# Handbook on Reporting Conflict of Interest and Commitment

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Overview of Outside Activities

In order to disseminate knowledge and expertise in research and teaching outside the institution, Johns Hopkins University faculty members engage in a variety of outside activities and the institution supports and encourages these activities. It is important to recognize, however, that the financial interests and time commitment that may be associated with providing advisory services, and engaging in entrepreneurship, inventorship, and related activity have the potential to conflict with one's primary obligations to Johns Hopkins and to impact academic integrity and objectivity. Permitted outside activities will vary depending on the individual’s employment or appointment status, relationship to research, and other factors. All disclosures of outside activities must be submitted through JHU eDisclose, an online system. http://edisclose.jhu.edu/

Conflict of Interest

A conflict of interest may arise when a financial interest is related to one’s research and may affect or appear to affect the objectivity of the research, the safety and welfare of human research subjects, or the interests of students and trainees. A conflict of interest also may arise if a financial interest has the potential to affect one’s responsibilities other than research, such as teaching or administrative duties.

A disclosed financial interest is considered related to one’s research if the research could impact the value of the company in which the financial interest is held (or from which it derives) or the value of its products or those of its competitors. If the financial interest is related to one’s research and it has the potential to impact the objectivity of the research, the safety of human research subjects, or the rights and interests of students or trainees, there is a conflict of interest.

Review for conflict of interest with research follows the JHU Policy on Financial Interests and Financial Conflicts of Interest with Research, which complies with PHS regulations on objectivity in research. The goal of each review is to determine whether a disclosed financial interest relates to an individual's research, regardless of research sponsor, and, if so, whether it creates a conflict of interest with the research.

Disclosures are reviewed for:

- potential of disclosed interests to directly and significantly affect the design, conduct, or reporting of research funded by a PHS Awarding Component or other sponsor (“financial conflict of interest" or "FCOI"); and
- risks to the rights and safety of human research subjects; and
- impact on the integrity of research data; and
- risks to the rights and obligations of students and trainees participating in research; and
- impact on the availability of research results to the scientific community for use in the public interest; and
- appearance of a conflict of interest.

What Constitutes a Conflict of Interest?

The questions posed below, when answered “yes”, are examples of potential conflicts of interest:
• Does your external activity involve the uncompensated use of facilities or resources belonging to Johns Hopkins University by or on behalf of another organization?

• Does your external activity involve the transfer of your intellectual or tangible property rights including patent ownership or licensing to an organization other than the University?

• Does your external arrangement or agreement restrict the public disclosure of the existence of the external arrangement?

• Does the external activity restrict your right to publicly disclose information developed by you through your involvement in the activity?

• Does your involvement in the external activity appear to influence either the conduct of the University’s business or the conduct of research within the University?

• Is your research and/or academic work sponsored by a company for which you consult or have a paid position?

• Is your research and/or academic work sponsored by a company for which you (or your spouse or your children) hold any ownership interest (stock, not including stock owned through a mutual fund) or from which you are entitled to receive royalties from a licensing agreement?

• Is your research and/or academic work sponsored by a company for which you serve on its scientific advisory board or board of directors?

• Are you (or your spouse or child) in a position to influence University decision making regarding purchasing products or services from an organization that you (1) hold an equity interest (not mutual funds) in the organization, (2) hold a position in the organization or on its governing board, and/or (3) serve as a paid or unpaid consultant to the organization?

• Is your spouse/child involved in one of your sponsored projects, either directly or through a subcontract?

• Does your external activity involve use of the name of the Johns Hopkins University or any of its schools or divisions by another organization?

This list is not exhaustive. There may be other instances when an external activity could pose a potential conflict and would need to be reported. Contact our office for guidance if you are unsure if an activity needs to be reported.

**Familial Conflicts**

Familial relationships may also give rise to potential conflicts of interest. A familial conflict can occur when a faculty member hires a spouse, domestic partner, child, or other relative to work on his or her projects. A familial conflict can also occur when the faculty member’s spouse, domestic partner, child, or other relative has a financial interest related to the faculty member’s research or institutional
responsibilities. Such arrangements must be reported. Faculty members are prohibited from supervising relatives or determining salary or remuneration for relatives.

**Conflict of Interest Committee Review and Management**

The Conflict of Interest Committee reviews all reports of outside activities to determine whether a potential conflict of interest exists. If the Committee finds a potential conflict exists, the Committee informs the faculty member in writing of required conditions to manage the conflict. Common management conditions required by the Committee could include:

- Disclose relationship with external entity in relevant publications and presentations
- Limit of a faculty member’s role in the research study (e.g. Exclusion from consenting participants, data analysis, etc)
- Appoint an independent oversight committee for the study
- Require that the PI places equity in escrow account
- Transfer supervision of a spouse to another individual

If the Committee finds that the conflict cannot be managed, the Committee can prohibit the proposed external activity.

Changes in previously disclosed relationships with outside entities may require that the Conflict of Interest Committee re-review both the disclosure and any conditions in place to manage the conflict. For example, a consulting relationship with a company disclosed in eDisclose could pose a conflict if the faculty member subsequently receives a grant from the company to do research. In these situations, faculty should provide information about this additional relationship to the company in eDisclose.

**Conflict of Commitment**

The primary duty of full-time faculty members is to the University. Faculty members engage with industry, government, and professional associations to further their knowledge, research, and other professional activity. At the same time, faculty must not let outside commitments interfere with their obligations to fulfill their University responsibilities. Faculty members are expected to act in the best interests of the University and in furtherance of the University’s mission at all times. A Conflict of Commitment may occur when faculty members’ time and attention devoted to external activities interferes with their ability to fulfill their obligations to the School. The existence of a potential conflict does not indicate that the activity is prohibited; most conflicts of commitment can be managed. Disclosures on outside commitments are reviewed for compliance with institutional policies and standards, including:

- Time commitment
- Conflict of commitment with Johns Hopkins duties
- Use of the Johns Hopkins name by or in connection with an outside activity
- Use of Johns Hopkins facilities and resources
- Academic freedom
- Regulated activity, such as provision of clinical care outside the institution

Faculty members who receive their full-time salary are allowed to consult or engage in entrepreneurial activity one day (ten hours) per week. Faculty members who receive less than full-time salaries are allowed to consult beyond the one-day per week limit when classes are not in session. The total number of days per year that faculty on part-time appointments may consult may be determined by the formula 

\[ 52 \times F + \left(1-F\right) \times 6 \times 52 \]

where F is the fraction of full-time equivalent salary that the Academic Staff member receives. Faculty who wish to pursue outside activities that exceed these limits must receive approval from the Dean of the appropriate School.

Faculty members may not hold a substantive appointment at another academic institution without approval of the Dean of the appropriate School. Significant management roles (e.g., officer in company or positions that involve supervision of the work of others and/or day-to-day responsibility for operating decisions) usually are demanding in terms of both time and energy. Accordingly, Faculty members who wish to accept significant managerial responsibilities in a company or another organization must negotiate an appropriate reduction in University responsibilities and compensation with the Dean of the appropriate School.

**Who Must Disclose in eDisclose**

The following individuals need to disclose:

- **Full-time or salaried part-time JHU faculty member** (tenured and tenure track faculty and members of the research staff including professors, scholars, scientists, and engineers with research titles) are required to disclose outside activities and financial interests whether or not they participate in research.
- **Non-salaried part-time faculty** must disclose outside activities and financial interests if they are related to their Johns Hopkins Institutional Responsibilities and if they participate in research at JHU.
- **Other individuals involved in research at Johns Hopkins who are Investigators** must disclose outside activities and financial interests if they are related to their Johns Hopkins Institutional Responsibilities.
  - **Institutional Responsibilities are those responsibilities and roles assigned to an individual in the course of their appointment or employment with the institution. These may include, among other things, research, teaching, clinical care/practice, and administrative responsibilities.**
  - **Investigator is the project director or principal investigator and any other person responsible for the design, conduct, or reporting of research, including collaborators and consultants, and all study team members on IRB applications.**
- JHU staff members must disclose financial interests if they are related their Institutional Responsibilities.
- All Academic Staff must report the outside activities of their immediate family members if the activity relates to the Institutional Responsibilities of the Academic Staff member. The
immediate family of an Academic Staff member includes her or his spouse, domestic partner, and/or dependent children.

- **Subrecipient** investigators on PHS-funded research must disclose occurrences of reimbursed or sponsored travel that are related to subrecipient’s work for JHU, regardless of the relationship of the travel to PHS funding, when the amount of travel during the 12 months preceding the disclosure reaches or exceeds $5,000 in the aggregate for a particular entity. (Note: This aggregate value includes travel for spouses, domestic partners and dependent children unless the travel occurs in the course of their employment by the entity.)
  - This does not include travel that is reimbursed or sponsored by a U.S. federal, state, or local government agency, teaching hospital, medical center, U.S. institution of higher education, or related research institute. Exceptions also include travel reimbursements to Johns Hopkins, travel payments made by Johns Hopkins, or travel charged to a Johns Hopkins account.

**When to Disclose in eDisclose**

- Prior to undertaking an outside commitment
- Prior to submission of an application for PHS-funded research on which you are an investigator
- Within 30 days of acquiring or discovering a financial interest related to your institutional responsibilities
- Whenever a disclosed interest or activity changes (e.g., the amount or type of remuneration, type of service, or time commitment) or ends
- **If you do not participate in any reportable outside activities, you are only required to certify on an annual basis that you have not participated in any outside activities. When it is time for your annual certification, you will receive an email reminder.**

In addition, all full-time and salaried part-time faculty are required to complete an Annual Certification. Please see Page 29 for more information on Annual Certification.

Late disclosure and failure to disclose may have serious consequences. Under federal conflict of interest regulation, if there is a failure to disclose, belated disclosure, or belated review of financial interests that the institution determines create financial conflicts of interest with PHS-supported research, the institution must undertake a retrospective review of the completed research for bias. In addition, failure to comply with policies on conflict of interest and commitment may lead to review under professional misconduct procedures.

**What to Disclose in eDisclose**

Individuals must **disclose the outside activities and financial interest listed below if they are related to your “institutional responsibilities.”** Institutional responsibilities may include, among other things, research, teaching, clinical care/practice, and administrative responsibilities. Disclosure is required so the School can review outside interests and activities for conflict of interest and conflict of commitment.

**Activities – whether or not compensated:**
• Service on advisory committees or boards and review panels, except when provided to a U.S. state, federal or local government agency, teaching hospital, medical center or institution of higher education or related research institute
• Publishing/editing/authoring, if remuneration is anticipated.
• Board of Directors
• Founder
• Officer
• Manager
• Speaking, teaching and lecturing, except when provided to a U.S. state, federal or local government agency, teaching hospital, medical center or institution of higher education or related research institute

Financial Interests:

• Inventor of licensed technology
• Receipt of income from licenses, whether equity, royalty, or other
• Entitlement to equity and/or royalty
• Equity ownership (except mutual funds)

You must disclose any of the above outside activities or financial interests of your spouse, domestic partner and/or minor dependents if they relate to your institutional responsibilities.

If you are an investigator on PHS-funded research, you must disclose occurrences of reimbursed or sponsored travel related to your institutional responsibilities when the amount of travel during the 12 months preceding the disclosure reaches or exceeds $5,000 in the aggregate for a particular entity. (Note: This aggregate value includes travel for spouses, domestic partners and dependent children unless the travel occurs in the course of their employment by the entity.) This does not include travel that is reimbursed or sponsored by a U.S. federal, state, or local government agency, teaching hospital, medical center, U.S. institution of higher education, or related research institute. Exceptions also include travel reimbursements to Johns Hopkins, travel payments made by Johns Hopkins, or travel charged to a Johns Hopkins account.

The following do not need to be disclosed:

• The exceptions listed above
• Activities that are governed by an institutional agreement or contract between Johns Hopkins and a third party
• Payments from Johns Hopkins (e.g., salary, salary supplement, reimbursements), other than payments derived from institutional licenses of intellectual property
• Confidentiality agreements with no services or remuneration
• Participation in local community activities (including, but not limited to, religious institutions, schools, clubs, and local charities outside the biomedical field), unless (i) you conduct research that relates to the organization, or (ii) the organization has a relationship with Johns Hopkins or seeks to do business with Johns Hopkins and you have any role in that relationship or business.
Outside Commitments and Private Agreements

Faculty are responsible for ensuring that private agreements are in compliance with all University policies. All commitments to provide consulting or other services to outside entities must be governed by a written agreement that is established in advance, includes a detailed outline of the services to be provided, and specifies the associated compensation. You may wish to consult your own legal advisor before signing a private agreement or contract with an outside organization.

Below are some general guidelines to follow when entering into private agreements:

- Outside agreements should not interfere with your institutional responsibilities at the University.
- Private agreements should be entered into by you as an individual and the company; you are not allowed to enter into private agreements as a representative of the University.
- JHU is not a party in private agreements and will, therefore, have no liability under them. Consequently, JHU, or a representative thereof, will not sign any private agreements. You cannot use any JHU facilities, resources or funds in the fulfillment of your responsibilities under the agreement.
- You are not allowed to engage any JHU employees, including students, trainees, and postdoctoral fellows to provide services under the Agreement.
- The outside entity is not allowed to use the name of JHU in any documents or marketing materials.
- You should not disclose, or be asked to disclose, any confidential information that is proprietary to JHU, including providing early or exclusive access to JHU research or disclosing inventions.
- You should make sure that the outside entity will only have rights to any intellectual property that is developed by you alone or in collaboration with others as a sole and direct result of the performance of services under the Agreement. The entity shall have no rights under the Agreement to any intellectual property that is developed as a result of a program financed in whole or in part by funds provided by or under the control of JHU.
- Do not participate in any activity that could constitute endorsement, promotion, or marketing of any product, technology or service.
- Your role should be limited to providing expert advice. You should not participate in, direct or conduct research for or on behalf of an outside entity.
- You should disclose your relationship to the outside entity in all publications and presentations of research supported by the outside entity. Disclosure is especially important in journal articles.
- "The Johns Hopkins University Uniform Provisions" should be added to the Agreement. (See Appendix).
- If you want to make sure that your agreement is in compliance with JHU policies, you can email the agreement to cemerson@jhu.edu for review.

Tech Transfer Activities

Conflicts of interest can arise in tech transfer when a faculty member is conducting research involving a product for which the faculty member is a licensed inventor. Faculty should report conflicts arising out of tech transfer activities at the time the research activities are proposed and provide relevant updates in eDisclose as they arise.
Conflicts of Interest in Human Subjects Research

Conflicts of interest in human subjects research deserve special scrutiny because of the potential for such conflicts to affect the rights and welfare of human subjects. Faculty conducting human subjects research must indicate a potential conflict of interest on the IRB application and must report this through eDisclose. The COI Committee will review the report and make management recommendations to the IRB and the PI. A common management condition includes disclosure of the arrangement in the consent form.

The IRB can decide whether to a) accept the Conflict of Interest Committee recommendations, b) accept the recommendations with additional management measures prescribed by the IRB, or c) conclude that the human subjects research cannot proceed.

NIH Conflict of Interest Reporting Requirements

In accordance with 42 CFR 50 Subpart F, the School must report to NIH those conflicts that are determined to be financial conflicts of interest (FCOI) related to Public Health Service (PHS) funded research. If the COI committee determines that a financial interest could directly and significantly affect the design, conduct or reporting of PHS supported research, the School will report this FCOI to the NIH. However, this does NOT mean that the research cannot be done but, instead, that a management plan for avoiding biased research must be in place. Federal regulations also require that the school respond to requests from any member of the public for information regarding FCOIs reported to NIH that are associated with PHS-funded research.

Grant and contract submission requires disclosure of potential conflicts related to the research to the Office of Research Administration (ORA) and in eDisclose. The Conflict of Interest Committee considers these disclosures for review and management.
### Appendix A: Summary of Reportable Outside Activities in eDisclose

You must disclose the following types of **outside activities provided to ANY entity**, over the previous 12 months and upcoming 12 months, whether non-profit or for-profit, if related to your **institutional responsibilities** (including, but not limited to, research, teaching, clinical/practice, and administrative responsibilities):

<table>
<thead>
<tr>
<th><strong>Outside Activities</strong></th>
<th><strong>If remuneration is anticipated.</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Consulting</td>
<td>Founder</td>
</tr>
<tr>
<td>Publishing/editing/authoring*</td>
<td>Officer</td>
</tr>
<tr>
<td>Clinical care/practice</td>
<td>Manager</td>
</tr>
<tr>
<td>Board of Directors</td>
<td></td>
</tr>
</tbody>
</table>

*If remuneration is anticipated.*

You must disclose the following **financial interests in ANY entity**, over the previous 12 months and upcoming 12 months, whether non-profit or for-profit, if related to your **institutional responsibilities** (including, but not limited to, research, teaching, clinical/practice, and administrative responsibilities):

<table>
<thead>
<tr>
<th><strong>Financial Interests</strong></th>
<th><strong>Receipt of income from licenses, whether equity, royalty, or other</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Inventor of licensed technology</td>
<td>Entitlement to equity and/or royalty</td>
</tr>
</tbody>
</table>

You must disclose the following types of **outside activities provided to ANY entity**, over the previous 12 months and upcoming 12 months, whether non-profit or for-profit, if related to your **institutional responsibilities** (including, but not limited to, research, teaching, clinical/practice, and administrative responsibilities), with some exceptions:

<table>
<thead>
<tr>
<th><strong>Outside Activities</strong></th>
<th><strong>Teaching, speaking, seminars, lectures</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Service on advisory committees or boards and review panels</td>
<td>Exceptions: when provided to Johns Hopkins or sponsored by a U.S. state, federal or local government agency, teaching hospital, medical center or U.S. institution of higher education or related research institute</td>
</tr>
<tr>
<td>o Exceptions: these services when provided to a U.S. state, federal or local government agency, teaching hospital, medical center or U.S. institution of higher education or related research institute</td>
<td></td>
</tr>
</tbody>
</table>

You must also disclose any of the above **outside activities or financial interests** of your **spouse, domestic partner and/or minor dependents** if it could be considered to be or appear to be related to your institutional responsibilities.

**You may need to disclose reimbursed or sponsored travel**

- **If you are an investigator who participates in PHS funded projects**, you must disclose each occurrence of reimbursed or sponsored travel related to your institutional responsibilities if the value of the reimbursed or sponsored travel occurring during the 12 months prior to the disclosure, **when aggregated for a particular entity, is $5,000 or more**.
  - If sponsored/reimbursed travel for a particular entity reaches or exceeds $5,000 in the 12 month reporting period, the investigator needs to report on each occurrence of travel, both those leading up to and exceeding the $5,000 threshold.
  - This includes the value of sponsored or reimbursed travel for the covered party's spouse, domestic partner, and dependent children, if applicable.
  - Exceptions to this requirement include travel that is reimbursed or sponsored by the grantee institution (e.g., JHU), a US federal, state or local government agency, an institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education.
If you do not participate in any reportable outside activities, you will be required to certify on an annual basis that you have not participated in any outside activities. When it is time for your annual certification, you will receive an email reminder.**

**What do I need to do?**

- **Disclose early and often at [http://edisclose.jhu.edu/](http://edisclose.jhu.edu/)**
  - **Immediately** if you participated in covered outside activities over the previous 12 months and plan to participate in covered activities in the upcoming 12 months
  - Prior to undertaking an outside activity
  - Within 30 days of acquiring or discovering a financial interest related to your institutional responsibilities
  - Whenever a disclosed interest or activity changes or ends (e.g., remuneration, type of services)
  - If submitting a PHS grant application you must disclose when you submit the application (you cannot wait until the project is reviewed or funded)
  - Certify annually that disclosures are accurate and up-to-date (you will receive an email reminder in early 2013)
  - Impact of “late” disclosure/review: Detailed, onerous requirements for retrospective review, including assessment of research for bias, possible stop to ongoing research

- **Complete online training immediately**
  - Go to MyLearning and search for “Conflict of Interest and Commitment” or go to [http://lms4.learnshare.com/l.aspx?CID=89&A=2&T=412863](http://lms4.learnshare.com/l.aspx?CID=89&A=2&T=412863)
  - Training is also required every four years or any time the policy changes

**How to disclose...**

- **JHU eDisclose at [http://edisclose.jhu.edu/](http://edisclose.jhu.edu/**/)
  - Log in using JHED credentials
  - User-friendly format walks user through the information required for reporting
  - System automatically emails users with annual updates and reminders

**What can eDisclose do for me?**

- Single portal for annual certifications and transactional disclosures
- Submit, update, terminate disclosures in one place
- Real-time access to each of your disclosures, status of review, outcome of review, and management plan/conditions
- Generate a single report of all your disclosures, for journals, conferences, etc.

**What happens to my disclosures?**

- Staff review disclosures for completeness and compliance with policies on conflict of interest, professional commitment, and the policy on interaction with industry; some disclosures are reviewed by the Conflict Review Committee
- You will be notified of the outcome of the review by email that will direct you to your eDisclose account
- Conditions may apply and some arrangements may need to be modified

**Questions?**

Carley Benham Emerson, MS  
Senior Policy Analyst  
Email: cemerson@jhu.edu  
Telephone: 410-516-4820
Appendix B: eDisclose User Guide
Getting Started in eDisclose

Recommended Web Browsers

For the best experience use one of the following recommended browsers:

<table>
<thead>
<tr>
<th>Platform</th>
<th>Browser</th>
</tr>
</thead>
<tbody>
<tr>
<td>Microsoft Windows (all versions)</td>
<td>Internet Explorer 7 or later, Firefox 7 or later, Chrome* 9 or later</td>
</tr>
<tr>
<td>Apple Mac OS X 10.4x or later</td>
<td>Safari 4 or later, Firefox 3 or later</td>
</tr>
</tbody>
</table>

System Login

The eDisclose system is located at: [http://edisclose.jhu.edu](http://edisclose.jhu.edu). Users can login using their JHEDID and password. If you have trouble logging in for the first time, it may be because you do not have an account. Please contact Carley Emerson at cemerson@jhu.edu or 410-516-4820 for assistance.

Getting Help

The eDisclose Help Desk page is available in the system (after login) and contains guides, resources, and FAQs to help you become acquainted with the eDisclose system. It is recommended that you review these documents prior to using the system as well as any time you have a basic question.

If your questions are not answered by the Help Desk resources or you need regulatory/process assistance, please contact Carley Emerson at cemerson@jhu.edu or 410-516-4820.
As a Faculty, when you log into eDisclose you will be taken to the “My Disclosures” workspace, which contains the disclosures you created as well as allows you to start a new disclosure. This can be considered your “home page” or “Inbox”. To get to this page at any time, click on the “My Home” tab on the upper right corner of the screen.

The screenshot below points out key areas of this workspace:

Below is a description of each numbered item indicated on the workspace above:
1. **My Disclosures:** This tab contains disclosures that you created. It is broken into groups (Pending My Action, Active Relationships, and Inactive Relationships). Check this tab frequently to see if any disclosures are pending your action.

2. **My Gift Disclosures:** This tab contains gift disclosures that you created.

3. **Name:** The ‘Name’ is the ID Number of the disclosure. If you click on the number, you will be taken to the workspace of that disclosure, where you can perform various activities.

4. **Entity:** The ‘Entity’ is the name of the Entity you have selected on that Disclosure form.

5. **State:** The ‘State’ indicates where the disclosure is in the review/workflow process. “User Submission Prep” state means this disclosure has not yet been submitted for review.

6. **Filter bar:** This feature allows you to filter the contents of a section by the headings it contains, such as keywords in the ‘Name’, Disclosure ID #, State. The percent sign (%) is used as a “wildcard” to search for a part of a word or phrase. **Ex. To search for disclosures in the Waiting User Response state, you could search by “%Wait”**.

7. **Create Disclosure:** This activity button allows you to create a New Disclosure. Only the Faculty Member/Researcher can create and submit his or her own disclosure.

8. **Create Gift Disclosure:** This activity button allows you to create a New Gift Disclosure. Only the Faculty Member/Researcher can create and submit his or her own gift disclosure.

9. **Help Desk:** This area of the system contains guides, resources, and FAQs to help you become acquainted with the system.

10. **My Home:** ‘MyHome’ is located at the top-right corner of any screen in the system. You may use My Home at any time to be returned to your workspace, or “home page”.
Appendix C: eDisclose User Guide
How to Submit a New Disclosure in eDisclose

Please first refer to the eDisclose Getting Starting Guide on page 11 before continuing.

NOTE: Only the Faculty Member/Researcher can create and submit his or her own disclosure.

Follow the steps below to submit a new disclosure:

STEP 1. Close all open web browsers.

STEP 2. Open a new browser and go to: http://edisclose.jhu.edu

STEP 3. Login using your JHEDID and password. If you have trouble logging in for the first time, it may be because you do not have an account in eDisclose. Please contact Carley Emerson at cemerson@jhu.edu or 410-516-4820 for assistance.

STEP 4. Select the “Create Disclosure” button on the left.

STEP 5. Section 1 of the SmartForm will appear.

- In Question 1, you must select the name of the entity for which you wish to disclose. When searching for your entity, the percent sign (%) can be used as a “wildcard” to search for a part of a word or phrase. Ex: To search for the entity “Society of Electrical Engineering”, you could search by “%Electric”.

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If your entity is not listed, type "unlisted" in the textbox. Select one of the unlisted options that appear. The type in the name of the entity in Question 1.1. (Please note that you may only select the specific unlisted option ((ex: Unlisted Entity 1)) for one disclosure until your disclosure is updated by a staff member with the actual entity name. You may then reuse the unlisted entity if needed.)

Answer questions pertaining to your activity using the smart form. If you provide more than one service to an entity, all services should be disclosed under the single disclosure for that entity.

All required questions (indicated with a red asterisk *). Section 1 must be answered in order for the disclosure to be created and saved in the system.

STEP 6. Select “Continue” to proceed through the remaining sections of SmartForm.
Every time you select “Continue” your work is automatically saved.

If you select “Back” your work will NOT be saved. Select “Save” before you click the “Back” button.

You may select “Save” at any time and exit the SmartForm.

STEP 7. Once you have completed your disclosure, select “Finish” on the last page of the SmartForm (9- Final Page). You will be automatically taken to the Disclosure workspace, where you can view the Current Status of the Disclosure, view an overview of the relationship, and run activities.

NOTE: The SmartForm has not yet been submitted for review at this point.

If you need to make additional changes to the disclosure, select the “View/Edit Form” button on the right side to open the SmartForm again and resume working on it until it is complete.

STEP 8. Select the “Submit” activity button, located on the left side to check for errors and warning messages.

NOTE: Only the Faculty Member/Researcher can create and submit his or her own disclosure.
If the system does not display any errors, proceed to Step 9.

If the system finds errors they will be displayed for you. Resolve all warning/error messages that are listed by selecting the Section Number from the “Jump To” list. You will be taken directly to the section of the SmartForm that contains the required question(s) that have been left unanswered or where there is a problem with your response.

Once all warning/error messages have been resolved, click “Finish” and “Submit” again. Then proceed to Step 9.

STEP 9. Read the Certification text, complete the form by answering Question 1.0, and if needed, 2.0. Then click “OK”.

- You will note that the Status on the top left of the application workspace changes from “User Submission Prep” to “Submitted”.
- The Disclosure will now appear in the appropriate COI Staff’s workspace where they can begin processing your submission.
- You will receive an email that confirms the submission of the Disclosure.
After you disclose

Disclosures are reviewed for conflict of interest and, for full-time and salaried part-time faculty, conflict of commitment. You will be contacted via e-mail or telephone if additional information is needed. Every effort is made to review disclosures in a timely way. Timing of review depends on a number of factors, including, but not limited to, review by the Committee on Outside Interests and submission during high-volume periods. If you need immediate review of a disclosure, please contact cemerson@jhu.edu.

When the review of a disclosure is completed, the discloser will receive an e-mail notification that the review outcome is available in their eDisclose account. Outcomes and decisions can be appealed by rejecting the electronic management plan that is sent via eDisclose. Appeals must be submitted within 30 days of receipt of an outcome (10 days if the disclosure involves federal funding). Appeals should be accompanied by an explanation of the reason for the appeal. You may be asked to submit more material and/or meet with the Committee.
Appendix D: eDisclose User Guide
How to Respond to Reviewer Notes in eDisclose

Use of Reviewer Notes: When the COI Staff need additional information from the researcher/owner of the disclosure, the questions/comments can be relayed via the system using electronic notes called Reviewer Notes. The staff reviewer enters their notes directly onto the relevant page of the disclosure (called a ‘SmartForm’) to request a change to the form. The Researcher/Owner of the Disclosure must then respond to each reviewer note, as well as make the required changes in the Smartform.

Follow the steps below to respond to reviewer notes from the COI Staff:

STEP 1. You will receive an email notification when the COI Staff have requested additional information of you via Reviewer Notes. Click the Link to Workspace within the email to be taken to the disclosure that requires your attention. If you are not already logged in, you will be prompted to do so. Use your JHEDID and password.

STEP 2. Select the “View/Edit Form” button to open the disclosure SmartForm.
STEP 3. Reviewer Notes will appear at the top of the form, under the yellow bar.  
➢ Where the message “Response Required!” appears, you must provide a response.

STEP 4. Select the “Click here to respond…” link to provide your response in the pop-up form.

STEP 5. Select “Next”, on the yellow bar to view the next Reviewer Note. (Tip: The “Next” and “Previous” buttons will allow you to navigate back and forth to pages containing Reviewer Notes, while skipping pages that do not have any notes.)
STEP 6. Make all necessary changes to the Smartform as requested in the Reviewer Note.

- **Tip:** Almost all Reviewer Notes require you to do two things: Respond to the note, and make a revision to the relevant section of the disclosure form so that it becomes part of the disclosure itself.

STEP 7. Once you have responded to all reviewer notes and made the required changes in the disclosure, **Select** the “Finish” button on the last page and you will be taken back to the Disclosure workspace.

- **Tip:** You are **NOT** finished just yet! Your responses are **NOT** sent back to the COI Staff until the “Submit” activity on the workspace is selected.

STEP 8. If you are sure you have completed all required changes, select the **“Submit”** activity button on the left-hand side of the workspace.

- **NOTE:** Only the Faculty Member/Researcher can create and submit his or her own disclosure.
The system checks for completeness and will show validation errors (such as required questions that have not been answered, or reviewer notes that have not been responded to).

All Error/warning messages must be resolved before the disclosure can be submitted. Click the hyperlinked Section number from the list to go the page where issues can be resolved.

STEP 9. After all error/warning messages are resolved, save and exit the SmartForm, and select the “Submit” activity again on the disclosure workspace.

STEP 10. Read and confirm the Certification text, and then select “OK”.

You may need to scroll slightly down to see the OK button.
STEP 11. Two events will let you know that the disclosure has been successfully submitted back to the COI Staff:

- First, you will receive an email from the system verifying receipt of your submission, and explaining that no action is required of you at this time.
- Second, the Current Status of the disclosure will change to Submitted. This means that the disclosure now appears back in the COI Staff’s workspace or “Inbox” where they can continue processing your disclosure.

STEP 12. Your disclosure has been submitted and review has been resumed. If the COI Staff have questions, they will contact you. To return to your workspace, you can select “My Home” located in the top left corner.
Appendix E: eDisclose User Guide
How to Update a Disclosure in eDisclose

If your disclosed relationship with an entity changes in any way, you need to update your disclosure in eDisclose. For example:

- Your relationship with the company/entity has ended
- Your service has changed (e.g., type of service provided, time commitment, amount or type of remuneration)
- You propose to participate in research related to the entity (a new protocol or a new research grant or contract)
- Your intellectual property is licensed to the entity

**NOTE:** Only the Faculty Member/Researcher can create/update and submit his or her own disclosure.

Follow the steps below to update a disclosure:

**STEP 10.** Close all open web browsers.
**STEP 11.** Open a new browser and go to: [http://edisclose.jhu.edu](http://edisclose.jhu.edu)
**STEP 12.** Login using your JHEDID and password.
**STEP 13.** Select the “My Disclosures” workspace link on the left side.
**STEP 14.** Select a disclosure from the workspace whose state is “Review Complete”. To select a disclosure, click on the Disclosure ID which is hyperlinked.

- Once you click on the ID, you will be taken to the Disclosure Workspace.
- **NOTE:** Only disclosures that appear in the “Review Complete” state can be updated. If you need to update a disclosure that is in another state, contact Carley Emerson at cemerson@jhu.edu or 410-516-4820 for assistance. You can also use the “Contact Staff” button to notify the staff that you need to make changes to the disclosure.
STEP 15. Select the “Update Disclosure” button that appears on the left.

STEP 16. Begin filling out the Update form.

STEP 17. Select “Continue” to proceed to the Disclosure SmartForm where you can make any necessary updates to the disclosure.
All required fields are indicated with a red asterisk “*”. You must enter at least one character of text, or answer yes or no in these required fields.

You can select “Save” at any time and exit the form.

Every time you select “Continue” your work is automatically saved.

If you select “Back” your work will NOT be saved.

STEP 18. Proceed through all sections of the SmartForm until you arrive at the Final Page

STEP 19. Once you have completed your disclosure, select “Finish” on the last page of the SmartForm (9- Final Page). You will be automatically taken back to the Update workspace.

NOTE: The updated disclosure has not yet been submitted for review at this point.

If you need to make additional changes to the disclosure, select the “View/Edit Form” button on the right side to open the SmartForm again and resume working on it until it is complete.
STEP 20. Select the “Submit” activity button.

- If the system does not display any errors, proceed to Step 12.
- If the system finds errors, they will be displayed for you. Resolve all warning/error messages that are listed by selecting the Section Number from the “Jump To” list. You will be taken directly to the section of the SmartForm that contains the required question(s) that have been left unanswered or where there is a problem with your response.

Once all warning/error messages have been resolved, click “Finish” and “Submit” again.

STEP 21. Read the Certification text, complete the form by answering Question 1.0, and if needed, 2.0. Select “OK” on the Submit form.

- Note: You may have to scroll down to see the “OK” button.
STEP 22. Review the Update workspace summary.

- You will note that the Status on the top left of the workspace changes from “User Submission Prep” to “Submitted”.

- The Update will now appear in the appropriate COI Staff’s workspace where they can begin processing your update submission.

- You will receive an email that confirms the submission of the update.
Appendix F: eDisclose User Guide
How to Submit an Annual Certification in eDisclose

Full-time faculty and salaried part-time faculty must submit an Annual Certification, including those in the following categories:

- Professor/Associate Professor/Assistant Professor/ Instructor
- Research Professor/Associate Research Professor/Assistant Research Professor
- Scholar/Scientist/Engineer
  - Principal Research/Research/Associate Research/Assistant Research
- Visiting Professor/Associate Professor/Assistant Professor
- Visiting Research Professor/Associate Research Professor/Assistant Research Professor

**ONLY IF FULL-TIME:**
- Senior Lecturer/Lecturer/Junior Lecturer
- Teaching Professor/Associate Teaching Professor

**IF PARTICIPATING IN ANY RESEARCH:**
- Adjunct Professor/Adjunct Associate Professor/Adjunct Assistant Professor

The purpose of the Annual Certification is to confirm that all your disclosures are complete, accurate, and up-to-date. If you do not participate in any reportable outside activities, you will certify on an annual basis that you have not participated in any outside activities.

Faculty members who are required to submit the certification will be notified via personal e-mail when their Annual Certifications are ready for submission. They will also receive weekly e-mail reminders during their submission period.

The Annual Certification is accessible via eDisclose, the online disclosure system. Faculty members will be notified via e-mail when their Annual Certifications are ready for submission.

Submitting an Annual Certification is mandatory for all full-time and salaried part-time faculty. Failure to submit a completed Annual Certification as required may be reviewed under the Procedures for Dealing with Issues of Professional Misconduct. The Annual Certification does not affect the obligation to disclose outside activities and interests as they arise and before proposing related research.

**NOTE:** Only the Faculty Member/Researcher can create and submit his or her own disclosure.

**Follow the steps below to submit your Annual Certification:**

**STEP 1.** Close all open web browsers.

**STEP 2.** Open a new browser and go to: [http://edisclose.jhu.edu](http://edisclose.jhu.edu), or click the link that is located in the reminder notice send to you email address.

**STEP 3.** Login using your JHEDID and password. Please contact Carley Emerson at cemerson@jhu.edu or 410-516-4820 for assistance.
STEP 4. Once logged in, you will see a red bar instructing you that your Annual Disclose is pending. Before completing the Annual Certification, you must review all your disclosures to ensure you have disclosed all outside activities and your disclosures are up to date and accurate. **If you do not have any outside activities to disclose, go to Step 5.**

STEP 5. Once you have verified that you have disclosed all outside activities and that your disclosures are up to date and accurate, click on the statement “>Click here to complete your Annual Certification<”.

STEP 6. Click the “Complete Annual Certification” button on the left of the screen.

STEP 7. Answer Questions 1 and 2 on the popup window, then click “OK”.
STEP 8. You will then be notified that you have completed your Annual Certification.

STEP 9. Click the My Home link that is located in the upper right to return to your My Disclosures folder. The red bar notifying you that your Annual Certification is pending will have disappeared once you have completed your disclosure.
Appendix G

Conflict of Interest Training Instructions

In accordance with federal regulation, all faculty are required to receive training related to conflict of interest whenever the institution’s policy changes and every four years thereafter. The JHU course can be accessed at [http://lms4.learnshare.com/l.aspx?CID=89&A=2&T=412863](http://lms4.learnshare.com/l.aspx?CID=89&A=2&T=412863) or through MyLearning. Log in to the MyLearning system using your JHED ID and password and search for “Conflict of Interest and Commitment”.

The course can be accessed at the “Take Course” link. **If the module does not come up in a separate window, check to make sure the internet browser’s pop-up blockers are switched off, or try holding down the control key while clicking the “Take Course” button.** The training module will pop up in a separate screen.
After completing the training, close the course pop-up window. Then, select "My Learning History" from the menu on the far left side of the screen. The COI course will be included in your list of completed courses and certificates. Scroll over to the right side of the screen to the “Certificate” column and click “View PDF” to print/save the PDF of the completion certificate.
Appendix H

Frequently Asked Questions

1. What is eDisclose? (http://edisclose.jhu.edu)
The eDisclose system is a University-wide electronic method to submit, track, and review disclosures of outside interests and/or financial and fiduciary Interests. The system provides a platform for the review of disclosures, annual disclosures, and updated disclosures.

2. How do I get an account in eDisclose?
Users can login with their JHEDID and passwords. If you have trouble logging in or if you need an account created for you, contact Carley Emerson at cemerson@jhu.edu or 410-516-4820.

3. I can't remember my JHED ID and/or password. What should I do?
Contact JHED directly at (410) 516-HELP.

4. What browsers are recommended to use with eDisclose?
For the best experience, use one of the following recommended browsers:

<table>
<thead>
<tr>
<th>Platform</th>
<th>Browser</th>
</tr>
</thead>
<tbody>
<tr>
<td>Microsoft Windows (all versions)</td>
<td>Internet Explorer 7 or later, Firefox 7 or later, Chrome* 9 or later</td>
</tr>
<tr>
<td>Apple Mac OS X 10.4x or later</td>
<td>Safari 4 or later, Firefox 3 or later</td>
</tr>
</tbody>
</table>

5. How do I report in eDisclose that I do not participate in any reportable outside activities?
eDisclose is a transactional disclosure system, so if you do not participate in any reportable activities, you will only need to go into eDisclose once a year to certify that you have not participated in any reportable activities. You will receive an email notification when it is time for you to complete your certification.

6. Who sees the information I submit via eDisclose? Is the information safe?
Staff members in your school or division’s reviewing office have access to your disclosures. In addition, members of your school or division’s conflict of interest committee will be provided access to the information necessary for their review. Staff members in the IRB offices and the Johns Hopkins Technology Transfer Office have limited access to the information in eDisclose. Department directors and chairs and their designees, in some cases including department administrators, have access to the disclosures of faculty members in their departments. A financial interest that is judged to be related to PHS-supported research and is determined to be a financial conflict of interest under regulatory standards is subject to additional disclosure requirements. The University is required to provide certain information about the conflict of interest to the PHS awarding agency and to make certain information available to the public.
7. **Can I save my work and come back to the disclosure later?**
   Yes, you can save your work at any time by using the ‘Save’ button at the top or bottom of any SmartForm page. In addition, clicking ‘Continue’ also saves your work. The ‘Back’ button, however, does NOT save.

8. **Why do I keep getting error/warning messages when I try to submit?**
   - The system will not allow the disclosure to be submitted until all required items are completed on the SmartForm.
   - To assess completeness of the form, you can **Turn on the Hide/Show Errors** feature, from the blue navigation bar, to provide a list of validation errors that the system finds along the way.
   - Click the name of the section to address the required item. As required questions are answered in each section, the error/warning messages will disappear from the list.
   - The hide/show errors feature is optional and can be turned on/off at any time from the blue navigation bar.

9. **Can a faculty member/researcher allow someone to have access/submit their disclosure in eDisclose?**
   No, the faculty member/researcher must create and submit his or her own disclosure.
10. **How do I know the status of disclosure review?**
   On the disclosure workspace, you will find the Current Status is located at the top left corner.

11. **How do I make changes to a disclosure?**
   From your completed disclosure workspace, select the ‘Update Disclosure’ activity button and follow the instructions for creating an update. The system only allows one update for an entity to be in review at a time. Only disclosures in the Review Complete state are eligible for update. If you need to make changes to a disclosure that has not yet been reviewed by the COI staff, you can use the “Contact Staff” button to let the staff know you need the disclosure returned so you can make a change.

12. **Can I delete a disclosure?**
   eDisclose retains a record of all user disclosures. When a user updates a disclosure to indicate that the relationship has ended or the financial interest no longer exists, the “ended” status is reflected in the system.
If a disclosure was submitted erroneously or in duplicate, you can request to "withdraw" the disclosure. This action is permanent. It is suggested you contact the COI staff before withdrawing a disclosure.

13. **Can I submit one disclosure for two companies if I am performing the same consulting services for each of them?**
No. eDisclose is an entity-based system. You must create a new disclosure for each company or organization with which you have a relationship or interest. Reporting by entity allows the institution to effectively manage each relationship and provide accurate reporting of outside commitments and conflicts of interest.

14. **I am providing two different services (or have two separate agreements) with one company. Should I submit two disclosures?**
No. eDisclose is an entity-based system. All aspects of your relationship with one company or organization (e.g., services provided, ownership of equity, other financial interests or roles related to the entity) should be included in your disclosure. Moreover, relationships with an entity are reviewed as a whole, and remuneration received based on that relationship may be considered in the aggregate for purposes of reviewing and reporting financial conflicts of interest and monitoring compliance with institutional policies. Reporting by entity allows the institution to effectively manage each relationship and provide accurate reporting of outside commitments and conflicts of interest.

15. **Will the information that I submit via eDisclose be available to the public?**
Federal regulation requires that the University respond to requests from any member of the public for information regarding arrangements the institution determines are financial conflicts of interest associated with PHS-funded research. (Note: not all disclosures of outside interests or activities are determined to be financial conflicts of interest with PHS-funded research.) Within five business days of the receipt of a sufficiently complete written request, the institution must provide the following information: (1) investigator's name; (2) investigator's title and role with respect to the research project; (3) name of the entity in which the investigator's significant financial interest is held; (4) the nature of the significant financial interest; and (5) the approximate dollar value of the significant financial interest (with the following dollar ranges being permissible: $0-$4,999; $5,000-$9,999; $10,000-$19,999; amounts between $20,000-$100,000 by increments of $20,000; amounts above $100,000 by increments of $50,000) or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value.

**Disclosure Basics**

16. **Who has to disclose and what do I have to disclose?**
Disclosure requirements are outlined starting on Page 4.

17. **When do I have to disclose?**
It is important to make disclosures times, including: (1) prior to undertaking a disclosable outside commitment; (2) no later than the time of application for PHS support; (3) within thirty days of acquiring or discovering a financial interest related to your institutional responsibilities; and (4) whenever a disclosed interest or activity changes (e.g., in terms of remuneration, type of service, or
time commitment) or ends. In addition, full-time and salaried part-time faculty must submit an Annual Certification stating that their disclosures are accurate and up-to-date.

18. **What happens to my disclosure?**
   Staff members review disclosures for completeness and compliance with policies on conflict of interest and professional commitment. Some arrangements require review by the school or division’s conflict of interest committee. You will be notified via e-mail when a review is complete. The e-mail will direct you to your eDisclose account to read and accept (or appeal) the outcome of the review. The outcome will list the conditions or management plan associated with the review and you may be required to make some changes to your role in research and/or financial interest or relationship with the entity.

19. **Do students and post-docs need to disclose?**
   All individuals who meet the definition of “investigator” on a PHS-supported research project must report their outside activities and financial interests. Under JHU’s conflict of interest policy, an investigator is:
   - The project director or principal investigator and any other person responsible for the design, conduct, or reporting of research. Includes collaborators and consultants.
   - All study team members on IRB applications.
   This definition is independent of whether one is appointed or employed by the Johns Hopkins University. The phrase “responsible for the design, conduct, or reporting of research” should be interpreted to mean any individual involved in the research who works independently enough to affect the objectivity of the design, collection, or analysis of research data or reporting of research results. In addition to faculty members, this may include graduate and post-doctoral trainees, research staff, consultants, or other collaborators. The ultimate determination as to who is considered an investigator in PHS-supported research is the decision of the PI of the project.

20. **If I am on sabbatical, do I need to submit disclosures?**
   Yes.

21. **What if I write a book chapter and, although I do not receive any income, the publisher gives me a copy of the book? Should I disclose receipt of the book?**
   The receipt of the book does not need to be disclosed.

22. **I receive royalties from sales of an academic textbook. Do I need to disclose this?**
   Yes. Pursuant to revised federal regulations on conflict of interest and institutional policy, income received from publishing, editing, or authoring must be disclosed.

23. **I'm involved in research using licensed intellectual property for which I'm entitled to royalties, although there are no royalties flowing yet. Do I need to disclose this since I haven't received any income from royalties?**
   Yes. Entitlement to future royalties under a licensing agreement or contract is a disclosable financial interest.

24. **Do I need to disclose if Johns Hopkins owns equity in the start-up company in which I have equity or a licensing interest?**
You still need to disclose your equity and licensing interests in the company for review under the policy on individual conflict of interest. The university’s ownership interest in the start-up can create an institutional conflict of interest, which is reviewed under the University’s policy on institutional conflict of interest.

25. **How do I determine whether a company in which I own stock is related to my institutional responsibilities?**

   Institutional responsibilities are those responsibilities and roles that covered parties are assigned in the course of their appointment or employment at the university. This includes, for example, clinical practice, teaching, research, research consultation, professional practice, administrative roles, committee service, purchasing-related responsibilities, and service on IRBs or DSMBs. Ownership of equity in an entity whose business is in the same field as any of your institutional responsibilities is considered related.

26. **Do I need to disclose stock if it is included in a mutual fund or IRA?**
   No. Only stock purchases over which you can or do exercise direct control should be disclosed.

27. **Do I need to disclose honoraria received for teaching in a Johns Hopkins CME course? What if the payment came from an outside entity?**
   You do not need to report an honorarium received for teaching in a Johns Hopkins CME course. You probably received payment from a third party because the Johns Hopkins CME office contracted with an external organization to handle certain logistics such as payment to instructors. However, since you were engaged to teach in this course by the Johns Hopkins CME office, you do not need to disclose the income.

28. **Do I need to disclose if I am advising Johns Hopkins students who started a company based on the technology they invented at the university?**
   If you are advising the students in their roles as company founders, you are engaging in an activity with an outside organization and you need to make a disclosure. This is especially important if you are compensated in any way. If you are mentoring the students with regard to their university-based research activity, no disclosure is needed.

29. **Can you provide some examples of when to disclose the financial interest of a spouse/domestic partner/dependent child?**
   Examples include:
   - ownership of stock in an entity that relates to your institutional responsibilities; and
   - service on the board of directors of an entity that relates to your institutional responsibilities; and
   - receipt of remuneration for consulting or any other service provided to an entity that relates to your institutional responsibilities.

30. **My spouse works for a company that is related to my institutional responsibilities and I am required to disclose his income and stock options to JHU. However, his employer imposes confidentiality requirements on disclosure of his compensation.**
   To comply with institutional policy and federal regulation, limited information about interests of immediate family members must be disclosed. If you have questions about a particular case, please contact your school or division’s reviewing office.
31. **If both members of a married couple or domestic partnership are faculty and/or investigators at Johns Hopkins, do they need to disclose each other's interests or activities?**
   Yes. Although each member of the couple has certain disclosure requirements, it is important for each to include the other’s financial interests and indicate they are the spouse or domestic partner’s interests. This is so the institution can determine whether an individual’s financial interests are related to the research being conducted by the other member of the couple.

32. **Do I need to disclose if my spouse is employed by NIH?**
   No.

33. **Do I need to disclose my spouse’s employment for a company whose business is related to my institutional responsibilities?**
   Yes.

34. **Do I need to disclose if my spouse is a lobbyist for a company whose business is related to my institutional responsibilities?**
   Yes.

35. **What happens if I fail to make a disclosure or my disclosure is “late”?**
   Late disclosure and failure to disclose may have serious consequences. Under applicable regulation, if there is a failure to disclose, belated disclosure, or belated review of financial interests that the institution determines create financial conflicts of interest with PHS-supported research, the institution must undertake a retrospective review of the completed research to determine whether there was bias in the research conducted to date. In addition, failure to comply with policies on conflict of interest and commitment may lead to review under your division’s professional misconduct procedures.

**Travel**

36. **When do I have to disclose travel?**
   If you are an investigator on any PHS-supported grant or contract, you need to disclose each instance of travel that is reimbursed or sponsored by an outside entity, when the amount of travel during the preceding 12 months reaches or exceeds $5,000 in the aggregate for a particular entity. (Note: This aggregate value includes travel for spouses, domestic partners and dependent children unless the travel occurs in the course of their employment by the entity.) Disclosures must be made within 30 days of reaching the $5,000 threshold and of every instance of sponsored or reimbursed travel occurring thereafter.

37. **Do I need to disclose travel if I’m not an investigator on a PHS grant or contract?**
   No. Only investigators on PHS grants and contracts are required to disclose sponsored or reimbursed travel.

38. **What is meant by “reimbursed” and “sponsored” travel?**
Reimbursed travel is when an entity directly reimburses you for your purchase of transportation or lodging. Sponsored travel is when an entity purchases your airline or train ticket or pays for your hotel stay.

39. **What if I don't know the specific value of the sponsored travel I am disclosing?**

eDisclose allows users to provide either the specific value, an estimate of the value, or a description of the travel costs covered by the entity. To determine whether the aggregate value of sponsored and reimbursed travel has reached $5,000, investigators should make their best efforts to learn the value of the sponsored and reimbursed travel.

40. **Do non-faculty investigators such as research coordinators need to disclose sponsored or reimbursed travel if they're listed on a PHS-sponsored grant? What if a research coordinator is a study team member on an IRB protocol?**

All individuals who meet the definition of “investigator” on a PHS-supported research project must report their outside activities and financial interests. Under JHU’s conflict of interest policy, an investigator is:

- The project director or principal investigator and any other person responsible for the design, conduct, or reporting of research. Includes collaborators and consultants.
- All study team members on IRB applications.

The phrase “responsible for the design, conduct, or reporting of research” should be interpreted to mean any individual involved in the research who works independently enough to affect the objectivity of the design, collection, or analysis of research data or reporting of research results. In addition to faculty members, this may include graduate and post-doctoral trainees, research staff, consultants, or other collaborators. The definition of investigator is independent of whether or not an individual is employed or appointed by Johns Hopkins University. The ultimate determination as to who is considered an investigator in PHS-supported research is the decision of the PI of the project.

41. **I am a consultant on an NIH grant to Johns Hopkins, and the grant paid for me to go to a conference. Do I have to disclose that?**

   No. Travel payments made by the institution do not need to be disclosed.

42. **What if I give grand rounds out of town and the trip is paid for by my professional society?**

   If you are an investigator on any PHS-supported grant or contract, the travel must be disclosed when/if the aggregate value of the travel sponsored or reimbursed by the professional society reaches or exceeds $5,000.

43. **What if my travel is sponsored or reimbursed by a non-U.S. institution of higher education?**

   Only institutions of higher education chartered under U.S. law are exempt from the reporting requirements. Therefore, if you are an investigator on any PHS-supported grant or contract, you need to disclose travel that is sponsored or reimbursed by a foreign institution of higher education when/if the aggregate value of the travel sponsored or reimbursed by the institution reaches or exceeds $5,000.
44. **What if an academic society or disease-advocacy organization pays for me to attend its annual meeting? Do I need to disclose this as sponsored or reimbursed travel? What if they waive my registration fee for the annual meeting?**

If you are an investigator on any PHS-supported grant or contract and the organization pays (or reimburses you) for your flight or hotel stay, you need to make a disclosure when/if the aggregate value of the travel sponsored or reimbursed by the entity reaches or exceeds $5,000. Waiver of the registration fee does not need to be disclosed.

45. **What if I travel to a meeting where dinner is included and the sponsoring entity buys an expensive bottle of wine? And what if they pay for my cab fare? What if they just pay for meals during my trip?**

For the purposes of reporting travel-related expenses, you need to disclose only sponsored or reimbursed transportation and lodging.

46. **What if I extend a trip at my own expense? How do I disclose this?** For example, I am traveling to Singapore to give a talk at a Singaporean medical society and the society will pay for my transportation and two nights at a hotel. I am going to take a vacation and extend the trip for one week at my own expense.

You must disclose the transportation and lodging that are paid for by the Singaporean medical society.

47. **If I take one trip at the invitation of multiple organizations, do I need to submit a disclosure for each entity from which I receive reimbursement/sponsorship?** For example, I am invited to give talks at three different organizations in Germany and each will pay for about one-third of my travel and lodging expenses.

Yes, you need to disclose each organization’s sponsorship of your trip (provided the aggregate value of any travel sponsored or reimbursed by that entity over the past 12 months reaches or exceeds $5,000) and indicate, if possible, what each organization paid for.

**Conflict of Interest and Professional Commitment/Federal Regulations**

48. **Why have new policies and requirements been adopted?**

Johns Hopkins has revised its policies and procedures with respect to both disclosure and professional commitment *and* conflict of interest in order to comply with revised Public Health Service regulations on objectivity in research (conflict of interest), which took effect on August 24, 2012.

49. **What is “PHS”?**

PHS is the Public Health Service of the U.S. Department of Health and Human Services. PHS agencies include

- Administration for Children and Families (ACF)
- Administration on Aging (AoA)
- Agency for Healthcare Research and Quality (AHRQ)
- Agency for Toxic Substances and Disease Registry (ATSDR)
- Centers for Disease Control and Prevention (CDC)
- Centers for Medicare & Medicaid Services (CMS)
- Federal Occupational Health (FOH)
• Food and Drug Administration (FDA)
• Health Resources and Services Administration (HRSA)
• Indian Health Service (IHS)
• National Institutes of Health (NIH)
• Substance Abuse and Mental Health Services Administration (SAMHSA)
•
50. **Who is covered by the PHS regulation? Must all institutions that receive PHS support adhere to the regulation?**
Yes. The regulation is applicable to all institutions that apply for or receive PHS support by means of a grant, cooperative agreement, or contract and, through the implementation of the regulation by the institution, to all investigators on PHS-supported projects.

51. **What is meant by a “U.S. institution of higher education”?**
A U.S. institution of higher education is defined [here](#). To qualify as a U.S. institution of higher education under 20 U.S.C. 1001(a), an institution must be public or non-profit, legally authorized by states to provide post-secondary education accredited, and award bachelor’s degrees or provide full credit toward bachelor’s degrees, and meet other criteria.

52. **Is income from for-profit institutions of higher education like the University of Phoenix exempt from reporting requirements?**
No. To be exempt from reporting requirements, an institution must be either public or nonprofit.

53. **Why do I need to disclose information about income from non-profit organizations?**
Revisions to the federal regulation on conflict of interest require that institutions obtain this information from investigators.

54. **Do students and post-docs need to disclose?**
All individuals who meet the definition of “investigator” on a PHS-supported research project must report their outside activities and financial interests. Under JHU’s conflict of interest policy, an investigator is:
- The project director or principal investigator and any other person responsible for the design, conduct, or reporting of research. Includes collaborators and consultants.
- All study team members on IRB applications.
This definition is independent of whether one is appointed or employed by the Johns Hopkins University. The phrase “responsible for the design, conduct, or reporting of research” should be interpreted to mean any individual involved in the research who works independently enough to affect the objectivity of the design, collection, or analysis of research data or reporting of research results. In addition to faculty members, this may include graduate and post-doctoral trainees, research staff, consultants, or other collaborators. The ultimate determination as to who is considered an investigator in PHS-supported research is the decision of the PI of the project.

55. **Does the policy apply only to new awards as of August 24, 2012? What if my grant is in year four of a five-year award?**
The revised regulation applies to all PHS awards made on or after August 24, 2012, including new awards, competitive renewals, non-competitive renewals, supplements, and no-cost extensions.

56. **What is a “FCOI”?**
“FCOI” stands for “financial conflict of interest.” Under PHS regulations, an FCOI exists when the institution determines that an investigator’s significant financial interest could directly and significantly affect the design, conduct or reporting of research.

57. **What happens if the review of my arrangements results in an FCOI determination and I don’t agree? Can I appeal?**
The outcomes of the review can be appealed. The appeal can be submitted electronically in eDisclose.

58. **What if changes to my research are required in order to manage my conflict of interest? Who is notified of the required changes?**
The review outcome or management plan sent to you via eDisclose will explain the conditions necessary to manage the conflict of interest. For example, you may need to revise your eHIRB/eIRB protocol by submitting a Further Study Action for a Change in Research. In that case, the IRB will be notified of the required change. However, it is your responsibility to ensure that the change to the eHIRB/eIRB protocol is made.

59. **What disclosure information has to be made public and why?**
Federal regulation requires that the University respond to requests from any member of the public for information regarding arrangements the institution determines are financial conflicts of interest associated with PHS-funded research. (Note: not all disclosures of outside interests or activities are determined to be financial conflicts of interest with PHS-funded research.) Within five business days of the receipt of a sufficiently complete written request, the institution must provide the following information: (1) investigator’s name; (2) investigator’s title and role with respect to the research project; (3) name of the entity in which the investigator’s significant financial interest is held; (4) the nature of the significant financial interest; and (5) the approximate dollar value of the significant financial interest (with the following dollar ranges being permissible: $0-$4,999; $5,000-$9,999; $10,000-$19,999; amounts between $20,000-$100,000 by increments of $20,000; amounts above $100,000 by increments of $50,000) or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value. This requirement exists to support transparency about interests of investigators that may affect the objectivity of publicly-supported research.

60. **Will an investigator receive a notification if a member of the public asks for information regarding his/her FCOI?**
Yes.

61. **What happens if I fail to make a disclosure or my disclosure is “late”?**
Late disclosure and failure to disclose may have serious consequences. Under applicable regulation, if there is a failure to disclose, belated disclosure, or belated review of financial interests that the institution determines create financial conflicts of interest with PHS-supported research, the institution must undertake a retrospective review of the completed research to determine whether there was bias in the research conducted to date. In many cases, this may mean that the research must be stopped until the retrospective review is completed. In addition, failure to comply with policies on conflict of interest and commitment may lead to review under your division’s professional misconduct procedures.
62. **What are “institutional responsibilities”?**
   Institutional responsibilities are those responsibilities and roles assigned to an individual in the course of their appointment or employment with the institution. These may include, among other things, research, teaching, clinical care/practice, and administrative responsibilities.

63. **When do I have to complete conflict of interest training?**
   There are various triggers for the training requirement. You must complete training prior to engaging in PHS-funded research and at least every four years thereafter; immediately after a change in institutional conflict of interest policy that affects the requirements placed upon investigators; if you are new to an institution; whenever the institution determines that are you not in compliance with the institutional conflict of interest policy or your management plan.

64. **I am an investigator on a sub-award for research funded by a PHS agency. Does this regulation still apply to me?**
   Yes. If you meet the definition of an “investigator,” the regulatory requirements apply to you. The awardee institution is required to incorporate conflict of interest terms in agreements with sub-recipients that specify which institution’s conflict of interest policy will apply to investigators at the sub-recipient institution. If the sub-recipient institution does not have a policy that complies with the regulation, the prime awardee’s policy must be followed.

**Contact Information for Assistance**
For questions about conflict of interest and commitment, please contact Carley Emerson at cemerson@jhu.edu or 410-516-4820.
Appendix I

Additional Resources:

JHU Conflict of Interest and Commitment Website
http://web.jhu.edu/conflict_of_interest

JHU Policy on Individual Financial Interests and Financial Conflicts of Interest in Research

JHU Policy on Disclosure and Professional Commitment

KSAS and WSE Divisional Policy on Conflict of Interest and Commitment
http://eng.jhu.edu/wse/page/policies-services-forms

NIH Policy on Conflict of Interest
http://grants.nih.gov/grants/policy/coi/
Do I need to disclose this travel expense?

**STOP** You are not required to disclose these travel expenses.

Do you participate in PHS funded research?

- **YES**
  - Did you get reimbursed for travel from a grant, contract, or other source through the School or University?
    - **YES**
      - You are not required to disclose these travel expenses.
    - **NO**
      - Were the travel expenses paid by any of the following: U.S.** state, federal or local government agencies, teaching hospitals, medical centers, institutes of higher education or their related research institutes?
        - **YES**
          - You are not required to disclose these travel expenses.
        - **NO**
          - Did the amount of travel expenses received from the same entity reach or exceed $5,000 during the 12 months preceding the disclosure?
            - **YES**
              - **GO** You must disclose the amount received for these travel expenses in eDisclose.
            - **NO**
              - **STOP** You are not required to disclose these travel expenses.

**STOP** You are not required to disclose these travel expenses.

*Disclosures for travel expense associated with outside activities paid directly to you or for you may include: transportation, lodging, and meals.

**STOP** You are not required to disclose these travel expenses.

**STOP** You are not required to disclose these travel expenses.

**Travel of $5000 or more paid by foreign entities must be disclosed.**

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47
eDisclose Travel Expense Tracking Worksheet

The following information about travel is required for entry in eDisclose. Remember, this is ONLY for travel expenses that were either paid on your behalf or reimbursed directly to you (i.e. payments that are not processed through the university) by an organization other than Johns Hopkins that have already or will likely reach $5,000 or more in the last 12 months.

You do NOT need to disclose travel from U.S. state, federal or local government agencies (NIH, CDC, state health departments, etc), teaching hospitals, medical centers, or institutes of higher education and their related research institutes.

You need to report these expenses within 30 days of the conclusion of the trip.

1. Entity from which payment/reimbursement was received: ____________________________

2. Departure Date: __________________

   Return Date: ______________________

3. Purpose:

   □ Consulting
   □ Scientific Advisory Board meeting
   □ Sponsored research meeting
   □ Other: _____________________________________________________

4. Destination (City/State or City/Country): _______________________________________

5. Reimbursed or paid expenses: (Value can be “unknown” if paid on your behalf; eDisclose does not require itemization within category but may be helpful for record-keeping)

<table>
<thead>
<tr>
<th>Expense Description</th>
<th>Value ($USD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lodging</td>
<td></td>
</tr>
<tr>
<td>Transportation (air, taxi, etc)</td>
<td></td>
</tr>
<tr>
<td>Meals</td>
<td></td>
</tr>
</tbody>
</table>
UNIFORM PROVISIONS FOR SELECTED CONSULTING AGREEMENTS

1. It is the policy of the Johns Hopkins University, its Schools and Divisions, (hereinafter individually and collectively “JHU”) that these Uniform Provisions for Selected Consulting Agreements (“Uniform Provisions”) must be attached and incorporated by reference into any written agreement (an “Agreement”) that covers consulting services by a JHU investigator at or on behalf of an organization, and must be signed by both parties to the Agreement. By signing these Uniform Provisions, the parties to the Agreement agree to abide by these Uniform Provisions, and further agree that if anything in the Agreement is inconsistent with these Uniform Provisions, these Uniform Provisions shall govern.

2. The parties acknowledge that JHU is not a party to this Agreement, which is a private contract between __________________________ (“Consultant”) and __________________________ (the “Organization”). Consultant and Organization also agree that JHU has no liability or responsibility to either party under this Agreement. Each party to the Agreement acknowledges that the Consultant is entering into the Agreement, and providing services to the Organization, in the Consultant’s individual capacity and not as an employee or agent of JHU, and that JHU shall have no responsibility whatsoever in connection with the Agreement, including without limitation, any use by the Organization of information obtained from the Consultant in the course of the Consultant’s provision of services under the Agreement. Nothing in this Agreement shall in any way inhibit Consultant’s ability to conduct academic research at JHU, regardless of the sponsor of such research, during or at any time after the term of this Agreement.

3. In accordance with JHU policy, the Consultant may disclose to the Organization any information that the Consultant would normally freely disclose to other members of the scientific community at large, whether by publication, by presentation at seminars, or in informal scientific discussions, but the Consultant shall not disclose to the Organization information that is proprietary to JHU and is not generally available to the public other than through formal technology transfer procedures. Consultant shall not use the facilities, equipment, materials, funds, or resources owned or administered by JHU, or located on any of the premises thereof; or engage or employ students, post-doctoral fellows, or other employees thereof, to provide services under this Agreement. Further, any unpublished research or data generated at or by JHU or unpublished results of research conducted at or by JHU that Consultant may disclose in the course of providing services under this Agreement shall remain the intellectual property of JHU, and shall not be presented or published by Organization or by any of the Organization’s affiliates in any way or form without the prior written consent of JHU and Consultant.

4. Nothing in the Agreement shall limit or be construed to limit the Consultant’s right to use, disseminate, or publish any information that (i) is or becomes available to the public through no breach of the Agreement by Consultant; (ii) is obtained by the Consultant from a third party who had the legal right to disclose the information to the Consultant; (iii) is already in the possession of the Consultant on the date the Agreement becomes effective; or (iv) is required to be disclosed by law, government regulation, or court order. In addition, information generated by the
Consultant pursuant to the Agreement shall be proprietary to the Organization only if (i) such information is generated as a direct result of the performance of consulting services under the Agreement; and (ii) is not generated in the course of the Consultant’s activities as a JHU employee or faculty member.

5. The Organization shall have no rights by reason of the Agreement in any publication, invention, discovery, improvement, or other intellectual property whatsoever, whether or not publishable, patentable, or copyrightable, which is developed as a result of a program of research financed in whole or in part, by funds provided by or under the control of JHU. Organization agrees to provide the Johns Hopkins Technology Transfer Office (100 North Charles Street, 5th Floor, Baltimore, MD 21201) with a copy of any patent application on which Consultant is listed as an inventor as a result of the services provided under this Agreement. Organization and Johns Hopkins will enter into a confidentiality agreement to govern the transmission of the patent application to the Office of Licensing and Technology Development, with transmission to occur within 120 days of filing of the application with the patent office(s).

6. With the limited exception of citing Consultant’s faculty title (subject to the conditions outlined below), Organization and its affiliates will not use the names, likenesses, or logos of JHU in any of their fund-raising or investment documents, general publications, advertisements, or marketing and promotional materials (hereinafter “Materials”). If Organization cites Consultant’s title and affiliation with JHU in its Materials, it agrees to include the following statement in such Materials as a parenthetical comment or footnote next to the Consultant’s name, title, and affiliation: ‘Participation by <<Faculty Name>> as an advisor does not constitute or imply endorsement by the Johns Hopkins University.’

Organization: _____________________________________

Signature of Authorized Representative of Organization: _____________________________________ Date: __________________________

Signature of Consultant: _____________________________________ Date: __________________________