BRISTOL AND WESTON NHS PURCHASING CONSORTIUM
"Working smarter, Working better, Working Together"

Suppliers/Sales Representative Code of Conduct

Including

Pharmaceutical Industry Representatives

Effective Date: 1st October 2013 to 30th September 2016

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Approved by: Richard Ward (Director of Purchasing and Supply), Bristol and Weston Purchasing Consortium

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Supplier/Sales Representative Code of Conduct

Introduction

This section outlines the standards expected by the Trust of manufacturers and suppliers of medical devices, pharmaceuticals, interventional radiology and their representatives. The Trust aims to achieve an effective, efficient and consistent relationship with all its suppliers and their representatives.

It is the responsibility of all staff dealing with representatives of suppliers to ensure that they have received the Code of Conduct below and are familiar with it.

Code of Conduct

All company representatives should contact the Bristol and Weston NHS Purchasing Consortium on
Telephone: 0117 342 0416 / 0401 to inform them of any proposed activity, prior to visiting any clinical areas. An appointment should first be made with the clinician and relevant Theatre Co-ordinator / Ward Manager, or other trust representative officer, and a Letter of Authority collected from the Purchasing Consortium, valid for the date of the appointment only. It is then the responsibility of the company representative to ensure that he/she informs the department 24 hours prior to their visit.
This policy also applies to all clinical evaluations carried out across the Consortium, and also company led audits.

The Consortium membership as at the effective date of this code of conduct is:

North Bristol NHS Trust,
University Hospitals Bristol NHS Foundation Trust,
Weston Area Healthcare NHS Trust,
Bristol Community Health CIC,
North Somerset Community Partnership CIC.

All 'Cold Calling' is totally prohibited and action will be taken to prevent repeated offences.

1. As part of the Trust's infection control policy, representatives are required, when working in theatres, to ensure that all jewellery, including rings and watches are removed (with the exception of wedding rings), and are therefore 'naked' below the elbow.
2. Prior to visiting any clinical area the supplier or representative must comply with infection control guidelines for supplier/sales representatives. (see appendix 1).
3. Whilst on hospital property, suppliers and representatives must conduct themselves in a responsible and business-like manner.
4. Suppliers and their representatives (including supplier service engineers) must wear company photographic identity badges and/or uniforms at all times when on Trust premises, and be prepared to identify themselves when challenged by any member of Trust staff**.** All Trust staff are encouraged to only see suppliers and representatives wearing a photographic identification badge.
5. Suppliers' representatives are expected to adhere to Trust mobile communication policies.
6. The Manufacturer's Master Indemnity Agreement must be approved by Bristol and Weston NHS Purchasing Consortium prior to all trials and evaluations taking place. Details can be found by using the below link

   http://nhsmia.bipsolutions.com/
7. Purchase Orders – Suppliers or their representatives should be aware that any order or commercial agreement made (verbal, telephone, written) will not be valid or binding unless accompanied by an official purchase order. The Trust will not make payment for unauthorised purchases which fail to comply with this agreement.
8. Samples – Medical and Nursing staff who request samples of medical/surgical products for evaluation are responsible for their usage. Any samples that are left for evaluation must be indemnified and carry the CE mark.
9. The Trust will **not** be liable for any supplier's property left on hospital premises.

Hospitality and Gifts.

1. Only inexpensive gifts such as pens, pads, diaries etc. which are relevant to work, may be offered to or accepted by hospital staff, in accordance with Trust hospitality policy.
2. Any hospitality received must be declared according to Trust policy on Standards of Business Conduct and Hospitality for Trust employees (NBT and WAHT), or recorded in the Divisional Register of Hospitality (UHBristol).
3. Sponsorship of educational meetings or publications are without obligation and must not be allowed to affect Trust procurement decisions.
4. Sponsorship of the whole or part of any post must receive prior approval from the Director of Human Resources. Such sponsorship must be without obligation and not allowed to affect Trust procurement decisions.

Declaration of Interests.

1. Trust employees must declare any interest or position of responsibility which they hold in organisations outside the Trust.
2. Trust employees must not show favouritism in awarding contracts.
3. Trust employees must not accept commercial sponsorship of any posts (linked deals) where sponsorship is linked to the purchase of particular products or supply from a particular source.

Theatres and all Critical Care Areas.

1. All companies must hold a current indemnity agreement whilst
    a. Undertaking a loan of equipment and or goods for any trials or evaluations, that is overseen by Procurement.
    b. Undertaking a loan of equipment and or goods not for trials or evaluations.
    c. Free of Charge Stock.

2. All companies to produce a competency statement re: all their representatives are fully trained, and are
    a. competent and familiar with their company's instruments/implants

3. All company representatives visiting theatres, in any capacity, must hold a current AFPP Theatre
    a. Access Course or its equivalent. Failure to present this will invalidate the meeting planned for that day.
    b. Theatre access course is Mandatory effective from 1st January 2014.

4. Naked from the Elbow' is to be strictly enforced in <u>all clinical areas,</u> As part of the Trust's Infection Control Policy, representatives when working in theatres must ensure that all jewellery including rings, bracelets, watches are removed (with the exception of wedding rings) and are therefore naked below the elbow

5. All <u>New</u> representatives, <u>before</u> they attend theatre for the first time, must contact BWPC for an appointment to see the CPS, before going into theatres to keep their initial appointment. They will be given a letter of introduction which must be presented to the Theatre Co-ordinator on arrival. A faxed letter or email are not acceptable.

6. It is preferable that all new representatives are introduced to the theatre by their Area Manager

7. All company representatives must wear current company photographic ID at all times

8. All company representatives must report to theatre reception on arrival. The Theatre Receptionist will
    a. inform the Theatre Co-ordinator of their arrival

    b. All company representatives must sign in and sign out when entering/leaving the theatre complex. The
    c. sign in/sign out book will be held in reception

9. Company representatives will be directed by the Theatre Co-ordinator to the appropriate areas

10. Subsequent visits by company representatives:
    a. When the company representative has been contacted by surgeon/theatre, the company representative

b. must contact BWPC and inform them of the forth coming visit. BWPC will raise a letter of introduction for
c. the company representative which will be faxed to theatres On receipt of the letter of introduction the
d. company representative can keep their appointment

11. If company representatives are attending Clinical areas, but the area is not essential to the meeting, Clinicians should be encouraged to meet in their offices.

12. It will be at the discretion of the Theatre Manager/Co-ordinator to refuse entry into the Clinical area if the Sales representative does not have – Photographic ID, Current AFPP Theatre Access course licence, even if the representative has been invited into theatres by a Surgeon.

13. All electrical equipment that is required to go into theatres as part of the evaluation process will be required to undergo a formal electrical check by Clinical Engineering Services prior to evaluation. A signed indemnity form/delivery note will also accompany the companies kit into Clinical Engineering Services. A copy of the indemnity form will then sit with Clinical Engineering Services in the office, and be given a specific log number, which will become part of the audit trail of the kit during the evaluation process.

14. At all times and in ALL areas of the BWPC sites sales representatives will be expected to observe a high professional standard, and maintain patient privacy and dignity.

15. A data base is to be kept as to the competencies/ specialities of sales representatives going into theatres.

16. Where trials and evaluations are in progress and a letter of access will be required for a longer period of time (i.e. up to 3 months), a letter can be raised to that effect providing discussions have first been undertaken with the various Theatre Manager/Coordinator/Procurement, and also the Supplier.

17. Where the above letter of access is in place, a regular review will be undertaken.

18. All loan sets to have photographic layout of tray, with all instruments identified.

19. Where suppliers attend theatres as part of an evaluation process of their kit, they will be subject to the BWPC trials and evaluations policy, a copy of which will be made available to the company upon request.

Decontamination and Sterile Services

Decontamination is a combination of processes including cleaning and disinfection, sterilisation and storage to render an item free from transmissible or infectious material.

The extent of a decontamination process depends upon the specific piece of equipment, its previous use and its intended use.

	Application of Item	**Examples**	**Decontamination**
HIGH RISK	• In close contact with a break in the skin or mucous membrane; or, • For introduction into sterile body areas	Surgical instruments, IV cannula, Needles	**Sterilisation by**: • Autoclave • Irradiation • Ethylene Oxide • Low temperature sterilisation system
MEDIUM RISK	• In contact with mucous membranes: or, • Contaminated with particularly virulent or readily transmissible organisms; or • Prior to use on immune-compromised patients	Respiratory equipment, Urinals, Bed pans	**Sterilisation as above** Disinfection by: Heat Chemical
LOW RISK	• In contact with healthy skin; or, • Not in contact with the patient	Washbowl, Bath, Trolleys	Cleaning usually adequate. Disinfection sometimes needed if known infection risk.

Prior to the purchase or loan of a medical device that will need to undergo some form of decontamination process consideration will need to be given by the Trust as to whether that device/item is suitable to be reprocessed and whether there are suitable facilities in the Trust. This is in order that:

- The decontamination of reusable medical devices takes place in the appropriate dedicated facilities
- The appropriate methods/procedures/equipment required for the decontamination of each medical device is fully understood and in turn can be made available
- The range of appropriate chemicals/products required to be used as part of the decontamination process are fully understood and in turn can be made available
- Manufacturer's instructions for decontamination and compatibility with decontamination agents can be understood and adhered to or negotiated upon in order to comply with Trust procedures/machinery.

Early liaison with Trust Sterile Services Department will be necessary with regards to reusable surgical instrumentation prior to the item coming into the Trust for use, even if it is a loan/trial/evaluation item.

Early liaison with clinical staff in areas where local decontamination of specific and specialised medical devices will be undertaken i.e. theatres, endoscopy, radiology, will also be necessary prior to the item coming into the Trust for use.

All new representatives, before they attend Sterile Services or any other Trust department must contact BWPC for an appointment. At this appointment they will be given a letter of introduction which must be presented to the relevant department lead on arrival. A faxed letter is not acceptable.

All companies are to produce in both electronic and paper versions Manufacturer's instructions for decontamination and compatibility of their device with regards to decontamination agents.

From the 1st October 2013 it will be necessary for a Pre-Purchase Questionnaire to be completed by manufacturers/suppliers in relation to their respective product – only upon Trust approval and sign off of this document will the medical device be allowed to be used in the Trust.

All loan sets to have photographic layout of tray, with all instruments identified, in addition to a comprehensive list of all items supplied.

All loan sets/items to be clearly identified with regard to their status in terms of sterility/cleanliness i.e. non-sterile, to be sterilised before use. If the item is from a previous user and the item has been processed through a sterile services department then that 'users' sterile services facility must be accredited (BS EN ISO 9002 – EN 46002 – ISO 13488 and Directive 93/42 EEC Sterility only.)

All loan sets/items to be supplied with full processing instructions, including how instruments should be presented for sterilisation – where possible these should be demonstrated to Sterile Services Personnel by the company representative.

All loan sets/items need to be with the relevant decontamination facility at least 48 hours prior to them being required by the clinical team.

All new medical devices/surgical instruments need to be with the relevant decontamination facility at least 10 working days before being required by the clinical team.

All medical devices/items being brought into the Trust for trial/evaluation purposes need to be with the relevant decontamination facility as follows:

- Sterile Services – at least 7 working days before being required by clinical teams
- Endoscopy – at least 48 hours before being required by clinical teams
- Radiology – at least 48 hours before being required by clinical teams
- Other specialities – at local managers discretion but it is suggested that the minimum time would be 48 hours

At least 36 hours will be allocated prior to loan instruments/items being collected or returned to the manufacturer/other lender in order that a decontamination process can be undertaken.

UNDER NO CIRCUMSTANCES WILL MEDICAL DEVICES BE TRASNPORTED OUTSIDE OF THE TRUST WITHOUT BEING DECONTAMINATED FIRST.

All electrical equipment that is required to go into a department and is associated with the reusable surgical instrumentation/medical device to be decontaminated/sterilised requires being seen and checked by UH Bristol's MEMO department prior to use.

At all times and in ALL areas of the BWPC sites, Sales representatives will be expected to observe a high professional standard and maintain confidentiality.

All company representatives must wear current company photographic ID at all times

Pharmaceutical Suppliers.

1. All representatives must work within the ABPI (Association of British Pharmaceutical Industry) code of practice – even if they are not ABPI members, and comply with all BNSSG (Bristol, North Somerset, and South Gloucestershire) and Trust's local policies. Detailed guidance is available from the Pharmacy Departments.
2. Representatives are not allowed on Trust premises without an agreed appointment, which should be arranged through departmental secretaries.
3. Requests for appointments should **not** be made in person
4. Representatives should **not** contact staff via the bleep or Trust email system unless by prior arrangement.
5. No promotional materials of any kind should be left or displayed in patient areas.
6. Representatives **must not** approach junior medical staff without an appointment.
7. Representatives wishing to discuss non-formulary drugs must only discuss this with consultant staff or lead pharmacists responsible for formulary development.
8. The Trust has a policy for the introduction of new drugs into the formulary. Representatives may clarify the current status of a drug with the lead pharmacist responsible for formulary development. Representatives must not complete the new drug application documentation on behalf of a consultant.
9. NBT does NOT undertake unstructured "trials" or product evaluations. Representatives **must not** supply pharmaceutical samples to **ANY** trust staff.
10. Representatives should not provide hospitality without an educational value.

Radiology/Interventional Radiology for BWPC.

1. All representatives attending NBT must first contact the Interventional Stock Management lead at NBT for an appointment. They can be contacted on 0117 3233693 / 0117 3402352.

2. Once a confirmed appointment has been made, BWPC will be notified and asked to raise a letter of introduction for the company representative.

3. The letter will be faxed to the Interventional Stock Management Lead ready for the company representative to collect

4. Once in receipt of the letter of introduction the company sales representative can keep their appointments.

5. The above standards are expected by all company/sales representatives visiting the trust during normal working hours, where an emergency visit is not required*

6. For visits to UH Bristol and Weston, company sales representatives will be required to collect the letters from BWPC after first making an appointment with the relevant Clinician.

7. Where a sales representative has been asked to into the Trust to discuss a potential evaluation of new products with a Clinician the process to be followed is that CPS will have a discussion with the company/sales representative before any evaluation is commenced, usually at Whitefriars, Bristol.

*For clarity any Non-NBT/UH Bristol or Weston staff must have a letter to visit the department during standard working hours

FAILURE OF SUPPLIERS, OR THEIR REPRESENTATIVES, TO COMPLY WITH THIS CODE OF CONDUCT MAY RESULT IN INDIVIDUAL REPRESENTATIVES BEING BARRED FROM NORTH BRISTOL NHS TRUST (NBT) / UNIVERSITY HOSPITALS BRISTOL NHS FOUNDATION TRUST (UHBRISTOL) / WESTON AREA HEALTHCARE NHS TRUST (WAHT) PROPERTY AND IN ADDITION COMPLAINTS MAY BE MADE TO THE ABPI WHICH IN TURN COULD LEAD TO A REVIEW OF ANY CONTRACTS HELD WITH THE COMPANY.

Appendix 1- Infection Control Guidelines

Background

Suppliers' representatives must be aware that all personnel who visit clinical areas have the potential to introduce and transmit micro-organisms. Whether a piece of equipment is invasive or non-invasive, there is a risk that if adequate cleaning and decontamination is not carried out, organisms can be transmitted not only from one patient to another, but from one hospital to another. The infectious status of patients is not always known; therefore all patients should be treated as possible infection risks. Frequent hand washing by users and decontamination of decontamination equipment must be a priority. A valid decontamination notice must accompany any equipment, which may undergo multiple usages.

Guidelines

In recognising these factors, suppliers' representatives are asked to observe the following:

Suppliers' representatives may not visit the Trust if they are suffering from, or may be incubating, any infectious disease, e.g. chickenpox, or are suffering from mild infections e.g. colds and flu. These conditions may be hazardous to susceptible patients, particularly the immune-compromised. Similarly, they must not enter the hospital environment should they be experiencing symptoms of diarrhoea and/or vomiting. Where representatives have been suffering from such symptoms, they should not enter the hospital environment until they have been free of symptoms for at least 48 hours. The supplier/representative may also be expected to inform the infection control team should it subsequently transpire that a representative was incubating a modifiable disease during their visit to the Trust, and to state which areas had been visited.

On entering a clinical area, all persons should remove outdoor coats or jackets and wash their hands. Disposable aprons should be worn if there is to be a direct contact with a patient. All persons should remove their aprons and wash their hands between patients and on leaving the clinical area

All company representatives should follow hospital practice of decontaminating their hands (using alcohol gel) when moving between one clinical area and another.

Equipment should not be used on any patient known to have an infection unless it is part of the selection criteria for the device. Advice should be taken from staff when selecting a suitable patient for demonstration purposes.

Demonstration equipment must have been cleaned thoroughly beforehand (see list of methods of cleaning), and between each patient, using recommended processes for all components which may come into contact with the patient. These must be cleaned or sterilised between patients.

Suppliers' representatives will be held responsible for effective cleaning and safe and clean transportation of demonstration equipment between patients, between departments and between hospitals.

The potential exists for supplier representatives to come in contact with blood and body substances. It is in their own interest to establish Hepatitis B immunity by immunisation and be fully aware of the importance of Standard Precautions against blood borne viruses and transmission of organisms.

"Naked below the Elbow"(Theatre)

As part of the Trust`s infection control policy. Representatives are required , when working in theatres to ensure that all rings and watches are removed (with the exception of plain band wedding ring), and are therefore "naked below the elbow"

Cleaning and Decontamination of Equipment

Ease of cleaning and decontamination should be an effective selling point. Cleaning of equipment after each patient usage is an important preventative measure against the spread of micro-organisms. Hands do not only carry organisms from patient to patient, they also transfer organisms from one piece of equipment to another. Cleaning must be sufficient not only to remove visible soiling, but also to remove and reduce micro-organisms. For this reason, even equipment that does not come into contact with the patient needs to be cleaned and decontaminated.

- An automated process must always be used in preference to a manual process
- When washing by hand, total immersion of the item is preferable

Manufacturers should give recommendations as to the cleaning and decontamination methods for their equipment. However, if these are not given, the following guidelines can be followed for the cleaning and decontamination of equipment:

Equipment	Decontamination method
Syringe drivers **Intravenous Infusion pumps** **Enteral feeding pumps** **PCA pumps** **Ventilators**	Wear a plastic apron and disposable examination gloves. Use a disposable cloth wrung out in hot detergent water to clean the piece of equipment, being careful to reach all the corners and paying particular attention to the parts most frequently touched e.g. controls switches and panels. Detergent wipes are also available. DRY all parts thoroughly Alcohol wipes (no longer used at UHBristol) can be used only after removing organic soiling as above, e.g. blood, body substances, IV infusate, enteral feed etc. If the equipment is splashed with blood or bodily fluids the manufacturer's recommendations need to be adhered to. The use of hypochlorite solution is required following the initial clean with appropriate detergent solution.
▪ Invasive and non-invasive monitoring equipment ▪ Diagnostic equipment	All single use components must be disposed of as clinical waste. Clean as recommended by the manufacturer, paying attention also to leads and additional components. Re-usable invasive equipment, e.g. scopes must be autoclaved or sterilised by suitable chemical means.

Glossary of Terms.

BWPC Bristol and Weston Purchasing Consortium
Whitefriars,
Level 3 ((South Wing)
Lewins Mead
Bristol
BS1 2NT.

NBT North Bristol NHS Trust.
UHBristol University Hospitals Bristol NHS Foundation Trust.
WAHT Weston Area Healthcare NHS Trust.
CPS Clinical Purchasing Specialist.
AFPP Association of Perioperative Practioners.
ABHI Association of British Healthcare Industries
ABPI Association of British Pharmaceutical Industries.

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