

## COMMERCIAL SUPPORT AGREEMENT Regarding Terms, Conditions and Purposes of an Educational Grant for an Independent Educational Activity

Case Western Reserve University School of Medicine ("Accredited Provider"), an ACCME-accredited "Accredited Provider" of continuing medical education, is committed to presenting Continuing Medical Education ("CME") activities, the content of which promotes improvements in physician performance or patient health status and is independent of the control of commercial interests. As part of this commitment, and in accordance with its Commercial Support Policy, the Accredited Provider has outlined in this agreement the terms, conditions and purposes for commercial support associated with its CME activities. Commercial support is defined as financial or in-kind contributions given by a commercial interest<sup>1</sup> used to pay all or part of the costs of a CME activity.

Title of CME Activity					CID #
Activity Location					Activity Date(s)
Name of Commercial	Interest				
Value of Grant or	Description of In-kind	Durable equip	ment Facilities/Space	Disposable Sup	plies (non-biological)
\$	Support (check one):	Animal parts o	or tissue Human parts	or tissue	
		Other (descrip	otion required):		
Grant will be used for	the following (check below	/):			
Speaker Honoraria	Speaker Expe	enses	Meeting/Other Expenses	Unrestric	ted

## TERMS, CONDITIONS and PURPOSES

- 1. **Statement of Purpose:** CME activities shall be conducted for scientific and educational purposes only and will not promote any specific proprietary business interest or products of the Commercial Interest, directly or indirectly.
- 2. **Compliance with Applicable Laws and Regulations:** The Accredited Provider and the Commercial Interest agree to abide by all requirements of the ACCME *Standards for Commercial Support of Continuing Medical Education* (*"Standards"*), the AMA Guidelines on Gifts to Physicians from Industry (Ethical Opinion 8.061), all requirements of the U.S. Food and Drug Administration policy on commercially-supported scientific and educational activities and all applicable federal and state laws, regulations and policies. The Commercial Interest agrees to cooperate in the instance that any regulatory, judicial or other government authority inquires into the Accredited Provider's or Commercial Interest's actions under this agreement.
- 3. **Control of Content & Selection of Presenters & Moderators.** The Accredited Provider is responsible for control of content and selection of presenters, moderators and anyone in a position to control the content of the activity. The decision of the Accredited Provider will be final. The Accredited Provider is not required to seek or accept advice or services from Commercial Interest.
- 4. **Disclosure of Financial Relationships:** The Accredited Provider will require all CME Activity planners and faculty to disclose prior to participation in the CME Activity any financial relationships with (a) any Commercial Interest providing support for the CME Activity or (b) any Commercial Interest to whose products the CME faculty member may refer. Accredited Provider's shall resolve real or apparent conflicts of interest pursuant to its Conflict of Interest.
- 5. Acknowledgement of Commercial Support: The Accredited Provider will acknowledge commercial support, either direct or "in-kind," from the Commercial Interest in program announcements, syllabi or other activity materials to ensure compliance with the *Standards*.
- 6. **Appropriate Use of Commercial Support:** The Accredited Provider will make all decisions regarding the disposition and disbursement of the funds from the Commercial Interest. All commercial support related to this activity will be given with the full knowledge and approval of the Accredited Provider. No other payments shall be given the Activity Director, planning committee members, teachers or authors, joint sponsor or any others involved with the supported activity.

- 7. **Documentation of Receipt of Commercial Support:** In addition to this agreement, each instance of commercial support will be documented with a photocopy of the grant check or similar evidence of the in-kind contribution (e.g. description of the in-kind service.)
- 8. **Exhibits and Ancillary Promotional Activities:** Promotional and educational activities will be separate. Promotional or sales activities must be kept physically separate from the CME Activity. Promotional materials or product-specific advertisement cannot be displayed or distributed in the educational space immediately before, during or after a CME Activity. Exhibits will be permitted in space authorized by the Accredited Provider for that purpose. The Commercial Interest may not be the agent providing the CME Activity to the learners.
- 9. **Objectivity & Balance:** The Accredited Provider will make every effort to ensure that data regarding the Commercial Interest's product(s) (or competing products) are objectively selected and presented by the activity faculty in the CME Activity, with favorable and unfavorable information and balanced discussion of prevailing information on the product(s) and/or alternative treatments. The Accredited Provider will ensure, to the extent possible, that the activity faculty makes meaningful disclosure of limitations on data, e.g., ongoing research, interim analyses, or unsupported opinion.
- 10. **Discussion of Unapproved Uses:** The Accredited Provider will require that activity faculty acknowledge their obligation to disclose to the audience when a product is not approved ("off-label") or for investigational purposes in the United States for the use under discussion.
- 11. Enduring Materials: This agreement applies to any enduring material, or "self-study" activity whether in the form of a publication, analog or digital recording, software, other audio-visual component, Internet program or any combination of these media. If the Accredited Provider records, re-purposes or otherwise produces CME enduring materials derived from, based on or archived from the scientific educational activity funded under this agreement, the Accredited Provider and the Commercial Interest agree that all the terms, conditions and purposes of this agreement apply to the planning, production and dissemination of the enduring material. If the enduring material is, or includes, an Internet component, it must comply in all respects with the ACCME's policy for Internet CME. In self-study education the juxtaposition of editorial and advertising material on the same products or subjects is not allowed.
- 12. **Payment of Funds:** Grants should be made payable to the Accredited Provider, Case Western Reserve University (Tax ID# 34-1018992).

Commercial Interest	CME Activity Director
Signature and Date	Signature and Date
Print Name	Print Name
Title	Department
	Accredited Provider stern Reserve University School of Medicine
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	Accredited Provider stern Reserve University School of Medicine

<sup>1</sup> Accredited Provider follows the ACCME definition of Commercial Interest. The ACCME defines Commercial Interest as any entity producing, marketing, re-selling, or distributing health care goods or services, consumed by or used on patients, with the exception of non-profit or government organizations and non-health care related companies. The ACCME does not consider providers of clinical service directly to patients to be commercial interests.

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