University of Oklahoma College of Medicine - Irwin H. Brown Office of Continuing Professional Development

**Annual Activity Disclosure and Resolution Form (ADRF)**

**Name\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ E-Mail Address\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Activity Number/Date\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ CME Activity Name \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Phone Number\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Roles (check all that apply): CME Organizer/Reviewer Presenter Moderator Abstract or Poster Author Other\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

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| **Disclosure:** (**See Glossary of Terms for guidance) All Roles must complete Statement 1A and Sign and Date the form.** |

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| **YES NO**  **If NO, Skip to Attestation (Abstract and Poster Authors-skip the Attestation and sign the bottom of the form.)**  **If YES, Complete the information below regarding commercial interests (use an additional page if necessary)** |
| |  |  |  | | --- | --- | --- | | **Commercial Interest** | **Nature of Relevant Financial Relationship**  **(Include all those that apply)** | | | **What was received?** | **For What Role?** | | Example: Company XYZ | Speaker Fee | Promotional Speaker | |  |  |  | |  |  |  | |  |  |  | | (Refer to Glossary of Terms on page 4 for further explanation of relevant financial relationships)  **Organizers/Reviewers and Moderators:** You must complete the Resolution of Conflict on page 2  **Presenters: Please complete the following two statements:**  **Statement 1B.** Will your presentation(s) include discussion of any products or services from the above listed commercial interest(s)? 🞏 Yes, it will 🞏 No, it will not  **Statement 2.**  I will make clinical recommendations in this/these presentation(s).  🞏 Yes, I will 🞏 No, I will not  **Statement 3.**  I will make references to off-label or investigational drugs/therapies in this/these presentation(s).  🞏 Yes, I will 🞏 No, I will not  **Presenters: If you answered yes to both statements 1B and 2, you must complete the Resolution of Conflict on page 2** | | | |

**Statement 1A.**  I or my spouse/partner presently (within the past 12 months) has relevant financial relationships with a commercial interest(s):

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| **Attestation-Complete the appropriate attestation for the role(s) you are undertaking** |
| **Organizers/Reviewers: Read the following statements and sign and date the form below.**   1. This activity is for scientific and educational purposes only and will not promote any specific proprietary business. 2. Topics and presenters were selected free of the control of a commercial interest. |
| **Presenters: Read all of the following statements sign and date the form below**  **Moderators: Read statements G-J and sign and date the form below**   1. I will teach to the competencies identified by objectives. 2. I will present the source and type or level of evidence (e.g. common practice, expert opinion, case series, case control study, clinical guidelines, randomized controlled trial, systematic review, meta-analysis, etc.) 3. All the recommendations involving clinical medicine in a CME activity are based on evidence that is accepted within the profession of medicine as adequate justification for their indications and contraindication in the care of patients. 4. All scientific research referred to, reported or used in CME in support or justification of a patient care recommendation must conform to the generally accepted standards of experimental design, data collection and analysis. 5. I agree to obtain the necessary copyright permission(s) if any portion of my CME activity materials that I prepare is not my original work or for which I do not hold the copyright. 6. I understand that my CME presentation may be peer-reviewed for fair balance and validation of content and will be evaluated by participants for fair balance. 7. I will uphold academic standards to insure balance, independence, objectivity and scientific rigor 8. I will disclose all relevant financial relationships. 9. I will notify participants of any off-label or investigational treatments discussed within the presentation or during the question and answer period. 10. I agree to comply with the requirements to protect health information under the Health Insurance Portability and Accountability Act of 1996 (HIPAA). 11. I agree that if my materials include any Protected Health Information, as defined by HIPAA, I have obtained all necessary consents and authorizations. I will be fully responsible for claims arising from my failure to do so. |
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| **CME Organizers/Reviewers, Presenters, Moderators and Abstract or Poster Authors:** Sign and Date |
| By signing this document, I agree to the above elements expected of individuals involved in the planning and implementation of educational activities certified by the University of Oklahoma College of Medicine, Office of Continuing Professional Development. I certify that the information I have provided is true and complete to the best of my knowledge. |

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**Signature Date**

University of Oklahoma College of Medicine - Irwin H. Brown Office of Continuing Professional Development

**Resolution of Conflict of Interest (COI) Form**

All course directors, planning committee members, organizers, reviewers, course contacts and moderators answering yes to **Statement 1A** must complete this form. All presenters, panelists, abstract and poster presenters answering yes to **Statement 1B and 2** must complete this form. This information is necessary in order for us to be able to move to the next steps in planning this CME activity. If a CME organizer/reviewer or presenter refuses to identify resolutions, they will be disqualified from being a part of the planning and implementation of any CME activity.

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| **PRESENTER’S Conflict Resolution: If statements 1B and 2 are both yes, select one or more of the following statements to resolve the conflict and sign below:**  In order to comply with ACCME requirements, I \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ agree that:  (print your name)  \_\_\_\_\_ I will refrain from making recommendations on topics in which the conflict exists.  \_\_\_\_\_ I will only present peer-reviewed, published data and recommendations that have been previewed by the OU/CPD. If  time for previewing materials is not available, I understand that no CME credit will be offered for my presentation.  \_\_\_\_\_ My presentation(s) does not have any relevance to this commercial interest: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  (Name of Commercial Interest)  \_\_\_\_\_ I will limit my content to data and information while other faculty members address the implications and make  recommendations.  \_\_\_\_\_ I have divested myself of the financial relationship with the commercial entity: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  (Name of Commercial Interest)  **The OU/CPD office will contact you regarding the next step in the resolution process.** |

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| **MODERATOR’S Conflict Resolution: Select one or more of the following statements to resolve the conflict and sign below:**  In order to comply with ACCME requirements, I \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ agree that:  (print your name)  \_\_\_\_\_ I will limit my role to the introduction of presenters, fielding questions, and moderating the flow of discussion between  participants and presenters.  \_\_\_\_\_ I have divested myself of the financial relationship with the commercial entity: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  (Name of Commercial Interest) |

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| **ORGANIZER’S/REVIEWER’S Conflict Resolution**: **one or more of the following statements to resolve the conflict and sign below:**  In order to comply with ACCME requirements, I \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ agree that:  (print your name)  \_\_\_\_\_ I will recuse myself from planning content in the conflicted area.  \_\_\_\_\_ I have divested myself of the financial relationship with the commercial entity: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  (Name of Commercial Interest) |

Name\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (please print) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Signature Date**

# University of Oklahoma College of Medicine - Irwin H. Brown Office of Continuing Professional Development

Disclosure Policies and Procedures

The University of Oklahoma College of Medicine Office of Continuing Professional Development (OU/CPD) is accredited by the Accreditation Council for Continuing Medical Education (ACCME). As an accredited provider, The University of Oklahoma College of Medicine, Office of Continuing Professional Development requires that all of its CME activities will adhere to the ACCME’s commercial support, independence and content validation requirements.

1. **Information for Learners.** Information on needs, expected results, and purpose or objectives will be provided to learners. These have been framed in terms of physician change or health status improvement which is in keeping with our CPD mission.
2. **Safeguards against Commercial Bias/Independence.** OU/CPD expects that the content or format of CME activities and related materials will promote improvements or quality in healthcare and not a specific proprietary business interest of a commercial interest. CME must give a balanced view of therapeutic options. Use of generic names will contribute to this impartiality. If CME educational material or content includes trade names, trade names from several companies should be used where available, not just trade names from a single company.
3. **Content Validation.** All the recommendations involving clinical medicine in a CME activity must be based on evidence that is accepted within the profession of medicine as adequate justification for their indications and contraindications in the care of patients. All scientific research referred to, reported, or used in CME in support or justification of a patient care recommendation must conform to the generally accepted standards of experimental design, data collection, and analysis. Please contact the CPD office if you do not feel your presentation can meet these standards.
4. **Honoraria.**  OU/CPD has developed an honoraria policy in an ongoing effort to provide consumers of continuing medical education programs with objective and scientifically rigorous education. All honoraria must comply with the ACCME Standards for Commercial Support and not influence the choice of presenter or the content of the presentation. Presenters are prohibited from accepting any reimbursement (financial, gifts or in-kind exchange) for their presentation from any source other than the accredited CME provider (OU/CPD) or its educational partner.
5. **Presenter and Commercial Interest Relationships.** The OU/CPD office requires disclosure of relevant affiliations between presenters, moderators, panelists, abstract or poster authors, residents, planning committee members, course contacts and the course director, and their spouses/partners *(****CME organizers/reviewers/presenters****)* and any organization that may have a direct interest or financial involvement in the educational activity, product, or service provided by the University of Oklahoma College of Medicine. In addition, ***CME organizers/reviewers/presenters and their spouses/partners*** are required to disclose any financial relationships they may have with the manufacturer of any product or class of products. Should it be determined that a conflict of interest exists as a result of a financial relationship, this must be resolved prior to the activity.

Course directors are required to have written disclosure within their handouts or syllabus that contains all of the CME organizers/presenters and which is required to be distributed to all participants. This policy is designed to provide the target audience with an opportunity to review any affiliations between the ***CME organizers/reviewers/presenters*** and supporting organizations for the purpose of determining the potential presence of bias or influence over educational content.

1. **Resolution of Conflict.** It is the responsibility of the OU/CPD office to resolve any conflict of interest prior to the activity. Any presenter answering “yes” to statements 1B and 2 on the Disclosure Form must complete the Resolution of Conflict form. In addition, the following actions must be completed in order to assure that all conflict has been resolved:
   * 1. The course director will contact each speaker with a conflict and discuss the issues and concerns and will confirm that the speaker understands that no clinical recommendations will be presented unless the presentation slides and a statement of clinical recommendations are previewed by the OU/CPD office for potential bias.
     2. The speaker will need to submit the presentation to the OU/CPD office for content validation and potential bias at least three weeks prior to the activity. If time for previewing is not available, no CME credit will be offered for the presentation.
     3. Each presentation will be monitored by the course director or designated physician for bias and/or recommendations and the monitor will report the findings in writing to the OU/CPD office at the end of the course. Monitors are also required to ask question or make comments to counter the commercial bias if presented.
     4. The following questions regarding the speaker’s presentation will be added to the course evaluation:
        + 1. Were clinical recommendations made during the presentation?
          2. Did you perceive any commercial bias during this presentation?
     5. If the evaluation results show that more than 15% of the audience heard clinical recommendations or commercial bias, the speaker will not be asked to participate in future accredited activities.

1. **Disclosures.**  At the beginning of their presentations, presenters must verbally and visually disclose to learners any relevant financial relationship(s), to include the following information: the name of the presenter; the name of the commercial interest(s); and the nature of the relationship the person has with each commercial interest. Disclosure must never include the use of a corporate logo, trade name, or a product-group message of an ACCME-defined commercial interest.

Presenters with no relevant financial relationship(s) must be inform the learners that no relevant financial relationship(s) exist.

1. **Discussion of Off-Label or Investigational Uses.**  Activities formally designed as certified for *AMA PRA Category 1 Credit(s)™* by an organization accredited by the ACCME may allow presenters to discuss off-label or investigational uses of drugs or medical devices. When this occurs, however, the audience must be advised of the off-label or investigational status so that learners may take this information into consideration in making determination as to whether or not they will implement the information they learned in their medical practice.
2. **Measurements of Effectiveness.** The OU/CPD office will be seeking feedback from the learners on the effectiveness of this CME activity through session and/or overall course evaluations. Evaluations will include questions about undue commercial bias and the quality of the evidence cited.

**Glossary of Terms**

**Commercial Support:** Commercial support is financial or in-kind contributions given by a commercial interest which is used to pay all or part of the costs of a CME activity.

**Commercial Interest:**  A **commercial interest** is any entity producing, marketing, re-selling, or distributing health care goods or services consumed by, or used on, patients.  The ACCME does not consider providers of clinical service directly to patients to be commercial interests. A commercial interest is not eligible for ACCME accreditation. Within the context of this definition and limitation, the ACCME considers the following types of organizations to be eligible for accreditation and free to control the content of CME:

* 501-C Non-profit organizations *(Note:  ACCME screens 501c organizations for eligibility.  Those that advocate for 'commercial interests' as a 501c organization are not eligible for accreditation in the ACCME system.  They cannot serve in the role of joint sponsor, but they can be a commercial supporter.)*
* Government organizations
* Non-health care related companies
* Liability insurance providers
* Health insurance providers
* Group medical practices
* For-profit hospitals
* For profit rehabilitation centers
* For-profit nursing homes
* Blood banks
* Diagnostic laboratories

**Financial Relationships:** Financial relationships are those relationships in which the individual benefits by receiving a salary, royalty, intellectual property rights, consulting fee, honoraria, ownership interest (e.g., stocks, stock options or other ownership interest, excluding diversified mutual funds), or other financial benefit. Financial benefits are usually associated with roles such as employment, management position, independent contractor (including contracted research), consulting, speaking and teaching, membership on advisory committees or review panels, board membership, and other activities from which remuneration is received, or expected. ACCME considers relationships of the person involved in the CME activity to include financial relationships of a spouse or partner.

**Relevant Financial Relationships:** The ACCME defines “relevant financial relationships” as financial relationships in any amount occurring within the past 12 months that create a conflict of interest. ACCME has not set a minimal dollar amount for relationships to be significant. Inherent in any amount is the incentive to maintain or increase the value of the relationship.

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| **Commercial Interest** Company, Institution, etc… | **What Role**  Example: Employment, management position, independent contractor (including contracted research), consulting, speaking and teaching, membership on advisory committees or review panels, board membership and other activities (please specify) | **What was received?** Salary, royalty, intellectual property rights, consulting fee, honoraria, ownership interest (e.g., stocks, stock options or other ownership interest, excluding diversified mutual funds) or other financial benefit |

**Conflict of Interes**t**:** Circumstances create a conflict of interest when an individual has an opportunity to affect CME content about products or services of a commercial interest with which he/she has a financial relationship.