PHILIPPINE GENERAL HOSPITAL
The National University Hospital
University of the Philippines Manila
Taft Avenue, Manila

PHIC Accredited Health Care Provider
ISO 9001: 2008 Certified

TERMS OF REFERENCE

FOR CONSIGNMENT OF VARIOUS MEDICAL DEVICES / IMPLANTS FOR THE DIFFERENT DEPARTMENTS OF THE PHILIPPINE GENERAL HOSPITAL

I. PROJECT DESCRIPTION

PGH is in need of a **CONSIGNOR** to consign **brand-new** medical devices for the different Clinical Departments of the Philippine General Hospital (PGH).

For the purpose of this project, a medical device shall be understood as "*any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material or other similar or related article*":

a) Intended by the manufacturer to be used, alone or in combination, by human beings for one or more of the specific purpose(s) of:
   - Diagnosis, prevention, monitoring, treatment, or alleviation of disease;
   - Diagnosis, monitoring, treatment, alleviation of, or compensation for an injury;
   - Investigation, replacement, modification, or support of the anatomy or a physiological process;
   - Support and sustenance of life, control of conception, or disinfection of medical devices;
   - Provision of information for medical or diagnostic purposes by means of in-vitro examination of specimens derived from the human body.

b) Which does not achieve its primary intended action in or on the human body by pharmacologic, immunologic, or metabolic means, but which may be assisted in its intended function by such means.

The number of source/s for **CONSIGNOR**/s, whether single or multiple shall be determined the PGH-Consignment Committee.

Multiple sources shall be allowed in instances when the responsive **CONSIGNOR** with the lowest price offer cannot adequately fill up the quantity demanded by the Hospital within a given consignment period.

In case that the contract is awarded to multiple sources, the schedule shall be set on the sourcing of said item(s) from all the **CONSIGNOR**/s. However, identification of specific **CONSIGNOR**/s may be allowed for items considered highly specialized, or where small variations may significantly influence the safety, efficacy, and general outcome of the treatments or procedures where the item will be used, provided that it is supported with valid justification by the respective Department Head and approved by the PGH Director.

II. CONTRACT DURATION

The Consignment Agreement shall be valid until the end of the year, renewable subject to satisfactory performance to be recommended by the Consignment Committee and approval by the Director.

III. ELIGIBILITY REQUIREMENTS *(Please refer to ANNEX A)*

IV. SCOPE OF WORK

Ensure high quality, brand-new, timely or immediate delivery, and stock availability of the medical devices for operational use of the said selected clinical departments at reasonable prices based on the Consignment List *(Please refer to ANNEX B)*.

V. TERMS AND CONDITIONS

1. The **CONSIGNOR** shall be required to fulfill the following:

    1.1. Deliver, as the need arises, brand-new medical devices indicated in the consignment orders;

    1.2. Deliver variable items (as to size, models, quality) to be confirmed by the Doctor based on the actual need of the patient/s in case the items to be used are not yet determined due to compatibility concerns, which will then be reflected in the Consignment Order;

    1.3. Deliver/supply consigned items within 48 hours upon receipt of order, with commitment to stock availability;

1.4. Deliver a "*custom-made medical device*", which refers to a medical device, other than a mass-produced medical device, that is:

(i) Assembled or adapted in the manner that is intended for individual patient; or
(ii) Specially fabricated or imported for the sole use of a particular person, in accordance with the specifications of a qualified practitioner;

1.5. Open to inspection and/or testing of all deliveries by the PGH to the extent practicable and necessary prior to acceptance;

1.6. Comply with the security, safety, and PGH house rules related to the issuance of medicines and other pharmacy products to patients;

1.7. Is subject to the investigation and submission of report/s to PGH for any incident or medication safety issue related to the activities done by the **CONSIGNOR**;

1.8. Relieve the PGH from any responsibility for any loss of consigned items arising from fortuitous events beyond the control of the PGH; provided, however, that such loss is not due to negligence resulting to theft or pilferage, and in which case the PGH Pharmacist-on-Duty/Nurse-on-Duty/Administrative Officer-on-Duty, or those staff physically present within the immediate vicinity of incident, including the security guards shall be held jointly and severally liable for the monetary value of the goods pilfered/stolen;

1.9. Certify that all the documents submitted are complete and authentic copies of the original, and that all statements and information provided therein are true and correct.

2. The consigned items shall be delivered and accepted as follows:

2.1. ***Just-In-Time Inventory Item***/s[1] – the **CONSIGNOR** agent delivers item directly to Operating Room (OR)/Procedure Supply Center;

2.2. ***Non-General/Special Inventory Item/s***[2] – the **CONSIGNOR** delivers initial stock items to OR/Procedure Supply Center and the item shall be inspected immediately together with the representatives of the Internal Audit Services Staff (IASS) assigned to do the inspection; and

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[1] Item V. (11) of the Consignment Guidelines, *Just in Time Inventory* - refers to the inventory management system where the items are made available only when the need for the item arises and no stocks are kept on standby.
[2] Item V. (17) of the Consignment Guidelines, *Special/Non-General Inventory Item/s* - refers to the inventory management system where supplies for special use are directly requested by concerned department/area and made available.

2.3. ***General Inventory Item/s (Property and Supply Division or PSD Floor Stocks)***[3] – the **CONSIGNOR** delivers initial stock items to PSD Warehouse and the items shall be inspected immediately together with the representatives of the IASS assigned to do inspection.

3. The **CONSIGNOR**s are prohibited from the following acts:

3.1. Offer/Deliver "*counterfeit medical device*", that is, a medical device, the label or outer packing of which is an imitation of, or resembles or so nearly resembles that of another medical device, as calculated to deceive into believing that it is the label or outer packing of a medical device of another manufacturer;

3.2. Offer/Deliver "*misbranded medical device*", that is, a medical device —

(a) Which is not labeled in the prescribed manner;

(b) Which has on the label or labeling, any word, statement, other matter or information required by these rules, to appear not prominently or with such conspicuousness as compared with other words, statements, designs, or devices on the label or labeling, and in such terms as may render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use;

(c) Which is not labeled with directions for use and such warnings against use in indications wherein its use may be dangerous to health, or against unsafe administration or application, in such manner and form as are necessary for the protection of users, or as may be prescribed;

(d) With a label or container, or anything accompanying which, bearing any statement, design, or device which makes any false claim for the medical device or which is false or misleading in any particular; or

(e) Which is so colored, coated, polished, or treated that damage is concealed, or which is made to appear of better or of greater performance than it really is;

3.3. Offer/Deliver "*substandard medical device*", that is, a medical device that is not of specifications.

3.4. Offer/Deliver "*refurbished medical device*", that is, a medical device that was previously owned and reconditioned for resale, even it meets the safety and performance parameters set by the manufacturer.

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[3] Item V. (10) of the Consignment Guidelines, *General Inventory Item/s (PSD Floor stocks)* – refers to the inventory management system where items are made available to (a) wards/areas through their respective departments, regarded as floor stock items, considered to be part of the operational costs and not charged to individual patients, and (b) supply outlet, where charged items are used by individual patients.

VI. TERM OF REMITTANCE OF THE SALES PROCEEDS

All payments shall be referred to the payment provision of the Consignment Agreement that is "*the consignee agrees to remit the sales proceeds to the **CONSIGNOR** in fourteen (14) days, after receipt of any of the following, whichever is applicable:*

(a) Receipt by the consignee of the funds from the funding agency/ies;
(b) Receipt by the consignee of the patient's payment."

VII. POINT OF CONTACT

The **CONSIGNOR** will liaise with only four (4) offices and will receive Job Orders only from the following:

1. Office of the Deputy Director for Health Operations – Represented by **Dr. Maria Antonia E. Habana**;

2. Offices of the Selected Clinical Departments – Represented by the Chairperson;

3. PGH-Consignment Committee – Represented by its Chairperson, **Dr. Juliet O. Sio-Aguilar**; and

4. PGH-Consignment Office – Represented by its Officer-In-Charge, **Ms. Anna Leah G. Vinluan**

All communications and requests are to be directed to the above named individuals. The above named individuals may designate a point person-in-charge of all requests and other communications regarding the **CONSIGNOR**.

JULIET O. SIO-AGUILAR, MD, MSc
PGH-CC Chairperson

ANNEX "A"

CHECKLIST OF REQUIREMENTS FOR CONSIGNMENT OF VARIOUS MEDICAL DEVICES / IMPLANTS FOR THE DIFFERENT DEPARTMENTS OF THE PHILIPPINE GENERAL HOSPITAL

PGH Consignment Committee (PGH-CC)

ENVELOPE NO. 1

Tick box if PRESENT	Eligibility Documents
	1. Appropriate Registration Certificate from the:
☐	➢ Securities and Exchange Commission (SEC), for corporation
☐	➢ Department of Trade and Industry (DTI), for sole proprietorship
☐	➢ Cooperative Development Authority (CDA), for cooperatives;
☐	2. Mayor's permit issued by the city or municipality where the principal place of business of the prospective **CONSIGNOR** is located;
☐	3. Company profile indicating the following 3.1 Company background; 3.2 That the company is a major distributor of medical devices in the Philippines for at least five (5) years; and 3.3 Preferably, with supply chain presence in major areas of the country;
☐	4. List of completed and all its ongoing government and private contracts, including contracts awarded but not yet started, if any, whether similar in nature and complexity to the contract to be consigned **using the prescribed format** regardless consignment or procurement contract;
☐	5. Sworn and duly notarized statement that the prospective **CONSIGNOR** has not been "*blacklisted*" to participate in biddings by any government agency;
☐	*6.* ISO 13485-Medical devices-quality management systems for manufacturer. *In case the prospective **CONSIGNOR** is not a manufacturer, its principal manufacturer's certified true copy of ISO 13485 and **Good Distribution Practice for** **Medical Devices** (**GDPMDS**) must be submitted. In case, the CGMP is in foreign language, it shall be officially translated to the English language by an appropriate foreign entity.*
☐	7. List of Consigned Items that is intended to be consigned with the corresponding duly certified copies of Certificate of Product Registration (CPR) issued by the Bureau of Health Devices and Technology of the Department of Health or in the absence of CPR, a Certificate of Compassionate Use issued by FDA for consigned item that requires FDA registration. In case a consigned item is non-registrable, a

	Certificate of Exemption issued by the FDA shall be submitted, **indicating specific item number therein**; **OR** List of Consigned Items that is intended to be consigned **using the prescribed format** with the corresponding CPR numbers, Date of Issuance, and Date of Validity; and
☐	8. Tax Clearance per Executive Order No.398, s. 2005, as finally reviewed and approved by the Bureau of Internal Revenue.
☐	9. Valid License to Operate (LTO) issued by the Food and Drug Administration
☐	10. Memorandum of Agreement (MOA) between the distributor and manufacturer. ***In lieu of the above-mentioned legal documents, a Certificate of Eligibility issued by the PGH Bids and Awards Committee may be submitted, only for those suppliers who have participated in any PGH competitive bidding within the last twelve (12) months for the products similar to the consigned items*** **as a substitute** for the legal documents **for Items Numbered 1, 2, and 7 only.** ***<u>However, for those who have already submitted their eligibility in the previous Consignment Offer, they will no longer be required to re-submit the same documents. Kindly coordinate with Ms. Vinluan of the PGH-Consignment Office regarding the eligibility status.</u>*** ***<u>Other Requirement</u>***
☐	11. Notarized Letter of Conformity with the Terms of Reference for the Consignment of Medical Devices of the Selected Clinical Departments of the Philippine General Hospital to be printed in the **CONSIGNOR**'s letterhead **using the attached prescribed format** together with a **notarized certificate** from the **CONSIGNOR** to assure that manufacturing defects will be corrected within a given time from receipt of the written notice of the defect by the authorized officer, and that the consigned items supplied/delivered are free from expiration, defects, and/or all the conditions imposed under the contract.

Note: This checklist shall be placed inside Envelope No. 1.

ENVELOPE 2

Tick box if PRESENT	**Consignment Price Offer shall contain:**
☐	**Accomplished Consignment Form / List**
☐	**An electronic format of their accomplished Consignment List / Form** in USB Flash Drive (virus-free)

CONSIGNOR's Letterhead

List of Completed and All Ongoing Government and Private Contracts

NAME OF THE CONTRACT	CONSIGNEE	CONTRACT PERIOD
ONGOING SIMILAR CONTRACTS *(including contracts awarded but not yet started)*		
COMPLETED SIMILAR CONTRACTS		

_____

(Signature over Printed Name of the Authorized Representative)

Date Signed: _____

CONSIGNOR's Letterhead

List of Consigned Items Intended for Consignment

Item No.	CONSIGNED ITEM(S)	CPR NUMBERS	DATE OF ISSUANCE	DATE OF VALIDITY

_____

(Signature over Printed Name of the Authorized Representative)

Date Signed: _____

CONSIGNOR's Letterhead

LETTER OF CONFORMITY

Title of the Project: **CONSIGNMENT OF VARIOUS MEDICAL DEVICES / IMPLANTS FOR THE DIFFERENT DEPARTMENTS OF THE PHILIPPINE GENERAL HOSPITAL**

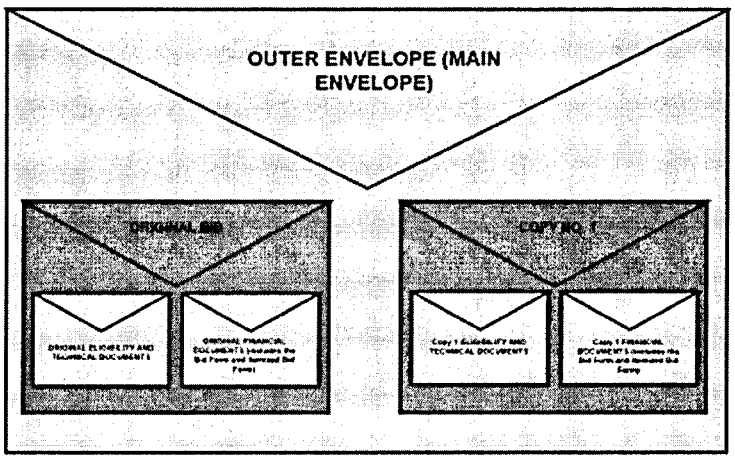
To: JULIET O. SIO-AGUILAR, MD, MSc
Chairperson
PGH CONSIGNMENT COMMITTEE (PCC)
Philippine General Hospital
Taft Avenue, Ermita, Manila 1000

This is to inform the **PGH-CONSIGNMENT COMMITTEE** that our company, _____, located at _____ conforms to the Terms and Reference of this project: **CONSIGNMENT OF VARIOUS MEDICAL DEVICES / IMPLANTS FOR THE DIFFERENT DEPARTMENTS OF THE PHILIPPINE GENERAL HOSPITAL**, and in the changes(s) to be issued.

_____
(Signature over Printed Name of the Authorized Representative)

Date Signed: _____

Please be guided with the following illustration:



ALL envelopes shall be sealed and marked, which shall contain the following details:
For the Main Envelope:
- Name of the Consignment Project in CAPITAL LETTERS
- Name and address of the prospective **CONSIGNOR** in CAPITAL LETTERS;
- Be addressed to the PGH-Consignment Committee in CAPITAL LETTERS
- Bear a warning "**DO NOT OPEN BEFORE**..." the date and time for the Opening Of Consignment Offer as stated in the Invitation to Consign or as change through a Bid Bulletin.

For other Envelopes (Original and Copy 1):

For Envelope 1:
- Bear a marking "ORIGINAL" or "COPY 1" for photocopy in CAPITAL LETTERS
- Below it "ENVELOPE 1: ELIGIBILITY"

For Envelope 2:
- Bear a marking "ORIGINAL" or "COPY 2" for photocopy in CAPITAL LETTERS
- Below it "ENVELOPE 2: ACCOMPLISHED CONSIGNMENT FORM"