## **Conflict of Interest Disclosure System**

## **Frequently Asked Questions**

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A detailed guide for using the Conflict Disclosure System (CDS) is located at: http://www.vanderbilt.edu/compliance/conflictofinterest.php

(Click the CDS User Guide link under Conflict Disclosure System (CDS) Login on the right side of the page)

## **Vanderbilt University FAQs**

## **System Access FAQs**

1. How do I access the Conflict Disclosure System (CDS)?

**ANSWER**: The CDS can be accessed at: <a href="https://webapp.mis.vanderbilt.edu/coi/">https://webapp.mis.vanderbilt.edu/coi/</a>.

2. What if Ido not know my VUNet ID and/or e-password?

**ANSWER**: Everyone who uses the Conflict Disclosure System should have a VUNet ID. If you don't know what it is, or if it has never been activated, you may activate it at the following link: <a href="http://www.vanderbilt.edu/accessvu/">http://www.vanderbilt.edu/accessvu/</a> (for additional help, contact the IT Help Desk at (615) 343-9999).

3. How do I access the CDS user guide?

ANSWER: The User Guide can be found at the following link:

<a href="http://www.vanderbilt.edu/compliance/conflictofinterest.php">http://www.vanderbilt.edu/compliance/conflictofinterest.php</a>
(Click the CDS User Guide link under Conflict Disclosure System (CDS) Login on the right side of the page)

4. Whom do I contact if I have problems accessing the Conflict Disclosure System?

**ANSWER**: You should call the Help Desk at (615) 343-9999. Questions may also be directed to the mailbox at <a href="mailto:coi@vanderbilt.edu">coi@vanderbilt.edu</a>.

5. Whom should I contact if I have questions about a specific activity that either I or my department currently engages in, to ensure we are in compliance with the policy?

**ANSWER**: Questions regarding conflicts of interest and commitment will be answered by representatives monitoring the mailbox at <a href="mailto:coi@vanderbilt.edu">coi@vanderbilt.edu</a>. Our goal is to have your questions answered within seven (7) working days.

6. If I use my browser's Back button to return to the previous page, I get a message that the page has expired. How can I go back to a previous page?

**ANSWER**: Please do not use your browser's navigation buttons to move through the disclosure. The buttons for moving through the system are provided at the bottom of each screen.

7. Why is there a save button?

**ANSWER:** Because the Conflict Disclosure System has an automatic time-out feature, it is advisable for you to save your work frequently as you proceed. The Previous and Continue buttons do perform a save function, but if you are entering a lot of text, you may want to save your work periodically (i.e., every few minutes).

#### 8. Can I print my disclosure(s)?

**ANSWER**: Yes, both Disclosers and Approvers can print the entire disclosure. Disclosures will remain in the system and you may access them at any time, however, so printing should not be necessary.

## 9. Why do the column headings appear to be clickable/sortable if we can only create one disclosure?

**ANSWER**: The system retains your disclosures from year to year. When you have several, it may be helpful to sort them.

### 10. Why don't I see a Create Disclosure button?

**ANSWER**: The CDS only allows for one Draft disclosure at a time, so if you have a disclosure in Draft status already in the system, you must complete and submit that disclosure rather than beginning a new one. If you need to create a new disclosure for whatever reason, you may delete the Draft disclosure and then use the Create Disclosure button to do so.

#### 11. What is my COIID number?

**ANSWER**: This is a system-generated number that is used primarily by the system administrators. However, once you have completed several disclosures, it may be helpful to you and your Approver to refer to them by their COIID number.

#### 12. Why does my Approver section say "Not yet selected?"

**ANSWER**: This means that your department has not been assigned a pre-selected Approver by the system, and you therefore must manually select your Approver in order to complete a disclosure. The field will be marked "Not yet selected" until you search for and select the appropriate Approver.

## 13. Is there a way for the system to automatically enter the Approver name, based upon the user's home department?

**ANSWER**: For University faculty and staff, your Approver will generally be assigned by the Office of Conflict of Interest and Commitment Management (COI Office). In some cases, your department may not have an assigned Approver. Please contact your direct supervisor to determine who should be selected as your Approver.

#### 14. What is the purpose of the Reset button?

**ANSWER**: If you wish to return the current page to its last unsaved status, you may use Reset to do so. However, text typed in text boxes will not be erased by the Reset button.

## 15. How will this disclosure tie back to my annual performance evaluation?

**ANSWER**: There is no relationship between your disclosure and annual performance evaluation for University faculty and staff.

#### 16. How do I know when I'm finished?

**ANSWER**: When you see a green message on your My Disclosures page that says "Your disclosure has been submitted," your disclosure is complete and you may log out of the CDS and close your browser.

## **Discloser FAQs**

### 1. Who must complete a disclosure in the Conflict Disclosure System?

**ANSWER**: All University faculty and staff members are required to complete a disclosure in the CDS. Student workers, including undergraduates, graduate students, and pre-doctoral students, are exempted from this requirement.

#### 2. How often do I need to complete a disclosure?

**ANSWER**: Each fiscal year (annually, between July 1 and June 30), you are required to complete a new COI disclosure. You should also complete a new disclosure if a change occurs in your circumstances during the year that may create a potential conflict of interest or commitment. It is not unusual for staff to have multiple disclosures completed during a fiscal year.

#### 3. Could (or should) I complete more than one disclosure during the fiscal year?

**ANSWER**: You should complete a new disclosure at any time in the fiscal year, or when a change occurs in your circumstances that may create a potential conflict of interest or commitment.

#### 4. Who determines whether a conflict exists?

**ANSWER**: If you and your Approver believe a potential conflict exists, please report it. A review committee will evaluate all disclosures to determine whether an actual conflict exists.

#### 5. What happens when I report that a conflict is present?

**ANSWER**: The description of the conflict is reviewed by your Approver and our Office of Conflict of Interest and Commitment Management. If further information is needed to understand the situation, they will contact you directly. They will also work with you to develop a management plan, if one is needed.

## 6. What if I have more than one conflict to report?

**ANSWER**: The Conflict Disclosure System will allow you to enter more than one conflict. After you enter information about your first conflict, return to the Disclosure Details Summary page. Select the Create Conflict Detail tab to add additional conflicts. Each conflict entered will be shown individually on your Disclosure Details Summary page.

#### 7. What does the "appearance of a conflict" mean?

**ANSWER**: If you have a situation you think might fall into this category, go ahead and report it. Neither you nor your Approver need to determine whether or not an actual conflict exists. You are simply reporting anything which might be a conflict.

#### 8. What is an Approver and what is their role?

**ANSWER**: For the University, most departments are assigned a pre-selected Approver, who is generally a division administrator and not the person you report to on a daily basis. In some cases, your department may not have an assigned Approver. Please contact your direct supervisor to determine who should be selected as your approver. The Approver reviews your disclosure each year and approves it within the Conflict Disclosure System. They are also responsible for ensuring a management plan is followed during the year, if one has been designed for you.

#### 9. How do I know if my disclosure has been approved?

**ANSWER**: Once your disclosure is approved, the Conflict Disclosure System will automatically send you an email. If a management plan is in place for you, the email will direct you to your management plan.

#### 10. Whom should I select as my Approver?

**ANSWER:** For University faculty and staff, your Approver will either be the pre-selected Approver assigned by the system, or if no Approver has been pre-assigned, you may contact your direct supervisor to determine who you should select as your Approver.

#### 11. What if I selected the wrong Approver and need to change it?

**ANSWER**: After the disclosure is submitted, you will need to contact the Approver and ask them to return the disclosure to you (within the system) to allow you to change the Approver. If the wrong Approver was selected, they will also most likely return the disclosure to you upon discovery of the error.

#### 12. What steps do I follow to change my Approver?

ANSWER: Once your disclosure has been returned to you, open the disclosure and move within the system to the Select Approver page. Enter the last name of the new Approver into the Search for Approver field. Select the Search key. The system will list all staff having the last name you entered. Select from the listing the appropriate staff member to be your Approver. Once you confirm that the staff member listed is the correct person to approve your disclosure, select the Continue key. Then proceed to select the Submit key to finish.

# 13. If I report a potential conflict and my Approver provides a management plan and approves my disclosure, what happens next?

**ANSWER**: The Office of Conflict of Interest and Commitment Management will review all reported conflicts and will notify you and your Approver if more information is necessary. In all cases, you will receive a status report, either to seek additional information or to inform you that no further action is necessary.

#### 14. Why do I continue to receive emails?

**ANSWER:** The system automatically sends emails to individuals who have an activity to complete in the disclosure process. For Disclosers, the activity may be that your disclosure has been saved, but not yet submitted and remains in Draft status. You will continue to receive the emails until you complete the required activity. If you have a disclosure in Draft status and it is not needed, please delete it. Otherwise, you will continue to receive the emails.

### 15. What happens when a disclosure is returned to me from my Approver?

**ANSWER:** You should follow the instructions in the email sent to you to determine what action is required. You should also contact your Approver if you have questions about why a disclosure was returned.

### 16. What is a management plan?

**ANSWER**: A management plan is a written plan created to protect faculty/staff members, as well as the University, from even the appearance of a conflict of interest or commitment.

#### 17. What is my role as a faculty or staff member working under a management plan?

**ANSWER:** Individuals working under a management plan should follow the management plan at all times. If at any time during their employment a change occurs in their conflict situation, it is the responsibility of the employee to inform their supervisor and the COI Office of the change by creating a new disclosure. The details about the change will determine if the management plan should be adjusted.

#### 18. Whom should I contact to answer any question that I might have about this process?

**ANSWER**: Questions regarding conflict of interest and commitment will be answered by representatives monitoring the mailbox at <a href="mailto:coi@vanderbilt.edu">coi@vanderbilt.edu</a>.

#### 19. Do I have to answer a question if I don't think it applies to me?

**ANSWER**: All questions must be answered (and all acknowledgements and the assignment checked) in order for your disclosure to be submitted. Please contact the COI Office at <a href="mailto:coi@vanderbilt.edu">coi@vanderbilt.edu</a> if you are unsure how to answer a question.

## 20. What does "private question" (as indicated above Question E on the disclosure form) mean?

**ANSWER**: A private question can be viewed by only the COI administrators (not your supervisor or Approver) and by Human Resources, if you are a staff member; or by the Provost's Office, if you are University faculty. Neither your response to the question nor any detailed information you may provide for a "Yes" answer can be viewed by your supervisor or Approver. (The question is completely omitted from view of the Approver.)

21. [University Only] Whom can I contact if I want more information before checking the Technology assignment at the bottom of the disclosure form?

**ANSWER**: You may contact the Center for Technology Transfer & Commercialization at <a href="mailto:cttc@vanderbilt.edu">cttc@vanderbilt.edu</a>.

## **Approver FAQs**

### 1. What is an Approver and what is their role?

**ANSWER**: For University faculty and staff, an Approver for a particular department will generally be a division administrator assigned by the system. The Approver reviews the disclosure each year and approves it within the Conflict Disclosure System. The Approver is also responsible for ensuring a management plan is followed during the year, if one has been designed for the employee. More specifically, an Approver:

- 1) Reviews all disclosures submitted to them.
- 2) Returns any disclosure received in error.
- 3} Reviews the information and determines if the disclosure should be approved. If the information is sufficient, he or she should approve the disclosure.
- 4) Returns a disclosure to an employee to obtain additional information about a conflict.
- 5} If a conflict requires a management plan, works with the COI Office to develop it, certify that the plan is in place, and insure it is followed during the fiscal year.
- 6} Certifies that the management plan has been implemented by clicking the checkbox at the bottom left of the Management Plan page.

#### 2. How will I know if my assigned disclosures have been approved?

**ANSWER:** Once a disclosure is approved, the Conflict Disclosure System will automatically send both you and the Discloser an email, and the disclosure will no longer appear in your My Approvals page in the Conflict Disclosure System.

# 3. How does the system notify an Approver that a disclosure requires their review and approval?

**ANSWER**: The system automatically generates an email to the Approver when a disclosure is present to approve. The Approver will continue to receive these notifications until all disclosures (pre-assigned by the system or submitted by staff who selected the person) have been approved.

#### 4. How do I approve a submitted disclosure?

**ANSWER**: The Approver should log in to the system and view My Approvals.

- A disclosure can be viewed by clicking the faculty/staff member name link corresponding to the disclosure.
- Disclosures with no reported conflicts can be approved directly from the My Approvals page by selecting the disclosure and clicking the Approve Selected Disclosures button.
- Disclosures with conflicts can be approved only from the Management Plan page, which is found on the last page of the disclosure. The Approver should review all the details of a disclosure when a conflict is reported. Once all information is reviewed and

the Approver has entered their comments in the Follow-Up and Management Action Plan sections, the Approver can approve the disclosure.

- The Office of Conflict of Interest and Commitment Management will then review the
  approved disclosure and make the final determination of the management action plan
  content. The Discloser and the Approver are then asked to review the plan for accuracy
  and all three areas work together to resolve any issues with the plan to ensure that it
  is drafted to adequately address the disclosed conflict.
- The final step for the Approver is to certify that the management plan has been implemented by clicking the checkbox at the bottom left of the Management Plan page: "Approver Only: Check this box if you agree with the management plan and can acknowledge that the plan is in place."
- 5. Should I approve a disclosure from someone that I do not know? If not, what should I do if this happens?

**ANSWER**: No, you should not approve a disclosure for someone you do not know. Please return the disclosure to the person who submitted it to you. (A "Return Selected Disclosures" button is displayed on the My Approvals page.) The system provides a field for you to add an explanation about the reason the disclosure was returned.

6. What should an Approver do when more information is needed to understand a disclosed conflict?

**ANSWER**: The Approver should return the disclosure to the person who submitted it. The system provides a field for you to add an explanation about what additional information is needed.

7. If I need to return a disclosure, will the Conflict Disclosure System alert the Discloser that their disclosure has been returned for further action?

**ANSWER**: The Discloser will receive an email alerting them that their disclosure has been returned, along with your reasons for the return. You will have an opportunity to write specific comments when you need to return a disclosure.

8. Does the status change to Resubmitted once the Discloser resubmits a returned disclosure?

ANSWER: No, the status will return to Submitted.

9. Should I be able to make changes to the management plan while a disclosure is in a Returned status waiting for more information from the Discloser?

**ANSWER**: Yes, if you wish. The disclosure cannot be submitted to the review committee until the Discloser has resubmitted the disclosure to you for final action and you have submitted it for review.

#### 10. What is a management plan?

**ANSWER**: A management plan is a written plan created to protect faculty/staff members, as well as the University, from even the appearance of a conflict of interest or commitment.

#### 11. What do I do to indicate that the management plan is in place?

**ANSWER**: The final step for the Approver is to certify that the management plan has been implemented. After the Approver receives the email from the COI Office letting him/her know the management plan content has been reviewed, the Approver should then log in to the system, click My Approvals, and select the disclosure to be certified (under My Approvals, click "Mgt Plans Awaiting Confirmation"). Once the disclosure is open, scroll to the bottom and click "View Management Plan." Scroll to the bottom of the Management Plan page and click the checkbox at the bottom left: "Approver Only: Check this box if you agree with the management plan and can acknowledge that the plan is in place."

## 12. What is my role as a supervisor when I have a staff member working under a management plan?

**ANSWER**: It is the supervisor's duty to be aware of the existence of the conflicts of their staff members and to be knowledgeable about the contents of their assigned management plans. They have the task of ensuring that the management plan is implemented in a timely fashion and followed by the staff member at all times. It is also the supervisor's duty to monitor any changes in the staff member's conflict situation and determine whether the management plan should be adjusted based on those changes.

## 13. Why do some names have check boxes next to them and some do not in the My Approvals section?

**ANSWER**: A disclosure will only have a check box if the Discloser has reported no conflicts. If there is no check box, the Discloser has reported one or more potential conflicts and you must open the disclosure to provide a management plan (or to indicate that no management plan is necessary).

#### 14. What if the conflict changes and the Discloser has a management plan?

**ANSWER:** If the conflict changes, the faculty/staff member should inform their supervisor and create a new disclosure in the system indicating the changes to the conflict. The Approver and the Office of Conflict of Interest and Commitment Management will review the new disclosure to determine if the management plan needs to be changed.

#### 15. What if the conflict is removed and the Discloser has a management plan?

**ANSWER**: If the conflict is removed, the faculty/staff member should inform their supervisor and create a new disclosure in the system. The system allows Disclosers to add comments. The Discloser should add a comment to their disclosure explaining why they no

longer have a conflict to report. The Office of Conflict of Interest and Commitment Management will review the new disclosure and the comments of the Approver to determine whether a management plan is still required.

#### 16. Whom should I contact if I have a question about a management plan?

**ANSWER**: All management plan questions should be sent to the coi@vanderbilt.edu mailbox. If you do not have access to email, please call the Office of Conflict of Interest and Commitment Management at 322-8363 or 322-2401.

#### 17. If the Discloser has a management plan to follow, how long should he/she follow it?

**ANSWER**: The management plan created should be followed at all times. If the conflict situation changes, instruct the employee to simply create a new disclosure. At that point, the new disclosure should be reviewed to determine if another plan should be put in place or if a plan is needed at all.

#### 18. Why did I receive an email telling me to review the management plan?

**ANSWER**: The Office of Conflict of Interest and Commitment Management reviews all approved disclosures and makes the final determination of the management action plan content. The Discloser and the Approver are then asked to review the plan for accuracy and all three areas work together to resolve any issues with the plan to ensure that it is drafted to adequately address the disclosed conflict.

#### 19. How do I return a disclosure, if I need to return it to the person who submitted it?

**ANSWER:** For those disclosures where no conflict was reported, the Approver can return the disclosure from the My Approvals page by selecting the disclosure and clicking the Return Selected Disclosures button at the bottom of the page. Disclosures with potential conflicts can be returned from the Management Plan page by clicking the Return Disclosures button. If a disclosure is returned, the Approver will select a reason for return and can enter additional comments about the return.

#### 20. Whom should I contact to answer any question that I might have about this process?

**ANSWER**: Questions regarding conflict of interest and commitment will be answered by representatives monitoring the mailbox at <a href="mailto:coi@vanderbilt.edu">coi@vanderbilt.edu</a>.

## **Policy General FAQs**

### 1. How do I access the current Conflict of Interest Policy?

**ANSWER**: The current policy may be accessed using the following link: <a href="http://www.vanderbilt.edu/compliance/conflictofinterest.php">http://www.vanderbilt.edu/compliance/conflictofinterest.php</a>. Click on "Conflict of Interest Policy" in the gray box to the right on the page. Or you can navigate directly to the policy at <a href="http://www.vanderbilt.edu/compliance/includes/CurrentCOIPolicy.pdf">http://www.vanderbilt.edu/compliance/includes/CurrentCOIPolicy.pdf</a>.

### 2. What is the effective date of the policy?

**ANSWER**: The most recent policy was approved on January 17, 2014. The policy is periodically updated.

#### 3. What is a conflict?

**ANSWER**: A conflict is defined in our policy. Please use the following link to view the policy and read the definition provided:

http://www.vanderbilt.edu/compliance/includes/CurrentCOIPolicy.pdf.

### 4. Whom should I contact if I have questions about the policy?

**ANSWER**: Questions regarding conflict of interest and commitment will be answered by representatives monitoring the mailbox at coi@vanderbilt.edu.

#### 5. What educational resources are available to me as an employee to understand the policy?

**ANSWER**: Faculty/staff can always send questions to the <u>coi@vanderbilt.edu</u> mailbox. Additional information is available at the following link:

http://www.vanderbilt.edu/compliance/conflictofinterest.php.

## **Vanderbilt University Medical Center FAQs**

## **System Access FAQs**

1. How do I access the Conflict Disclosure System (CDS)?

**ANSWER**: The CDS can be accessed at: <a href="https://webapp.mis.vanderbilt.edu/coi/">https://webapp.mis.vanderbilt.edu/coi/</a>.

2. What if Ido not know my VUNet ID and/or e-password?

**ANSWER**: Everyone who uses the Conflict Disclosure System should have a VUNet ID. If you don't know what it is, or if it has never been activated, you may activate it at the following link: <a href="http://www.vanderbilt.edu/accessvu/">http://www.vanderbilt.edu/accessvu/</a> (for additional help, contact the IT Help Desk at (615) 343-HELP (4357)).

3. How do I access the CDS user guide?

ANSWER: The User Guide can be found at the following link:

<a href="http://www.vanderbilt.edu/compliance/conflictofinterest.php">http://www.vanderbilt.edu/compliance/conflictofinterest.php</a>
(Click the CDS User Guide link under Conflict Disclosure System (CDS) Login on the right side of the page)

4. Whom do I contact if I have problems accessing the Conflict Disclosure System?

**ANSWER**: You should call the Help Desk at (615) 343-HELP (4357). Questions may also be directed to the mailbox at <a href="mailto:coi.vumc@vanderbilt.edu">coi.vumc@vanderbilt.edu</a>.

5. Whom should I contact if I have questions about a specific activity that either I or my department currently engages in, to ensure we are in compliance with the policy?

**ANSWER**: Questions regarding conflicts of interest and commitment will be answered by representatives monitoring the mailbox at <a href="mailto:coi.vumc@vanderbilt.edu">coi.vumc@vanderbilt.edu</a>. Our goal is to have your questions answered within seven (7) working days.

6. If I use my browser's Back button to return to the previous page, I get a message that the page has expired. How can I go back to a previous page?

**ANSWER**: Please do not use your browser's navigation buttons to move through the disclosure. The buttons for moving through the system are provided at the bottom of each screen.

7. Why is there a save button?

**ANSWER:** Because the Conflict Disclosure System has an automatic time-out feature, it is advisable for you to save your work frequently as you proceed. The Previous and Continue buttons do perform a save function, but if you are entering a lot of text, you may want to save your work periodically (i.e., every few minutes).

#### 8. Can I print my disclosure(s)?

**ANSWER**: Yes, both Disclosers and Approvers can print the entire disclosure. Disclosures will remain in the system and you may access them at any time, however, so printing should not be necessary.

## 9. Why do the column headings appear to be clickable/sortable if we can only create one disclosure?

**ANSWER**: The system retains your disclosures from year to year. When you have several, it may be helpful to sort them.

### 10. Why don't I see a Create Disclosure button?

**ANSWER**: The CDS only allows for one Draft disclosure at a time, so if you have a disclosure in Draft status already in the system, you must complete and submit that disclosure rather than beginning a new one. If you need to create a new disclosure for whatever reason, you may delete the Draft disclosure and then use the Create Disclosure button to do so.

#### 11. What is my COIID number?

**ANSWER**: This is a system-generated number that is used primarily by the system administrators. However, once you have completed several disclosures, it may be helpful to you and your Approver to refer to them by their COIID number.

#### 12. Why does my Approver section say "Not yet selected?"

**ANSWER**: This means that your department has not been assigned a pre-selected Approver by the system, and you therefore must manually select your Approver in order to complete a disclosure. The field will be marked "Not yet selected" until you search for and select the appropriate Approver.

## 13. Is there a way for the system to automatically enter the Approver name, based upon the user's home department?

**ANSWER**: For Medical Center staff, you must select the appropriate person. This should be the person who completes your annual performance evaluation or your immediate supervisor.

#### 14. What is the purpose of the Reset button?

**ANSWER**: If you wish to return the current page to its last unsaved status, you may use Reset to do so. However, text typed in text boxes will not be erased by the Reset button.

## 15. How will this disclosure tie back to my annual performance evaluation?

**ANSWER**: For Medical Center staff, your compliance with COI will automatically be reflected in Vanderbilt's Compliance Portal.

#### 16. How do I know when I'm finished?

**ANSWER**: When you see a green message on your My Disclosures page that says "Your disclosure has been submitted," your disclosure is complete and you may log out of the CDS and close your browser.

## **Discloser FAQs**

### 1. Who must complete a disclosure in the Conflict Disclosure System?

**ANSWER**: All VUMC staff are required to complete a disclosure in the CDS. VUMC faculty (who have their own system for reporting conflicts), undergraduates, graduate students, and pre-doctoral students are exempted from this requirement.

### 2. How often do I need to complete a disclosure?

**ANSWER**: Each fiscal year (annually, between July 1 and June 30), you are required to complete a new COI disclosure. You should also complete a new disclosure if a change occurs in your circumstances during the year that may create a potential conflict of interest or commitment. It is not unusual for staff to have multiple disclosures completed during a fiscal year.

## 3. [Medical Center Staff Only] If I complete a disclosure each year as part of my annual performance evaluation process, have I met the reporting requirements?

**ANSWER**: Yes, you are required to complete a new disclosure each fiscal year. Once your Approver has approved your disclosure for the fiscal year in the Conflict Disclosure System, the annual requirement is met. Compliance with the disclosure requirement is reflected in your performance evaluation on the "Policy & Safety Compliance" page.

### 4. Could (or should) I complete more than one disclosure during the fiscal year?

**ANSWER**: You should complete a new disclosure at any time in the fiscal year, or when a change occurs in your circumstances that may create a potential conflict of interest or commitment.

#### 5. Who determines whether a conflict exists?

**ANSWER**: If you and your Approver believe a potential conflict exists, please report it. A review committee will evaluate all disclosures to determine whether an actual conflict exists.

### 6. What happens when I report that a conflict is present?

**ANSWER**: The description of the conflict is reviewed by your Approver and the COI Director. If further information is needed to understand the situation, you will be contacted directly. They will also work with you to develop a management plan, if one is needed.

#### 7. What if I have more than one conflict to report?

**ANSWER**: The Conflict Disclosure System will allow you to enter more than one conflict. After you enter information about your first conflict, return to the Disclosure Details

Summary page. Select the Create Conflict Detail tab to add additional conflicts. Each conflict entered will be shown individually on your Disclosure Details Summary page.

## 8. What does the "appearance of a conflict" mean?

**ANSWER**: If you have a situation you think might fall into this category, go ahead and report it. Neither you nor your Approver need to determine whether or not an actual conflict exists. You are simply reporting anything which might be a conflict.

#### 9. What is an Approver and what is their role?

**ANSWER**: For VUMC, an Approver is typically the person you report to on a daily basis. It may be your supervisor or someone that reviews and approves your pay. To determine the correct Approver to select, please talk with your supervisor. The Approver reviews your disclosure each year and approves it within the Conflict Disclosure System. They are also responsible for ensuring a management plan is followed during the year, if one has been designed for you.

#### 10. How do I know if my disclosure has been approved?

**ANSWER**: Once your disclosure is approved, the Conflict Disclosure System will automatically send you an email. If a management plan is in place for you, the email will direct you to your management plan.

#### 11. Whom should I select as my Approver?

**ANSWER:** For MC staff, your Approver is typically the person you report to on a daily basis. It may be your supervisor or someone who reviews and approves your pay. To determine the correct Approver to select, please talk with your supervisor.

#### 12. What if I selected the wrong Approver and need to change it?

**ANSWER**: After the disclosure is submitted, you will need to contact the Approver and ask them to return the disclosure to you (within the system) to allow you to change the Approver. If the wrong Approver was selected, they will also most likely return the disclosure to you upon discovery of the error.

#### 13. What steps do I follow to change my Approver?

**ANSWER**: Once your disclosure has been returned to you, open the disclosure and move within the system to the Select Approver page. Enter the last name of the new Approver into the Search for Approver field. Select the Search key. The system will list all staff having the last name you entered. Select from the listing the appropriate staff member to be your Approver. Once you confirm that the staff member listed is the correct person to approve your disclosure, select the Continue key. Then proceed to select the Submit key to finish.

## 14. If I report a potential conflict and my Approver provides a management plan and approves my disclosure, what happens next?

**ANSWER**: The COI Director will review all reported conflicts and will notify you and your Approver if more information is necessary. In all cases, you will receive a status report, either to seek additional information or to inform you that no further action is necessary.

#### 15. Why do I continue to receive emails?

**ANSWER:** The system automatically sends emails to individuals who have an activity to complete in the disclosure process. For Disclosers, the activity may be that your disclosure has been saved, but not yet submitted and remains in Draft status. You will continue to receive the emails until you complete the required activity. If you have a disclosure in Draft status and it is not needed, please delete it. Otherwise, you will continue to receive the emails.

### 16. What happens when a disclosure is returned to me from my Approver?

**ANSWER:** You should follow the instructions in the email sent to you to determine what action is required. You should also contact your Approver if you have questions about why a disclosure was returned.

#### 17. What is a management plan?

**ANSWER**: A management plan is a written plan created to protect faculty/staff members, as well as the University, from even the appearance of a conflict of interest or commitment.

#### 18. What is my role as a faculty or staff member working under a management plan?

**ANSWER:** Individuals working under a management plan should follow the management plan at all times. If at any time during their employment a change occurs in their conflict situation, it is the responsibility of the employee to inform their supervisor and the COI Office of the change by creating a new disclosure. The details about the change will determine if the management plan should be adjusted.

#### 19. Whom should I contact to answer any question that I might have about this process?

**ANSWER**: Questions regarding conflict of interest and commitment will be answered by representatives monitoring the mailbox at <a href="mailto:coi.vumc@vanderbilt.edu">coi.vumc@vanderbilt.edu</a>.

#### 20. Do I have to answer a question if I don't think it applies to me?

**ANSWER**: All questions must be answered (and all acknowledgements and the assignment checked) in order for your disclosure to be submitted. Please contact the COI Office at <a href="mailto:coi.vumc@vanderbilt.edu">coi.vumc@vanderbilt.edu</a> if you are unsure how to answer a question.

## 21. What does "private question" (as indicated above Question E on the disclosure form) mean?

**ANSWER**: A private question can be viewed by only the COI administrators (not your supervisor or Approver) and by Human Resources, if you are a staff member; or by the Graduate Medical Education Office, if you are Housestaff. Neither your response to the question nor any detailed information you may provide for a "Yes" answer can be viewed by your supervisor or Approver. (The question is completely omitted from view of the Approver.)

## **Approver FAQs**

### 1. What is an Approver and what is their role?

**ANSWER**: For the MC, an Approver is typically the person to whom an employee reports on a daily basis. It may be their supervisor or someone that reviews and approves their pay. The Approver reviews the disclosure each year and approves it within the Conflict Disclosure System. The Approver is also responsible for ensuring a management plan is followed during the year, if one has been designed for the employee. More specifically, an Approver:

- 1) Reviews all disclosures submitted to them.
- Returns any disclosure received in error.
- 3} Reviews the information and determines if the disclosure should be approved. If the information is sufficient, he or she should approve the disclosure.
- 4) Returns a disclosure to an employee to obtain additional information about a conflict.
- 5} If a conflict requires a management plan, works with the COI Office to develop it, certify that the plan is in place, and insure it is followed during the fiscal year.
- 6) Certifies that the management plan has been implemented by clicking the checkbox at the bottom left of the Management Plan page.

## 2. How will I know if my assigned disclosures have been approved?

**ANSWER:** Once a disclosure is approved, the Conflict Disclosure System will automatically send both you and the Discloser an email, and the disclosure will no longer appear in your My Approvals page in the Conflict Disclosure System.

# 3. How does the system notify an Approver that a disclosure requires their review and approval?

**ANSWER**: The system automatically generates an email to the Approver when a disclosure is present to approve. The Approver will continue to receive these notifications until all disclosures (pre-assigned by the system or submitted by staff who selected the person) have been approved.

#### 4. How do I approve a submitted disclosure?

**ANSWER**: The Approver should log in to the system and view My Approvals.

- A disclosure can be viewed by clicking the faculty/staff member name link corresponding to the disclosure.
- Disclosures with no reported conflicts can be approved directly from the My Approvals page by selecting the disclosure and clicking the Approve Selected Disclosures button.
- Disclosures with conflicts can be approved only from the Management Plan page, which is found on the last page of the disclosure. The Approver should review all the details of a disclosure when a conflict is reported. Once all information is reviewed and

the Approver has entered their comments in the Follow-Up and Management Action Plan sections, the Approver can approve the disclosure.

- The Office of Conflict of Interest and Commitment Management will then review the
  approved disclosure and make the final determination of the management action plan
  content. The Discloser and the Approver are then asked to review the plan for accuracy
  and all three areas work together to resolve any issues with the plan to ensure that it
  is drafted to adequately address the disclosed conflict.
- The final step for the Approver is to certify that the management plan has been implemented by clicking the checkbox at the bottom left of the Management Plan page: "Approver Only: Check this box if you agree with the management plan and can acknowledge that the plan is in place."
- 5. Should I approve a disclosure from someone that I do not know? If not, what should I do if this happens?

**ANSWER**: No, you should not approve a disclosure for someone you do not know. Please return the disclosure to the person who submitted it to you. (A "Return Selected Disclosures" button is displayed on the My Approvals page.) The system provides a field for you to add an explanation about the reason the disclosure was returned.

6. What should an Approver do when more information is needed to understand a disclosed conflict?

**ANSWER**: The Approver should return the disclosure to the person who submitted it. The system provides a field for you to add an explanation about what additional information is needed.

7. If I need to return a disclosure, will the Conflict Disclosure System alert the Discloser that their disclosure has been returned for further action?

**ANSWER**: The Discloser will receive an email alerting them that their disclosure has been returned, along with your reasons for the return. You will have an opportunity to write specific comments when you need to return a disclosure.

8. Does the status change to Resubmitted once the Discloser resubmits a returned disclosure?

ANSWER: No, the status will return to Submitted.

9. Should I be able to make changes to the management plan while a disclosure is in a Returned status waiting for more information from the Discloser?

**ANSWER**: Yes, if you wish. The disclosure cannot be submitted to the review committee until the Discloser has resubmitted the disclosure to you for final action and you have submitted it for review.

#### 10. What is a management plan?

**ANSWER**: A management plan is a written plan created to protect faculty/staff members, as well as the University, from even the appearance of a conflict of interest or commitment.

#### 11. What do I do to indicate that the management plan is in place?

ANSWER: The final step for the Approver is to certify that the management plan has been implemented. After the Approver receives the email from the COI Office letting him/her know the management plan content has been reviewed, the Approver should then log in to the system, click My Approvals, and select the disclosure to be certified (under My Approvals, click "Mgt Plans Awaiting Confirmation"). Once the disclosure is open, scroll to the bottom and click "View Management Plan." Scroll to the bottom of the Management Plan page and click the checkbox at the bottom left: "Approver Only: Check this box if you agree with the management plan and can acknowledge that the plan is in place."

## 12. What is my role as a supervisor when I have a staff member working under a management plan?

**ANSWER**: It is the supervisor's duty to be aware of the existence of the conflicts of their staff members and to be knowledgeable about the contents of their assigned management plans. They have the task of ensuring that the management plan is implemented in a timely fashion and followed by the staff member at all times. It is also the supervisor's duty to monitor any changes in the staff member's conflict situation and determine whether the management plan should be adjusted based on those changes.

## 13. Why do some names have check boxes next to them and some do not in the My Approvals section?

**ANSWER**: A disclosure will only have a check box if the Discloser has reported no conflicts. If there is no check box, the Discloser has reported one or more potential conflicts and you must open the disclosure to provide a management plan (or to indicate that no management plan is necessary).

#### 14. What if the conflict changes and the Discloser has a management plan?

**ANSWER:** If the conflict changes, the faculty/staff member should inform their supervisor and create a new disclosure in the system indicating the changes to the conflict. The Approver and the Office of Conflict of Interest and Commitment Management will review the new disclosure to determine if the management plan needs to be changed.

#### 15. What if the conflict is removed and the Discloser has a management plan?

**ANSWER**: If the conflict is removed, the faculty/staff member should inform their supervisor and create a new disclosure in the system. The system allows Disclosers to add comments. The Discloser should add a comment to their disclosure explaining why they no

longer have a conflict to report. The Office of Conflict of Interest and Commitment Management will review the new disclosure and the comments of the Approver to determine whether a management plan is still required.

#### 16. Whom should I contact if I have a question about a management plan?

**ANSWER**: All management plan questions should be sent to the <a href="mailto:coi.vumc@vanderbilt.edu">coi.vumc@vanderbilt.edu</a> mailbox. If you do not have access to email, please call the COI Director at 875-7593.

#### 17. If the Discloser has a management plan to follow, how long should he/she follow it?

**ANSWER**: The management plan created should be followed at all times. If the conflict situation changes, instruct the employee to simply create a new disclosure. At that point, the new disclosure should be reviewed to determine if another plan should be put in place or if a plan is needed at all.

#### 18. Why did I receive an email telling me to review the management plan?

**ANSWER**: The Office of Conflict of Interest and Commitment Management reviews all approved disclosures and makes the final determination of the management action plan content. The Discloser and the Approver are then asked to review the plan for accuracy and all three areas work together to resolve any issues with the plan to ensure that it is drafted to adequately address the disclosed conflict.

#### 19. How do I return a disclosure, if I need to return it to the person who submitted it?

**ANSWER:** For those disclosures where no conflict was reported, the Approver can return the disclosure from the My Approvals page by selecting the disclosure and clicking the Return Selected Disclosures button at the bottom of the page. Disclosures with potential conflicts can be returned from the Management Plan page by clicking the Return Disclosures button. If a disclosure is returned, the Approver will select a reason for return and can enter additional comments about the return.

## 20. Whom should I contact to answer any question that I might have about this process?

**ANSWER**: Questions regarding conflict of interest and commitment will be answered by representatives monitoring the mailbox at <a href="mailto:coi.vumc@vanderbilt.edu">coi.vumc@vanderbilt.edu</a>.

## **Policy General FAQs**

### 1. How do I access the current Conflict of Interest Policy?

**ANSWER**: The current policy may be accessed using the following link: <a href="http://www.vanderbilt.edu/compliance/conflictofinterest.php">http://www.vanderbilt.edu/compliance/conflictofinterest.php</a>. Click on "Conflict of Interest Policy" in the gray box to the right on the page. Or you can navigate directly to the policy at <a href="http://www.vanderbilt.edu/compliance/includes/CurrentCOIPolicy.pdf">http://www.vanderbilt.edu/compliance/includes/CurrentCOIPolicy.pdf</a>.

#### 2. What is the effective date of the policy?

**ANSWER**: The most recent policy was approved on January 17, 2014. The policy is periodically updated.

#### 3. What is a conflict?

**ANSWER**: A conflict is defined in our policy. Please use the following link to view the policy and read the definition provided:

http://www.vanderbilt.edu/compliance/includes/CurrentCOIPolicy.pdf.

#### 4. Whom should I contact if I have questions about the policy?

**ANSWER**: Questions regarding conflict of interest and commitment will be answered by representatives monitoring the mailbox at <a href="mailto:coi.vumc@vanderbilt.edu">coi.vumc@vanderbilt.edu</a>.

#### 5. What educational resources are available to me as an employee to understand the policy?

**ANSWER**: Faculty/staff can always send questions to the <a href="mailto:coi.vumc@vanderbilt.edu">coi.vumc@vanderbilt.edu</a> mailbox. Additional information is available at the following link:

http://www.vanderbilt.edu/compliance/conflictofinterest.php.

# FAQs Related to Gifts, Healthcare-Sponsored Activities, and Educational Events

See <a href="http://www.vanderbilt.edu/compliance/includes/CurrentCOIPolicy.pdf">http://www.vanderbilt.edu/compliance/includes/CurrentCOIPolicy.pdf</a> for the current Conflict of Interest and Commitment Policy and <a href="https://medapps.mc.vanderbilt.edu/COI/docs/COI">https://medapps.mc.vanderbilt.edu/COI/docs/COI</a> Industry Policy.pdf for the Policy on Conflicts of Interest and Interactions between the Health Care Industry and Personnel of the Vanderbilt University Medical Center and its Affiliated Entities.

#### 1. Healthcare Vendors at Regularly Scheduled Conferences

A. Since healthcare vendors are not allowed to sponsor/provide food for regularly scheduled departmental meetings/conferences, is it possible for the healthcare representatives to meet with the physicians a few minutes prior to each event as a concession to them not being allowed to sponsor the event?

**ANSWER:** In regards to the questions about whether healthcare vendor reps can be on the premises of regularly scheduled conferences and have a set time to meet with the physicians prior to the event, this activity would be not be allowed under the Conflict of Interest policy. The intent of the policy is to remove the marketing intent from these events and keep them wholly educational in nature. Having a set time for healthcare industry reps to make their pitch to the physicians prior to these conferences would negate that intent.

#### B. May vendors attend educational events at all?

**ANSWER**: No. If the event is off campus and exhibit tables are set up, the vendor representative may man the table, but may not enter the presentation area.

#### 2. Medical Device/Pharmaceutical Vendor Providing Education

A. A pharmaceutical/medical device company is offering a program to provide further education on a product already in use in the Medical Center. The program includes a day of education and lectures on this product, as well as a first-hand look at how the product is made. The company would pay for the travel expenses and the meal. Under the Conflict of Interest policy, is it permissible to attend this program?

**ANSWER**: This event seems to be intended more for marketing and would, therefore, not be endorsable. The policy is written to capture those products that would necessitate an in-service to make sure that everyone is well trained on how to use the product. It is within the policy for the company to provide financial support to meet the training needs, but only if specified in the procurement contract. This product appears to be in use already in multiple locations throughout the hospital, so there is uncertainty of the need for an inservice. If this product is already being used properly, there is no reason to attend this program.

B. A pharmaceutical/medical device vendor is hosting an educational roundtable to discuss a type of therapy currently being provided at the Medical Center. This discussion is off campus and dinner will be provided. There will be a lecture, some education on the science behind the therapy and some hands-on training. Under the Conflict of Interest policy, is it permissible to attend this event?

**ANSWER**: The policy states that "VUMC personnel may not accept meals or other hospitality funded directly by the Healthcare Industry, whether on or off campus." It goes on to say that, "In certain instances, ...meals may be offered by the Healthcare Industry related to necessary education regarding equipment, products, or other medical devices purchased previously by VUMC. Generally, these activities are foreseeable and should be addressed by specific language in the purchasing contract."

It appears as though this type of therapy has been used in the Medical Center for a while and that the staff are already trained on how to administer the therapy. If this sort of follow-up training wasn't discussed in the current purchasing agreement with the vendor, then it probably isn't endorsable for VUMC staff to attend this dinner, under the policy.

## 3. National Organizations Holding Conferences on the Vanderbilt Campus:

Each year, institutions that have staff at meetings of a national professional organization rotate hosting the annual meeting on their own campus, and this year is Vanderbilt's turn to host. Typically, healthcare industry vendors sponsor certain sessions by providing refreshments, lunch, etc. The local branch of the organization could handle the receipt of donations and funds from industry. Is this type of sponsorship allowed, given that this is not a Vanderbilt event, but rather an event of a national organization?

ANSWER: The policy does not deal directly with how national organizations holding events on Vanderbilt's campus should deal with healthcare vendors. It does state that "promotional items which incorporate or display a product or company logo of a Health Care Industry entity must not be used or displayed on the VUMC campus. This prohibition shall include exhibitions by industry representatives at, or adjacent to, certified continuing education activities." Therefore, the national organization should inform their vendor-sponsors of Vanderbilt's policy against the display or use of promotional items on its campus.

#### 4. Gifts

A. Is it allowable under the policy to accept vendor handouts (pens, water bottles, etc.) at a convention?

**ANSWER**: It is allowable to take copies of educational materials but no gifts (pens, water bottles, etc.). Approved vendor fairs would be those sanctioned by Vanderbilt for the purpose of better business planning. For example, there is an annual catering vendor fair during which employees can visit booths from various vendors which allows for awareness of new business and assessment of appropriate caterers for planning functions.

B. Is it permissible to accept healthcare vendor items (pens, notepads, etc.) which are out of sight from patients' view?

**ANSWER**: Acceptance of these items is not permitted. This applies to all faculty and staff, including those who work in administrative areas as opposed to patient care areas.

C. Article II, C of the policy states: "NO GIFTS, of any amount, may be accepted by individuals from . . . Health Care Industry." Does this mean that staff are not allowed to attend a dinner sponsored by a rep whose talk is related to a particular drug?

ANSWER: Correct.

D. The following paragraph in Article II, C of the policy states that "Individuals may, however, accept gifts...no greater in value than \$300 per year..." Can you please clarify this?

**ANSWER**: This paragraph goes on to say, "provided that the source is not a Health Care Industry entity or its agent as noted above and such amenities are not otherwise extravagant under the circumstances." The policy prohibits gifts from Healthcare Industry vendors, not from all vendors.

E. What is the process to request monies to support events?

**ANSWER**: Funds may still be donated by industry to support education but must be received as gifts through the VU Development office. If requests are for CME-certified activities, the Division of CME must be made aware of the requests, and funding must be sent to the Division of CME for processing. In addition, a Letter of Agreement is required for each grant received, whether in support of a CME-certified activity or a non-CME certified event.

F. What percentage will DAR take for processing gifts?

**ANSWER:** DAR does not take a percentage for processing gifts.

G. May industry representatives attend patient reunions? If so, may they provide giveaways to patients if Vanderbilt staff promise not take any for themselves?

**ANSWER**: No, industry representatives may not attend patient reunions. If a vendor wants to support these types of events, they may give an unrestricted gift to the department through the Development Office.

H. A healthcare organization is organizing a bi-annual conference in which multiple vendors are present to discuss the current services they provide or could potentially provide to VUMC. The organizing company would pay the expenses for the Vanderbilt employee to attend. This conference is funded by the pharmaceutical industry to support the actual operation.

It has been beneficial to attend this conference in the past as it equips us in our preparation for purchase of equipment and medications and allows great networking opportunities. Is attendance endorsed under the policy?

ANSWER: The policy states that "VUMC personnel may not accept or use personal gifts from Healthcare Industry representatives, regardless of the nature or value of the gift." It goes on to say that, in certain instances, travel expenses or meals may be offered by the Healthcare Industry related to necessary education regarding equipment, products, or other medical devices purchased **previously** by VUMC, in which case the payments should be addressed in the procurement contract with that particular vendor......Under no circumstance may VUMC personnel accept offers from the Health Care Industry to pay for travel, meals, or other expenses which are related to procurement activities by VUMC and/or VUMC personnel."

Having the healthcare organization pay for the personal expenses of attending the Conference would be considered a gift under the policy, as these expenses are not related to education on previously purchased equipment. The policy does not provide for acceptance of personal expenses from the healthcare industry for the purpose of procurement activities. If these vendor fairs are important to the Vanderbilt employee's education about potential hospital purchases, that employee's department should pay for the expenses of attending the conference.

#### 5. <u>Conference Presentations</u>

A. Is it allowable under the policy for a conference sponsor to pay for an attendee's registration if that attendee is presenting at the conference?

**ANSWER**: That is allowable as long as (1) the content of the session is the work of the presenter, (2) slides are not used to promote the vendor sponsor's product in any way and (3) the vendor has not approved the material presented.

#### B. Can staff receive educational funding for conferences from vendors?

**ANSWER**: Individual staff may not directly receive educational funding. Funding may be accepted by the leadership of the operational unit provided that the provision is free from any actual or perceived conflict of interest. This funding is viewed not as a gift, but as revenue to the department. Industry may not earmark contributions to fund specific recipients or to support specific expenses. The funds must be provided to the department or the sponsoring professional organization rather than directly to the individual. The personnel must be selected according to clear criteria. The department must determine that the conference or training has educational merit. The recipient of the funds must not be subject to any implicit or explicit quid pro quo.

#### 6. Peer Inquiries

Is it allowable to share vendor and product information with peer institutes through phone calls, list serves, etc.?

**ANSWER**: If staff receive questions about whether their area uses a particular company or product, they can answer and give information on their satisfaction, but should not be marketing on behalf of the company or give the impression that Vanderbilt is endorsing any company/product.

#### 7. Vendor-Provided Meals

A. Is it okay for a vendor to provide lunch for a go-live celebration and for training if there is no purchase involved?

**ANSWER:** Health Care Industry vendors should not be providing food for training events, unless specified in the purchasing agreement. For non-healthcare vendors, please contact the Office of Conflict of Interest and Commitment Management to determine whether the lunch or refreshments are allowable.

B. If a rep is providing education on a new piece of equipment, are they allowed to provide candy/food during the training?

**ANSWER**: If a rep is to provide food during training regarding equipment purchased by VUMC, this should be delineated by language in the purchasing contract specifying the party to be responsible for all training expenses, timing and location of training, and related items such as food.

C. May vendors take physicians and residents to dinner?

**ANSWER:** No. These types of gifts are strictly prohibited under the policy.

#### 8. Vendor Logos

A. Are we allowed to use educational material with a company logo?

**ANSWER:** If the branded materials are intended to promote safe and appropriate use of medication or a medical device that has been clinically judged to be the best product for the care of an individual patient, the materials are permissible.

B. Is it allowable to wear any clothing, uniform or item that displays the name of a non-Vanderbilt health care service, product or logo?

**ANSWER**: VUMC personnel should not wear non-Vanderbilt logos.

#### C. Outside of permitted educational materials, are vendor logos allowed?

**ANSWER**: No. Promotional items which incorporate or display a product or company logo of a health care industry entity must not be used or displayed on Vanderbilt's campus.

#### D. May staff accept/use giveaways with vendor logos?

**ANSWER:** No. Giveaways from vendors would be viewed as gifts under the policy and should not be accepted.

### E. Are logos for groups such as "Donate Life" allowed on badge pulls?

**ANSWER**: The policy prohibits VU personnel wearing or displaying anything with the name of a non-Vanderbilt health care service, health care product or company logo. Logos from non-profit and/or professional organizations which promote health in general or promote research, prevention, treatment and/or education in a specific disease or health area are permitted under the policy. If Donate Life falls into the latter group, use of its logo is prohibited.

### 9. Continuing Education

Some companies provide free medical education. Is this allowed?

**ANSWER**: VUMC personnel cannot receive compensation for participating as a learner in education sponsored by the Health Care Industry. If the education (e.g., web site training) is offered to anyone at no charge, then there is no prohibition against VUMC personnel utilizing such a resource.

#### 10. Tax-Exempt Payments

Under the policy, how will the service of faculty members on boards of tax-exempt organizations be treated? What if payments are made to the faculty member or his/her department from the organization? What if the faculty member makes funding decisions for this tax-exempt organization?

**ANSWER**: Service by faculty members on boards of tax-exempt organizations should be treated as consulting (under a written agreement between the entity and the faculty member), especially if there are any payments by the organization. If there is payment of travel and lodging expenses related to attending meetings, these could be paid directly by the organization or reimbursed to the faculty. Payments of any honoraria should be specified under the contracting agreement to be paid to the faculty member. Alternately, the faculty member could designate that the company would gift any potential honoraria to the University through the Development and Alumni Relations Office. If the faculty consultant reviews grant applications or otherwise can influence allocation of the foundations funds, recusal for any discussion involving Vanderbilt or a VU faculty member would be appropriate.

#### 11. Exhibits

#### A. Should exhibit fees be sent to DAR?

**ANSWER**: No. Exhibit fees represent an exchange of goods; i.e., they are paid directly to a department or division to purchase space at events held off-campus.

#### B. Are exhibits allowed at educational events?

**ANSWER**: Exhibits are NOT allowed at on-campus events, but ARE permitted at off-campus events.

C. I understand that the policy allows exhibits off-campus only, but what is meant by "off campus?"

**ANSWER**: "Off Campus" would be property that is not leased or owned by Vanderbilt University. For example:

- 100 Oaks Mall = on campus
- Student Life Center = on campus
- Peabody Campus = on campus
- University Club = on campus
- Marriott at Vanderbilt = off campus
- D. Is it possible to allow different levels of exhibit support at educational events? For example, Platinum level exhibitors will be given table space next to the meeting room and will receive full page acknowledgment in the course syllabus, while Silver level exhibitors will be given space farthest away from the meeting room and receive no acknowledgment in the course syllabus.

**ANSWER**: No, as this could be construed as preferential treatment. The space and acknowledgments provided should be as uniform as possible. The course syllabus or program should acknowledge all of the supporters in a group listing, i.e., "Thanks to Company A, Company B, Company C, etc. for their generous support of this program...."

#### E. What kinds of materials may be distributed by exhibitors?

**ANSWER**: Educational materials may be distributed at exhibit tables. It is best if the materials do not contain logos; however, if the logo cannot be easily removed, the logo may remain. Promotional items, giveaways, or any sorts of gifts devoid of educational purpose MAY NOT be distributed.

#### 12. COI Vendor List

#### A. What is the COI vendor list and where do I find it online?

**ANSWER**: The vendor list is a listing of businesses that are considered to be Health Care Industry and currently doing business with Vanderbilt. These businesses (along with all other vendors in the healthcare industry) would be prohibited from providing "gifts" directly to an individual. The list may be found online at <a href="http://vanderbilt.edu/compliance/vendors.php">http://vanderbilt.edu/compliance/vendors.php</a>.

#### B. Is the list of suppliers on the COI vendor list all inclusive?

**ANSWER:** No, this list is not all-inclusive. Gifts should not be accepted from the healthcare industry. If you have a question about whether a vendor is considered "healthcare," you may direct your questions to the COI inbox at <a href="mailto:coi@vanderbilt.edu">coi@vanderbilt.edu</a> or <a href="mailto:coi.vumc@vanderbilt.edu">coi.vumc@vanderbilt.edu</a>, as applicable.

## C. Some suppliers on the list have several divisions; does this mean all divisions are restricted or just the medical divisions?

**ANSWER**: Businesses are considered to be one entity; therefore, if there is a division of the business that is a Health Care vendor, all divisions of the business should fall under the COI Policy.

#### 13. Implementation

#### A. Whose responsibility is it to make a visiting speaker aware of the COI policy?

**ANSWER**: It is the responsibility of whoever is coordinating the program involving that speaker. Faculty members should sponsor any on-campus speakers.

### B. If a violation is observed, who should be notified?

**ANSWER**: If the person in violation of the policy is a Vanderbilt faculty/staff member, there is always the option of reporting it to your supervisor or on up the chain of command, if you feel comfortable doing so. If you do not, a message can always be sent to the <a href="mailto:coi@vanderbilt.edu">coi@vanderbilt.edu</a> or <a href="mailto:coi.vumc@vanderbilt.edu">coi.vumc@vanderbilt.edu</a> mailbox, as applicable, explaining the situation. If you prefer to remain anonymous, an anonymous, confidential, independently-run hotline is available to report compliance concerns and complaints. Reports can be made online at <a href="www.vanderbiltcompliancehotline.ethicspoint.com">www.vanderbiltcompliancehotline.ethicspoint.com</a> for VU or <a href="https://www.tnwgrc.com/Vanderbilt/">https://www.tnwgrc.com/Vanderbilt/</a> for VUMC, or by toll-free call to 844-814-5935 for VU or 866-783-2287 for VUMC. If the person in violation of the policy is a vendor, please contact Michael O'Neal (pharmaceuticals) or David Bearden (devices).

#### 14. Gift Processing

## A. Will all gift funds remain in DAR for allocation, or will funds be distributed to respective departments?

**ANSWER**: The gift processing office routinely receives checks and other documentation either through campus mail or by hand delivery. Once received, the check is immediately deposited and routed within 2-3 business days (or less) into the appropriate account if back-up documentation is on-hand to indicate intended use and there is no COI issue present. When additional documentation is needed or COI questions exist, the goal is to have the money in the account within 5-7 business days. But, to be clear, the funds are distributed to the appropriate account for the department's use.

## B. Who will approve and sign off on the letters of agreement with the industry funding agent?

**ANSWER**: There are two parts to this response as the processes and procedures for CME and non-CME events vary. If your approved CME activity receives educational grants from pharmaceutical companies and/or medical device manufacturers, a signed letter of agreement (LOA) must be obtained from each company that provides a grant. This must be achieved prior to the CME activity taking place. Because Vanderbilt School of Medicine is the accredited provider, the director of the Division of Continuing Medical Education is the only individual authorized to sign off on an LOA. For non-CME events, letters of agreement are typically circulated between the Development Office (DAR), Office of Faculty Affairs, and others (General Counsel's Office) when necessary.

## C. Should grant monies and exhibit fees for CME and non-CME events be sent to Development and Alumni Relations (DAR)?

ANSWER: Exhibit fees should be sent directly to the department, as these are not gifts, but the funds derived from the vendor purchasing an exhibit table. As to grant monies there are two parts to this response as the processes and procedures for CME and non-CME events vary. Grant monies in support of approved CME activities must be sent to the Division of CME (VCME). Upon receipt, VCME will send checks to the Development Office (DAR) for processing. VCME will also send a copy of the check to you for your records. DAR will contact you to obtain your conference cost center number and deposit your check accordingly. All of these processes should be completed within a matter of days.

For non-CME events and in cases where the only option is payment to the department, these payments should be routed to the Development Office. When received by the department, the check should be sent to the attention of gift processing. They can ensure quick review and transfer of the funds into the appropriate accounts and can contact the department staff to obtain back-up documentation on the support, its purpose and appropriate allocation.

#### 15. What precipitated the policy changes that occurred in 2009?

ANSWER: The policy changes involving gifts and healthcare-sponsored activities were added to adequately address increased federal attention and scrutiny on conflicts of interests between academic medical centers and major research universities and the pharmaceutical/medical device industry. Our institution's goal is to better manage these relationships to ensure that all activities involving Vanderbilt faculty/staff are aligned with the mission of Vanderbilt University.

### 16. What precipitated the policy changes that occurred in 2012?

**ANSWER:** The policy was revised in August 2012 to reflect more restrictive federal regulations placed on PHS-funded research.

### 17. What is the process for medical supply vendor representatives to visit Vanderbilt?

**ANSWER**: All vendors must be registered and approved by the vendor liaison office (<a href="https://finance.vanderbilt.edu/procurement/procurement/liaison.shtml">https://finance.vanderbilt.edu/procurement/procurement/liaison.shtml</a>). VUMC has partnered with Vendormate credentialing services to insure vendor representatives visiting our facilities are appropriate, productive, and beneficial.

## 18. Are vendor fairs allowed on campus?

**ANSWER**: Vendor fairs involving non-medical suppliers must be approved in advance by the VU Office of Conflict of Interest and Commitment Management or the VUMC Director of COI (<a href="mailto:coi@vanderbilt.edu">coi@vanderbilt.edu</a> or <a href="mailto:coi.wumc@vanderbilt.edu">coi.wumc@vanderbilt.edu</a>, as applicable). Any vendor events involving medical suppliers must be approved in advance by the vendor liaison office.