Program

PROCESS & ISSUES:

- "Loaner" equipment can be used for two reasons:
  - Borrowed for a particular (single case) either because PHC has never had the equipment on site before or because PHC does not have enough of the particular instrument to meet operating room needs on a given day
  - Equipment is on "consignment" by the company, usually due to either not enough space at PHC to permanently store the equipment and/or it is not used frequently to warrant purchase of it
- When loaner equipment is used for either of the reasons indicated above, there may be costs incurred by PHC (i.e. freight, rental fee, damage fee, etc.). This will be considered by the Surgical Program when deciding on the use of loaner equipment.
- The form indicated above shall be completed and forwarded to MDRD within at least 2 weeks of the surgery (when possible). Upon receipt of the form, MDRD will confirm that validated

reprocessing instructions have been provided by the vendor. If the vendor cannot accommodate for the standardized chemicals, equipment or cycles used in MDRD, approval to proceed may be denied.

2B. Instruments – New Purchase

FORM TO BE COMPLETED:

- PHC Surgical Program Request Form***

FORM COMPLETION INITIATED BY:

- Surgeon and/or CNL (surgeon must sign off on request)

APPROVAL MECHANISM:

- The Surgeon must complete the form indicated above
- This form is forwarded to the OR Equipment and Supply Manager who will obtain a price quotation and present the request at the biweekly supply budget meeting. An impact analysis will be completed and presented to the Surgical Program Supply Chain Committee for final approval before procurement.

PROCESS & ISSUES:

- ***This form is currently used by the PHC Surgical Program to determine the cost impact of purchasing a new instrument, to ensure that the program has the financial resources to proceed with the purchase, to determine the impacts on other areas (i.e. MDRD) and to promote transparency across the program (i.e. request is not based on a single surgeon request but rather is approved at department/division level). This completed document is kept for internal purposes only.
- If a new instrument purchase is attached to a new consumable product, MDRD and the OR supply and Equipment Manager must be advised so that education sessions can be arranged for MDRD and OR staff, to ensure that reprocessing requirements have been met, etc.

2C. Instruments – Trial Use

FORM TO BE COMPLETED:

- PHC Surgical Program Request Form

FORM COMPLETION INITIATED BY:

- Surgeon

APPROVAL MECHANISM:

- The Surgeon must complete and sign the form indicated above
- This form is forwarded to the OR supply and Equipment Manager

PROCESS & ISSUES:

- Given the request for new instrumentation is for trial use only, the intent is to evaluate it clinically before deciding to move to ongoing use, either to purchase or loan – no formal approval mechanism is require by the Surgical Program
- At time of request, the Surgeon (or delegate) must indicate the anticipated duration of the trial

- Trial is dependent on MDRD approval of validated reprocessing instructions
- The OR Supply and Equipment Manager will contact the vendor to determine if there will be a cost to the Surgical Program to use instruments on a trial basis (and what new consumables/price is associated with the instrument). If there is a program cost incurred, this will be discussed with the Business Director, Surgical Program.
- The OR Supply and Equipment Manager will vet for MDRD approval of validated reprocessing instructions and will coordinate vendor education and support.
- Surgeon is responsible for completion of Evaluation Form after every case in which trial instrument is used (and forward it to the OR Supply and Equipment Manager)
- If the decision is made to purchase the item, the completed evaluation forms will provide the results and feedback for the trial, and the *PHC Surgical Program Request for Consumables, Instruments and Equipment form* provides the impact analysis of ongoing use in the Surgical Program
- If at such time the decision is made to purchase the new equipment, the process in 2B will be followed.

INTRODUCTION OF NEW EQUIPMENT

3A. New Equipment – Loaner

FORM TO BE COMPLETED:

- No forms are required

PROCESS & ISSUES:

- "Loaner" equipment is brought on site (borrowed for use) in the event of existing equipment failure due to breakage, malfunctioning, etc.
- The Operating Room has a "STAT" Biomedical pager that is used to notify Biomedical Engineering of equipment failures
- Biomedical Engineering is responsible for the repair and/or arrangement for repair of all equipment and if necessary, the coordination of loaner replacements
- If the equipment failure is anticipated to affect OR slates or completion of cases, the Biomedical Engineering department must notify the OR Patient Care Manager and the OR Supply and Equipment Manager or delegates (i.e. OR CNL). The OR CNL is responsible for contacting the OR Booking Office and advises them of slate postponements.
- The OR Patient Care Manager is responsible for notifying affected surgeons if any cases are impacted.

3B, 3C, 3D. Equipment – New Purchase

The Surgical Program is responsible for maintaining their own Major and Minor Equipment lists.

The Surgical Program is responsible for completion of Capital Request – Form A for Major/Minor Equipment requests.

New equipment can be funded through multiple sources – the Foundation as part of a major project, as a condition of a contract through BCCSS (for use of a supply), transfer from a hospital, purchase from operating budget or securement of capital funding (received from the Ministry of Health). If/when capital funds are received; the existing committees will determine the priority allocation of funds across the organization, based on requests submitted by all programs.

Introduction of new equipment may be received through capital acquisition (new spend), terms of a supply-contract or by transfer from other facilities (gently used). New equipment may also be brought in upon request of a surgeon, in collaboration with a vendor, for trial purposes. When this occurs, Biomedical Engineering, MDRD, the Surgical Program Director and the Medical Director of the Surgical Program must be informed.

The reason for introduction of new equipment can include:

1. No charge equipment associated with new consumable usage.
2. Replacement platforms for failed technology.

3. Platform requirements associated with a new contract (consumable, instrument or equipment related).
4. Service transfers i.e. program/select activity moves from one facility to another such as excimer laser lead extraction.

Once the Surgical Program receives new equipment, the follow individuals (in the listed order) must be advised so that staff education and vendor support in the OR can be arranged:

1. OR Supply and Equipment Manager of the Surgical Program. At MSJ, the Patient Care Manager is informed.
2. MDRD Manager or Coordinator
3. OR CNL
4. OR Educators
5. Biomedical Engineering

PROCESS & ISSUES:

- Corporate acquisitions are coordinated by the Director of Biomedical Engineering and the OR Supply and Equipment Manager, with sign-off by MDRD to cover off reprocessing and flag potential issues for Infection Control.
- The OR Supply and Equipment Manager coordinates required educational in-services for the OR nurses and the Department of Anesthesia.

PHC Policies and Forms

Existing Policies

- **A.** Special Access Requiring Health Canada Approval – General
- **B.** PHC Borrowing & Lending of Medical Devices for Urgent or Emergent Surgery
- **C.** PHC Borrowing & Lending of Medical Devices for Elective Surgery
- **D.** PHC Visitors Policy (June 2011)
- **E.** BCCSS Product Concern Process Flowchart & Process (March 2014)

Forms for Completion

A-1. Application Form for Custom-Made Devices and Medical Devices for Special Access (Health Canada version 2011)

B-1 & C-1. Request to Order Non-standard Implants, Loaner Instrumentation or Loaner Equipment for Surgery (PHC – March 2013)

PHC Surgical Program – Request for Introduction of New Consumable, Instrument or Equipment *(Internal form developed for use by PHC Surgical Program)*

BCCSS Product Concern Form

Evaluation Form – Providence Health Care Operating Rooms

For Information Only:

- ✓ PHC Consumable – Addition (new, substitution or change) or Deletion

Special Access Requiring Health Canada Approval

For Custom-Made Devices and Medical Devices for Special Access

Process to be followed for: Product Not Yet Approved for Use in Canada

1. It is the surgeon's responsibility to apply to Health Canada for special approval to use a medical device that has not yet been licensed for use in Canada.
   - 1.1 ***"Application Form for Custom Made Devices and Medical Devices for Special Access"*** is completed by surgeon and forwarded to Health Canada.
   - 1.2 The request can be for a single patient or a limited number (batch) of patients.
   - 1.3 Additional information will be provided to Health Canada (by the surgeon) upon request (e.g. name of patient, etc.)
2. At time of approval Health Canada will assign a "special access number" and advise the surgeon accordingly.
3. The surgeon will complete ***the "Request to order Non-Standard Implants, Loaner Instrumentation or Loaner Equipment for Surgery"*** and indicate the "special access number" provided by Health Canada on this form.
   - 3.1 The completed form is forwarded to MDR Department.
   - 3.2 The documentation must be provided at least 10 business days (2 weeks) prior to date of surgery – for booked surgeries - in order to ensure device availability on day of surgery and to ensure that proper sterilization of product (if necessary) is completed prior to surgery.
4. The individual responsible for ordering new products will create a new Purchase Order (PO#) with BCCSS for the special access device.
   - 4.1 The "special access number" must be indicated on the PO as this is what confirms for HSSBC that the product can be brought in. Added in comment section will be "please forward PO to vendor".
   - 4.2 BCCSS buyer will be responsible for confirming the price of the product and will advise the specific hospital site accordingly.
5. The PO is issued and confirmation number is sent to the vendor. Once the PO has been finalized, the product will be ordered from the vendor.
   - 5.1 The vendor can either ship the special access device to the specific site of surgery or hand-deliver it in.
   - 5.2 The vendor must ensure that the product is brought on site via Stores Receiving Department.
6. Patients requiring a Special Access Device will not be put on the OR Slate until such time as Health Canada approval has been obtained and submitted as part of the OR Booking Package.
7. In the event that a device required reprocessing, this device will not be used for a case until MDR can confirm that the device can be reprocessed at PHC (this is part of the work done in point 3.2).

Applicable Health Canada Form (see links below)

- ***Custom-Made Devices and* [unlicensed] *Medical Devices for Special Access***

http://www.hc-sc.gc.ca/dhp-mps/alt_formats/pdf/acces/md-im/md_sap_im_pas_form-eng.pdf

- ***Drugs – Special Access Programme - Form A (Patient Specific Request)***
  http://www.hc-sc.gc.ca/dhp-mps/alt_formats/hpfb-dgpsa/pdf/acces/sapf1_pasf1-eng.pdf
- ***Drugs – Special Access Programme – Form B (Future Use Request)***
  http://www.hc-sc.gc.ca/dhp-mps/alt_formats/hpfb-dgpsa/pdf/acces/sapf2_pasf2-eng.pdf

REFERENCES

Health Canada's *Medical Devices Regulations*, Minister of Justice, Last amended December 16, 2011.

http://laws-lois.justice.gc.ca/PDF/SOR-98-282.pdf (retrieved from website, March 21, 2012).

Health Canada, *The Medical Device Special Access Programme* Information Sheet,

http://www.hc-sc.gc.ca/dhp-mps/alt_formats/hpfb-dgpsa/pdf/acces/sapmdfs_pasimfd-eng.pdf (retrieved from website, March 21, 2012).

Health Canada, *Special Access Programme – Drugs* Information Sheet

http://www.hc-sc.gc.ca/dhp-mps/acces/drugs-drogues/sapfs_pasfd_2002-eng.php (retrieved from website, March 21, 2012).

Health Canada, *Health Canada's Special Access Programme (SAP) Instructions for Making a Special Access Request – Form A.*

http://www.hc-sc.gc.ca/dhp-mps/alt_formats/hpfb-dgpsa/pdf/acces/sapf1_pasf1-eng.pdf (retrieved from website, March 21, 2012).

Interior Health *Regional Formulary*, last revised February 23, 2012.

http://inet.interiorhealth.ca/clinical/pharmacy/Documents/Categorized%20Formulary.pdf

Health Canada Santé Canada

APPLICATION FORM FOR CUSTOM-MADE DEVICES AND MEDICAL DEVICES FOR SPECIAL ACCESS

OFFICE USE ONLY

Return by Facsimile to 1-613-957-1596 or e-mail to sap_devices_mdb@hc-sc.gc.ca.
Please note that all fields must be completed or the application cannot be processed.

Health Care Professional Information: **(Note: One Application per Health Care Professional)**

Name and Title: Provincial Licence Number: Address: Number and Street: City, Province/Territory: Postal Code:
Telephone: Facsimile: E-Mail:

Health Care Facility Information

Health Care Facility Name: Address: Number and Street: City, Province/Territory: Postal Code:	
Date of Procedure (YYYY-MM-DD):	☐ Check this box if this device is needed for an emergency procedure

**Additional Facilities can be listed by inserting additional Health Care Facility fields*

Information Regarding Unlicensed Device

Name of Device, Components and Accessories:	
Device Identifier (catalogue or model number):	Quantity of each catalogue or model number required:
☐ Check this box if this is a custom-made device and provide a copy of the health care professional's written direction to the manufacturer giving the design characteristics of the device.	

Manufacturer Information

Manufacturer's Name:
Contact Name and Title: Address: Number and Street: City, Province/Territory/State: Postal Code or ZIP Code:
Telephone: Facsimile: E-Mail:

Importer (Distributor) Information

Name of Importer or Distributor:
Contact Name and Title: Address: Number and Street: City, Province/Territory: Postal Code:
Telephone: Facsimile: E-mail:

Application Form for Custom-Made Devices and Medical Devices for Special Access

Medical Rationale

1. Provide the diagnosis, treatment or prevention for which the unlicensed device is requested and the reasons why this unlicensed device was chosen.

2. List the licensed devices considered and provide a rationale as to why these licensed devices would not adequately meet the requirements of the patient.

Device Name	Medical Device Licence Number [1]	Rationale as to why this licensed device would not adequately meet the requirements of the patient

[1]NOTE: A searchable database of medical devices licensed by Health Canada can be found at: www.mdall.ca

3. Identify and list the risks and benefits associated with the use of the unlicensed device and indicate how the benefits obtained would outweigh the risks.

4. Summarize the known safety and effectiveness information in respect of the device.

5. In the case of a request for Batch Release,
   (a) describe the emergency condition requiring treatment, and

   (b) provide the number of devices required for one month: _____

Application Form for Custom-Made Devices and Medical Devices for Special Access

Undertaking

Pursuant to Section 71.(2)(i) of the Medical Devices Regulations, health care professionals are required to make an undertaking that they will inform the patient for whom the device is intended of the risks and benefits associated with its use. Please check the following boxes as appropriate and sign below:

☐ I, the Health Care Professional, undertake to inform the patient, _____ ,
Patient's Initials or Identifier
who is to be treated with the device of the risks and benefits associated with the use of this unlicensed medical device.

☐ I, the Health Care Professional, confirm that I have informed the patient, _____ ,
Patient's Initials or Identifier
who is to be diagnosed or treated with the device of the risks and benefits associated with the use of this unlicensed medical device.

In the case of a batch release request

☐ I, the Health Care Professional, undertake to inform the patients who are to be treated with the device of the risks and benefits associated with the use of this unlicensed medical device.

☐ I, the Health Care Professional, confirm that I cannot inform the patients, who are to be diagnosed or treated with the device of the risks and benefits associated with the use of this unlicensed medical device. I attest that institutional policies will be followed.

Health Care Professional's Signature and Date: _____
Signature Date (YYYY-MM-DD)

Notes

1. In the case of a Batch Release, it is the manufacturer or importer's responsibility to maintain a distribution record in respect of the device in accordance with Sections 52 to 56 of the *Medical Devices Regulations*.
2. Health care professionals are requested to return any unused devices to the manufacturers or importers.

Declaration

I, the Health Care Professional, certify that the information given is true, correct and complete to the best of my knowledge.

Health Care Professional's Signature and Date: _____
Signature Date (YYYY-MM-DD)

Health Care Professional's Name : _____

Return the completed application form with any supporting documentation to the following address by fax or e-mail to:

Special Access Program
Medical Devices Bureau
Health Canada
2934 Baseline Road, Tower B
Address Locator 3430A
Ottawa, Ontario K1A 0K9

Telephone: 1-613-946-8711
Facsimile: 1-613-957-1596
e-mail: sap_devices_mdb@hc-sc.gc.ca

PHC - Surgical Program Request Form for New Consumable, Instrument, Equipment

Date: Circle: **SPH** **MSJ**

A. Request Information:

Name: Position: Dept/Div:

Request Type: (Check all that apply)			Item Description:		
		Replacement			Consumable
		Service Expansion			Instrument
		New Technology			Equipment
		Capital Item (>$5K)	Reason for		for Trial Use
		Repair of Item			Purchase

B. Current Item Description (if available):

Name of Item Currently Used: _____ Est. Annual Usage: _____

Vendor Name (if known): Price / Unit (if known):

C. Requested Item Description:

Description of Requested Item: _____ Est. Annual Usage: _____

Item Name: Vendor Name:

D. Clinical Rationale - Please provide a brief clinical justification for this request including advantages to patient, any cost savings that will be incurred (eg. decreased LOS), supporting documentation for validity of request.

E. Additional Information:

Capital (>$5K)	Is this the original request?	Yes	No
	Has the item been brought to the Foundation?	Yes	No
New Technology	Has this item been approved by Health Canada?	Yes	No
	Has this technology been used regionally?	Yes	No
	Has this technology been used in Canada?	Yes	No

Where is this new technology in use? _____

Please provide supporting data to support request, including: publications, clinical data, evaluation results, etc)

F. Approval Signatures: For large items / new technology / capital (>$5K)

Department/Division Head: Date:

G. Summary Information: Costing & Contractual Impacts & Operational Impacts:

Estimated unit cost: _____

Estimated annual usage: _____

Estimated annual cost: _____

Any contractual impact? Yes No Maybe

SPD _____

Access/Beds _____

OR Efficiency _____

SSO _____

BioMed

H. Program Director Recommendation:

Further information needed to recommend requested item		Date:
No support for item at this time		Date:
Item request accepted / Item to be prioritized		Date:

Program Director or Physican Head (or delegate) Signature Date:

Submit to Manager, Supply & Equipment

Please Provide Any Further Information Here

A. Request Information:

B. Current Item Description (if available):

C. Requested Item Description:

D. Clinical Rationale - Please provide a brief clinical justification for this request: (More space on back)

E. Additional Information:

G. Costing Information - OFFICE USE ONLY **Date:**

Current Item	Item Description	Vendor	VMID #	Unit Cost	D.P.	Stores PS #	Yearly Usage	Yearly Cost
1								
2								
3								
New Item	**Item Description**	**Vendor**	**VMID #**	**Unit Cost**	**D.P.**	**Stores PS #**	**Yearly Usage**	**Yearly Cost**
1								
2								
3								

On Contract?	Current Item	Yes	No		New Item	Yes	No

Cost Analysis:

Comments:

EVALUATION FORM

PROVIDENCE HEALTH OPERATING ROOMS

INSTRUMENT _____ SITE MSJ_____ DATE _____

PRODUCT _____ SPH _____

DESCRIPTION OF PRODUCT OR INSTRU.	VENDOR	VMID

EVALUATED BY: _____ SERVICE: _____

PLEASE COMPLETE THE FOLLOWING:

1. Does the item meet the need? YES _____ NO _____

   Please explain: _____
   _____
   _____

2. How does it compare with the item now in use?

The same	Less Effective	More Effective	No current item in use

Comments _____

3. Would you recommend use of this item? Yes_____ No _____
4. If PHC uses this item, are we deleting an item? Yes _____ No _____
5. If yes please list item for deletion. _____
6. Does this item require reprocessing by MDRD?

MSJ: **PLEASE RETURN FORM TO:**
Clinical Nurse Leader

SPH: PLEASE RETURN FORM TO
Manager Equipment & Supplies

COST COMPARISON – OFFICE USE ONLY

CURRENT ITEM

ITEM DESCRIPTION	VENDOR	VMID #	UNIT COST	D.P.	STORES PS #

NEW ITEM

ITEM DESCRIPTION	VENDOR	VMID #	UNIT COST	D.P.	STORES PS #

YEARLY USAGE OF CURRENT ITEM _____

YEARLY COST OF CURRENT ITEM _____

ESTIMATED ANNUAL USAGE PROPOSED PRODUCT _____

ESTIMATED COST OF PROPOSED ITEM _____

COST ANALYSIS DIFFERENCE _____

CONTRACT CURRENT PRODUCT: YES_____NO_____ PROPOSED: YES_____NO_____

APPROVAL: YES_____ NO_____

RATIONAL _____

_____

DATE: _____