Conflict of Interest Metrics Project: Data To Be Collected

The following describes the data that will be collected from institutions participating in the AAMC initiative to measuring the cost and outcomes of the new rule on financial conflicts of interest in research funded by the Public Health Service (PHS). Additional information about the project can be found at www.aamc.org/metricsproject. Please note that the data will not be collected through this document, but that participating institutions will be provided with instructions on submitting annual aggregate data to AAMC.

I. INSTITUTIONAL CHARACTERISTICS

Information Provided at Time of Registration

1. Institutional Identification: What is the name of the institution and from what type of entity will financial conflict of interest data be collected (e.g. medical school, university, hospital, health system)?

2. Institution Type: Is this a public or private institution?

3. Institutional Authority: What is the name and title of the person who will authorize your institution’s participation in the program and release of the data described in this document to AAMC?

4. Institutional Contact: What is the name, title, and contact information for the individual who will take responsibility for collecting the core and supplemental data from your institution, providing that information to AAMC, and serving as the primary contact for AAMC?

5. Institutional Annual Disclosure Process: 42 CFR 50.604(e)(2) of the new rule requires institutions to “require each Investigator who is participating in the PHS-funded research to submit an updated disclosure of significant financial interests at least annually, in accordance with the specific time period prescribed by the Institution.” Does your institutional policy require disclosures from investigators based on a calendar year, fiscal year, or another system? Would it be most convenient for you to provide aggregate data to AAMC about the previous 12 month disclosure process in February, May, or August of each year of your participation in the AAMC COI Metrics Project?

6. Public Accessibility: Will your institution publish identified financial conflicts of interest on a publicly available website or provide to individual requestors?

Information Provided After Registration, Prior to First Annual Report

7. Policy Location: What is the internet address (URL) for your institution’s conflict of interest policy?
8. **Policy Application**: Does your institution’s conflict of interest policy apply the new rules uniformly to all investigators, regardless of the source of their research funding?

If your policy is not universally applied please indicate, for each of the following requirements, whether your policy applies the requirement to (a) all researchers or (b) only researchers with PHS funding:

- Disclosure of significant financial interests with an aggregate annual value over $5000 (as required by 42 CFR 50.603)
- Disclosure of sponsored or reimbursed travel (as required by 42 CFR 50.603)
- Retrospective reviews for bias whenever a financial conflict of interest is not identified or managed in a timely manner (as required by 42 CFR 50.605(a)(3))
- Mandatory training (as required by 42 CFR 50.604(b))
- Making information about identified financial conflicts of interest publicly available (as required by 42 CFR 50.604(a))
- Subrecipient monitoring procedures (as required by 42 CFR 50.604(c))

9. **PHS Funding**: How many principal investigators are funded through PHS grants at your institution as of August 24, 2012? What is the total dollar amount that your institution received in direct and indirect PHS funding in calendar year 2011?

10. **Conflict of Interest Committee Structure**: What is the structure of your conflict of interest committee or review process? Is there one committee? How many people sit on the committee? How often do they meet? Has this structure changed since your institution implemented the new rule?

## II. CORE DATA

Core data will be provided each year by each institution participating in the AAMC COI Metrics Project. In addition, where indicated below, “Related Historical Data” will be collected for the designated time period before the institutions implemented the new rule.

1. **Individuals making disclosures to the institution**
   - What is the total number of unique individuals who made disclosures in accordance with your policy’s requirements in the most recent 12 month disclosure period? (For the first year’s data collection, this is the first annual disclosure process after August 24, 2012)
   - **Related historical data**: What is the total number of unique individuals that made disclosures in the previous disclosure period? (The last completed annual disclosure process prior to August 24, 2012 or before the institution changed its policy to comply with the new rule. E.g. Calendar Year 2011)

2. **Financial interests disclosed to the institution**
   - **Total Disclosures**: What is the total number of financial interests disclosed to the institution by investigators in accordance with your policy in the first annual disclosure process after August 24, 2012? This number should exclude travel
disclosures and be limited to those aggregated disclosures with a known or estimated financial value. (If the institution collects more financial interest information than is required by the rule, this information will be noted in the institutional characteristics)

- **Disclosures greater than $5,000 and equal to or below $10,000:** Out of the total number of financial interests disclosed during the first annual disclosure process after August 24, 2012 how many had an value greater than $5,000 and less than or equal to $10,000?

- **Disclosures greater than $10,000:** Out of the total number of financial interests disclosed during the first annual disclosure process after August 24, 2012 with a value equal to or greater than $10,000?

- **Related historical data:** What was the total number of disclosed financial interests in the previous disclosure period? (The last completed annual disclosure process prior to August 24, 2012 or before the institution changed its policy to comply with the new rule.) How many had a value greater than $5,000 but less than $10,000? How many had a value equal to or greater than $10,000?

3. **Reportable financial conflicts of interest (FCOIs) identified**

- **Total reportable FCOIs:** What is the total number of financial conflicts of interest that were identified by the institution during the first annual disclosure process after August 24, 2012? The FCOIs included in this number should only be those FCOIs that are required to be reported to the PHS funding entity (e.g. NIH) under the new rule.

- **Reportable FCOIs based on travel disclosures:** Of the total number of reportable FCOIs identified during the first annual disclosure process after August 24, 2012, how many were based on travel disclosures?

- **Reportable FCOIs greater than $5,000 and equal to or below $10,000:** Of the total number of reportable FCOIs identified during the first annual disclosure process after August 24, 2012, how many were based on disclosed significant financial interests with a value greater than $5,000 but equal to or less than $10,000?

- **Reportable FCOIs greater than $10,000:** Of the total number of reportable FCOIs identified during the first annual disclosure process after August 24, 2012, how many were based on disclosed significant financial interests with a value greater than $10,000?

- **Related historical data:** What is the total number of financial conflicts of interest related to PHS-funded research that were reported to the PHS funding entity during the previous disclosure period? (The last completed annual disclosure process prior to August 24, 2012 or before the institution changed its policy to comply with the new rule.)
4. Personnel administering COI review activities

- What is the total number of full time equivalent (FTE) employees administering the conflict of interest programs at your institution as of the date of this submission?

- Related historical data: What was the total number of FTE employees administering the conflict of interest program as of August 1, 2011?

III. SUPPLEMENTAL DATA

These data will be collected from institutions participating in the AAMC COI Metrics Project that are able to provide the data. The ability to provide this information is not a prerequisite for participation.

1. Institutional investment in implementing the new rule

- Personnel Costs: Between August 25, 2011 and August 24, 2012, what additional personnel costs, if any, did the institution incur in preparing to implement the new rule? Were additional staff hired or moved from other job responsibilities?

- Investment in capital expenditures: Between August 25, 2011 and August 24, 2012, did the institution incur in specific capital expenditures in preparing to implement the new rule (e.g. software systems)? If so, what was the nature and the amount of the expenditures?

- Other preparation costs: Other than personnel or capital expenditure costs, did the institution incur any other substantial costs between August 25, 2011 and August 24, 2012, in preparing to implement the new rule? If so, what was the nature and the amount of the costs?

2. Institutional costs for ongoing administration of the new rule

- Personnel Costs: What is the estimated annual personnel costs for the institution to administer the implemented rule as of the date of this submission to the AAMC COI Metrics Project?

- Other administration costs: Other than personnel costs what are the estimated annual costs for the institution to administer the implemented rule as of the date of this submission to the AAMC COI Metrics Project? What is the nature of these costs?

3. “Relatedness” analysis

- Number of “related” significant financial interests: Under the new rule, investigators are required to disclose significant financial interests related to their institutional responsibilities, and the institution is required to determine if the disclosed interests are related to the PHS-funded research (42 CFR 50.604(f)).
Of the significant financial interests disclosed to your institution, what is the total number that were deemed *related* to PHS-funded research?

- **Percentage of disclosed financial interest deemed “related”:** Of the significant financial interests disclosed to your institution by those conducting PHS funded research, what percentage was deemed *related* to PHS-funded research?

4. **Retrospective reviews for bias**

- **Number of retrospective reviews:** Under the new rule, an institution is required to undertake a retrospective review of PHS-funded research activities when certain identified financial conflicts of interest are not identified or managed in a timely manner to determine whether the design, conduct, or reporting of research was biased (42 CFR 50.605(a)(3)). What is the total number of retrospective reviews for bias your institution undertook during the first annual disclosure process after August 24, 2012?
- **Mitigation Plans:** If any retrospective reviews were undertaken by your institution, did any of those reviews result in the development or implementation of a mitigation plan? If so, how many?

5. **Travel disclosures**

- **Total number:** What is the total number of occurrences of sponsored or reimbursed travel that were disclosed by investigators to your institution during the first annual disclosure process after August 24, 2012?

IV. **NARRATIVE INSTITUTIONAL INFORMATION**

This information may be provided by institutions but is not required for participation in the AAMC COI Metrics Data Project.

1. **Policy requirements:** Other than the dollar amount of the disclosure threshold of other characteristics discussed elsewhere in this document, does your institutional policy differ substantially from the requirements of the PHS rule? If so how?

2. **Implementation Impact:** Other than the financial and personnel costs incurred by your institution in preparing for and administering the new rule, what impact has the implementation of the rule had on your institution?