

# **Financial Conflict of Interest (FCOI) Policy**

## **Lucerna, Inc.**

(Last Updated September 2022)

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## **DEFINITIONS**

### **1. Conflict of Interest Officer ('COI Officer'):**

The employee hired at the Company is responsible for advising employees about potential individual conflicts of interests and the administrative duties of collecting and processing conflict of interest/conflict of commitment disclosures.

### **2. Financial Interest:**

Anything of monetary value including, but not limited to, an interest in a business consisting of any stock, stock option, or similar ownership interest in such business; or receipt of, or the right or expectation to receive, any income. The following is a non-exhaustive list of examples: a consulting fee, honoraria, salary, allowance, forbearance, forgiveness, interest in real or personal property, dividend, royalty derived from the licensing of technology or other processes or products, rent, capital gain, loans, or any other form of compensation.

"Financial Interest" means anything of actual or potential monetary value, whether or not the value is readily ascertainable. The term financial interest does not include the following types of financial interests:

- a) salary, royalties, or other remuneration paid by the Company to the employee if the employee is currently employed or otherwise appointed by the Company, including intellectual property rights assigned to the Company and agreements to share in royalties related to such rights;
- b) income from investment vehicles, such as mutual funds and retirement accounts, as long as the employee does not directly control the investment decisions made in these vehicles;
- c) income from seminars, lectures, or teaching engagements sponsored by a federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education; or
- d) income from service on advisory committees or review panels for a federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.

### **3. Financial Conflict of Interest (FCOI):**

A significant financial interest that could directly and significantly affect the design, conduct, or reporting of PHS-funded research.

### **4. FCOI report:**

An Institution's report of a financial conflict of interest to a PHS Awarding Component.

**5. HHS**

The United States Department of Health and Human Services, and any components of the Department to which the authority involved may be delegated.

**6. Immediate Family:**

The employee's spouse or domestic partner and dependent children.

**7. Company:**

Lucerna, Inc., a New York State Corporation with the address of 760 Parkside Avenue, Suite 327C, Brooklyn, NY 11226.

**8. Investigator:**

Project Director or Principal Investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by the PHS or NSF, or proposed for such funding, which may include, for example, collaborators or consultants.

**9. Public Health Service (PHS):**

The Public Health Service of the U.S. Department of Health and Human Services, and any components of the PHS to which the authority involved may be delegated, including the National Institutes of Health (NIH).

**10. PHS Awarding Component:**

The organizational unit of the PHS that funds the research.

**11. Significant Financial Interest (SFI):**

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

a. With regard to any 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;

b. With regard to any non-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, 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); or

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

The term significant financial interest does not include the following types of financial interests: salary, royalties, or other remuneration paid by the Institution to the Investigator if the Investigator is currently employed or otherwise appointed by the Institution, including intellectual property rights assigned to the Institution and agreements to share in royalties related to such rights; any ownership interest in the Institution held by the Investigator, if the Institution 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, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education; or income from service on advisory committees or review panels for a federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.

**12. Small Business Innovation Research (SBIR):**

A program for small businesses that is established by the Awarding Components of the Public Health Service and certain other Federal agencies under Public Law 97-219, the Small Business Innovation Development Act, as amended. For purposes of this policy, the term SBIR Program also includes the Small Business Technology Transfer (STTR) Program, which was established by Public Law 102-564.

**13. Company Responsibilities:**

Employee's responsibilities for which such Employee was hired and which are conducted at or undertaken on behalf of the Company, which may include, but is not limited to, activities such as research, research consultation, teaching, outreach/extension, professional practice, institutional committee memberships and service on Company-based panels.

## II. OVERVIEW

This policy pertaining to conflicts with the interests of federal grant agencies is applicable to investigators, as defined below, involved in proposed or awarded research funded by Public Health Services (PHS), including NIH. The Department of Health and Human Services has its own financial conflict of interest regulation- [Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service Funding is Sought and Responsible Prospective Contractor](#). The regulation, which took effect on August 24, 2012, governs research sponsored by NIH, CDC, AHRQ, and other Public Health Service (PHS) agencies and applies to all investigators on new awards, new proposals, non-competing renewals, and no cost extensions received or submitted on or after that date. This policy also applies to all SBIR/STTR (except phase I) subcontracts funded by NIH. **All Company employees are also subject to CRR 330.015, pertaining to conflicts with the interests of the Company. Researchers on Human Subjects and certain Company officials are also subject to CRR 410.020 pertaining to Institutional Conflicts in Human Subjects Research.**

## III. TRAINING

All Investigators are required to complete conflict of interest training prior to engaging in any PHS-funded research and at least every four years, and immediately when any of the following circumstances apply:

- (1) If there are revisions to the financial conflict of interest policies or procedures in any manner that affects the requirements of Investigators.
- (2) An Investigator is new to the Institution or
- (3) An Institution finds that an Investigator is not in compliance with the financial conflict of interest policy or management plan.

## IV. DISCLOSURE:

Each Investigator shall disclose financial interests (and those of the Investigator's spouse and dependent children) that reasonably appear to be related to the Investigator's institutional responsibilities no later than the time of application for Public Health Services (PHS) funded research.

In addition, each Investigator who is participating in the PHS-funded research must submit an updated disclosure of SFIs at least annually during the period of the award. Such disclosure shall include any information that was not disclosed initially, or in a subsequent disclosure of SFIs (e.g., any financial conflict of interest identified on a PHS-funded project that was transferred from another Institution), and shall include updated information regarding any previously disclosed SFI (e.g., the updated value of a previously disclosed equity interest).

Each Investigator participating in the PHS funded research is required to submit an updated disclosure of significant financial interests within thirty (30) days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new significant financial interest.

## **WHAT IS REQUIRED TO BE DISCLOSED**

### **SIGNIFICANT FINANCIAL INTERESTS:**

Investigators are required to disclose financial interest(s) consisting of one or more of the following interests of the Investigator (and those of the Investigator's spouse and dependent children).

(i) With regard to any 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 non-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, 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); or

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

(2) The term *significant financial interest* does not include the following types of financial interests: salary, royalties, or other remuneration paid by the Institution to the Investigator if the Investigator is currently employed or otherwise appointed by the Institution, including intellectual property rights assigned to the Institution and agreements to share in royalties related to such rights; any ownership interest in the Institution held by the Investigator, if the Institution 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, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education; or income from service on advisory committees or review panels for a Federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.

### **SPONSORED TRAVEL:**

When a PHS Investigator participates in any reimbursed or sponsored travel (i.e., that which is paid on behalf of the Investigator and not reimbursed to the Investigator so the exact monetary value may not be readily available), related to their Company responsibilities; provided, however, that this disclosure requirement does not apply to travel that is reimbursed or sponsored by a federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.

The Institution will require the following elements be submitted as part of any PHS Investigator Sponsored Travel Report:

- Purpose of the trip
- Identity of the sponsor/organizer
- Destination, and the duration
- Value of travel

The Committee will determine if further information is needed in order to determine whether the travel constitutes an FCOI with the PHS-funded research.

#### **V. HOW TO DISCLOSE**

All disclosures are required to be submitted to the COI Officer. The COI Officer will ensure all investigators have a current disclosure on file in accordance with this policy.

#### **VI. SUBRECIPIENTS AND COOPERATIVE AGREEMENTS**

For any research through a subrecipient (e.g., subcontractors or consortium members), the Company will:

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

(i) If the subrecipient's Investigators must comply with the subrecipient's FCOI policy, the subrecipient will certify that its policy complies with 42 CFR, Part 50, subpart F. If the subrecipient cannot provide such certification, the agreement shall state that subrecipient Investigators are subject to the FCOI policy of the Company for disclosing significant financial interests that are directly related to the subrecipient's work for the Company.

(ii) Additionally, if the subrecipient's Investigators must comply with the subrecipient's FCOI policy, the agreement shall specify time period(s) for the subrecipient to report all identified financial conflicts of interest to the Company. Such time period(s) shall be sufficient to enable the Company to provide timely FCOI reports, as necessary, to the PHS.

(iii) If the subrecipient's Investigators must comply with the Company's FCOI policy, the agreement shall specify time period(s) for the subrecipient to submit all Investigator disclosures of significant financial interests to the Company. Such time period(s) shall be sufficient to enable the Company to comply timely with its review, management, and reporting obligations under this policy.

2. Other Procedures as outlined in the OSPA document "Financial Conflict of Interest in PHS-Funded Research".



## **VII. REVIEW AND MONITORING**

The Company will designate one or more individuals to review the disclosure for all investigators, including subrecipients subsumed by the Institution, to determine whether an Investigator's significant financial interest is related to PHS-funded research and, if so related, whether the significant financial interest is a Financial Conflict of Interest (FCOI).

### **A. Initial Award:**

For all PHS-funded investigators the designated official shall review all Investigator disclosures for a determination of Significant Financial Interest (SFI); determine whether any SFI relates to the research and determine whether a financial conflict of interest (FCOI) exists prior to the Company expenditure of any funds. An Investigator's SFI is related to PHS-funded research when the designated official(s) reasonably determines that the SFI could be affected by the PHS-funded research or is in an entity whose financial interest could be affected by the research. The designated official(s) may involve the Investigator in its determination of whether an SFI is related to the PHS-funded research. An FCOI exists when the designated official(s) reasonably determines that the SFI could directly and significantly affect the design, conduct or reporting of PHS-funded research. Once the designated official(s) determine an FCOI exists, a management plan must be developed and implemented specifying the actions that have been, and shall be, taken to manage such financial conflict of interest.

### **B. New Investigator and/or New Outside Interest added to a Project:**

During an ongoing research project, if a new Investigator is added to the project or an existing Investigator discloses a new significant financial interest to the Company, the designated official(s) will review the disclosure within sixty days. A determination is required for whether any SFI is related to the research and whether an FCOI exists. If a determination of FCOI is made, the Company will implement, on at least an interim basis, a management plan, specifying the actions that have been, and will be, taken to manage the FCOI. Depending on the nature of the significant financial interest, the Company may determine that additional interim measures are necessary with regard to the Investigator's participation in the PHS-funded research project between the date of disclosure and the completion of the Company's review.

### **C. Initial reports:**

Prior to authorizing the expenditure of any funds for a PHS-funded research project, the Company shall provide to the PHS Awarding Component an FCOI report regarding any Investigator's FCOI reporting that a management plan has been implemented in accordance to the PHS rule. For cases in which the Company identifies a financial conflict of interest and eliminates it prior to the expenditure of PHS-awarded funds, the Company shall not submit an FCOI report to the PHS Awarding Component.

Each Company will provide the FCOI reports to the PHS Awarding Component regarding all financial conflicts of interest of all sub-recipient Investigators consistent with this policy, i.e., prior to the expenditure of funds and within 60 days of any subsequently identified FCOI.



For any significant financial interest that the Institution identifies as conflicting subsequent to the Company's initial FCOI report during an ongoing PHS-funded research project (e.g., upon the participation of an Investigator who is new to the research project), the Company shall provide to the PHS Awarding Component, within sixty days, an FCOI report regarding the financial conflict of interest and ensure that the Company has implemented a management plan in accordance with this policy.

Pursuant to section VII of this policy, 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 the Company (e.g., was not timely reviewed or reported by a sub-recipient), the Company also is required to complete a retrospective review to determine whether any PHS-funded research, or portion thereof, conducted prior to the identification and management of the financial conflict of interest was biased in the design, conduct, or reporting of such research. Additionally, pursuant to section VII of this policy, if bias is found, the Company is required to notify the PHS Awarding Component promptly and submit a mitigation report to the PHS Awarding Component.

#### **FCOI Management Plans:**

Prior to the Company expenditure of any funds, the designated official(s) will ensure management of the FCOI. Examples of conditions or restrictions that might be imposed to manage a financial conflict of interest include, but are not limited to:

- (i) Public disclosure of financial conflicts of interest (e.g., when presenting or publishing the research);
- (ii) For research projects involving human subjects research, disclosure of financial conflicts of interest directly to participants;
- (iii) Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from the financial conflict of interest;
- (iv) Modification of the research plan;
- (v) Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research;
- (vi) Reduction or elimination of the financial interest (e.g., sale of an equity interest); or
- (vii) Severance of relationships that create financial conflicts.

Whenever Company requires a management plan pursuant to this policy, the Company shall monitor compliance with the management plan on an ongoing basis until the completion of the research project.

All FCOI reports shall include sufficient information to enable the PHS Awarding Component to understand the nature and extent of the financial conflict, and to assess the appropriateness of the management plan. Elements of the FCOI report shall include, but are not necessarily limited to the

following:

- Project number;
- PO/PI or Contact PD/PI if a multiple PO/PI model is used;
- Name of the Investigator with the financial conflict of interest;
- Name of the entity with which the Investigator has a financial conflict of interest;
- Nature of the financial interest (e.g., equity, consulting fee, travel reimbursement, honorarium);
- Value of the 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;
- A description of how the financial interest relates to the PHS-funded research and the basis for the determination that the financial interest conflicts with such research; and
- A description of the key elements of the management plan, including:
  - a) Role and principal duties of the conflicted Investigator in the research project;
  - b) Conditions of the management plan;
  - c) How the management plan is designed to safeguard objectivity in the research 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.

For any financial conflict of interest previously reported by the Company with regard to an ongoing PHS-funded research project, the Company shall provide to the PHS Awarding Component an annual FCOI report that addresses the status of the financial conflict of interest and any changes to the management plan for the duration of the PHS-funded research project. The annual FCOI report shall specify whether the financial conflict is still being managed or explain why the financial conflict of interest no longer exists. The Company shall provide annual FCOI reports to the PHS Awarding Component for the duration of the project period (including extensions with or without funds) in the time and manner specified by the PHS Awarding Component.

### **VIII. FAILURE TO DISCLOSE OR REVIEW IN A TIMELY MANNER**

When a significant financial interest is not disclosed in a timely manner by an Investigator or, for whatever reason, was not previously reviewed by the Company during an ongoing research project (e.g., was not timely reviewed or reported by a sub-recipient), the Committee shall within sixty days: review the significant financial interest; determine whether it is related to research; determine whether a financial conflict of interest exists; and 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. The FCOI management plan will be submitted as required.

#### **A. Retrospective Review:**

Whenever an FCOI is not identified or managed in a timely manner including:

- Failure by the Investigator to disclose within 30 days a SFI that is determined to constitute an FCOI;
- Failure by the Company to review or manage an FCOI within sixty days; or
- Failure by the Investigator to comply with a financial conflict of interest management plan.

The Company shall, within 120 days of the Company determination of noncompliance, complete a retrospective review of the Investigator's activities and the research project to determine whether any research, or portion thereof, conducted during the time period of the noncompliance, was biased in the design, conduct, or reporting of such research. The Company shall document the retrospective review.

#### **B. Retrospective Review Documentation:**

Such documentation shall include, but not necessarily be limited to, all of the following key elements:

- Project number;
- Project title;
- PD/PI or contact PD/PI if a multiple PD/PI model is used;
- Name of the Investigator with the FCOI;
- Name of the entity with which the Investigator has a financial conflict of interest;
- Reason(s) for the retrospective review;
- Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed);
- Findings of the review; and
- Conclusions of the review.

Based on the results of the retrospective review, if appropriate, the Company shall update the previously submitted FCOI report to PHS, specifying the actions that will be taken to manage the financial conflict of interest going forward.

#### **C. Retrospective Review, Bias Found:**

If bias is found, the Company is required to notify the PHS Awarding Component promptly and submit a mitigation report to the PHS Awarding Component. The mitigation report must include, at a minimum, the key elements documented in the retrospective review above and a description of the impact of the bias on the research project and the plan of action or actions taken to eliminate or previously submitted FCOI report to PHS, specifying the actions that will be taken to manage the

financial conflict of interest going forward.

### **C. Retrospective Review, Bias Found:**

If bias is found, the Company is required to notify the PHS Awarding Component promptly and submit a mitigation report to the PHS Awarding Component. The mitigation report must include, at a minimum, the key elements documented in the retrospective review above and a description of the impact of the bias on the research project and the plan of action or actions taken to eliminate or mitigate the effect of the bias (e.g., impact on the research project; extent of harm done, including any qualitative and quantitative data to support any actual or future harm; analysis of whether the research project is salvageable). Thereafter, the Company will submit FCOI reports annually, as specified elsewhere in this policy. Depending on the nature of the financial conflict of interest, an Institution may determine that additional interim measures are necessary with regard to the Investigator's participation in the PHS-funded research project between the date that the financial conflict of interest or the Investigator's noncompliance is determined and the completion of the retrospective review.

### **D. Remedies**

Any case in which the HHS determines that a PHS-funded project of clinical research whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment has been designed, conducted, or reported by an Investigator with a financial conflict of interest that was not managed or reported by the Company as required, the Company shall require the Investigator involved to disclose the financial conflict of interest in each public presentation of the results of the research and to request an addendum to previously published presentations .

## **IX. NONCOMPLIANCE**

Should it come to light that a potential conflict of interest concerning an employee exists and that employee failed to disclose such potential conflict to the appropriate authority, the COI Officer should be contacted in addition to the employee's supervisor and director. The Director will contact the employee and request that a formal disclosure of the potential conflict be made. This request shall be copied to the employee's departmental chair/supervisor and dean/director. The Director will also request that the employee provide specific reasons and justification for the failure to disclose. The information will then be provided to the COI Committee for review.

If an Investigator fails to comply with the management plan, the information will be provided to the COIC for review.

The COIC has authority to recommend sanction of an employee for failure to cooperate with or upon finding a violation of COI policy (CRR 330.015.A.3). The President may apply sanctions as they deem appropriate. Possible sanctions include, but are not limited to, the following:

- a) Letter of warning or admonishment.
- b) Suspension or termination of research compliance committee approvals.
- c) Suspension or termination of the privilege to submit sponsored activity proposals.
- a) Suspension or termination of sponsored research activity spending authority.

- e) Demotion or removal from assigned administrative roles.
- f) Referral to the Company Committee on Tenure or other appropriate committee for discipline or dismissal for cause of faculty.
- g) Suspension or termination of employment (pursuant and subject to CRR 310.060, Procedures in Case of Dismissal for Cause, for those faculty covered by that rule).

**X. APPEAL/RECONSIDERATION PROCESS:**

If an employee believes the determined course of action is inappropriate, the employee may ask for the decision to be reconsidered by the Company legal council by submitting a request to the COIC Officer.

**XI. PUBLIC ACCESSIBILITY:**

Prior to the Company expenditure of any funds under a research project, the Company shall ensure public accessibility. Such accessibility is coordinated through the Company COIF Officer. Following submission of a written request and via a written response to the requestor within the time frame of five business days), information will be provided concerning any significant financial interest disclosed to the Company that meets the following three criteria:

- (a) The significant financial interest was disclosed and is still held by the senior/key personnel as defined by this policy;
- (b) The Company determines that the significant financial interest is related to the research; and
- (c) The Company determines that the significant financial interest is a financial conflict of interest.

The information that the Company makes available via written response to any requestor shall include, at a minimum, the following:

- the Investigator's name;
- the Investigator's title and role with respect to the research 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

The Company 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 60 days of the Company's identification of a new financial conflict of interest, which should be requested subsequently by the requestor.

**Maintenance of Records**

The Company will maintain records relating to all Investigator disclosures of financial interests and the review of, and response to, such disclosures (whether or not a disclosure resulted in a determination of an FCOI) and all actions under this policy or retrospective review, if applicable, for at least three years from the date the final expenditures report is submitted to the PHS or, where applicable, from other dates specified in 45 CFR 75.361 for different situations.

Related Policies and Regulations:

[42CFR50 Subpart F](#)

[NIH GPS 15.2.1](#)

[NIH GPS 4.1.10](#)