

Centers for Medicare & Medicaid Services Conflict of Interest Policy

Recipients must maintain written standards of conduct covering conflicts of interest. Individuals affiliated with a recipient organization cannot participate in the selection, award, or administration of a contract supported by a federal award if they have a real or apparent conflict of interest with:

- Employees
- Officers
- Agents
- Board members
- Immediate family members, spouses, or partners
- Potential employer

These individuals are prohibited from soliciting gratuities, favors, or anything of monetary value from subrecipients. However, recipients may set standards for situations where financial interest is not substantial or the gift is an unsolicited item of insignificant value. These standards of conduct must be applied for violations of the standards by officers, employees, board members, or agents of the organization. Recipients that are part of a parent, affiliate, or subsidiary organization that is not a state, local government, or Indian Tribe are required to have an organizational conflict of interest policy.

Definitions:

"Significant financial interest" means anything of monetary value, including, but not limited to, salary or other payments for services (e.g., consulting fees or honoraria); equity interest (e.g., stocks, stock options or other ownership interests); and intellectual property rights (e.g., patents, copyrights and royalties from such rights).

This term does not include:

- a. salary, royalties or other remuneration from the applicant organization;
- b. income from seminars, lectures, or teaching engagements sponsored by public or non-profit entities;
- c. income from service on advisory committees or review panels for public or nonprofit entities;
- d. an equity interest that, when aggregated for the PI/PD and the PI/PD's spouse and dependent children, meets both of the following tests: does not exceed \$10,000 in value as determined through reference to public prices or other reasonable

measures of fair market value, and does not represent more than a 5% ownership interest in any single entity; or

e. salary, royalties or other payments that, when aggregated for the PI/PD and the investigator's spouse and dependent children, are not expected to exceed \$10,000 during the prior twelve-month period.

The term "or other interest" means a non-financial benefit which results in a potential or real conflict of interest. The potential or real conflict of interest poses the same possible harm received from a financial conflict of interest such as bias due to personal gain. Such benefits may be received from a tangible or intangible personal benefit.

"Organizational conflicts of interest" means that because of relationships with a parent company, affiliate, or subsidiary organization, the non-Federal entity is unable or appears to be unable to be impartial in conducting a procurement action involving a related organization.

"Authorized Organizational Representative (AOR)" means the individual(s), named by the applicant/recipient organization, who is authorized to act on behalf of the applicant/recipient and to assume responsibility for the obligations imposed by federal laws, regulations, requirements, and conditions that apply to CMS grant awards.

Requirements:

All recipients must disclose, in writing, any potential conflict of interest to the awarding or passthrough agency in accordance with 2 CFR 200.112 and 300.112. The majority of CMS' grant programs are not supported by Public Health Service (PHS) funding; therefore, CMS is not subject to the requirements of 42 CFR Part 50, Subpart F, "Promoting Objectivity in Research." Notwithstanding, CMS expects grant activities (including research activities) to be free from bias by any conflicting interest of the PI/PD and any other person regardless of title or position, who is responsible for the design, conduct, or reporting of grant activities which may include collaborators or consultants.

Recipient's conflict of interest policies must include the following:

- A written and enforced administrative process to eliminate conflicting financial or other interests with respect to CMS grant/cooperative agreement funds awarded. This process should ensure:
 - The merits for determining a conflict of interest are clearly articulated in writing – i.e., the assigned reviewer(s) can reasonably determine that a significant or other interest could directly and significantly affect the design, conduct, or reporting of CMS-funded grant activities. This process should be inclusive of the appearance of such conflicts.

- Each PI/PD discloses to the AOR of the Recipient all significant financial and/or other interests including personal relationships of the PI/PD (for example, PI/PD's spouse, dependent children, etc.):
 - i. that would reasonably appear to be affected by the grant activities funded or proposed for funding by CMS; or
 - ii. in entities whose financial or other interests would reasonably appear to be affected by such activities.
- One or more objective persons (1) reviews the potential conflict of interest; (2) determines whether a potential (appearance of) or real conflict of interest exists; and (3) establishes what conditions, or restrictions, should be imposed to eliminate the conflict of interest.
- This information is conveyed to the AOR for the organization who is designated to act on behalf of the applicable CMS award.
- Prior to expending funds under a new CMS award, the AOR must inform the CMS Grants Management Specialist (GMS) and Project Officer (PO) of any real or potential conflict of interest. The report must detail Recipient's plan to eliminate the conflict prior to spending CMS funding on the activities in question.
- Similar reports for subsequently identified conflicts be made within 30 days of identifying them. Funding for those specific activities must cease until the aforementioned steps are completed.
- Continual updates be made for any real or potential conflicts of interest not fully resolved. Recipient must make additional information available to the CMS GMS and PO, upon request, as to how it is handling (or had handled) the real or potential conflict of interest.
- Recipients must maintain records of all disclosures and of all actions taken to resolve conflicts of interest for at least three years beyond the termination or completion of the grant to which they relate, or until the resolution of any CMS action involving those records, whichever is longer.
- The Recipient's policy must include adequate enforcement mechanisms and provide for sanctions where appropriate.

Recipient may resolve such conflicts of interest through one or more of the following options outlined below. This is not an exhaustive list and Recipient may pursue other remedies.

- Modification of approved project to remove potential or real conflict of interest.
- Termination of agreement or other services that create potential or real conflict of interest.
- Removal of individuals with potential or real conflict of interest.
- Severance of relationships that create potential or real conflicts of interest.
- Divestiture of significant financial interests.

Recipient must ensure that funds are administered in accordance with conflict-of-interest policies that meet, at a minimum, the standards outlined above, inclusive of pass-through entities, subrecipients, contractors, or collaborators. Each entity must have its own policies in place that meet these requirements or mandate that the PIs/PDs working for such entities follow those of the Recipient.

Subaward agreements must include a conflict of interest requirement.

Procurement:

The Recipient or subrecipient must also maintain written standards of conduct covering conflicts of interest and governing the actions of its employees engaged in the selection, award and administration of contracts in accordance with [2 CFR 200, Procurement Standards](#). No employee, officer, agent, or board member with a real or apparent conflict of interest may participate in the selection, award, or administration of a contract supported by a Federal award.

A conflict of interest includes when the employee, officer, agent, or board member, any member of their immediate family, their partner, or an organization that employs or is about to employ any of the parties indicated herein, has a financial or other interest in or a tangible personal benefit from an entity considered for a contract. An employee, officer, agent, and board member of the recipient or subrecipient may neither solicit nor accept gratuities, favors, or anything of monetary value from contractors. However, the recipient or subrecipient may set standards for situations where the financial interest is not substantial or a gift is an unsolicited item of nominal value. The recipient's or subrecipient's standards of conduct must also provide for disciplinary actions to be applied for violations by its employees, officers, agents, or board members.

If the recipient or subrecipient has a parent, affiliate, or subsidiary organization that is not a State, local government, or Indian Tribe, the recipient or subrecipient must also maintain written standards of conduct covering organizational conflicts of interest. Organizational conflicts of interest mean that because of relationships with a parent company, affiliate, or subsidiary organization, the recipient or subrecipient is unable or appears to be unable to be impartial in conducting a procurement action involving a related organization.