Winnipeg Regional Health Authority / Office régional de la santé de Winnipeg Caring for Health / À l'écoute de notre santé	**REGIONAL** Applicable to all WRHA governed sites and facilities (including hospitals and personal care homes), and all funded hospitals and personal care homes. All other funded entities are excluded unless set out within a particular Service Purchase Agreement.		Level: **1**
POLICY	Policy Name: **INDUSTRY RELATIONSHIPS**	Policy Number: 10.00.110	Page: 1 of 6
	Approval Signature: *Original signed by A. Wilgosh*	Section: GOVERNANCE & GENERAL ADMINISTRATION	
	Date: September 2010	Supercedes: New	

1.0 PURPOSE:

Interactions with Industry occur in a variety of contexts, including marketing of new pharmaceutical products, medical devices and/or equipment; on-site training for newly purchased products; provision of Industry-sponsored programs and educational support. These interactions are important for promoting the clinical, educational and research goals of the WRHA. However, these interactions and resulting relationships must be ethical and avoid any actual, potential or perceived Conflicts of Interest. To achieve this balance, the purpose of this policy is:

1.1 To manage interactions between WRHA Representatives and Industry and thereby promote a standard of conduct that preserves and enhances public confidence in the integrity, objectivity, and impartiality of WRHA clinical and business activities.

1.2 To facilitate transparency and accountability by WRHA Representatives who have relationships with Industry where that relationship and subsequent interactions may be interpreted as a potential, perceived or real Conflict of Interest.

2.0 DEFINITIONS:

2.1 Industry: Any vendor seeking to do or doing business with the WRHA.

2.2 WRHA Representative(s): All persons employed or contracted by WRHA Facilities and WRHA Funded Facilities as well as members of the WRHA Board and members of the medical staff including physicians with privileges at all sites governed by this policy.

2.3 Conflict(s) of Interest: A situation in which a WRHA Representative has a Private Interest or a relationship with a Related Person that creates, either in appearance or in reality, a perceived or real opportunity for improper influence in the performance of their duties and responsibilities to the WRHA. This would include all situations which would cause an independent observer to reasonably question whether the professional actions or decisions of the WRHA Representative are compromised by considerations of personal gain, financial or otherwise.

2.4 Related Person: Any person or entity associated with a WRHA Representative, including a family member, personal friend, business associate or partner, or any corporation, joint venture, partnership or business entity owned or operated wholly or in part by the WRHA Representative.

For the purposes of this policy, a family member includes parent, spouse, common-law spouse, child, siblings, mother-in-law, father-in-law, daughter-in-law, son-in-law, brother-in-law, sister-in-law, grandparent, grandchild, former guardian, fiancé as well as step-relationships of the same degree. It also includes any other relative who is or has been residing in the same household.

2.5 Private Interest: Any matter including, without limitation, a financial, personal and/or private affiliation, relationship or other involvement, that might influence the actions taken or decisions made by a WRHA Representative when acting on behalf of the WRHA. These include, but are not limited to, having a financial ownership interest, a fiduciary role in, or receive payments from Industry in any form including, without limitation, consulting fees, honoraria or royalties.

2.6 Gift(s): Items of any value that are given by a business or individual seeking to do or doing business with the WRHA to either the WRHA Representative or Related Person, and for which the recipient neither paid nor provided services. This includes, but is not limited to, items such as pens, notepads, textbooks, electronic media, meals, gift certificates, tickets, devices, products or services, travel, hotel accommodations, entertainment or payments for attending a meeting.

2.7 Clinical Evaluation Package (CEP): A package containing a limited quantity of a pharmaceutical product sufficient to evaluate clinical response; distributed to authorized health care professionals free of charge, for patient treatment.

2.8 Patient Care Area: Any portion of a healthcare facility wherein patients are intended to be examined or treated.

2.9 Industry Support: The provision of support by Industry to the WRHA including funds, or goods and services provided in kind for the purpose of education, training, quality improvement, research and other initiatives being sponsored by the WRHA.

2.10 Continuing Professional Development: is the updating of professional knowledge and the improvement of professional competence throughout a person's working life. Although it does not necessarily have to be sanctioned by or linked to a professional association, it needs to relate to the WRHA Representative's knowledge base given their role within the WRHA.

3.0 **POLICY:**

3.1 Disclosure

3.1.1 WRHA Representatives are required to disclose through a Conflict of Interest declaration all of their outside relationships with Industry that could result in a Conflict of Interest situation and have an obligation to update and revise this declaration should there be any relevant and material changes.

3.1.2 All vendors that have contractual arrangements with the WRHA shall be required to disclose any payments or other transfers of value provided to WRHA Representatives.

3.2 Gifts

3.2.1 WRHA Representatives shall not accept Gifts on their own behalf or for their own benefit from Industry, regardless of the nature or value of the gift.

3.3 Distribution of Samples

Clinical Evaluation Packages (CEPs)

3.3.1 CEPs, otherwise known as drug samples will only be provided to health care professionals in a manner that follows the rules set out by the Food and Drugs Act and Regulations.

3.3.2 CEPs distributed by Industry representatives may be accepted by WRHA Representatives for use in all ambulatory care and emergency department settings.

3.3.3 Acceptance and use of CEPs within acute care settings is prohibited, except when permitted for patient education.

3.3.4 Physicians and other providers working in facilities and programs at sites governed by this policy are expected to carefully consider cost and effectiveness when making prescribing decisions and not be unduly influenced by the availability of free CEPs.

3.3.5 The WRHA reserves the right to prohibit the distribution and use of CEPs that have been rejected by the national Common Drug Review.

3.3.6 Physicians and other prescribing care providers shall be responsible for ensuring that CEPs are securely stored, properly labeled for safe patient use, not past the expiry date, and unused samples properly disposed of.

3.3.7 Pharmaceutical companies having contractual relationships with WRHA shall be required to disclose information regarding any CEPs they distribute within the region in accordance with the Industry disclosure requirements stated under Section 3.1.2 of this Policy.

Other Than Drugs

3.3.8 Medical devices and other non-drug samples may be accepted by WRHA Representatives providing they submit the appropriate documentation to their Site Materiel Managers. This documentation will include product information as well as confirmation of requirements such as Health Canada Medical Device Licensure, Clinical Engineering approval (required for any electrical device), Medical Device Reprocessing (required if a reusable device) approval and Facility Management approval where appropriate.

3.4 Site Access by Industry Representatives

3.4.1 Industry representatives are not permitted in a Patient Care Area unless invited by the appropriate WRHA Representative for the following purposes only:

i. Provision of in-service training on devices & equipment.
ii. Contracted servicing of equipment or assistance on devices & equipment.
iii. Industry representative presence is required to demonstrate a clinical problem that current products and devices cannot address or defects with current products and devices.

3.4.2 Industry representatives are permitted in a non-Patient Care Area by appointment or invitation for the following purposes only:

i. In-service training, contracted servicing or assistance on devices & equipment already purchased.
ii. Evaluation of prospective purchases of equipment, devices, or related items.
iii. Provision of useful information about vendor products or services.

3.4.3 Appropriate consent by the patient or a person authorized to act on behalf of the patient shall be obtained beforehand if a representative is present during patient care interactions.

3.4.4 The WRHA Representative who is responsible for the appointment or invitation shall ensure that the Industry Representative agrees to comply with the confidentiality requirements concerning personal health information in accordance with the WRHA Confidentiality of Personal Health Information Policy (10.40.020).

3.5 Marketing or Promotional Materials

3.5.1 Industry on-site displays or commercial exhibits of any promotional products shall not be allowed unless it relates to a regional or site-sponsored educational event.

3.5.2 WRHA sites shall develop mechanisms whereby Industry representatives who wish to provide educational information on their new or existing products may do so by appointment or invitation only.

3.6 Industry Support of WRHA Educational Programs and Events

3.6.1 WRHA Representatives shall not solicit or accept Industry Support for a WRHA program or event unless it relates to Continuing Professional Development or initiatives such as quality improvement or patient safety, which supports the learning needs of WRHA Representatives and the WRHA.

3.6.2 All requests for and/or offers of Industry Support shall be managed through a regional approval process utilizing an Industry Support Request Form and where applicable, subsequent receipt of funds shall be managed through WRHA or Site Corporate Finance.

3.6.3 Industry financial support shall be provided in the form of a grant.

3.6.4 Industry sponsors shall not be allowed to determine the program content or selection of speakers for WRHA sponsored programs and events.

3.6.5 Industry support shall be formally documented in a Commercial Support Letter of Agreement between the WRHA/Site and the Industry sponsor.

3.6.6 Meals and other hospitality provided or sponsored by Industry will not be permitted on-site including events relating to lunch and learns.

3.7 Travel Sponsored by Industry

3.7.1 Industry sponsored travel by WRHA Representatives to attend out-of-town programs shall only be allowed under the following circumstances:

i. Training is being provided on products or equipment already purchased by the WRHA when it cannot be reasonably provided locally or on-site.

ii. Products or equipment are being evaluated for purchase as part of the Request for Proposal process where there is an identified requirement that vendors must defray all or part of the costs of the off-site visit.

iii. Approved by the WRHA Chief Executive Officer/Designate to evaluate possible expansion of WRHA services or adoption of innovative practices within the WRHA.

3.7.2 WRHA Senior Management and Logistics Services shall be informed by WRHA Corporate Finance of all Industry-sponsored travel and where applicable, the WRHA Representative shall complete a Conflict of Interest declaration if this sponsorship may potentially result in a Conflict of Interest.

3.7.3 Discretion shall be used by WRHA Representatives in attending these programs in terms of the reasonableness of the venue and nature of the hospitality being provided.

3.7.4 If deemed necessary for a WRHA Representative to attend a program that does not meet the aforementioned circumstances, then the cost of the registration, travel, accommodations and meals should be approved by the responsible WRHA Vice President and funded by the WRHA. A WRHA Travel Authorization Form shall be completed and approved.

3.8 Attendance at non-WRHA Programs and Events (Locally Off Site)

3.8.1 WRHA Representatives shall be allowed to attend programs and events organized by professional organizations or associations, regulatory bodies and non-profit organizations.

3.8.2 Programs and events that are directly organized and sponsored by Industry may be attended by WRHA Representatives if approved by the responsible WRHA Vice President (or delegate) as Continuing Professional Development (CPD) as defined within this policy. Factors to be taken into account when making the CPD determination include but are not limited to educational content or learning opportunity, relevant to WRHA Representative's role and responsibilities, involves a qualified presenter and qualifies as an accredited learning event (by professional body).

3.8.3 Discretion shall be used by WRHA Representatives in attending these programs in terms of the reasonableness of the venue and nature of the hospitality being provided.

3.8.4 WRHA Representatives shall be allowed to present or teach in off-site Industry-sponsored programs if the following requirements are met:

i. Content of the meeting or lecture shall be determined by the WRHA Representative and not by the Industry sponsor.

ii. Compensation for participation is limited to reimbursement of reasonable travel expenses and an honorarium proportional to the defined service.

3.9 Industry Support for Research

3.9.1 All Industry-sponsored research proposals must be reviewed and approved in accordance with the WRHA "Research and Quality Improvement – Ethical Conduct Policy (10.50.080).

3.9.2 Industry funding received by the WRHA for research purposes shall be administered in accordance with the WRHA "Research Accounts" Policy (30.40.010).

3.10 Endorsements and Testimonials

The WRHA shall not provide product or service endorsements for Industry products or services for public or promotional use by the vendors of those products and services. However, WRHA Representatives are permitted to provide verbal references or written references authorized by the WRHA Chief Executive Officer when requested by other organizations including healthcare entities that are considering those vendor products and services.

3.11 Ghostwriting

WRHA Representatives are prohibited from publishing articles or presentations as well as producing other forms of media, under their names that are written in whole or in part by Industry representatives.

3.12 Reporting and Enforcement

3.12.1 Suspected violations of this Policy shall be reported under the WRHA Conflict of Interest Policy (20.10.011) or the WRHA Disclosure of Staff Concerns Policy (20.50.100).

3.12.2 Breaches of this policy will be reviewed and appropriate action taken including without limitation, discipline and/or remedial action.

4.0 **PROCEDURE:** N/A

5.0 **REFERENCES**:

5.1 University of Manitoba (U of M) Faculty of Medicine Policy; Interactions between U of M's Faculty of Medicine and the Pharmaceutical, Biotech, Medical Device, and Hospital and Research Equipment and Supplies Industries

5.2 WRHA Policy 10.40.020 Confidentiality of Personal Health Information

5.3 WRHA Policy 10.50.080 Research and Quality Improvement – Ethical Conduct

5.4 WRHA Policy 20.10.011 Conflict of Interest

5.5 WRHA Policy 20.50.010 Discipline and Discharge

5.6 WRHA Policy 20.50.100 Disclosure of Staff Concerns

5.7 WRHA Policy 30.40.010 Research Accounts

5.8 WRHA Policy 110.220.050 Visitors and Control of Traffic – Operating Room

5.9 Interactions between Stanford University School of Medicine, the Stanford Hospital and Clinics, and Children's Hospital with the Pharmaceutical, Biotech, Medical Device, and Hospital Equipment and Supplies Industry

5.10 Interactions between University of Rochester Medical Center and the Pharmaceutical, Biotech, Medical Device, and Hospital Equipment and Supplies Industry

5.11 Johns Hopkins Medicine Policy on Interaction with Industry

5.12 UMass Memorial Medical Center Policy on Vendor Relationships

5.13 Industry Funding of Medical Education; Report of an AAMC Task Force

5.14 Physician Payment Sunshine Act (September 2007; USA)

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