Procedure for company commercial representatives and their dealings with the organisation

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<tr>
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<th>Procedure</th>
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<tbody>
<tr>
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<td>Initially written by Trust Procurement Department. Updated by Clare Worvill, Medicines Information Technician and Gary Welch, Interim Head of Procurement.</td>
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| Further Information: | Medicines.information@ouh.nhs.uk  
Medicines.effectiveness@ouh.nhs.uk |
| This Document replaces: | Policy for company commercial representatives and their dealings with the organisation |

**Lead Director:** Clinical Director of Pharmacy and Medicine: Management

**Issue Date:** November 2013
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Introduction
1. This procedure sets out the standards that company commercial representatives should follow when dealing with the Oxford University Hospitals NHS Trust.

2. The Oxford University Hospitals NHS Trust appreciates the role that its current and potential suppliers play in supporting health practitioners in providing safe, effective and economic products and services to the patients in their care, and other staff working within the NHS in the delivery of their duties.

Scope
3. The procedure covers all areas of the trust. Separate additional guidelines have been prepared for pharmacy and the estates which are attached as appendices 1 and 2.

4. Further, more detailed guidance is in place for visitors and company representatives to theatres areas - Procedure for Visitors & Company Representatives in Perioperative Units. Company representatives visiting the theatres areas should familiarise themselves with this guidance.

Aim
5. The aim of this procedure is to put the relationship between the staff of OUH and its current and potential suppliers on a sound and professional footing. Also to provide suppliers and their commercial representatives with information on how they are expected to behave and what behaviour they can expect from the trust’s clinical and non-clinical staff.

6. The policy aims specifically to:

   6.1 Minimise disruption to trust staff during the course of their duties;
   6.2 Control access to clinical and areas and protect the privacy of patients;
   6.3 Enable trust staff to engage with supplier representatives on a proper and mutually beneficial basis for both organisations;
   6.4 Ensure that goods and services being brought into the trust are appropriately procured and contracted for;
   6.5 Ensure that interaction between industry and Trust staff is not misused to influence purchasing decisions through undue or improper advantage;
   6.6 Ensure that interaction between industry and Trust staff is transparent.

Definitions
7. The terms in use in this document are defined as follows:

   7.1. ABHI – Association of British Healthcare Industries
   7.2. ABPI - Association of the British Pharmaceutical Industry
   7.3. BIVDA - British In Vitro Diagnostics Association
   7.4. MMTC – Medicines Management and Therapeutics Committee
   7.5. NRES - National Research Ethics
Legal Framework and National Guidance

8. The large trade associations representing businesses supplying the NHS have guidance in place outlining the standards of business conduct expected of suppliers and their employees.

9. The Bribery Act 2010 provides a legal framework to combat bribery in the public or private sectors and replaces the fragmented and complex offences at common law and in the Prevention of Corruption Acts 1889-1916.

10. Under NHS Standing Orders and European Commission Directives on Public Purchasing for Works and Supplies, the requirement is for fair and open competition between prospective contractors or suppliers.

Responsibilities

11. All managers are responsible for ensuring the procedure is disseminated and implemented and necessary resources are available. They are also responsible for ensuring all staff are aware of the procedure and that the procedure is followed in their area.

12. All staff should follow this standard operating procedure.

13. Pharmacy Staff should follow this procedure. Appendix 1 specifically relates to pharmacy staff.

14. Estates staff are to follow guidance as set out in Appendix 2.

15. The Clinical Effectiveness Pharmacist is responsible for ensuring company commercial representatives who visit pharmacy follow this procedure.

16. Company Commercial Representatives must follow this procedure and must comply with the current codes of practice for their particular industry (e.g. ABPI, ABHI, BIVDA, etc.). They are reminded to keep the procurement or pharmacy department informed of their activities within the trust.

17. Company Commercial Representatives are not permitted to use OUH treatment guidelines for promotional activities outside the trust.

General Principles

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

19. When on site all representatives must comply with any instructions given to them by an authorised member of staff in the event of an emergency situation arising – e.g. a fire or major incident.

20. When on site all representatives would be expected to comply with trust policies, for example, the no smoking policy, the car parking policy and any other such policies, procedure or guidance as would be relevant at the time.

21. Commercial representatives should note that the trust has an Incident Reporting and Investigation Policy. In the event of an incident the affected person (patient, staff, student, visitor, volunteer or contractor) should complete an incident report via Datix. Appropriate steps would then be taken by the trust’s senior management.

22. Suppliers should not ask Trust staff to sign or accept agreements, proposals or other documents that may be interpreted as forming the basis of a contract between the Trust and the supplier. Trust staff should take extreme care when signing or
approving such documentation and should refer to the Trust’s Standing Financial Instructions and seek the advice of the Procurement Department.

23. The trust’s staff will be made aware of this procedure so that if direct contact is made between an individual member of staff and a commercial representative, the procedure is followed.

Visits to hospital sites

24. To reduce disruption to the Trust, Company Representatives should not visit the hospital sites on business without a pre-booked appointment. The Procurement Department can provide advice on how appointments might be made with individual departmental managers.

25. A representative arriving for an appointment must arrange to be met by the host. Hosts will be expected to make arrangements for visitors’ badges to be available where applicable. Representatives should respect their position as a visitor to the trust and comply with security regulations by wearing a visitor’s identification badge.

26. All visitors’ badges must be returned before leaving the site.

27. Representatives may not enter any clinical areas (including wards, laboratories and outpatient areas) without being accompanied by their host at all times.

28. All visitors to pharmacy or estates should refer to separate procedures outlined in appendices 1 and 2.

Information Governance Guidelines

29. Trust staff and supplier representatives should be aware that the Trust has strict Information Governance policies in place. Supplier representatives are required to comply with the Trust Information Governance policies at all times and should familiarise themselves with these policies.

30. It is particularly important that Information Governance requirements are carefully considered where a supplier representative may have access to clinical areas; be in contact with patients; or where there is a chance of incidental access to patient data, such as patient notes.

Personal Appointments

31. Commercial representatives may not seek personal appointments with junior members of the clinical staff (junior clinical staff include medical staff below the level of specialist registrar) or nursing staff (below level of Matron) but may seek an open meeting with the staff in a group. The emphasis in such meetings must be educational and not exclusively promotional.

Promotional Activity

32. 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.

33. Price comparisons should not be used, unless they are approved by the trust’s Procurement Department. Trust staff should not share competitors’ pricing with suppliers.

34. Where any teaching and/or promotional activity is planned, representatives must advise the Department Manager. The intent of the meeting must not contravene/challenge existing trust policies.
35. Leaflets and posters produced by suppliers may not be distributed or displayed in clinical areas unless approved by the ward or departmental sister/manager.

36. Commercial representatives must not inform staff about the trust’s policies, except with the written permission of the trust. Misrepresentation of this information within or outside the trust will be construed as a deliberate attempt to contravene the trust’s policy.

**Code of Ethics**

37. Supplier representatives are required to comply with the Trust policies on Gifts, Hospitality and Commercial Sponsorship and should familiarise themselves with these policies before entering the Trust.

38. The staff of the trust are subject to standards of conduct in line with national guidance and staff should be aware of the Standards of Business Conduct for NHS Staff (January 1993), published by the NHS Management Executive. This document was updated by the publication of the ‘Commercial Sponsorship – Ethical Standards for the NHS’ guidance paper issued by the Department of Health in December 2000. Commercial representatives should note the following points.

39. Suppliers should not attempt to influence business decision making by offering hospitality to trust staff. The frequency and scale of any hospitality accepted will be managed openly and with care by the trust.

40. Commercial sponsorship relating to conferences or courses is only acceptable if the attendance of the trust’s staff:

   40.1. Forms part of an educational/training course approved by an accountable manager of the trust, or,

   40.2. Is with the prior written authorisation of an Executive Director or Divisional Director.

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

41. For the purposes of this procedure, 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.

**Travel Costs**

42. Any travel arrangements for conferences or for viewing equipment and services should be paid for by the trust unless the Chief Executive or Director of Finance and Procurement gives written approval for the supplier to take responsibility for travel arrangements or travel costs.

**Active Procurement Process**

40. Trust staff and supplier representatives should exercise extreme caution when meeting or visiting the Trust, or visiting supplier premises, whilst an active procurement process is underway for the particular goods or services being discussed or promoted. Inappropriate discussions could jeopardise the procurement process and potentially result in increased risk and costs for both parties.

41. Trust staff and supplier representatives should be aware of the requirements of the Bribery Act 2010 which creates two general offences covering the offering, promising
or giving of an advantage, and requesting, agreeing to receive or accepting of an advantage.

**Medical Samples**

43. Approval to leave (free) samples or on loan goods must be sought from the Procurement Department and must only be left on wards or departments with the written permission of the ward sister/manager on duty. Samples must not be left with medical staff or clinical units without prior approval.

44. Samples should only be accepted by Trust personnel to inspect the product and get a look and feel of the product qualities and potential capabilities. Under no circumstances should samples be used on patients or as part of clinical procedures other than as part of a formal approved trial.

**Product trials, studies and research projects**

45. The introduction of new products into the Trust is strictly controlled. Commercial representatives must not expect to enter into any agreements in relation to the trial of products without the appropriate procedures being followed.

46. Clinical trial products must be supplied free of charge. In the event that there are circumstances where a charge may be considered appropriate then this must be agreed with the Procurement Department.

47. If there is any trial of products or drugs that involve human participants (patients/volunteers) that may result in new knowledge or a change in practice then it must be presented to the NRES. If this is the case, then an application form would need to be completed and submitted outlining what the trial is about, how long it would last, who would be involved, etc and a clinical agreement would have to be signed between the trust and the supplier. Clinical staff are not able to sign any agreement directly with the supplier.

48. Any commercially sponsored trial/agreement must go through to the Research and Development Department. Again, the commercial representative must not expect any agreements to be reached between themselves and individual members of staff without the appropriate authorisation.

49. For further information, please contact the Oxford Joint Research office.

50. All medical samples must be CE marked. ‘CE’ marking is an indication that the product has undergone some form of verification and validation process acceptable to the EU.

51. All product trials must be arranged through the Procurement Department to ensure that:

   51.1. trials are carried out in accordance with the Oxfordshire Clinical Research Ethics Committee Guidelines
   51.2. trials are carried out on a controlled basis
   51.3. the product in question meets the appropriate safety standards
   51.4. trials are not duplicated
   51.5. the objective of the trial and potential benefits are clear from the outset
   51.6. the trial does not contravene other contractual commitments
   51.7. that product indemnity is confirmed prior to the commencement of the trial

52. In any product trial, the following points will be considered and recorded:
52.1. the objective of the trial – i.e. what are the potential benefits if the trial is successful?
52.2. how the trial is to be administered
52.3. how the trial is to be financed
52.4. how samples are to be provided
52.5. how long the trial will last
52.6. whether technical staff need to be involved
52.7. current safety regulations and quality standards
52.8. how the trial will be assessed
52.9. whether other criteria (e.g. packaging) need to be taken into account
52.10. whether the supplier should be involved
52.11. the implications for existing contracts and purchasing agreements
52.12. how the results of the trial will be disseminated

53. No pharmaceutical products will be accepted by any department except pharmacy and then only in line with agreed procedures. (See also Appendix 1.)

54. Staff should carefully consider the intellectual property aspects of any arrangements with suppliers or third parties. It is particularly important to seek advice in ensuring that the trust position is protected at the earliest possible stage.

Non-Medical Procurement
55. Commitment to purchase all 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.

56. Contracts, product trials for non-medical equipment, e.g. photocopiers, mobile phones, fax machines, window cleaning, taxis, print, stationery, furniture, etc, must be arranged through the proper channels in accordance with Trust Standing Financial Instructions. Individual departmental managers are NOT authorised to enter into contracts or trials. Please contact the Procurement Department for further instruction.

Medical Equipment
57. The trust requires that all medical equipment is obtained via the Clinical Engineering department. This includes all equipment on loan (for trial or testing), equipment on loan (not for trial or testing), free issues and free issues (for trial or testing).

58. Under no circumstances should medical equipment be delivered directly to a ward/department without the prior knowledge of Clinical Engineering.

59. For further information please contact the Clinical Engineering Administrator on 01865 221548.

NHS Conditions of Contract
60. All goods (donated or otherwise) and services offered to the trust will be procured against the standard NHS Terms and Conditions.
Infection Prevention and Control Guidelines

61. Supplier representatives must be aware that all personnel who visit the Trust have the potential to introduce and transmit micro-organisms. Supplier representatives are required to comply with the Trust Infection Prevention and Control policies and practices and should familiarise themselves with these policies before entering the Trust. This relates primarily to hand hygiene and the “Bare Below the Elbow” policy for everyone who enters a clinical area. Representatives will be expected to use the hand sanitizer or wash their hands when entering and leaving each clinical area.

Signing of Contracts/Agreements

62. For the purposes of signing contracts and agreements for the purchase/hire/leasing of goods and services, your first point of contact should be the Procurement Department on 01865 572547.

Training

63. There is no mandatory training associated with this procedure. Ad hoc training sessions based on an individual’s training needs will be defined within their annual appraisal or job plan.

Monitoring Compliance

64. Compliance with the document will be monitored in the following ways.

<table>
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<tr>
<th>Aspect of compliance or effectiveness being monitored</th>
<th>Monitoring method</th>
<th>Responsibility for monitoring (job title)</th>
<th>Frequency of monitoring</th>
<th>Group or Committee that will review the findings and monitor completion of any resulting action plan</th>
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<tr>
<td>Incidents</td>
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<td>Ongoing</td>
<td>Medicines Safety Team, Procurement Manager</td>
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<td>Complaints</td>
<td>Complaints received</td>
<td>Ward/Department Manager</td>
<td>Ongoing</td>
<td>Local governance groups</td>
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65. In addition to the monitoring arrangements described above the trust may undertake additional monitoring of this policy as a response to the identification of any gaps or as a result of the identification of risks arising from the policy prompted by incident review, external reviews, or other sources of information and advice. This monitoring could include:

- Commissioned audits and reviews
- Detailed data analysis
- Other focused studies

Results of this monitoring will be reported to the nominated Committee.

Review

66. This procedure will be reviewed in 3 years, as set out in the Policy for the Development and Implementation of Procedural Documents.

References
67. The Bribery Act 2010
68. Standards of Business Conduct for NHS Staff (January 1993), NHS Management Executive.
69. Commercial Sponsorship – Ethical Standards for the NHS

**Equality Impact Assessment**

70. As part of its development, this policy and its impact on equality has been reviewed. The purpose of the assessment is to minimise and if possible remove any disproportionate impact on the grounds of race, gender, disability, age, sexual orientation or religious belief. No detriment was identified.

**Document History**

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<th>Version number</th>
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<td>April 2001</td>
<td>2</td>
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<td>April 2013</td>
<td>3</td>
<td>Updated by pharmacy department as previous version was out of date.</td>
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Appendix 1: Procedure for commercial representatives and companies in their dealings with the Pharmacy

General Information
1. It is recognised that, in addition to providing information to health practitioners, the prime function of representatives is to promote and sell their products and services. This function should be carried out in a proper and ethical manner and not contravene ABPI Code of Practice, trust, NHS or government policies.
2. Staff should not give out names and numbers of the Medicines Management and Therapeutics Committee (MMTC) members without prior permission.
3. Staff are reminded of the confidential nature of hospital medicine prices. OUH prices must not be divulged or discussed with competitor companies.

Personal Appointments
4. Commercial representatives may not seek appointments with junior members of pharmacy staff. They may seek an open meeting with the staff in a group. The emphasis in such meetings must be educational not exclusively promotional.

Promotional Activity
5. Representatives should be well informed about the products that they are promoting. In addition to standard technical and clinical data including information on comparative efficacy, pharmacists wish to know what is being promoted, the basis for the promotion and the specific place the product is expected to have in therapy. Price comparisons should not be used, unless the Clinical Effectiveness Pharmacist has approved them in advance.
6. Representatives must contact the appropriate pharmacist when teaching/promotional activity is planned anywhere on the hospital premises. The intent of the meeting must not contravene/challenge existing trust or NHS policies and procedures.
7. Leaflets and posters produced by the industry may not be distributed or displayed in clinical areas unless the Clinical Effectiveness Pharmacist has approved them.
8. Industry representatives must not inform staff about the trust's prescribing policies, except with the written permission of a member of MMTC. Misrepresentation of this information within or outside the trust will be construed as a deliberate attempt to contravene the trust's policy.

Medicine Samples
9. Medicine samples must never be left with medical or nursing staff. Pharmacy will accept samples for use in the hospital only if there has been a written and signed request from a consultant.
10. If product trials are proposed this must be discussed with the Clinical Effectiveness Pharmacist before any further steps are taken.
11. By adhering to this guidance it is hoped that the association between trust and the pharmaceutical industry will be a constructive one. Clarification of any of these issues may be sought from the Clinical Effectiveness Pharmacist or the Clinical Director of Pharmacy and Medicines Management.
Appendix 2: Procedure for commercial representatives and companies in their dealings with the Estates Directorate

General Information

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

Personal Appointments

2. Commercial representatives will be seen by appointment only, the appointment having been made with the appropriate estates officer / manager. They may not meet with other staff without the authorisation of the estates manager for the site being visited. Representatives should be well informed about the products that they are promoting. They will be expected to provide technical data for all products including information on annual running costs, maintenance requirements, cost of spares and availability, lead-time and any relevant compatibility issues.

3. Leaflets and posters produced by the industry may not be distributed or displayed unless the estates manager has approved them.

4. Representatives must contact the estates officer/manager prior to any training promotional activity within the trust.

Samples

5. Samples may be left with the appropriate member of the estates staff. The representative must make it clear as to whether the sample is to be returned after a period of time or is a ‘free sample’. Samples must be free of obligation and must, where appropriate, be issued with a data sheet.

6. If product trials are proposed this must be discussed with the estates manager before any further steps are taken.

Placing of orders

7. No ‘verbal’ contracts will be entered into. All orders placed with representatives during their visit must be accompanied by an official order signed by an authorised officer. This procedure will be enforced in the case of equipment provided on a trial (sale or return) basis. The order will state specifically the trial period, the purchase options and the fixed cost. Long term hire or lease agreements will not and must not be agreed.

Promotional material

8. Trust information, literature or photographs cannot be used for company promotional literature, trade articles etc. without permission of the trust. This includes using the trust’s name, as a customer, to sell goods to another organisation.

9. By adhering to this guidance it is hoped that the association between trust and industry will be a constructive one. Clarification of any of these issues may be sought from the office of the Director of Development and the Estate.
## Equality Analysis

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<tr>
<td>Date of Policy: November 2013</td>
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<td>Date due for review: November 2016</td>
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<tr>
<td>Lead person for policy and equality analysis</td>
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<tr>
<td>Clare Worvill, Medicines Information Technician, Administrator for Medicines Policy Steering Group</td>
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<td>Does the policy / proposal relate to people? If yes please complete the whole form. YES / NO</td>
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The only policies and proposals not relevant to equality considerations are those not involving people at all. (E.g. Equipment such as fridge temperature)

### 1. Identify the main aim and objectives and intended outcomes of the policy.

The aim of this procedure is to set out standards which company commercial representatives must adhere to when dealing with the OUH.

### 2. Involvement of stakeholders.

This procedure was originally written by the Trust procurement and finance department and approved by Trust Executive Board. This has been updated by pharmacy as the guidelines are required by pharmacy staff who deal with representative from pharmaceutical companies. Trust finance and procurement were contacted regarding this update. Trust estates department have also had the opportunity to comment on this procedure.

### 3. Evidence.

This procedure is designed to ensure company commercial representatives behave in an appropriate way when dealing with the OUH. There is no potential to discriminate against any of the following groups. All staff or company commercial representatives should follow this procedure to ensure their actions are appropriate and legal.

- **Disability**
- **Sex**
- **Age**
- **Race**
- **Sexual orientation**
- **Pregnancy and maternity**
- **Religion or belief**
- **Gender re-assignment**
- **Marriage or civil partnerships**
- **Carers**
- **Safeguarding people who are vulnerable**
- **Other potential impacts e.g. culture, human rights, socio economic e.g. homeless people**

### Section 4 Summary of Analysis

**Does the evidence show any potential to discriminate?**

No, this procedure sets out standards of behaviour expected from OUH staff and company commercial representatives.

**How does the policy advance equality of opportunity?**

This procedure ensures all OUH staff and company commercial representatives work in an appropriate and legal way. This will help to ensure staff, visitor and patient safety.

**How does the policy promote good relations between groups?**

This procedure sets out standards of behaviour for company commercial representatives visiting OUH sites to help promote good relations between commercial representatives and the OUH.