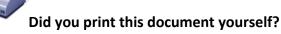




Supplier and Manufacturer Representative Policy

This procedural document supersedes: CORP/PROC 2 v. 6 - Representative Policy



The Trust discourages the retention of hard copies of policies and can only guarantee that the policy on the Trust website is the most up-to-date version. If, for exceptional reasons, you need to print a policy off, it is only valid for 24 hours.

Executive Sponsor(s)	Jon Sargeant – Director of Finance	
Author/reviewer: (this version)	Claire Burns – Deputy Head of Procurement	
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Approved by:	Policy Approval and Compliance Group	
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Target audience:	Trust Wide	

Amendment Form

Version	Date Issued	Brief Summary of Changes	Author
Version 7		 4.4 - Promotional activity reworded to reflect Conflict of Interest – actual and perceived 4.12 - Pricing – reworded around commercially sensitive information. 4.10 - Update Signing of Contracts 4.13 – Update to include Counter Fraud. 'Care Groups' amended to 'Divisions' Appendix 1 – Contact details updated. 	Claire Burns
Version 6	8 August 2018	 Document amended to reflect the new process following introduction of 'IntelliCentrics UK' kiosk Contact details amended – Appendix 1 	Tracy Holt
Version 5	6 January 2015	 New document template Contents page amended Job titles amended to reflect new Clinical Care Groups NHS Conditions of contract updated – section 4.8 Contact details amended – Appendix 1 	Allison O'Donnell
Version 4	January 2010	 Policy dates – page 1 Standards of Business Conduct and Employees declaration of Interests Policy added to paragraph 3 – page 1 Amendment form and contents page added Visits to Hospital Sites – paragraph 3 deleted – page 4 Medical Equipment – policy date change – page 6 Team Leader changed to Theatre Coordinator – page 7 NHS Conditions of Contracts – final paragraph deleted – page 8 Code of Ethics – paragraph 3, value changed to £25.00 – page 9 Contact details – page 10 	Ian Allcock

CORP/PROC 2 v.7

		 Equality Impact Assessment added – page 11 Monitoring of Policy added – page 11 	
Version 3	June 2007	 Policy dates – page 1 Medical Devices section – PPQ – page 3 Policy dates – page 4 Contact details – page 5 	Ian Allcock

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1. INTRODUCTION

Doncaster and Bassetlaw Teaching Hospitals NHS Foundation Trust (DBTH) appreciates the role that healthcare companies play to assist health care practitioners in providing safe effective and economic products and services to patients in their care. It is important that any new or amended products are introduced in conjunction with the Trust's Procurement Team.

This policy applies to all staff employed by Doncaster and Bassetlaw Teaching Hospitals NHS Foundation Trust and visiting company representatives whilst on business within the Trust.

2. PURPOSE

The purpose of this policy is to provide clear, understandable guidance on the processes to follow when dealing with manufacturers and suppliers. The policy applies to all company representatives and companies will be expected to accept this policy as part of a contract award.

3. DUTIES AND RESPONSIBILITIES

3.1 Divisional Directors, Clinical Directors, General Managers

To ensure that all staff in their Divisions with a responsibility for the reception areas within departments, purchasing of products and services or meeting with representatives are made aware of, and adhere to this policy.

3.2 Head of Procurement

To inform suppliers of the expectation to co-operate with this policy and for distribution throughout the Procurement Team.

3.3 Ward/Department Staff

All ward/department staff responsible for the purchasing of products or services are to familiarise themselves with the contents of this policy, and practice within the confines of the policy at all times. To report any cold calling by company representatives to Procurement.

3.4 Procurement Groups

To familiarise themselves with the contents of this policy, and practice within the confines of the policy at all times. To report any cold calling by company representatives to their wards/departments.

4. PROCEDURE

4.1 General Information

It is recognised that, in addition to providing information to health care practitioners, the prime function of company representatives is to promote and sell their products and services. This function should be carried out in a proper and ethical manner and must not contravene Trust, NHS or government policies.

If this policy is breached, representatives may be removed or barred from site or, reported to company, commercial / professional organisations if codes of practice are breached, e.g., Association of British Pharmaceutical Industry (ABPI) and Association of British Healthcare Products Industry (ABHI).

4.2 Visits to Hospital Sites

Representatives may not enter any clinical or non-clinical areas (*including wards and outpatient areas*) or visit the Procurement Department without an appointment. To make an appointment with a member of the procurement department, please see contact points/details listed at the end of this document. If a meeting is to discuss ANY new product or service then Procurement must be informed in advance and approve the meeting. 'Cold calling' is prohibited and action will be taken which may result in suspension of business related to that supplier.

A representative arriving for an appointment must arrange to be met by the host. The representative is not permitted to enter any department other than the department that has been agreed with the procurement department. Visits to multiple locations at the Trust require appointments in each location to be approved. As an example; being granted an approved appointment to visit Ward X does not permit the representative to visit Ward Y; if access is tested then the Representative will be in breach of adherence to this policy for cold calling / accessing a department without an appointment.

Theatres

On arrival at the Doncaster Royal Infirmary site, supplier representatives who are visiting theatres will report to the lift area through Gate 3 and check in using the IntelliCentrics UK kiosk, located opposite the lift area. If their credentials are in order a badge will be printed and should be worn at all times during the visit. If a badge is not issued then representatives will not be allowed to proceed.

Pharmacy

Medical representatives wishing to make an appointment with pharmacy staff are asked to complete a 'Request an Appointment' form detailing the reasons for the appointment; forms available from the pharmacy receptions. The forms should be forwarded to the Clinical Director or Deputy Director of Pharmacy and Medicines Management for consideration. Where an appointment is granted the representative will be contacted within two weeks.

No supplier should be involved in reviewing stock rooms or stock taking (including for consignment stock) without prior approval from the procurement department and a Trust representative being present at all times.

Should any emergency situation arise whilst on a hospital site, e.g.: fire alarm, all representatives <u>must</u> follow any instructions given to them by Trust staff.

4.3 Personal Appointments

Representatives may only seek an appointment where there is a valid reason for the visit, to meet with departmental managers, clinical and medical staff or an open meeting with medical and/or nursing/pharmacy staff in a group. The Trust's expectation is that such meetings are educational and not entirely promotional. Junior Doctors and Pharmacists should not be bleeped to make appointments.

4.4 Promotional Activity

Representatives should be well informed about the products that they are promoting. In addition, standard technical, and where appropriate, clinical data including information on product effectiveness should be available.

Where any teaching and/or promotional activity is planned, Representatives must advise the Department Manager and the Procurement Dept. The intent of the meeting must not contravene/challenge existing Trust policies.

Leaflets and posters produced by Representatives may not be distributed or displayed in clinical areas unless approved by the Head of Nursing and Head of Procurement.

Visits from Representatives are strongly discouraged during or immediately prior to any tender process that would create a conflict of interest, actual or perceived.

4.5 Samples – Medicines and Medical Devices

Medicines

Free samples of Medicines will only be requested by:

- Prescribers who carry overall clinical responsibility for the patient(s) the medicines will be administered or supplied to.
- Directorate Pharmacists acting with the knowledge of the Clinical Director of the Directorate concerned.

Free samples of medicines will be received solely through the Pharmacy, and will only be accepted where prior notification of their delivery has been supplied by one of the individuals requesting the supply.

Medical Devices

Medical device samples must not be left on the wards, but must be delivered to the Procurement Department in the first instance.

All medical device samples must be CE marked (Conformite Europeene). 'CE' markings are an indication that the product has undergone some form of verification and validation process acceptable to the European Commission. In addition, a Pre-Purchase Questionnaire may be required before a device can be left on the Trust's premises.

Any commercially sponsored trials/agreements of medical devices must be advised through to the Procurement Department to ensure that:

- trials are carried out in accordance with Trust guidelines and Standing Financial Instructions for trials
- trials or research carried out within the Trust should be notified to the Clinical Research Department
- trials are carried out on a controlled basis
- the product in question meets the appropriate safety standards
- trials are not duplicated
- there is a protocol to return unused products following the trial period

In any product trial, the following points will be considered and recorded:

- how the trial is to be administered
- how the trial is to be financed
- how samples are to be provided
- how long the trial will last
- whether technical staff need to be involved
- current safety regulations and quality standards
- how the trial will be assessed
- whether the other criteria (e.g. packaging) need to be taken into account
- whether the supplier should be involved
- the implications for existing contracts and purchasing agreements
- how the results of the trial will be disseminate

For further information, please contact any member of the Procurement Department as detailed at the end of this document.

Products brought into the Trust by Representatives, which are not on contract, or without an official Purchase Order number will be considered 'Free of Charge'.

4.6 Medical Equipment

The Trust requires that <u>all</u> medical equipment is delivered to the Medical Technical Services Department via Stores. This includes all equipment on loan (whether for trial or testing or not): free issues and free issues for trial and testing.

Under no circumstances should medical equipment be delivered directly to a ward/department without the prior knowledge of the Medical Technical Services Department. Please refer to the procedure for Use of Medical Equipment On Trial/On Loan.

For further information please contact the Medical Technical Services Department on 01302 642135.

4.7 Supplier Representatives and Operating Theatre Department

The aim of the Operating Theatre and staff is to provide and maintain high standards of patient care during surgical procedures. Supplier representatives must appreciate and recognise this as a priority. This policy is an effective risk management tool, which will control the access of supplier representatives to the Operating Theatre Department.

- All Supplier representatives will gain permission prior to entering the Operating Department, from the Theatre Coordinator or Lead Practitioner.
- A supplier will not attend theatre to introduce ANY new products without prior approval from Procurement.
- On arrival to the Operating Department, Supplier representatives will report to the Theatre Coordinator/Lead Practitioner of the Theatre, stating who they are and with whom their visit has been authorised. Identification must be produced at this stage.
- All the Trust's Theatre departments have implemented the use of a Theatre Visitors'
 Signing-in-book. This will be signed by all Supplier representatives (time in and out of
 the theatre department) in order to comply with fire safety regulations.
- Supplier representatives will be provided with appropriate theatre attire and instructed on how it should be worn. Representatives must NOT wear their own theatre attire for infection control reasons.
- Supplier representatives will be supervised by a named member of the Theatre staff throughout their visit to the theatre department.
- Any visitors to the operating theatre should be discussed at Team Brief or prior to surgery and agreement reached by the surgeon, anaesthetist and theatre practitioner in charge of the theatre on the day on the numbers of personnel present in theatre.
- Supplier representatives are reminded that all procedures within the Operating
 Theatre Department are confidential in nature and that any information, discussions,
 technical details or documentation must be treated as such. (They will only enter
 the theatre room once the patient is asleep and draped, in order to maintain the
 patient's dignity.)
- If the Supplier representative is required to scrub, for whatever reason, this must be authorised by both the Theatre Coordinator/Lead Practitioner and the attending surgeon.
- Informed Patient consent must be obtained verbally authorising the Supplier Representative to be present in the Operating Theatre observing/demonstrating/commissioning equipment. Consent should be documented in the patient's records by the organiser of the event. If the patient has not provided consent, the Supplier Representative will not be authorised to be present in the Operating Theatre.

- Any Supplier representatives gaining access to Theatre, to provide technical
 assistance during a surgical procedure, to observe, demonstrate, in service or
 commission equipment or products, must produce evidence of a recognised
 qualification, e.g. TAQ (Theatre Access Qualification), which states that they are
 competent to do so, prior to entry. They must also produce a company Indemnity
 Insurance certificate, before they will be allowed to scrub-up.
 A member of the theatre scrub team must be present while the Supplier
 representative "scrubs up" to assure that aseptic techniques are adhered to at all
 times.
- Whilst in Theatre, supplier representatives must seek permission to speak to the surgeon via the scrub nurse. Noise levels, including communication should otherwise be kept to a minimum. All medical products must be handed to scrub nurse and not directly to the surgeon.
- In the event of surgical emergency, the Supplier representative will be asked to leave the Theatre.
- The supervising member of the theatre staff will ensure that the Supplier representative does not act or move in such a way as to contaminate the sterile field.
- Should a Supplier representative feel unwell, they should immediately inform a member of the theatre who will take the appropriate form of action.
- Supplier representative should behave professionally at all times. If their behaviour
 is deemed unprofessional, by the nurse in charge, at any time, they will be asked to
 leave the theatre department.

4.8 NHS Conditions of Contract

All goods (donated or otherwise) and services offered to the Trust will be procured against the standard NHS Conditions of Contract; these include Indemnity and Insurance, which are also applicable to items supplied on loan that will require Indemnity Agreement being signed by both the supplier and the Trust.

Indemnity

This ensures that the Trust is given protection of an unlimited obligation on the part of the supplier to pay compensation for damage or injury to persons or property. This is in addition to any specific rights under the contract or under statute or common law.

Insurance

The supplier is required to have suitable insurance in place to at least the value stipulated in the NHS conditions of contract including Professional Indemnity Insurance Cover.

4.9 Purchase Orders

Commitment to purchase goods and services is only entered into by the raising of an official Trust Purchase Order. Suppliers must not deliver goods or provide a service without first receiving an official Trust Purchase Order unless it is part of a Trust approved trial and complies with laid down procedures for trials.

Any goods or services received without an official Purchase Order will be accepted on the basis of "Free Goods" and any subsequent invoices will be returned for a full credit. Any samples should be delivered to Procurement and not direct to a ward or department.

4.10 Signing of Contracts/Agreements

The nominated officers with the authority to sign contracts and agreements on behalf of the Trust are: Chief Executive, Director of Finance and Head of Procurement.

4.11 Introduction of New Medicines

New medicines will be considered for inclusion into the Trust's Formulary only after a written request from a Consultant. Initial requests should be made to the Director of Pharmacy & Medicines Management. The Consultant may be required to make a formal presentation to the Drugs and Therapeutics Committee.

Supplier representatives must keep the Pharmacy informed of which products, with reference to clinical indication, are currently being promoted.

4.12 Pricing

Staff and suppliers are reminded that all information shared for business purposes should be treated as commercially sensitive and confidential and must not be discussed or shared with other suppliers unless there is a disclosure in the public interest.

4.13 Code of Ethics/Standards of Business Conduct

This policy should be read in conjunction with the Trust's Standards of Business Conduct and Employees Declarations of Interest Policy (CORP/FIN 4), which is firmly based on guidance issued by NHS England in June 2017.

The purpose of the Trust's Standards of Business Conduct and Employees Declarations of Interest Policy is to ensure that all employees of the Trust maintain the highest standard of public accountability and are open and transparent in their business conduct. The policy details how staff should deal with offers of gifts, hospitality and sponsorship from suppliers or potential suppliers, to ensure that they are not placed in a position which renders them liable to prosecution (in line with the Bribery Act 2010; the Fraud Act 2006 or the Human Medicines Regulations 2012) or subject to internal disciplinary proceedings.

A number of points taken from the Standards of Business Conduct and Employees Declarations of Interest Policy linking staff responsibilities with suppliers' representatives, are reproduced here for information. Staff <u>must</u> refer to the complete Policy (available on the Trust website) for full details of their obligations:-

- Declarations of Interest. All employees must declare all instances where they, a close relative or associate, has a controlling and/or significant personal interest (including friendships) in any business, or any other activity or pursuit, which may compete for an NHS contract to supply goods or services.
- Gifts from suppliers or contractors: Gifts from suppliers or contractors doing business (or likely to do business) with the organisation should be declined, whatever their value. Low cost branded promotional aids such as pens or post-it notes may, however, be accepted where they are under the value of £6 in total, and need not be declared.
- Hospitality. Employees must not under any circumstances accept any hospitality from
 existing or potential suppliers which may, or be capable of being construed as, being able
 to influence a purchasing decision or cast doubts on the integrity of such decisions. This
 includes site visits to inspect equipment at the expense of the supplier. The Trust should
 meet the costs of an inspection visit so as to avoid putting in jeopardy the integrity of
 subsequent purchasing decisions.
- **Sponsorship.** Sponsorship of events by appropriate external bodies will only be approved if a reasonable person would conclude that the event will result in clear benefit to DBTH and the NHS.

In short, any employee of DBTH (particularly those defined as 'Decision Making Staff' in the Standards of Business Conduct Policy, should not give unfair advantage to one competitor over another, if your duties involve tendering or contracting for the supply of goods and/or services to the Trust. You must also be careful that your action, or inaction, does not create an impression that you might give such an advantage.

Representatives must not attempt to influence business decision making by offering any form of hospitality or other inducement to Trust staff. The frequency and scale of hospitality accepted will be managed openly and with care by the Trust.

It is incumbent on Trust staff, for reasons of probity, to declare any interests, gifts, hospitality or sponsorship that are defined in the Standards of Business Conduct and Employees Declarations of Interest Policy using the 'Interest Declaration Form' so that it can be recorded on the Trust's Electronic Probity Register (EPR) which is held on behalf of the Trust by the Trust Board Secretary.

All other offers of hospitality or entertainment will be refused unless the prior written permission of an Executive Director has been obtained.

For the purposes of this policy, commercial sponsorship is defined as including:

NHS funding from an external source, including funding of all or part of the costs of a member, NHS research, staff, training, pharmaceuticals, equipment, meeting rooms, cost associated with meetings, meals, gifts, hospitality, hotel and transport costs (including trips abroad), provision of free services (speakers), building or premises.

Where there are concerns in regard to conduct or probity in any transaction by staff or external parties, then it should be reported without delay to the Trust's Local Counter Fraud Specialist

(LCFS) or via the NHS Fraud and Corruption Reporting Line on 0800 0284060 (online at: www.cfa.nhs.uk/reportfraud). Further details of what constitutes fraud, bribery and corruption and how to report it correctly can be found within the Fraud, Bribery and Corruption Policy and Response Plan (CORP/FIN 1 (D)).

4.14 Travel and Accommodation Costs

Any travel/accommodation arrangements for conferences or for viewing equipment and services <u>must</u> comply with Section 9.3 of the Standards of Business Conduct and Declarations of Employees Interest Policy, in that it will be paid for by the Trust unless the Chief Executive or Executive Director gives written approval for the supplier to take responsibility for travel arrangements or travel costs.

5. TRAINING/SUPPORT

- This policy will be made available on the Trust website.
- This policy will be made available for Company Representatives.
- This policy will become part of the Standard Terms and Conditions and part of the Tender.

Evaluation and Award Criteria - Companies will be expected to accept this policy as part of the contract award.

6. MONITORING COMPLIANCE WITH THE PROCEDURAL DOCUMENT

What is being Monitored	Who will carry out the Monitoring	How often	How Reviewed/ Where Reported to
Complaints of cold calling from wards and depts.	Procurement	2 monthly	Reported at procurement meetings
Products being supplied without purchase order number	Procurement Department	Continuously	Reported to Division Managers
Products being delivered into stock rooms by reps	Materials Management, procurement	Continuously	Reported at procurement meetings

7. **DEFINITIONS**

Cold Calling: when a company representative visits the ward/department unannounced often for the purpose of introducing new product.

Procurement: The act of sourcing and buying products or services.

Purchase Order Number: The number generated when a product that has been requested has been authorised by the budget holder and processed by the Procurement Department.

"IntelliCentrics UK": A Representative Credentialing provider, which the Trust has chosen to partner with to provide this service.

NHS Conditions of Contract: intended for use by NHS bodies procuring goods and services from commercial organisations, not for the procurement of clinical services from other NHS bodies or independent sector providers.

8. EQUALITY IMPACT ASSESSMENT

The Trust aims to design and implement services, policies and measures that meet the diverse needs of our service, population and workforce, ensuring that none are disadvantaged over others. Our objectives and responsibilities relating to equality and diversity are outlined within our equality schemes. When considering the needs and assessing the impact of a procedural document any discriminatory factors must be identified.

An Equality Impact Assessment (EIA) has been conducted on this procedural document in line with the principles of the Equality Analysis Policy (CORP/EMP 27) and the Fair Treatment for All Policy (CORP/EMP 4). This can be found in Appendix 2.

The purpose of the EIA is to minimise and if possible remove any disproportionate impact on employees on the grounds of race, sex, disability, age, sexual orientation or religious belief. No detriment was identified.

9. ASSOCIATED TRUST PROCEDURAL DOCUMENTS

CORP/PROC 3 - Selection and Procurement of Medical Devices Policy

CORP/PROC 4 - Procurement of Medical Equipment Policy

CORP/FIN 4 - Standards of Business Conduct and Employees Declarations of Interest Policy

CORP/EMP 4 – Fair Treatment for All Policy

CORP/EMP 27 – Equality Analysis Policy

10. DATA PROTECTION

Any personal data processing associated with this policy will be carried out under 'Current data protection legislation' as in the Data Protection Act 2018 and the UK General Data Protection Regulation (GDPR) 2021.

For further information on data processing carried out by the trust, please refer to our Privacy Notices and other information which you can find on the trust website: https://www.dbth.nhs.uk/about-us/our-publications/information-governance/

APPENDIX 1 – CONTACT NUMBERS (for representative use)

Head of Procurement	01302 642379
Category Manager Corporate	01302 642386
Category Manager Clinical	01302 642385
Capital Equipment Category Specialist	07598 554929
Clinical Procurement Specialist	01302 642383

For appointments please contact the Procurement Administration Specialist on 01302 642380 who will direct you to the appropriate member of staff.

APPENDIX 2 – EQUALITY IMPACT ASSESSMENT PART 1 INITIAL SCREENING Service/Function/Policy/Project/ **Division/Executive Directorate Date of Assessment** Assessor (s) **New or Existing Service or** and Department Policy? Strategy CORP PROC 2 v7 Supplier and 13th September 2021 **Existing policy** Procurement Claire Burns Manufacturer Representative Policy Who is responsible for this policy? Finance & Infrastructure - Procurement 2) Describe the purpose of the service / function / policy / project/ strategy? To ensure that representatives attending the Trust act in an appropriate manner and that any products introduced into the Trust follow the policy. 3) Are there any associated objectives? All goods introduced are done so in a safe manner What factors contribute or detract from achieving intended outcomes? - Staff and Reps not adhering to the policy. 5) Does the policy have an impact in terms of age, race, disability, gender, gender reassignment, sexual orientation, marriage/civil partnership, Maternity/pregnancy and religion/belief? No • If yes, please describe current or planned activities to address the impact [e.g. Monitoring, consultation] 6) Is there any scope for new measures which would promote equality? No 7) Are any of the following groups adversely affected by the policy? **Protected Characteristics** Affected? **Impact** a) Age Nο b) Disability No c) Gender Nο d) Gender Reassignment No e) Marriage/Civil Partnership No Maternity/Pregnancy No g) Race No h) Religion/Belief No Sexual Orientation No 8) Provide the Equality Rating of the service / function /policy / project / strategy - tick (✓) outcome box Outcome 1 < Outcome 2 Outcome 3 Outcome 4 *If you have rated the policy as having an outcome of 2, 3 or 4, it is necessary to carry out a detailed assessment and complete a Detailed Equality Analysis form in Appendix 4 Date for next review: 31/03/2024

Date: September 2021

Checked by: Richard Somerset