
UUCME DISCLOSURE POLICY

EXPLANATION OF PURPOSE

Since healthcare professionals serve as the trusted authorities when advising patients, they must protect their learning environment from industry influence to ensure they remain true to their ethical commitments. Many healthcare professionals have financial relationships with ineligible companies. By identifying and mitigating relevant financial relationships, we work together to create a protected space to learn, teach, and engage in scientific discourse free from influence from organizations that may have an incentive to insert commercial bias into education.

The University of Utah School of Medicine's CME Office (UUCME) policy is that everyone in a position to control the content of a CME activity must disclose any financial relationships with ineligible companies. UUCME follows all Accreditation Criteria and Standards of Integrity and Independence set forth by Accreditation Council for Continuing Medical Education (ACCME). Those criteria and standards may be found on ACCME's website (accme.org). This policy explains how UUCME applies those criteria and standards.

Everyone in a position to control the content of a CME activity must disclose to UUCME and to the learners; all his/her relevant financial relationships must be mitigated. Individuals who refuse to disclose financial relationships or refuse to attest to the statements at the end of the survey will be disqualified from all aspects of associated CME activities. All relevant financial relationships and lack of financial relationships must be disclosed to the learners, before an activity begins.

UUCME uses a Speaker/Planner Disclosure survey form where individuals report whether they have any financial relationships to disclose or if they have nothing to disclose. If a person in control of content does have relationships, the survey will alert them to UUCME's preferred mitigation strategy appropriate to the person's role in the activity and additional options that may be selected. If a relationship is disclosed, UUCME first reviews the relationship(s) for relevancy and if it meets the ineligible company ACCME-definition. Relationships are then passed to planners (typically, the Director or other non-conflicted planning member) who might determine the relationships are not relevant to their content and/or must mitigate financial relationships, as appropriate to the person's role in the activity. UUCME then provides a format and language to disclose relevant financial relationships to the learners.

If an activity is seeking nursing contact hours through the University of Utah, UUCME may opt to accept the nursing disclosure forms. This is at the discretion of UUCME. If nursing forms are accepted, UUCME staff will verify the appropriate definitions and process are used, require all completed disclosure and mitigation documentation, and documentation of how disclosure will be made to learners. All forms must be received at least 3 days prior to the activity start.

RELEVANT FINANCIAL RELATIONSHIPS ARE NOT POSSIBLE

During the planning stages of an activity, with the activity director/coordinator, UUCME may consider if relevant financial relationships are possible given the content of the activity. If any of the following statements apply to the education, financial relationships do not need to be identified, mitigated, or disclosed:

1. It will only address a non-clinical topic (e.g., leadership or communication skills training).

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2. It is for a learner group that is in control of the content entirely (e.g., spontaneous case conversation among peers).
3. It is a self-directed educational activity where the learner will control their educational goals and report on changes that resulted (e.g., learning from teaching, remediation, or a personal development plan) using resources and methods for learning that are not controlled by ineligible companies.
4. None of the educational activity's content is related to the products of an ineligible company there are no *relevant financial relationships* to identify or mitigate. (Two things must be present for there to be a relevant financial relationship: financial relationship(s) with an ineligible company(ies) **and** the ability to control content *related* to products/services of the ineligible company(ies). If no financial relationships exist, or the content of the CME activity is not related to the products of an ineligible company, there are no *relevant financial relationships* to identify or mitigate.)

When UUCME determines these scenarios are happening, UUCME will provide the wording for a statement indicating no relevant financial relationships are possible and disclosure collection may not be required (as unnecessary). UUCME makes the decision of when to use this process based off information, content, and explanation provided by the planning committee around possible relationships to an ACCME-defined ineligible company. Notes will be made on the Education Plan. Learners must still be notified of the presence or absence of relevant financial relationships prior to the activity start.

Employees or owners of ineligible companies are prohibited from planning activities and may only speak at activities in three very narrow circumstances (see section on Employees of Ineligible company in the UUCME Administrative & Education Policy for more information).

All disclosures for planning committee members, presenters, moderators, or others in control of content are completed prior to the activity taking place, with enough time to mitigate any relevant financial relationships.

A refusal to disclose will automatically disqualify an individual from participation in the activity as a planning committee member, a teacher, or an author of CME, and the person cannot have control of, or responsibility for, the development, management, presentation or evaluation of the CME activity.

Best practice tip: When in doubt, contact UUCME for help.

EXPECTED TIMELINES

PLANNING COMMITTEE: members submit disclosure as soon as possible following the planning meeting, no later than one month prior to the activity start.

PRESENTERS/SPEAKERS/MODERATORS: best practice is that disclosure is requested and submitted at the time the person accepts the invitation to speak. Disclosure must be received in the UUCME office no later than 5 days prior to activity start.

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UUCME collects disclosure at least annually for those typically in control of content (ie. RSS directors or moderators). Disclosure must be completed at least once per year and covers all activities that person may be involved in during that year. Once disclosure is completed, all those in control of content are asked to update and re-do their disclosure survey anytime their financial relationships change.

UUCME recognizes that at times, planning committee members may be added after the activity is approved or that presenters/speakers/moderators may be added to agendas later, especially for courses. Disclosure forms must be completed as soon as possible; typically, within three days of these types of changes. A finalized agenda and all disclosure forms must be received within 5 days of the start of any CME activity. If not, CME credit may not be provided for the activity. All disclosures must be received and financial relationships must be mitigated and disclosure to learners MUST be completed prior to the beginning of the activity.

RSS ACTIVITIES: UUCME has instituted a flyer methodology as the preferred method of informing learners of the disclosures for anyone in control of content for RSS activities. The flyer for each session is sent to all learners by e-mail prior to the activity taking place. Flyers may also be physically posted or posted at the start of a webinar in the chat or on the screen. Flyers must be received by UUCME 5 days prior to any session and all relevant financial relationships must be mitigated at least 2 days prior to any session.

Best practice tip: Save your learners from opening attachments. Use the body of your email for the flyer, with the disclosure statements present. No need to also attach a pdf.

Best practice tip: Include the UUCME on your flyer distribution list. This way UUCME has easy access to the disclosure documentation.

ACCME DEFINITIONS

INELIGIBLE COMPANY

An ineligible company is any entity whose primary business is producing, marketing, selling, re-selling, or distributing healthcare products used by or on patients. The ACCME does not consider providers of clinical service directly to patients to be ineligible companies.

FINANCIAL RELATIONSHIPS

There is no minimum financial threshold; we ask that you disclose all financial relationships, regardless of the amount, with ineligible companies. Inherent in any amount is the incentive to maintain or increase the value of the relationship. Individuals must disclose regardless of their view of the relevance of the relationship to the education.

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Individual stocks and stock options should be disclosed; diversified mutual funds do not need to be disclosed. Research funding from ineligible companies should be disclosed by the principal or named investigator even if that individual's institution receives the research grant and manages the funds.

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 or advisory committees or review panels, board membership, and other activities from which remuneration is received, or expected.

RELEVANT FINANCIAL RELATIONSHIPS

The ACCME defines "relevant financial relationships" as financial relationships in any amount that exists between the person in control of content and an ineligible company occurring within the past 24 months where the content of the education is related to the products of an ineligible company with whom the person has a financial relationship. Relevant financial relationships depend on the situation, and not on the character or actions of the individual.

OWNERS AND EMPLOYEES OF INELIGIBLE COMPANIES

The owners and employees of ineligible companies must be excluded from controlling content or participating as planners or faculty in accredited education, except in rare, limited and specific circumstances. Owners and employees are individuals who have a legal duty to act in the company's best interests.

OWNERS are defined as individuals who have an ownership interest in a company, except for stockholders of publicly traded companies, or holders of shares through a pension or mutual fund.

EMPLOYEES are defined as individuals hired to work for another person or business (the employer) for compensation and who are subject to the employer's direction as to the details of how to perform the job.

PROCESS

COLLECTING DISCLOSURE INFORMATION

ABOUT THE TOOL

UUCME uses a Qualtrics survey to collect disclosures. To access the tool, speakers/planners should follow the link on the UUCME website or the link provided by UUCME coordinators. The disclosure form can be submitted electronically by completing the survey. UUCME will also accept printing the survey, completing and submitting to UUCME via email.

In limited circumstances, UUCME may opt to use verbal or emailed definitions and questions to collect disclosure information. In this case, if UUCME decides to offer this option, the ACCME-definition of an ineligible company will be read and/or emailed along with the specific question asked of all those in control of content. Responses will be documented in the Education Plan, the Qualtrics tool, or in the activity file, per UUCME's discretion.

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(Note: in 2021, UUCME moved from a Survey Monkey tool to the Qualtrics tool. Some 2021 activities may have used Survey Monkey tool. The Survey Monkey tool will be phased out over the 2021 calendar year.)

USING THE TOOL

Send the link provided by UUCME to all those in control of content for your activity. This includes all speakers, all planners, all moderators, all panel members; anyone who will be speaking or providing education or content at your activity. Provide a deadline to complete the disclosure. As your deadline approaches, check-in with UUCME to see which disclosures are still needed; follow-up with each speaker. If you do not get a response, ask your Course Director to request the disclosure. Follow up with UUCME with any technical issues or questions.

Sample instructions might be:

Thank you for participating in our educational activity (*name of activity*) on (*date of activity*). The title or subject of your presentation is (*title/subject*). We aim to create a high-quality educational activity independent of industry influence. To offer CME credit for your part of the activity, we must disclose any relevant financial relationships to learners. Please complete this short survey regarding your financial relationships as soon as possible, but no later than (*deadline*).

[Link here](#)

If you have relationships to disclose, the survey will suggest mechanisms of mitigation we may use. Someone from our planning committee will be in touch, after you complete the survey, to discuss the best ways to mitigate the financial relationship(s).

Best practice tip: As you invite speakers/planners/moderators to participate in your activity and they accept, send them the disclosure link along with other confirmation information like their topic or travel instructions. Do not wait until just prior to your activity.

Best practice tip: UUCME collects disclosure once per year. For RSS, this is typically in the summer, at the beginning of the academic year. However, if speakers/moderators/planners are added later into your series, remember to request that additional disclosure, as soon as you know of the addition.

REVIEW DISCLOSURE RESULTS

Watch for information & updates from UUCME. If requests are made to speakers directly to complete any incomplete disclosure, follow-up with the speaker to be sure that information is completed. Follow up with any speakers who have not completed their forms.

DETERMINING RELEVANCY

When someone discloses financial relationships, UUCME will review to determine if relationships are with ACCME-defined ineligible companies and if the relationships seem possibly relevant to your

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content. If the disclosed relationships are potentially relevant to the content, relationships will be passed on to activity planners. As the content experts, activity planners may then determine if the content of the education is related to the products of an ineligible company with whom the person has a financial relationship. This question will be asked of planners at the same time mitigation mechanisms are suggested.

MITIGATING RELEVANT FINANCIAL RELATIONSHIPS

Mitigation must be appropriate to the person's role with the activity (ie. Speaker or planner). For speakers, UUCME utilizes attesting that clinical recommendations are evidence-based and free of commercial bias, promoting quality or improvements in healthcare, and presenting well-balanced, evidence-based, and unbiased content, including any therapeutic options as our primary mechanism of mitigation. For planners, UUCME utilizes peer review of planning decisions by other planning committee members without relevant financial relationships or recusal from planning decisions relevant to their relationship as our primary mechanisms of mitigation. Additional mechanisms for mitigation may be used as deemed appropriate by UUCME and/or planners and might include replacement of that person in their role in the activity, review of slides or content, limiting or regulating a person's role in the activity.

Mitigation mechanisms are discussed during planning meetings and any on-going meetings and training that we do. UUCME's documents expectations in our Expectations document and in our activity level communications with our planners. We rely on our relationship with our planners and their relationships with speakers to ensure that any content meets this expectation.

When someone discloses a financial relationship, the survey educates the person on UUCME's expectations around mitigation. After UUCME's review of financial relationships and initial determination or relevancy, UUCME will share information along with the person's financial relationship(s) including role and ineligible company with the Director (or non-conflicted person). It is the expectation of UUCME that the activity Director (or non-conflicted person) will discuss the relevant financial relationships with the speaker and together come up with a plan to mitigate. As requests are made to mitigate by UUCME, complete these as soon as possible. Understanding and confirmation of mitigation mechanisms is handled via an email reply to UUCME indicated the mechanisms chosen and implemented. Relevant financial relationships should be mitigated at least 5 days prior to the start of the activity; all relevant financial relationships must be mitigated one day before the activity or CME credit will be withheld.

DISCLOSING TO THE LEARNER

UUCME decides which method of disclosure to learners that should be used and provides the activity planners the exact language to use. UUCME receives a copy of what was provided to learners. Disclosure includes a statement that all relevant financial relationships have been mitigated.

UUCME uses several methods of disclosure to learners and selects the appropriate method for the context and type of activity. Options include:

DISCLOSURE SUMMARY TABLE. This is the most common method for courses. The Disclosure Summary Table may be part of the syllabus or handout material or may be emailed to learners prior to the activity or may appear on event websites or apps. It must be provided prior to the activity start in a manner appropriate for the targeted audience.

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The Disclosure Summary Table lists each person in control of content by name and reports their disclosure, the nature of the relationship, and the name of the ineligible company. The Disclosure Summary Table also includes those who reported nothing to disclose.

Best practice tip: Once you receive the Disclosure Summary from UUCME, email it to learners along with any last-minute instructions for your activity (parking, reminders, etc.). Keep a few physical copies of the Disclosure Summary on hand at the registration table.

DISCLOSURE SUMMARY STATEMENT. At other times, depending on what has been disclosed by the speakers/planners or the number of those in control of content, summary disclosure statements included on the CME statements page may be used. The statement may state that no one in control of content has anything to disclose or that the content does not overlap with any products of an ACCME-defined ineligible company.

Disclosure statements are most often used in RSS activities on flyers for each session that are sent to all learners by e-mail prior to the activity taking place and/or posted on the door of the session or other appropriate locations. Live courses sometimes use disclosure summary statements when no one or a few people involved in the content had relevant financial relationships. Enduring materials will also typically use a statement that is posted prior to the learner engaging with the content of the activity.

Best practice tip: Once you receive the disclosure statement from UUCME, include it on your flyer template ASAP. Please note that the disclosure statements may change week to week, if your speakers change. Be in early contact with UUCME to be sure you are using the correct statement.

BACK-UP METHOD (USED RARELY)

If, for some reason, the Disclosure Summary Table or Statement does not get sent or given to learners prior to the activities, other methods may rarely be used, as a back-up method. In less common circumstances making an announcement prior to a presentation, or inclusion of the disclosure statement on a slide in the presentation are also methods but, are not encouraged. If a verbal announcement is used as disclosure it must be well documented with the person's name, the company name, and the nature of the relationship. A dated statement from the Director or Coordinator or other UUCME appointed person that they witnessed the disclosure being made will be required. This representative then attests in writing (email is fine) that the disclosure occurred and what was disclosure (name of person, role and name of ineligible company or none). This documentation must be completed within one month of the activity. Mitigation of relevant financial relationships must be completed and documented prior to the activity start and included as part of the verbal disclosure.