

ISRHML Guidelines on Interaction with Commercial Entities

Preamble

The primary purpose of ISRHML is to promote research related to human milk and lactation and provide opportunities to exchange research results. Conferences and other activities organised by ISRHML provide opportunities to present and discuss up-to-date scientific knowledge. They also create the opportunity for non-commercial and commercial entities involved in research and healthcare to interrelate with scientists and other health professionals involved in human milk and lactation research, given that research and development in the life sciences involve and often require the collaboration of a broad spectrum of actors from public and private organisations. Relationships among research, healthcare, and commerce (such as pharmaceutical, nutritional, biotechnology and device [e.g., breast pump] companies) have driven innovation in research and medical care, contributed to the well-being and economic strength of the community, and provided significant resources (financial and otherwise) for research and professional education, with potential benefits to the public as well as mothers and infants. However, the interests and obligations of research, healthcare, and commerce can diverge. An increasingly urgent challenge for all partners is to devise ways to preserve strong, productive collaborations for the benefit of research, healthcare, and the public, while at the same time ensuring clear and effective actions that manage relationships that could undermine public good and public trust.

These ISRHML Guidelines on Interaction with Commercial Entities build upon and complement the “Guidelines for Accepting Funds from External Sources” in the ISRHML bylaws, which have been approved by the ISRHML membership. The ISRHML Interaction Guidelines propose standards for ISRHML and its officers regarding the management of financial relationships with commercial entities and their affiliates that may have a direct interest in activities of ISRHML, and it defines strategies for mitigating the potential for such financial relationships to influence ISRHML activities in undesired ways. These Guidelines aim to maximize the benefits of relationships between ISRHML and commercial entities that may contribute to the research and educational missions of ISRHML, while minimizing the risks of potential conflicts of interest. These Guidelines do not provide guidance related to activities unrelated to ISRHML, such as research grants or other scientific and educational activities of its members which are guided by general scientific, ethical, and institutional standards.

Sources used

1. Code of Conduct of the European Society for Paediatric Gastroenterology, Hepatology and Nutrition (ESPGHAN)
2. The International Pharmaceutical Congress Advisory Association's (IPCAA) Code of Conduct and Medical Congress Guidelines and Housing Guidelines
3. Code for Interactions with Companies from the US Council of Medical Specialty Societies
4. Code of Conduct. Healthcare Professionals and Scientific Organizations. Members of the

Alliance for Biomedical Research in Europe.

5. Conflict of Interest Policy, Association of Neurovascular Clinicians.

Scientific and educational activities organised or sponsored by ISRHML

The practice of research is a “covenant of trust” between the parties involved and rests on the commitment to fidelity and service. ISRHML is a professional organisation that supports research, exchange and critical discussion of research findings in the field of human milk and lactation through the organisation of scientific meetings, educational symposia, networking opportunities, and other activities. ISRHML aims at supporting diversity and inclusion of all researchers working in the field of human milk and lactation.

Researchers have an obligation to dedicate themselves to continue to study, apply, and advance scientific knowledge and to maintain a commitment to information sharing. They maintain their knowledge and skills through education and other professional development activities. Thus, ISRHML feels obliged to set the agenda and to define the goals of scientific meetings and professional education, to control what subject matters are selected, to determine educational needs, and to take steps to ensure the independence of content and of those who present it. Financial relationships with commercial companies in scientific and educational meetings organised or sponsored by ISRHML

Relationships between researchers and commercial companies may or may not pose challenges for the independence and objectivity of scientific or educational events. However, commercial support is often needed to support the costs of scientific and educational activities in the face of uncertain funding from other sources, and it may help make such activities more accessible, especially for individuals working under resource-poor conditions. Along with lowering costs, commercial support may encourage greater participation than would otherwise be the case. However, there is concern that commercial funding might have undesirable effects, including potentially biasing content toward funders’ products or interests, and influencing the overall range of topics covered. The ISRHML Executive Committee takes responsibility to ensure appropriate measures to safeguard the independence and integrity of scientific and educational activities related to the society.

Ensuring the independence and integrity of scientific and educational activities

ISRHML has a responsibility to protect its reputation and the quality of its scientific and educational activities. While competing interests cannot be eliminated entirely, prudent judgment can be made about how to minimize potential influence and prevent or reduce undesired consequences of accepting financial support from commercial entities.

Minimizing the opportunity for undue influence

ISRHML should aspire to avoid the potential for undue influence or the chance that confidence in the integrity and independence of its activities is undermined. ISRHML should strive to obtain non-commercial sources of support whenever possible, should design and conduct scientific and educational activities so as to limit costs, and should insist that organizers and speakers at conferences and other outreach activities provide unbiased, high quality scientific and educational programmes. In addition, all organizers and speakers at ISRHML-sponsored symposia must disclose

all financial relationships that might result in or be perceived as resulting in conflicts of interest. The organizers of ISRHML-sponsored events should provide a respective template to all presenters.

It is not always feasible or even desirable for scientific or educational activities to disengage from commercial companies. In some situations, collaboration with a commercial company may in fact be necessary, for instance to achieve the goals of a research or educational activity (e.g., provision of a specific methodology or of specific equipment). Indeed, financial relationships with commercial companies can be desirable and ethically appropriate; for instance, if not accepting support from a commercial source or not permitting participation by individuals who have financial interests in the subject matter would significantly undermine ISRHML's capacity to ensure that participants have access to appropriate, high-quality science and education. In these cases, it is acceptable to permit such support or participation. Vigorous efforts should be made by the organizers of ISRHML events and by the ISRHML Executive Committee to ensure that financial support is not linked to any influence on decisions on program planning and content, and the selection of participants.

Independence

Taking concrete steps to ensure that the ISRHML activity is independent from the commercial interest of third parties and objective is important. Creating a separation between funders and decisions about goals, content, speakers, pedagogical methods and materials, and other substantive dimensions of the activities can help protect independence. ISRHML recommends clearly separating decisions about funding from substantive decisions about scientific and educational activities. Support of individual activities by multiple, competing funders also helps diffuse the potential influence of any one funder. Carrying out needs assessments prior to seeking or accepting commercial support or identifying speakers can similarly enhance the independence of the planning process and resulting programming.

Disclosure of interests of ISRHML officers

Transparency, defined as "disclosing the existence of a financial relationship," is a necessary first step in mitigating the potential of financial relationships that may create bias. Transparency can help to mitigate the potential for influence in an activity. Therefore, any relationships between ISRHML officers and commercial companies should be transparently disclosed to the ISRHML membership at the time of elections, including the financial support they receive privately and on accounts of their institutions, and the sources thereof.

It is important to recognize that not all relationships between ISRHML officers and commercial entities are problematic. A relationship that is only indirectly related to an activity, modest in scope, or distant in time is not likely to adversely affect the activity in question. For example, having conducted sponsored research governed by an academic institution of a researcher, or accepting a modest honorarium for speaking on behalf of a company, does not necessarily create a bias. Financial support from a variety of sources is more likely to reduce the potential influence of one source of support. Financial relationships that are direct or substantial, however, may have the potential to undermine confidence in scientific or educational activities, even if they do not actually compromise those activities. Examples of a direct or substantial financial interest may include ownership or equity interest in a company that has an interest in the subject matter, significant royalties, or employment. Relationships that involve responsibilities on behalf of the funder (such as

service on a corporate board of directors) or decision-making authority in financial matters can be similarly problematic.

PROCEDURES

1. Duty to disclose:

- a) All elected ISRHML Executive Committee members, including the past-president will annually submit a Disclosure Form detailing all actual and potential conflicts of interest to the ISRHML executive office by March 1st. Members continuing in elected leadership roles will be asked to update their existing Disclosure form.
- b) Prior to election, all candidates for ISRHML Executive Committee Membership will submit a Disclosure Form detailing all actual and potential conflicts of interest along with their CV and statement of interest.
- c) Those who organise ISRHML events and activities will also be required to submit a Disclosure Form at the time of submitting the proposal for the event/activity to the Executive Committee.

2. Review Process:

- a) The forms will be reviewed by the ISRHML COI Oversight Committee
- b) The COI Oversight Committee will consist of three previously elected officers of the society, who are appointed by the ISRHML President for 3-year terms. Members can be renewed for 1 additional terms.

3. Determining Whether of Conflict of Interest Exists:

- a) After disclosure of the potential conflict of interest and all material facts, the COI Oversight will determine whether additional information is needed, including a discussion with the interested person, they will determine whether an actual or perceived COI exists. If they determine that a conflict of interest exists, it will be presented to the Executive for discussion. The remaining board or committee members shall decide if a conflict of interest exists

4. Procedures for Addressing the Conflict of Interest

In most circumstances, the disclosure of financial, affiliated or other interests or relationships that pose potential COI likely will be sufficient in addressing the potential conflict. If, however, in the view of the ISRHML Executive Committee disclosure of such interests or relationships alone is not adequate to ensure the integrity and credibility of the ISRHML, the affected individual may be asked to resolve the conflict by either withdrawing from the outside conflicting interest or relationship or withdrawing from participation in some or all ISRHML activities. Alternatively, the Executive Committee may provide for other means to resolve the conflict. The following are steps that may be taken to resolve a conflict of interest.

- a) An interested person may make a presentation at the ISRHML Executive Committee, but after the presentation, he/she shall leave the meeting during the discussion of, and the vote on, the transaction or arrangement involving the possible conflict of interest.
- b) The President of the ISRHML shall, if appropriate, appoint a disinterested person or committee to investigate alternatives to the proposed transaction or arrangement.
- c) After exercising due diligence, the ISRHML Executive Committee shall determine whether ISRHML

can obtain with reasonable efforts a more advantageous transaction or arrangement from a person or entity that would not give rise to a conflict of interest.

d) If a more advantageous transaction or arrangement is not reasonably possible under circumstances not producing a COI, the ISRHML Executive Committee shall determine by a majority vote of the disinterested directors whether the transaction or arrangement is in ISRHML's best interest, for its own benefit, and whether it is fair and reasonable. In conformity with the above determination it shall make its decision as to whether to enter into the transaction or arrangement.

5. Violations of the Conflicts of Interest Policy

a) If the ISRHML Executive Committee has reasonable cause to believe a member has failed to disclose actual or possible conflicts of interest, it shall inform the member of the basis for such belief and afford the member an opportunity to explain the alleged failure to disclose.

b) If, after hearing the member's response and after making further investigation as warranted by the circumstances, the ISRHML Executive Committee determines the member has failed to disclose an actual or possible conflict of interest, it shall take appropriate disciplinary and corrective action which may include removal from any participation or service to ISRHML.

Accountability

Researchers and the public should be confident that ISRHML as a society and those individuals who organize, design or teach in its activities, will uphold principles of transparency and independence. The expectation that individuals involved in scientific and educational activities will hold themselves accountable to address the potential that financial relationships with commercial companies have to influence professional education is a cornerstone of self-regulation. In particular, ISRHML members involved in ISRHML-sponsored scientific and educational activities should transparently disclose their potential conflicts of interests and be able and willing to discuss how the principles of transparency and independence have been applied in the activities with which they are involved or over which they have decision-making authority.

Exceptional cases

At times it may be impossible to avoid a financial interest or extraordinarily difficult or even impossible to mitigate its potential impact on an activity. For the most part, accepting support from a single company or permitting participation by an individual when there is an irreducible financial interest would create increased risk. However, in certain circumstances, it may be justifiable. Such circumstances include instances when accessible, high-quality activities cannot reasonably be carried out without support from sources that have a direct financial interest in content. Similarly, in the early stage of adoption of a new research approach or technology, the only individuals truly qualified to inform professionals in its use are often those who developed the innovation or conducted the research. These individuals may have the most substantial and direct interests at stake, whether through employment, royalties, equity interests, or other direct financial interests in the adoption and dissemination of the new technology. ISRHML should ensure transparency about direct financial interests in a particular activity or its content.

Promotional activities by commercial companies

Promotional activities are those developed by or on behalf of a commercial entity and under the substantive influence of that entity to provide information on the use of a product or service. While promotional activities such as commercial exhibitions or advertisements may occur at ISRHML

events, ISRHML does not endorse commercial products and services. This fact will be clearly delineated at all such promotional events.

Awards and grants

ISRHML awards, such as the Macy-György Award and the Ehrlich-Koldovsky Award, are important in that they recognize the achievements of individuals conducting research related to human milk and lactation. The selection process for these awards must be completely devoid of commercial influence.

ISRHML grants for research, educational or other activities, such as the Trainee Support Programme, might be sponsored by commercial or other entities. These grants should bear the name of ISRHML while the sponsor's name may be linked to the name of the program.

The selection committee that awards the awards and grants will be defined in the ISRHML bylaws or by executive committee decision. The procedure to select individuals for awards and grants should be completely transparent and independent from commercial interests.

ISRHML conferences

The responsibility for the ISRHML scientific conferences lies with ISRHML. However, part of the organisational work (e.g., registration and accommodation, abstract handling, sponsoring activities, exhibition) for these conferences may be delegated to a third-party company (e.g., a professional conference organiser, PCO) which acts in the name and on behalf of ISRHML for all delegated activities.

Participating companies

Any exhibitor/sponsor company shall inform all subsidiaries, affiliates, third party companies, etc. involved on its behalf of the rules of these ISRHML Guidelines and related information provided by the conference organizer. It is the exhibitor's/sponsor's responsibility – being the official contracted partner to ISRHML – that its subcontractors adhere to all guidelines stated here.

Exhibition

An exhibition stand is a forum for commercial companies to create the opportunities to present their company and their products to researchers and other professionals. Exhibition stands should therefore create the opportunity for the company to show and display information relevant to both, the company and their products as well as other scientific information they may choose.

Give-aways and printed material

Give-aways and printed material may only be distributed in the space rented by the exhibitor in the exhibition hall or at a company's own satellite symposia. No such material may be distributed in any hotel used by ISRHML. Contests, lotteries, and raffles are subject to the approval by the organizer or PCO acting on behalf of ISRHML.

Space integrity / promotional activities

Exhibitors are prohibited from publicising, distributing, canvassing, and/or maintaining any activities, inducements, demonstrations, materials, or displays outside the space assigned to them,

unless agreed otherwise by ISRHML or PCO acting on behalf of ISRHML in writing ahead of the activity.

Exhibitor's participation in sessions

Conference sponsorship/exhibitor guidelines shared by the organizer or PCO will determine whether and how many participants registered as exhibitors can be permitted to attend scientific sessions at the conference. Otherwise, exhibitors interested in attending any scientific session must register as regular conference participants.

Exhibitors may receive complimentary exhibitor registrations. The number of complimentary registrations depends on the sponsorship package. ISRHML reserves the right to refuse applications of companies not meeting or not having met on previous occasions the standard requirements or expectations. ISRHML reserves the right to curtail or to close exhibits (wholly or partially) that reflect unfavourably on the character and the purpose of the conference.

Guidelines on scientific abstracts and their presentations at ISRHML meetings

Abstracts submitted to ISRHML meetings should focus on scientific findings and must not be used to promote products or companies. Any financial support by commercial companies and any ties to commercial companies such as employment and honoraria must be transparently disclosed. The use of brand names of commercial products should be avoided, unless the disclosure of brand names is necessary for the understanding of the abstract in which case the brand name should not be used more than once.

Oral and poster presentations should focus on the presentation and discussion of scientific data and should not in any way be abused for marketing or advertising purposes. Any financial support by commercial companies and any ties to commercial companies such as employment and honoraria must be transparently disclosed. The name of companies linked to the research should be disclosed. Company logos should not be used in scientific presentations more than once (e.g., in the title slide) to avoid undue promotional activities. The use of brand names of commercial products should be avoided, unless the disclosure of brand names is necessary for the understanding of the abstract in which case the brand name should not be used more than once.

The conference organiser should ensure that these guidelines on scientific abstracts and their presentations at ISRHML meetings are available on the conference website prior to abstract submission and are included in the information shared with presenters of accepted abstracts.

Industry-sponsored satellite symposia

If ISRHML offers the opportunity to hold satellite symposia organised by commercial companies, their main objective should be to communicate scientific material which will enhance the knowledge of participants. Satellite symposia slots may be allocated by ISRHML or the PCO acting on behalf of ISRHML, taking into account previous support to the meeting, a balanced match of programme content, and other considerations that serve to support attendees. There will be no material inducement or publication of a reward to attend the symposium. Delegates may be sent special invitations and may be offered reasonable meal or drink service, but no other reward to participants is allowed for attending a symposium.

The satellite symposium programme must be submitted to the meeting organisers in advance of the event. The organisers may raise objections in which case adaptations should be agreed upon, or otherwise the satellite symposium ought to be cancelled.

The chairperson of the satellite symposium should not be employed by or otherwise dependent on the sponsoring company, but should be an ISRHML member who is an independent researcher or professional not employed by a company related to the symposium. The chairperson has a responsibility to oversee that the messages and conclusions presented during the symposium are based on available scientific data. The sponsor should inform the chairperson(s) of this responsibility. In addition, the sponsor of a satellite symposium and the chairperson are jointly responsible for adhering to the assigned time slot of the symposium.

All satellite symposia must be held at the conference venue during the official time slots offered by the organizers. If any activities of a commercial partner are deemed to be in conflict with this policy or with the aims of the society, these will be assessed and will be treated in due course on a case-by-case basis.

Advertising and promotion of industry-sponsored satellite symposia during the conference

Satellite symposia programs and invitations may only be distributed in the space rented by the exhibitor in the exhibition hall (if applicable) and at the entrance to the auditorium used for the satellite symposium no more than 24 hours before the start of the symposium, unless otherwise agreed in writing with ISRHML or the PCO acting on behalf of ISRHML.

Photos, filming, and audio recording of satellite symposia

Photos, filming, and audio recording are permitted with the following conditions: in a written agreement between the company presenting the symposium and ISRHML it should be confirmed that the captured material must be used only for educational purposes. The company responsible for the symposium must inform its speakers and obtain written consent from its speakers directly. The captured material should not be profit making or for commercial purposes or incur additional costs to the organisers of the conference. ISRHML will retain the right of use for the captured material. Any such requests require official permission from ISRHML clearly outlining the purpose of the recording. Live and/or simultaneous broadcasting of satellite symposia in any way is prohibited unless otherwise agreed in writing.

Use of ISRHML name and logos

The use of the ISRHML name, ISRHML logo, and the conference logo in any fashion, by any commercial entity, for any purpose is expressly prohibited before, during, or after a conference without prior written consent of ISRHML. The conference logo without any modifications may be used on invitations for officially approved satellite symposia. It can be requested from the ISRHML secretary. The organiser is obliged to submit a copy of the draft and of the final version of the invitation to the PCO acting on behalf of ISRHML.

Press, media, and publication

Press conferences, briefings of any kind, or similar group events organised directly or indirectly by the commercial company may not be held in the conference centre and not be organised during the

official scientific programme hours unless approved in writing by ISRHML ahead of the event. All such events need the prior approval of ISRHML or the PCO acting on behalf of ISRHML. Picture taking, filming, and recording of the scientific programme or any part of it is not allowed unless approved in writing by the PCO acting on behalf of ISRHML.

Internet publication of material

The guidelines for press, media, and publications are likewise applicable for the publication of material and information on the internet. Given that all material presented at the congress is of public interest and not confidential anymore, ISRHML expects such publications to be accessible without prior registration to a site even if the registration is free.

Legal issues

Each exhibitor/sponsor is responsible for the material and information it makes available at the conference. Exhibitors/sponsors should only present material and information which has been approved by their legal departments and which is in compliance with the legislation of the host country of the conference. Exhibitors/sponsors should address these issues and any conflicts arising from such matters directly among themselves as ISRHML and/or the organisers will never intervene or arbitrate in any way in legal issues.

Enforcement

All ISRHML Executive Committee members, organizers and presenters of ISRHML meetings, and collaborating commercial and non-commercial organisations must comply with these ISRHML interaction guidelines, the ISRHML bylaws, and with any additional conference guidelines issued by the conference organizers. ISRHML may apply penalties when violations occur. The procedure for policing and enforcing the violation system is as follows.

1. Alleged violations shall be reported to ISRHML or to the PCO acting on behalf of ISRHML.
2. Once the alleged violation has been duly considered by the ISRHML Executive Committee, the responsible individual or a representative of the relevant company will be invited to share his/her view. The final decision on the applicable penalty will be taken by the ISRHML Executive Committee.

Conclusions and Recommendations

1. Healthy and robust relationships among researchers and commercial companies can play an important role in supporting and advancing science, healthcare, and education related to human milk and lactation.
2. ISRHML should define the goals of scientific and educational activities independent from other interests and sets its own priorities for such activities.
3. Financial or in-kind support from commercial entities or their affiliates that may have a direct interest in activities of ISRHML can, under some circumstances, create conditions in which external interests might influence the activities of ISRHML. However, support from commercial companies may be needed to enable access to appropriate, high-quality scientific, and educational activities. In these circumstances, participants should be confident that vigorous efforts will be made to maintain the independence and integrity of such activities.
4. Financial or in-kind support from commercial entities should be transparently disclosed prior to election by all candidates for ISRHML Executive Committee Membership, and again annually by all ISRHML Executive Committee Members and by others who organise ISRHML events and activities.

The ISRHML Executive Committee will determine the conditions of disclosure, its review and potential implications.

5. Organizers of ISRHML-sponsored events (conferences, webinars, etc.) should disclose all support received and will take measures to ensure independence and integrity of the event, as detailed in these guidelines.

6. Invited speakers and abstract presenters at ISRHML-sponsored events (conferences, webinars, etc) should comply with all applicable professional standards and be fully transparent about financial relationships that could potentially influence ISRHML activities.

Adopted by the ISRHML Executive Committee on 05.01.2019.