

H3D Conflict of Interest Policy

As used in this Policy:

Award, financial assistance award or Federal award means the same as the definition provided in 2 CFR 200.1 for Federal award.

Contracting Activity means an organizational element that has the authority to award and administer contracting and financial assistance instruments.

Disclosure of significant financial interests means an individual's disclosure of significant financial interests to a non-Federal entity.

Financial conflict of interest (FCOI) means a situation in which an Investigator or the Investigator's spouse or dependent children has a significant financial interest or financial relationship that could directly and significantly affect the design, conduct, reporting or funding of a project.

FCOI report means a non-Federal entity's report of a financial conflict of interest to the government program office.

Financial interest means anything of monetary value, whether or not the value is readily ascertainable.

Institution of Higher Education means the same as the definition provided at 20 U.S.C. § 1001(a).

Investigator means the principal Investigator (PI) and any other person, regardless of title or position, who is responsible for the purpose, design, conduct, or reporting of a project funded by the government or proposed for funding by the government. Government program offices have the discretion to expand the definition to include also any person who *participates* in the purpose, design, conduct, or reporting of a project funded by the government or proposed for funding by the government. Such expansion will be specified in the applicable funding opportunity announcement and/or terms and conditions of the financial assistance award.

H3D classifies all H3D employees as Investigators.

Subcontractors must identify Investigators using the definition above and guidance from H3D.

Investigator's non-Federal entity responsibilities means an Investigator's professional responsibilities on behalf of the non-Federal entity, and as defined by the non-Federal entity in its policy on financial conflicts of interest, which may include: activities such as research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards.

Manage means taking action to address a financial conflict of interest, which can include mitigating or eliminating the conflict of interest, to ensure, to the extent possible, that the purpose, design, conduct, and reporting of a project will be free from bias.

Non-Federal entity means a State, local government, Indian tribe, Institution of Higher Education, nonprofit organization, or for-profit organization that carries out a government award as a recipient or subrecipient.

Non-Federal entity's designated official means the individual designated by the non-Federal entity with the authority and responsibility to act on behalf of the non-Federal entity to ensure compliance with the COI Policy.

Organizational conflict of interest means a situation where 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. 2 CFR 200.318(c)(2).

Potential conflict of interest exists when an impartial observer reasonably believes that actual or apparent past, present, or currently planned interests could constitute a conflict of interest with a project funded under a government award.

Principal Investigator (PI) means a principal investigator of a project funded under a government financial assistance award; PI is included in the definitions of *senior/key personnel* and *Investigator*.

Project means the interdependent activities funded wholly or in part under the government financial assistance award. A project has a defined start and end point with objectives described in an application or in an approved scope that, when attained, signify completion and achievement of a specific goal, and creation of a unique product, service, or result. For awards that include recipient cost share as part of the approved budget, activities funded with that recipient cost share are included.

Recipient means an entity, usually but not limited to non-Federal entities, that receives a Federal award directly from a Federal awarding agency. The term recipient does not include subrecipients or individuals that are beneficiaries of the award.

Senior/key personnel means the PI; any other person who significantly influences the design, conduct, or reporting of a project funded under a government award; and any other person identified as senior/key personnel by the non-Federal entity in the application for financial assistance, approved budget, progress report, or any other report submitted to the government by the non-Federal entity under this Policy.

Significant financial interest means:

(1) A financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator's spouse and dependent children) that reasonably appears to be related to the Investigator's non-Federal entity responsibilities:

(i) With regard to any foreign or domestic publicly traded entity, a *significant financial interest* exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds \$5,000. For purposes of this definition, remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship); equity interest includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value;

(ii) With regard to any foreign or domestic non-publicly traded entity, a *significant financial interest* exists if the value of any remuneration, not otherwise disclosed as current, pending, or other support, received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds \$5,000, or when the Investigator (or the Investigator's spouse or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest);

(iii) Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.

(2) Investigators also must disclose the occurrence of any reimbursed or sponsored travel (*i.e.*, that which is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available) related to their institutional responsibilities that is not otherwise disclosed in current and pending or other support disclosures, provided that this disclosure requirement does not apply to travel that is reimbursed or sponsored by a Federal, state, or local government agency of the United States; a domestic Institution of Higher Education; or a domestic research institute that is affiliated with a domestic Institution of Higher Education. The non-Federal entity's FCOI policy will specify the details of this disclosure, which will include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. In accordance with the non-Federal entity's FCOI policy, the non-Federal entity official(s) will determine if further information is needed, including a determination or disclosure of monetary value, in order to determine whether the travel constitutes a FCOI with the project funded under the government award.

(3) The term *significant financial interest* does not include the following types of financial interests: salary, royalties, or other remuneration paid by the non-Federal entity to the Investigator if the Investigator is currently employed or otherwise appointed by the non-Federal entity, including intellectual property rights assigned to the non-Federal entity and agreements to share in royalties related to such rights; any ownership interest in the non-Federal entity held by the Investigator, if the non-Federal entity is a commercial or for-profit organization; income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles; income from seminars, lectures, or teaching engagements sponsored by a Federal, state, or local government agency of the United States, a domestic Institution of Higher Education, or a domestic research institute that is affiliated with a domestic Institution of Higher Education; or income from service on advisory committees or review panels for a Federal, state, or local government agency of the United States, a domestic Institution of Higher Education, or a domestic research institute that is affiliated with a domestic Institution of Higher Education.

Subrecipient means an entity, usually but not limited to non-Federal entities, that receives a subaward from a pass-through entity to carry out part of a Federal award, but does not include an individual that is a beneficiary of such award. A subrecipient may also be a recipient of other Federal awards directly from a Federal awarding agency.

IV. Responsibilities of H3D regarding Investigator financial conflicts of interest.

H3D shall:

(a) Maintain an up-to-date, written, enforced policy on financial conflicts of interest that complies with the government COI Policy regulations, and make such policy available via a publicly accessible website.

(b) Inform each Investigator of H3D's policy on financial conflicts of interest, the Investigator's responsibilities regarding disclosure of significant financial interests, and any relevant government COI policy issues that are not included in H3D's COI policy; and require each Investigator to complete training regarding the same prior to engaging in projects related to any government award and at least every four years, and immediately when any of the following circumstances apply:

(1) H3D revises its financial conflict of interest policies or procedures in any manner that affects the requirements of Investigators;

(2) An Investigator is new to H3D or a subcontractor; or

(3) H3D finds that an Investigator is not in compliance with H3D's financial conflict of interest policy or management plan, or the FCOI policy of the applicable subcontractor.

(c) If H3D carries out the government award through or with the assistance of one or more subrecipient, H3D must take reasonable steps to ensure that each subrecipient Investigator complies with this Policy by:

(1) Incorporating as part of a written agreement with the subrecipient terms that establish whether the financial conflict of interest policy of H3D or that of the subrecipient will apply to the subrecipient's Investigators.

(i) If the subrecipient's Investigators must comply with the subrecipient's financial conflict of interest policy, the subrecipient shall certify as part of the agreement referenced above that its policy complies with the government COI policy and the subrecipient shall make such policy available via a publicly accessible website. If the subrecipient does not have any current presence on a publicly accessible website (and only in those cases), the subrecipient shall make its written policy available to any requestor within five business days of a request. If the subrecipient cannot provide such certification, the agreement shall state that subrecipient Investigators are subject to the financial conflict of interest policy of H3D for disclosing financial conflicts of interest;

(ii) Additionally, if the subrecipient's Investigators must comply with the subrecipient's financial conflict of interest policy, the agreement referenced above shall specify time period(s) for the subrecipient to report all identified financial conflicts of interest to H3D. Such time period(s) shall be sufficient to enable H3D to provide timely FCOI reports, as necessary, to the government, as required by the government COI policy;

(iii) Alternatively, if the subrecipient's Investigators must comply with H3D's financial conflict of interest policy, the agreement referenced above shall specify time period(s) for the subrecipient to submit all Investigator disclosures of significant financial interests to H3D. Such time period(s) shall be sufficient to enable H3D to comply timely with its review, management, and reporting obligations under the government COI policy.

(2) Providing FCOI reports to the government program office regarding all financial conflict of interest of all subrecipient Investigators consistent with the government COI Policy, *i.e.*, prior to the expenditure of funds and within sixty days of any subsequently identified FCOI.

(d) Designate an H3D official(s) to solicit and review disclosures of significant financial interests from each Investigator who is planning to participate in, or is participating in, the project funded under a government award, including disclosures of subrecipient investigators pursuant to paragraph (c) of this section.

Rachel Jaworski (Contracts Coordinator) will solicit the SFI Disclosures

Dr. Michael Streicher (H3D President) will review the SFI Disclosures

(e) Require that:

(1) Each Investigator who is planning to participate in the government award disclose to H3D's designated official(s) the Investigator's significant financial interests (and those of the Investigator's spouse and dependent children) at the time of a government proposal application. In the event that H3D seeks to add an Investigator after the time of application, H3D must require the Investigator make such disclosures prior to participating in a project funded under a government award.

(2) Each Investigator who is participating in the government award to submit an updated disclosure of significant financial interests at least annually during the period of the award. Such disclosure shall include any information that was not disclosed initially to H3D pursuant to paragraph (e)(1) of this section, or in a subsequent disclosure of significant financial interests (e.g., any financial conflict of interest identified on a government award that was transferred from another non-Federal entity), and shall include updated information regarding any previously disclosed significant financial interest (e.g., the updated value of a previously disclosed equity interest).

(3) Each Investigator who is participating in the government award to submit an updated disclosure of significant financial interests within thirty days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new significant financial interest.

(4) Each disclosure and updated disclosure be signed and dated by the Investigator and include a certification statement that reads:

I understand that this Disclosure is required to obtain funding from the U.S. Government. I, [Full Name and Title], certify to the best of my knowledge and belief that the information contained in this Disclosure Statement is true, complete, and accurate. I understand that any false, fictitious, or fraudulent information, misrepresentations, half-truths, or omissions of any material fact, may subject me to criminal, civil or administrative penalties for fraud, false statements, false claims, or otherwise. (18 U.S.C. §§ 1001 and 287, and 31 U.S.C. 3729-3730 and 3801-3812). I further understand and agree that (1) the statements and representations made herein are material to U.S. Government's funding decision, and (2) I have a responsibility to update the disclosures during the period of performance of the award should circumstances change which impact the responses provided above.

(f) Provide guidelines consistent with the government COI Policy for H3D's designated official(s) to determine whether an Investigator's significant financial interest is related to a project funded under a government award and, if so related, whether the significant financial interest is a financial conflict of

interest. An Investigator's significant financial interest is related to a project funded under a government award when H3D, through its designated official(s), reasonably determines that the significant financial interest could be affected by the project, could affect the project, is in an entity whose financial interest could affect the project, or is in an entity whose financial interest could be affected by the project. H3D may involve the Investigator in the designated official(s)'s determination of whether a significant financial interest is related to the project funded under the government award. A financial conflict of interest exists when H3D, through its designated official(s), reasonably determines that the significant financial interest could directly and significantly affect the purpose, design, conduct, or reporting of the project funded under a government award.

(g) Take such actions as necessary to manage financial conflicts of interest, including any financial conflicts of a subrecipient Investigator pursuant to paragraph (c) of this section. Management of an identified financial conflict of interest requires development and implementation of a management plan and, if necessary, a retrospective review and a mitigation report pursuant to Section V(a).

(h) Provide initial and ongoing FCOI reports to the government as required pursuant to Section V(b).

(i) Maintain records relating to all Investigator disclosures of financial interests and H3D's review of and response to such disclosures (whether or not a disclosure resulted in H3D's determination of a financial conflict of interest) and all actions under H3D's policy or retrospective review, if applicable, for the time period specified in 2 CFR 200.334 or, where applicable, from other dates specified in the individual award terms and conditions.

(j) Establish adequate enforcement mechanisms and provide for employee sanctions or other administrative actions to ensure Investigator compliance as appropriate.

(1) An employee's failure to provide SFI info, a failure to sign the SFI disclosure form or a failure to follow a COI management plan will result in a review process that may lead to consequences ranging from removal from government awards up to and including termination from H3D.

(k) Certify, prior to award, that H3D:

(1) Has in effect an up-to-date, written, and enforced administrative process to identify and manage conflicts of interest with respect to all projects for which financial assistance funding is sought or received from the government;

(2) Shall promote and enforce Investigator compliance with H3D's COI Policy requirements including those pertaining to disclosure of significant financial interests;

(3) Shall manage financial conflicts of interest and provide initial and ongoing FCOI reports to the government consistent with this (and the government's) Policy;

(4) Agrees to make information available, promptly upon request, to the government relating to any Investigator disclosure of financial interests and H3D's review of, and response to, such disclosure, whether or not the disclosure resulted in H3D's determination of a financial conflict of interest; and

(5) Shall fully comply with the requirements of the government COI policy.

V. Management and reporting of financial conflicts of interest.

(a) Management of financial conflicts of interest.

(1) Prior to H3D's expenditure of any funds under a government award, the designated official(s) of H3D shall, consistent with Section IV(f): review all Investigator disclosures of significant financial interests; determine whether any of the disclosures relate to the project funded under the government award; determine whether a financial conflict of interest exists; and, if so, develop and implement a management plan that shall specify the actions that have been, and shall be, taken to manage such financial conflict of interest. A nonexclusive list of conditions or restrictions, one or more of which might be imposed to manage a financial conflict of interest, includes:

(i) Public disclosure of the financial conflict of interest (e.g., when presenting or publishing the project);

(ii) For projects involving human subjects, disclosure of financial conflicts of interest directly to participants;

(iii) Appointment of an independent monitor or oversight committee capable of taking measures to protect the purpose, design, conduct, and reporting of the project against bias resulting from the financial conflict of interest;

(iv) Modification of the project plan;

(v) Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the project;

(vi) Reduction or elimination of the financial interest (e.g., sale of an equity interest); or

(vii) Severance of relationship(s) that create financial conflicts of interest.

(2) Whenever, in the course of an ongoing project funded under a government award, an Investigator who is new to participating in the project discloses a significant financial interest or an existing Investigator discloses a new significant financial interest to H3D, the designated official(s) of H3D shall, within sixty days: review the disclosure; determine whether it is related to the project funded under the government award; determine whether a financial conflict of interest exists; and, if so, implement, on at least an interim basis, a management plan that shall specify the actions that have been, and will be, taken to manage such financial conflict of interest. Depending on the nature of the significant financial interest, H3D may determine that additional interim measures are necessary with regard to the Investigator's participation in the project funded under the government award between the date of disclosure and the completion of H3D's review.

(3) Whenever H3D identifies a significant financial interest that was not disclosed timely by an Investigator or, for whatever reason, was not previously reviewed by H3D during an ongoing project funded under a government award (e.g., was not timely reviewed or reported by a subrecipient), the designated official(s) shall, within sixty days: review the significant financial interest; determine whether it is related to the project funded under a government award; determine whether a financial conflict of interest exists; and, if so:

(i) Implement, on at least an interim basis, a management plan that shall specify the actions that have been and will be taken to manage such financial conflict of interest going forward;

(ii)(A) In addition, whenever a financial conflict of interest is not identified or managed in a timely manner, including failure by the Investigator to disclose a significant financial interest that is determined by H3D to constitute a financial conflict of interest; failure by H3D to review or manage such a financial conflict of interest; or failure by the Investigator to comply with a financial conflict of interest management plan, H3D shall, within 120 days of the determination of noncompliance, complete a retrospective review of the Investigator's activities and the project funded under the government award to determine whether any project activity, or portion thereof, conducted during the time period of the noncompliance, was biased in the purpose, design, conduct, or reporting of such project.

(B) H3D is required to document the retrospective review; such documentation shall include, but not necessarily be limited to, all of the following key elements:

(1) Award number;

(2) Project title;

(3) PI or contact PI if a multiple PI model is used;

(4) Name of the Investigator with the FCOI;

(5) Name of the entity with which the Investigator has a financial conflict of interest;

(6) Reason(s) for the retrospective review;

(7) Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed);

(8) Findings of the review; and

(9) Conclusions of the review.

(iii) Based on the results of the retrospective review, if appropriate, H3D shall update the previously submitted FCOI report, specifying the actions that will be taken to manage the financial conflict of interest going forward. If bias is found, H3D is required to notify the government program office promptly and submit a mitigation report to the government program office. The mitigation report must include, at a minimum, the key elements documented in the retrospective review above, a description of the impact of the bias on the project, and H3D's plan of action or actions taken to eliminate or mitigate the effect of the bias (e.g., impact on the project; extent of harm done, including any qualitative and quantitative data to support any actual or future harm; analysis of whether the project is salvageable). Thereafter H3D will submit FCOI reports as specified elsewhere in this Policy. Government program offices may, by language in Funding Opportunity Announcements (FOAs) or by terms and condition of award, require more frequent reporting for awards. Depending on the nature of the financial conflict of interest, H3D may determine that additional interim measures are necessary with regard to the Investigator's participation in the project funded under the government award between the date that the conflict of interest or the Investigator's noncompliance is determined and the completion of H3D's retrospective review.

(4) Whenever H3D implements a management plan pursuant to the COI policy, H3D shall monitor Investigator compliance with the management plan on an ongoing basis until the completion of the government award.

(5)(i) Prior to H3D's expenditure of any funds under a government award, H3D shall ensure public accessibility, via written response to any requestor within five business days of a request, of information concerning any significant financial interest disclosed to H3D that meets the following three criteria:

(A) The significant financial interest is still held by the senior/key personnel as defined by this Policy;

(B) H3D determined that the significant financial interest is related to the project funded under the government award; and

(C) H3D determined that the significant financial interest is a financial conflict of interest.

(ii) The information that H3D makes available via a publicly accessible website or written response to any requestor within five business days of a request, shall include, at a minimum, the following: the Investigator's name; the Investigator's title and role with respect to the project; the name of the entity in which the significant financial interest is held; the nature of the significant financial interest; and the approximate dollar value of the significant financial interest (dollar ranges are 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.

(iii) If H3D responds to written requests for the purposes of this subsection, H3D will note in its written response that the information provided is current as of the date of the correspondence and is subject to updates, on at least an annual basis and within sixty days of H3D's identification of a new financial conflict of interest, which should be requested subsequently by the requestor.

(iv) Information concerning the significant financial interests of an individual subject to paragraph (a)(5) of this section shall remain available, for responses to written requests, for at least three years from the date that the information was most recently updated.

(6) In addition to the types of financial conflicts of interest as defined in this Policy that must be managed pursuant to this section, H3D may require the management of other conflicts of interest in its policy on financial conflicts of interest, as H3D deems appropriate.

(b) Reporting of financial conflicts of interest.

(1) Prior to H3D's expenditure of any funds under a government-funded project, H3D shall provide to the government program office a FCOI report regarding any Investigator's unmanaged or unmanageable significant financial interest found by H3D to be conflicting. Government program offices may, by language in FOAs or term and condition of award, require H3D's FCOI report also list any Investigator's significant financial interest found by H3D to be conflicting and addressed by a management plan in accordance with this Policy. H3D shall provide, on request, FCOI reports and supporting documentation about any significant financial interest found by H3D to be conflicting, regardless of whether or not the conflict has been managed, mitigated, or eliminated. In cases in which H3D identifies a financial conflict of interest and eliminates it prior to the expenditure of government-awarded funds, H3D need not submit a FCOI report to the government program office.

(2) For any significant financial interest that H3D identifies as conflicting subsequent to H3D's initial FCOI report during an ongoing project funded under a government award (e.g., upon the participation of an Investigator who is new to the project), H3D shall:

(i) [Applicable when a government program office requires H3D to include only unmanaged or unmanageable Investigator FCOIs in the FCOI Report] Provide to the government within sixty days an FCOI report regarding the financial conflict of interest if H3D's designated official determines that the FCOI is unmanageable. Pursuant to paragraph (a)(3)(ii) of this section, where such FCOI report involves a significant financial interest that was not disclosed timely by an Investigator or, for whatever reason, was not previously reviewed or managed by H3D (e.g., was not timely reviewed or reported by a subrecipient), H3D also is required to complete a retrospective review to determine whether any project funded under a government award or portion thereof conducted prior to the identification of the financial conflict of interest was biased in the purpose, design, conduct, or reporting of such project. Additionally, pursuant to paragraph (a)(3)(iii) of this section, if bias is found, H3D is required to notify the government program office promptly and submit a mitigation report to the government program office.

(ii) [Applicable when a government program office requires H3D to include all Investigator FCOIs – including managed and unmanaged/unmanageable FCOIs – in the FCOI Report] Provide to the government within sixty days, an FCOI report regarding the financial conflict of interest and ensure that H3D has implemented a management plan in accordance with this Policy. Pursuant to paragraph (a)(3)(ii) of this section, where such FCOI report involves a significant financial interest that was not disclosed timely by an Investigator or, for whatever reason, was not previously reviewed or managed H3D (e.g., was not timely reviewed or reported by a subrecipient), H3D also is required to complete a retrospective review to determine whether any project funded under a government award, or portion thereof, conducted prior to the identification and management of the financial conflict of interest was biased in the purpose, design, conduct, or reporting of such project. Additionally, pursuant to paragraph (a)(3)(iii) of this section, if bias is found, H3D is required to notify the government program office promptly and submit a mitigation report to the government program office.

(3) Any FCOI report required under paragraphs (b)(1) or (b)(2) of this section shall include sufficient information to enable the government to understand the nature and extent of the financial conflict, and to assess the appropriateness of H3D's management plan. Elements of the FCOI report shall include, but are not necessarily limited to the following:

(i) Award number;

(ii) PI or Contact PI if a multiple PI model is used;

(iii) Name of the Investigator with the financial conflict of interest;

(iv) Name of the entity with which the Investigator has a financial conflict of interest;

(v) Nature of any applicable financial interest (e.g., equity, consulting fee, travel reimbursement, honorarium) and/or applicable external relationships or activities;

(vi) Value of any applicable financial interest (dollar ranges are 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;

(vii) A description of how the financial interest relates to the project funded under a government award and the basis for H3D's determination that there is a conflict with such project; and

(viii) [Applicable when a government program office requires H3D to include all Investigator FCOIs – including managed and unmanaged/unmanageable FCOIs – in the FCOI Report] A description of the key elements of H3D's management plan, including:

(A) Role and principal duties of the conflicted Investigator in the project;

(B) Conditions of the management plan;

(C) How the management plan is designed to safeguard objectivity in the project;

(D) Confirmation of the Investigator's agreement to the management plan;

(E) How the management plan will be monitored to ensure Investigator compliance; and

(F) Other information as needed.

(4) For any financial conflict of interest previously reported by H3D with regard to an ongoing project funded under a government award, H3D shall provide the government with an annual FCOI report that addresses the status of the financial conflict of interest and, if applicable, any changes to the management plan for the duration of the government award. The annual FCOI report shall specify whether the financial conflict is still being managed or if it remains unmanaged/unmanageable. Alternatively, the annual FCOI report shall explain why the financial conflict no longer exists. H3D shall provide annual FCOI reports to the government for the duration of the project period (including extensions with or without funds) in the time and manner required by terms and condition of award.

(5) In addition to the annual FCOI report, the government may require H3D to routinely submit all or some Investigator disclosures of financial interests. Circumstances when the government may require H3D to submit all or some of such Investigator disclosures include but are not limited to:

(i) As part of monitoring H3D's compliance with this Policy;

(ii) Bankruptcy of H3D;

(iii) Other legal winding down of H3D;

(iv) Acquisition of H3D by a foreign entity, where "acquisition" includes a foreign entity obtaining a controlling interest in H3D; or

(v) As otherwise set forth in 2 CFR 200, as amended by 2 CFR 910.

(6) In addition to the types of financial conflicts of interest as defined in this policy (and the government's COI policy) that must be reported pursuant to this section, H3D may require the reporting of other conflicts of interest in its policy, as H3D deems appropriate.

VI. Responsibilities of H3D regarding organizational conflicts of interest.

(a) If H3D has a parent, affiliate, or subsidiary organization that is not a state, local government, or Indian tribe, H3D must maintain written standards of conduct covering organizational conflicts of interest. 2 CFR 200.318(c)(2).

(b) The existence of written policies or procedures requiring that certain procurements or transactions be made with a parent, affiliate, or subsidiary organization that is not a state, local government, or Indian tribe is an effective manner of mitigating an organizational conflict of interest.

(c) H3D must disclose in writing any potential or actual organizational conflict of interest to the government program office. H3D must provide the disclosure to the government in an application for financial assistance or prior to engaging in a procurement or transaction using government funds with a parent, affiliate, or subsidiary organization that is not a state, local government, or Indian tribe. The elements of the disclosure shall include, but are not limited to the following:

(i) The name, address, and website (as applicable) of the entity that presents a potential or actual organizational conflict of interest;

(ii) The relationship between H3D and the entity at issue;

(iii) The nature of the anticipated procurement or other transaction with the parent, affiliate, or subsidiary organization; the anticipated value of the procurement or other transaction; and the basis for making the procurement or other transaction with a parent, affiliate, or subsidiary organization;

(iv) The basis for H3D's determination regarding the existence of an organizational conflict of interest; and

(v) How H3D will avoid, neutralize, or mitigate the organizational conflict of interest.

(d) If the effects of the potential or actual organizational conflict of interest cannot be avoided, neutralized, or mitigated, the anticipated procurement or other transaction using government funds may not be made. Where there is an organizational conflict of interest that cannot be avoided, neutralized, or mitigated, H3D must procure goods and services from other sources when using government funds.

VII. Remedies.

(a) If the failure of an Investigator to comply with H3D's financial conflict of interest policy or a management plan appears to have biased the purpose, design, conduct, or reporting of the project funded under a government award, H3D shall promptly notify the government of the failure to comply and of the corrective action taken or to be taken. The government will consider the situation and, as necessary, take appropriate action, or refer the matter to H3D for further action, which may include directions to H3D on how to maintain appropriate objectivity in the project funded under the government award. The government may, for example, require non-Federal entities employing such an Investigator to enforce any applicable corrective actions prior to a government award or when the transfer of a government award involves such an Investigator.

(b) The government may inquire, at any time before, during, or after an award, into any Investigator's disclosure of financial interests and H3D's review (including any retrospective review) of and response to such disclosure, regardless of whether the disclosure resulted in H3D's determination of a financial

conflict of interest. H3D is required to submit, or permit on-site review of, all records pertinent to compliance with this Policy. To the extent permitted by law, the government will maintain the confidentiality of all records of financial interests. Based on its review of records or other information that may be available, the government program office may decide that a particular financial conflict of interest will bias the objectivity of or adversely impact the project funded under the government award to such an extent that further corrective action is needed or that H3D has not managed the financial conflict of interest in accordance with the government's COI policy. The government may determine that the imposition of specific award conditions under 2 CFR 200.208 is necessary. The government may also take one or more the actions specified under 2 CFR 200.339, as appropriate in the circumstances.

(c) If H3D fails to disclose an organizational conflict of interest to the government prior to engaging in a procurement or transaction using government funds with a parent, affiliate, or subsidiary organization that is not a state, local government, or Indian tribe, the costs of such procurement or transaction may be disallowed. If H3D fails to disclose an organizational conflict of interest to the government prior to engaging in a procurement or transaction using government funds with a parent, affiliate, or subsidiary organization that is not a state, local government, or Indian tribe, and the organizational conflict of interest is not avoided, neutralized, or managed, the government may determine that imposition of specific award conditions under 2 CFR 200.208 is necessary. The government may also take one or more actions specified under 2 CFR 200.339, as appropriate in the circumstances.

(d) Any false, fictitious, or fraudulent information, or the omission of any material fact, on a disclosure, report, or other record required under this Policy or the government's COI policy may be subject to criminal, civil, or administrative penalties for fraud, false statements, false claims or otherwise. (U.S. Code Title 18, Sections 287 and 1001; and Title 31, 3729-3730 and 3801-3812).