III.F. POLICY ON CONFLICTS OF INTEREST RELATED TO RESEARCH

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Introduction

As an institution committed to academic excellence, innovative research, and the highest quality clinical care, the University of Pennsylvania consistently generates new knowledge with the potential to link theory with practice in ways that enhance and transform our society. Penn’s dedication to excellence, discovery, and collaboration lead our faculty, students, and staff to opportunities for engaging the world around us.

We support an environment in which faculty and staff are able to pursue teaching, research, and patient care responsibilities in ways that enrich their work and further the University’s mission. Faculty involvement with external entities—in academia, government, the nonprofit sector, and industry—offers many positive benefits consistent with the University’s goals, including the practical application of new scientific discoveries and the ability to obtain research funding.

We must recognize, however, that these opportunities also introduce the potential for conflicts of interest that could affect one’s responsibilities and activities as a member of the Penn community. Involvement with external entities may create the risk that these relationships could bias the work performed by our faculty. Identifying, understanding, and responding to conflicts of interest are of primary importance to protecting the credibility and objectivity of our work, the professional reputations of our faculty and staff, and respect for the role of the University as educator, care-giver, and researcher.

The purpose of this policy is to set forth the framework for identifying, evaluating, and managing financial conflicts of interest related to University research activities to control their ability to create bias and to maintain integrity, credibility, and respect for the work of Penn researchers.

This policy is applicable to all research being conducted under the University’s auspices, regardless of whether the research is externally or internally funded, including proposals and applications made by University researchers to external sponsors, protocols submitted to the University’s Institutional Review Board or Institutional Animal Care and Use Committee, research funded by the University’s Centers and Institutes, material transfer agreements, nonmonetary collaborative agreements, and similar types of research agreements.

I. Definitions

As used in this policy, the following terms shall have the meaning ascribed to them below:

Clinical trial shall have the same meaning as prescribed from time to time by the World Health Organization.¹

Clinical trial intellectual property means an Investigator’s interest in intellectual property that is the subject of a copyright, issued patent, or a patent application (regardless of whether the intellectual property has been patented, licensed, or assigned to the University) if such intellectual property is being tested, evaluated, or developed in, or if its commercial value could be affected by, the Clinical trial in which the Investigator is engaged or proposes to engage.²

Excluded payer means a Federal, state, or local government agency, a United States institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education. By way of example, the University, the University of Pennsylvania Health System, Children’s Hospital of Philadelphia, the Philadelphia Veterans Affairs Medical Center, the Howard Hughes Medical Institute, and Wistar Institute are Excluded payers.

Family member means an Investigator’s spouse or dependent child, or persons having such other relationships to the Investigator as the Institutional official may determine from time to time.

FCOI report means the University’s report of a financial conflict of interest required by law or otherwise by agreement to be made to a research sponsor or other oversight agency.

Fiduciary role means membership on the governing board of an entity, including service on its board of directors, or having a position of authority or responsibility to act in the best interest of the entity, including being an officer, manager, partner, or limited liability company member with management responsibility.

Financial conflict of interest (FCOI) means a Significant financial interest that could directly and significantly affect the design, conduct, or reporting of the Research.

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

Institutional official means the Vice Provost for Research or such other person as the Provost appoints from time to time as the individual within the University responsible to oversee the University’s compliance with conflict of interest regulations and policies.

Institutional responsibilities means an Investigator’s professional or employment-related responsibilities on behalf of the University or any of its Schools, which may include Research, Research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards.

Investigator means the 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, whether externally or internally funded, or proposed for such funding, which may include, for example, collaborators or consultants.

Outside organization means any organization other than the University, University of Pennsylvania Health System and its corporately-owned entities (e.g., Clinical Care Associates and Clinical Practices of the University of Pennsylvania) or other Excluded payer.

Research means a systematic investigation, study or experiment designed to develop or contribute to generalizable knowledge. The term encompasses basic and applied research (e.g., a published article, book, or book chapter) and product development (e.g., of a diagnostic test or drug).
Senior/key personnel means the project director or principal investigator and any other person identified as senior/key personnel by the University in a grant application, progress report, or any other report submitted to the sponsor related to the Research.

Significant financial interest (SFI) means one or more of the following of the Investigator (or the Investigator’s Family member) that reasonably appear to be related to the Investigator’s Institutional responsibilities:

i. With regard to any publicly traded Outside organization, an SFI exists if the value of any remuneration received from the Outside organization in the 12 months preceding the disclosure plus the value of any equity interest in the Outside organization as of the date of disclosure, when aggregated, exceeds $5,000. 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 Outside organization, an SFI exists if the value of any remuneration received from the entity in the 12 months preceding the disclosure, when aggregated, exceeds $5,000, or if the Investigator or Family member holds any equity interest (e.g., stock, stock option, or other ownership interest);

iii. Intellectual property rights and interests (e.g., patents, copyrights) not assigned to the University, upon receipt of any income related to such rights and interests;

iv. Clinical trial intellectual property rights (and royalties or other remuneration, if any; paid with respect to such rights); or

v. Any Fiduciary role in an Outside organization.

A Financial interest is related to an Investigator’s Institutional responsibilities if, for example, it arises from extramural activities that derive from the Investigator’s professional standing or that are within that Investigator’s expertise in the Investigator’s professional field(s) of discipline, such as consulting, serving on a scientific advisory board, providing continuing professional education services, or serving as an expert witness for an Outside organization that, to the best of the Investigator’s knowledge, conducts or seeks to conduct business related to the Investigator’s field of discipline. Moreover, equity in, or serving in a Fiduciary role for, an Outside organization that, to the best of the Investigator’s knowledge, conducts or seeks to conduct business related to the Investigator’s field of discipline, is related to the Investigator’s Institutional responsibilities.

Notwithstanding the foregoing, unless arising from the Investigator’s Clinical trial intellectual property, SFI does not include:

• salary, royalties, or other remuneration paid by the University to the Investigator if the Investigator is currently employed or otherwise appointed by the University;

• rights in intellectual property assigned to the University, including the right to participate in the University’s royalties or in the University’s equity pool if the equity interest is held and controlled by the University under the Patent and Tangible Research Property Policies and Procedures of the University of Pennsylvania, as amended from time to time;

• equity in or 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; or

• income from seminars, lectures, or teaching engagements sponsored by, or income from service on advisory committees or review panels for, an Excluded payer.

II. Investigator’s Duty to Disclose Significant Financial Interests and Travel

Disclosure of Significant financial interests: At least annually, each Investigator must submit to designated offices at the Investigator’s School a disclosure of Significant financial interests (SFI) and such other information as the Institutional official or the Investigator’s School shall require. This disclosure must be updated at the time of submission of a proposal for sponsored Research, upon submission of a protocol, upon being added (in a capacity that meets the definition of Investigator) to an ongoing Research project, and also within 30 days of the Investigator’s discovering or acquiring a new SFI. The means and format of the disclosure will be prescribed from time to time and communicated to the University research community.

In addition to the disclosure of SFIs, the Investigator must provide requested information to assist in the assessment of whether any of the Investigator’s SFIs are related to the Investigator’s Research.

Disclosure of travel: Investigators who are funded or proposed to be funded by the Public Health Service or other sponsor designated from time to time by the University, must also disclose the occurrence of any reimbursed or sponsored travel (i.e., travel 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 the Investigator’s Institutional responsibilities during the previous 12 months, other than travel reimbursed or sponsored by an Excluded payer. Travel disclosures must include the purpose of the trip, the identity of the trip’s sponsor or organizer, the trip’s origin and destination, and the duration of the trip.

In addition, the University or Investigator’s School may request other information about the trip as necessary to evaluate whether the travel may constitute a Financial conflict of interest (FCOI).

III. Assessment of Disclosures

Review by the School: Each School shall appoint a Conflict of Interest (COI) Office/Officer to review disclosures of SFIs and, where applicable, travel, and the Investigator’s assessment of relatedness of SFIs to the Research in which the Investigator engages or proposes to engage. The School COI Office/Officer shall review the disclosures and reasonably determine whether any of the disclosed SFIs or travel payments could be affected by the Research or are in an entity whose Financial interest could be affected by the Research. The determination of relatedness to the Research will be made based on both the Investigator’s assessment of relatedness and on other facts reasonably deemed relevant by the COI Office/Officer.

Review by the Institutional official: The Institutional official is responsible to make the ultimate determination regarding whether a related SFI constitutes an FCOI and, if so, whether the FCOI is amenable to management. If the School COI Office/Officer determines that one or more disclosed SFIs or travel relate to the Research, the School shall direct the Investigator to submit information regarding those related SFIs to the University’s Office of the Vice Provost for Research (OVPR), using such means of disclosure as prescribed by the OVPR from time to time and communicated to the University’s research community. The University may utilize several forms of review to reasonably determine FCOIs. The type of review to be utilized and review standards may be prescribed from time to time through guidance from the Institutional
In general, the following types of conditions, as well as other factors.

**Recommendations by the Conflict of Interest Standing Committee:** A Conflict of Interest Standing Committee (CISC) shall serve in an advisory capacity to the **Institutional official**, providing recommendations related to whether an SFI constitutes an FCOI, whether the FCOI is manageable, and if so, the management plan. The primary scope of inquiry of the CISC is to review matters involving SFIs and their potential to affect the objectivity of specific Research. Matters involving other types of conflicts of interest (e.g., procurement, conflict of commitment) will be referred to the Schools and/or other University offices, depending on the nature of the conflict.

The CISC will consist of approximately 10-20 members (or such number of members as the Institutional official may determine from time to time) of the standing faculty appointed by the **Institutional official**. Efforts will be made to have faculty representation on the CISC reflective of the volume of disclosures submitted by each School. In addition, the **Institutional official** may from time to time appoint one or more member(s) drawn from the community external to the University. The external member(s) shall comply with the same standards of conduct and duties applicable to participation by University-affiliated members of the CISC relative to their participation on the committee. Only appointed CISC members who are faculty and the external member(s), if any, shall have voting rights in CISC decisions. **Ex-officio**, non-voting members will include the Associate Vice Provost for Research; Associate Vice Provost Office of Research Services; the Associate Vice Provost for Research and Executive Director, Penn Center for Innovation; the Director, Human Research Protections; and an attorney from the Office of the General Counsel. Other non-voting participants may be appointed at the discretion of the **Institutional official**.

The recommendations of the CISC require approval by a majority of the voting members present during the meeting. A member may be present at a meeting either in person or by electronic means, such as telephone or internet conferencing, allowing participation in the meeting. A quorum of six voting members present, or such other quorum requirement as may be determined from time to time (and applied prospectively) by the **Institutional official**, is required for a meeting. A CISC voting member shall not vote on a particular case if: the case involves a member of the same departmental division, or if the department has no divisions or fewer than six divisions, the same department; the CISC member has a personal interest because of inter-departmental relationships, such as collaboration with the faculty member whose case is under consideration; or the CISC member has a financial or other relevant interest related to the case under discussion. Disclosure of any of the above conditions must be made by the CISC member prior to the beginning of the discussion. The Chair has discretion to request that a CISC member not participate in a discussion based on the above conditions.

In general, the following types of SFIs related to Research will be reviewed by the CISC, as they are likely to constitute an FCOI unless there are factors that would reasonably prevent any direct or significant effect on the design, conduct, or reporting of the Research:

i. Equity in a privately held Outside organization that is actively conducting or seeking to conduct business related to the Research;

ii. Equity with a value greater than $50,000 or greater than 5% ownership in a publicly traded Outside organization that is actively conducting or seeking to conduct business related to the Research;

iii. Payments greater than $25,000 in the preceding 12 months from an Outside organization;

iv. Fiduciary role on behalf of an Outside organization that is actively conducting or seeking to conduct business related to the Research;

v. Intellectual property interest (not assigned to the University or other Excluded payer) if any income has been received from such intellectual property interest in the preceding 12 months; or

vi. Clinical trial intellectual property.

The **Institutional official** may also choose to submit for CISC review other types of SFIs not listed above or instances where an Investigator has more than one type of SFI related to the Research.

Prior to commencement of a Research project, review and assessment of FCOIs shall be conducted within the timeframes required by law or otherwise by agreement with the sponsor and, where applicable, shall be concluded prior to the expenditure of funds from the sponsor. During an ongoing Research project, should an Investigator who is new to the project disclose an SFI or should a current Investigator disclose a new SFI, the disclosure will be reviewed in the manner described above to determine whether the SFI relates to the Research and constitutes an FCOI.

**IV. Determination and Management of FCOI**

Whether or not submitted for review by the CISC, an SFI may be found by the **Institutional official** to constitute an FCOI and may be subjected to a requirement that the FCOI be managed (including elimination of the Financial interest, where appropriate) as a condition to the Investigator’s participation in the Research to which it is related. The determination of whether an FCOI, including an FCOI involving a Clinical trial, is manageable without elimination of the Financial interest should take into account relevant factors such as the nature and design of the Research; the magnitude and nature of the Financial interest; the extent to which the Financial interest could be influenced by the Research; the uniqueness of the Investigator’s position with respect to the study (for example, whether safety or other factors will be diminished if the Investigator does not participate); whether the interest is amenable to management; and in addition, with respect to Clinical trials, the degree of risk to human subjects, the role of the Investigator in the study, and the degree of the Investigator’s influence upon the recruitment and enrollment of subjects or the results of the study.

**Management plan:** Where appropriate, a plan to manage the FCOI may be developed and recommended to the **Institutional official**. The **Institutional official** will have the authority to accept, modify, or reject the recommendations or to refer the FCOI to the CISC for additional consideration. The **Institutional official** will communicate the findings and elements of the management plan to the Investigator and other University personnel as appropriate. The Investigator will be granted the opportunity to review the management plan and must acknowledge in writing their acceptance of the obligation to abide by the plan.

**Reconsideration:** If the Investigator objects to the terms of the management plan, the Investigator may submit promptly to the **Institutional official** a written request for reconsideration, specifying the basis for the objection. The **Institutional official** has discretion to refer the matter back to the CISC for further review and recommendations, but is not required to do so. The **Institutional official** also has the option to consult with the relevant School officials. If the Investigator is not satisfied with the decision of the **Institutional official** after such reconsideration, the Investigator may appeal to the Provost, whose determination is final.
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Reporting: Once the management plan has been finalized, OVPR staff will prepare, if applicable, FCOI reports required to be submitted to the research sponsor or oversight agency. The FCOI reports shall contain information required by law or otherwise by the sponsor. The Investigator should be aware that information pertaining to FCOIs may be disclosed to sponsors or oversight agencies and, in some cases, to the public and may contain such details as the value and nature of the Financial interest and elements of the management plan.

V. Investigator’s Obligation to Complete Training

As part of the responsibility for participating in Research at the University, Investigators must receive training from the University related to Research-related FCOIs prior to engaging in Research at the University and at least every four years thereafter. Investigators new to the University shall undergo training promptly after commencement of employment. In addition, each Investigator must undergo training within a reasonable period of time following any substantive change to this policy that affects the requirements for Investigators, and must be retrained if it is determined that the Investigator has not complied with this policy or with a management plan related to their activities. Training shall include a description of this policy, the Investigator’s disclosure responsibilities, an overview of the relevant Public Health Service regulation, and such other topics as the Institutional official shall determine from time to time.

VI. Investigator’s General Obligation to Cooperate

The Investigator is required to cooperate fully with the University in all aspects of the administration of this policy. This includes, among other things, providing all information as required to allow the University to understand and assess the Investigator’s disclosure of SFI and the relatedness of the SFI to the Investigator’s Research, assisting in the conduct of retrospective reviews where appropriate, and responding promptly and appropriately to implementation and monitoring of management and mitigation plans or corrective action.

VII. Public Accessibility

This policy will be made available to the public via posting on the University’s website. In addition, to the extent required by law or otherwise by the terms and conditions of a Research project specified in the request, the University will, within five business days, provide as to Senior/key personnel with FCOI related to such project: the Investigator’s title and role with respect to the Research project; the name of the entity in which the SFI is held; the nature of the SFI; and the approximate value of the Financial interest reported in ranges ($0–$49,999; $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 reasonable measures of fair market value.

The written request to the University must identify the project in sufficient detail to permit identification of the specific grant or contract.

In lieu of response to individual requests as described above, the Institutional official may in the future determine to employ postings on the University’s website as the means of communication of information regarding FCOIs of Senior/key personnel to the public. In the event that the website is used for that purpose, the website will contain the information described above and shall be updated with the frequency and maintained for the periods required by law.

VIII. Response to Non-compliance

Review of untimely disclosures: Should the University identify an SFI that, for any reason, was not disclosed by an Investigator within the required timeline or was not previously reviewed by the University during an ongoing Research project, the Investigator’s School or the University will, within 60 days where required by law or by the terms of the Research award and in any event promptly as the circumstances allow, perform their respective responsibilities to review the SFI, determine whether it is related to the Research project, and determine whether an FCOI exists. If the Institutional official determines that the SFI constitutes an FCOI, the University shall implement a management plan describing the actions that have been and will be taken to manage the FCOI.

Retrospective review and mitigation: In addition, if an FCOI (including FCOIs of subrecipients) is not identified or managed within the designated timeframe for any reason, where required by law or by the terms of the Research award or otherwise as may be appropriate in the view of the Investigator’s School or the University, the University shall direct the School (or subrecipient, as applicable) to conduct in consultation with the University a retrospective review of the Investigator’s activities and the Research project to determine whether any portion of the Research conducted during the time period of the noncompliance was biased in the design, conduct, or reporting of such Research. This retrospective review shall be completed within 120 days of the determination of non-compliance where required by law or by the terms of the Research award and in any event promptly as the circumstances allow.

As appropriate, the University will provide an updated FCOI report, specifying actions that will be taken to manage the financial conflict of interest going forward. If the retrospective review finds bias related to the Research project, the University will notify the research sponsor as appropriate. As required by law or agreement or as otherwise appropriate, this notification shall include a mitigation report including the key elements documented in the retrospective review above, a description of the impact of the bias on the Research project, and the University’s plan for eliminating or mitigating the effect of the bias.

Sanctions for violation: If it is suspected that an Investigator has violated this policy, the Institutional official, in conjunction with the applicable
Deans and other administrative officials of the University, will make appropriate inquiry regarding the matter. If after such inquiry a violation is found, suitable corrective action may be taken. Such action may include the initiation of proceedings under other University policies, including the University’s Procedures Governing Sanctions Against Members of the Faculty and relevant Human Resources policies.

If the University determines that an Investigator has failed to comply with this policy or an FCOI management plan and that the non-compliance appears to have biased the design, conduct, or reporting of the Research, the University shall promptly notify the research sponsor as required by law or agreement or as otherwise appropriate, of the corrective action taken or to be taken. Among other actions, in the event that the Department of Health and Human Services determines that a clinical Research project funded by the Public Health Service (including the National Institutes of Health) with the purpose of evaluating the safety or effectiveness of a drug, medical device, or treatment has been designed, conducted, or reported by an Investigator with an FCOI that was not managed or reported by the University as required by Federal regulations, the University shall among other things require the Investigator involved to disclose the FCOI in each public presentation of the results of the Research and to request an addendum to previously published presentations.

IX. Responsibilities for Research Subrecipients
If required under the terms and conditions of a sponsored Research project, the University will require any written subaward agreement with any organization to include terms establishing the applicable FCOI policy governing the subrecipient’s work, whether it is the University of Pennsylvania policy or the policy of the subrecipient institution. The subrecipient will be required to provide certification that its policy is established in accord with sponsor requirements or, if unable to provide such certification, the University policy will be applicable to all subrecipient Investigators. (As a rule, the University will require subrecipient institutions to maintain and administer their own FCOI policies and will only in exceptional circumstances assume primary responsibility for directly soliciting and reviewing subrecipient personnel disclosures that enable the University to directly identify and manage identified FCOIs from the SFI disclosures of subrecipient personnel.) In addition, the written subaward agreement will establish timelines and information requirements that will allow sufficient time for the University to evaluate, as applicable, subrecipient disclosures or subrecipient FCOI reports in order for the University to meet any applicable sponsor reporting requirements.

X. Record Retention
In general, records related to the identification, evaluation, and response to FCOI in Research shall be retained for three years following the date that the final Research expenditure report has been submitted to the research sponsor or for a longer period when specified by applicable governmental or University requirements.

XI. Oversight by the Institutional Official
The Institutional official is responsible for:

- communicating the expectations of the University’s FCOI policy to the research community;
- providing access to appropriate FCOI training;
- designating tools and procedures for Investigator disclosure of SFIs;
- creating policies and guidelines for the determination of whether an FCOI exists;
- developing processes for the review of SFI disclosures, the evaluation of FCOIs, and the development and monitoring of management plans;
- establishing a process for providing FCOI reports to the research sponsor or other oversight agencies as appropriate;
- implementing a procedure to provide required notification to the research sponsor if bias is found in the design, conduct, or reporting of Research and to submit any required mitigation plan to the sponsor;
- establishing a procedure for notifying research sponsors of non-compliance with this policy as appropriate;
- establishing procedures for the maintenance of FCOI-related records in accordance with University and Federal record retention guidelines;
- establishing appropriate enforcement mechanisms, including actions to promote
  - Investigator compliance;
  - establishing procedures to implement that subrecipient agreements specify the use of University or subrecipient FCOI policies;
  - making this policy publicly accessible; and
  - establishing a process for making information related to FCOIs held by Senior/key personnel publicly available, where required, in the applicable timeframes.

These responsibilities may be delegated to other University or, in consultation with the applicable Dean, School personnel as necessary and appropriate to promote adherence with this policy and applicable sponsor guidelines.

XII. Related Authority
This policy implements the requirements of the Public Health Service, including the National Institutes of Health as set forth in Promoting Objectivity in Research, 42 CFR 50, Subpart F and Responsible Prospective Contractors, 45 CFR 94, and describes the University’s approach to meeting the requirements of other sponsors.


1 As of the date of this policy, the WHO definition reads: ...a clinical trial is any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes. Clinical trials may also be referred to as interventional trials. Interventions include but are not restricted to drugs, cells and other biological products, surgical procedures, radiologic procedures, devices, behavioural treatments, process-of-care changes, preventive care, etc. This definition includes Phase I to Phase IV trials.

2 Engaging in a trial includes, but is not limited to, serving as a Principal Investigator, Co-Investigator, regulatory sponsor/IND holder or in any other role responsible for the design, conduct, or reporting of the trial (including reporting results to the FDA); performing any other subject-related activity specific to the trial, such as the recruitment, selection, or enrollment of subjects, obtaining informed consent, providing
subject treatment and care specific to the trial, or performing study procedures; or collecting, analyzing, or interpreting data.

This includes proposals to transfer existing awards from another institution in connection with the commencement of an Investigator’s employment by the University.

As of the time of preparation of this policy, it is anticipated that the full implementation of the disclosure procedures in this policy will occur in stages, as necessary software and other resources are deployed to help support this process. Initial emphasis will be to first assure compliance with federal regulation and thereafter additional procedures will be phased in. The University will provide notice from time to time to its research community to advise of the specific means by which to submit disclosures.

The foregoing titles may be changed from time to time.

The request for reconsideration must be made with sufficient time to allow the University to respond to the objection and comply in a timely manner with reporting requirements under applicable law.

Current Public Health Service regulation requires that such reports be made prior to the expenditure of funds, within 60 days of identifying a new FCOI for an existing Investigator or appointing a new Investigator with an FCOI to the Research project, at least annually and in conjunction with progress reports or renewals, or when necessary to update a previously submitted report.

Requests must be submitted in writing to the Office of the Vice Provost for Research, Attention FCOI Request Department, 1 College Hall Room 118, Philadelphia, PA 19104-6303. FCOI information required to be furnished under this section shall remain available for the period required by applicable law.

Including where applicable, 45 CFR 74.53(b) and 92.42, and 48 CFR part 4, subpart 4.7