Medical Company Representative Visitors to Western Health

Procedure code: OP-GO4.2.1	Effective date: September 2016
Last review date: November 2013	Next review date: September 2019
Section: Governance	Std 15: Corporate Systems & Safety
Sub-section: External Services	

1. Overview

This procedure provides the conditions for visits by Medical Company Representatives (MCR) to Western Health (WH) and for the introduction of new products and equipment into the health service.

This ensures adherence to the codes of conduct, safety and suitability of products and minimises the costs associated with product proliferation.

MCR perform a valuable function in supporting patient and healthcare services at WH and are permitted fair and reasonable access.

2. Applicability

This procedure applies to all WH staff and visiting MCR.

3. Responsibility

The Clinical Services Directors, Divisional Directors, Heads of Departments/Units including NUMs are responsible for the ongoing application of and compliance with the procedure.

4. Authority

The designated chairs of the following committees have the authority to approve exceptions to the procedure:

- Drug and Therapeutics Committee (DTC).
- Product Evaluation and Endorsement Committee (PEEC).
- Perioperative Product Evaluation Committee, only after approval by the chair of the PEEC.

5. Associated Documentation

In support of this procedure, the following policies and procedures apply:

P-GO2.7	Gifts, Benefits and Hospitality
P-PS1.1	Medication Use and Management
P-SE1.1	Occupational Health and Safety
OP-SE5.4.3	Staff, Volunteer and Visitor Identification and Access Management
OP-PS1.2.6	Drug Prescription, Supply, Storage and Administration

6. Credentialing

None required.

7. Definitions and Abbreviations

For purposes of this procedure the following definitions and abbreviations apply:

DTC	Drug and Therapeutics Committee
Medical Company Representatives (MCR)	Representatives from pharmaceutical companies and representatives from medical and surgical device, equipment and prosthetic companies.
NUM	Nurse Unit Manager
PEEC	Product Evaluation and Endorsement Committee

8. Procedure Detail

8.1 Appointments

Visits to WH are by appointment only and MCR may only see heads of departments/units and senior medical staff. Appointments with registrars may only be made if authorised by relevant head of unit or senior medical staff.

MCR may visit NUMs by appointment only. Appointments must be made via the office of the relevant Divisional Director / Director of relevant area. MCR may only make appointments with Nurse Practitioners and Clinical Nurse Consultants or delegate if authorised by the relevant Divisional Director, Director of Nursing, Director or Supervisor.

MCR visits to Allied Health are by appointment only and must be made via the Allied Health discipline manager or their senior clinical delegate.

MCR are not permitted to canvas or make appointments with interns, resident medical officers, nursing staff, allied health staff, food service staff, pharmacists, volunteers or patients; access will be at educational meetings / in-services only.

MCR are not permitted to visit work areas or departments on the chance that a staff member will be available to see them.

MCR should only be on site within normal business hours unless approved by the supervising senior clinician.

Upon arrival the MCR must attend the main reception desk to sign in as a visitor to WH. The MCR will be issued a visitor identification badge, which must be worn whilst on site. The MCR will be required to record their name, company and the staff member being visited on the sign-in sheet. Before leaving WH, each MCR will attend the reception desk to return the identification badge and to sign out.

MCR shall be under the direct supervision of a Nurse, Medical Officer or Allied Health Professional when on WH premises.

MCR may participate in direct patient care only under certain circumstances at the request of and under the direct supervision of a Nurse, Medical Officer or Allied Health Professional who will remain responsible for the delivery of that care. The circumstances when this may occur are:

- Presence in the operating theatre, procedure rooms, wards or outpatient clinic to assist with implantable device programming for individual patients fitted with that company's device.
- Presence in a clinical area to provide Medical Company-specific advice regarding the use of that company's medical equipment.

MCR are not permitted to be present at clinical meetings where identifiable patient details are discussed.

Prior valid consent must be obtained in order for MCR to be present during any treatment, intervention or operation.

Areas where direct patient care is being provided are not to be used for appointments.

If an appointment is required in an operating theatre, procedural unit or laboratory the authorised staff member will inform the appropriate divisional director/NUM before confirming the appointment with the MCR. The MCR will be required to sign in upon entry to the operating theatre, procedural unit or laboratory.

Pharmaceutical MCR visits should not occur in an environment where promotional information could be easily heard by members of the public.

8.2 Code of Conduct

MCR shall respect and comply with the patient's right to privacy, dignity and confidentiality.

MCR will be required to wear the relevant company identification badge and hospital visitors pass.

Medical Companies may also be required to produce evidence of IproLive registration and compliance.

Pharmaceutical MCR must comply with the Medicines Australia Code of Conduct, to which this procedure is aligned.

If an emergency code occurs whilst an MCR is on site, the MCR must seek direction from the Nurse in Charge.

8.3 Product/Equipment Samples

MCR must not leave product samples in any department without approval from the WH PEEC, Perioperative Product Evaluation Committee or Allied Health Management Committee.

All products and equipment for evaluation must be accompanied by the appropriate documentation, and where relevant, user and service manuals.

The MCR must be in attendance if required whilst a trial is being conducted, e.g. in operating theatres.

All products/equipment for evaluation must be accompanied by the loan/lease documentation which includes any faults, damage or loss during use at WH.

8.4 Product/Equipment Trials

All product evaluations shall be coordinated through the WH PEEC and/or Perioperative Product Evaluation Committee.

Evaluations shall be rigorously conducted, identifying key evaluation criteria and testing a suitable patient sample.
In some cases, Hospital Ethics and Research Committee approval may be required.

8.5 Pharmaceutical Samples and Evaluations

All pharmaceutical sample distribution is coordinated by the Pharmacy Department.

MCR are not permitted to leave pharmaceutical samples in any ward / clinic or department or with individual prescribers.

New pharmaceutical products must be approved by the DTC or its delegated authority before being used at WH.

Pharmaceutical in-service education sessions will usually relate to products approved by the DTC.
Where an in-service education session is required for a medication that is not approved by the DTC, this must be approved by the Head of the relevant department prior to the in-service. In addition, the MCR must acknowledge during the session that the medication is not approved for use at WH.

All clinical drug trials must be approved by the Human Research Ethics Committee of Melbourne Health.

8.6 Biomedical/Electrical Equipment

Biomedical / electrical equipment shall not be introduced or evaluated without Biomedical Engineering Services inspection and approval, including:

- A completed and authorised indemnity form.
- User and service manuals.
- Information such as the value of the item, period of loan, location of use, education and support to be provided, contact information of the person and department within the organisation with which the loan has been arranged.

Inspection and approval should address:

- Responsibility for servicing/maintenance/insurance/product extraction upon the completion of loan period.
- Agreed cost of and responsibility for any consumables required for purchase.

8.7 Reports

Where required by the visited division, the MCR will submit a report at least every six months to the relevant clinical service director or divisional director to provide a summary of their activity over the time period, including:

- The date and time of the visit(s).
- Organisational site.
- Individual department(s) and personnel visited.
- Products discussed.
- In-service/education provided.

8.8 Procedure Breaches

MCR found in breach of this procedure may be refused future commercial access to WH.

9. Document History

Number of previous issues: 2

Previous issue dates: January 2009 and November 2013

10. References

Health Purchasing Victoria: Draft Hospital Guidelines for Visiting Company Representatives

Australian Confederation of Operating Room Nurses (ACORN) – Standards, Guidelines and Policy statements. May 1998; February 2004,S27

Medicines Australia Code of Conduct, 18th Edition, May 2015

Victorian Public Sector Code of Conduct

11. Sponsor

Product Evaluation and Endorsement Committee

12. Authorisation Authority

Right Care Committee