

# THOMAS JEFFERSON UNIVERSITY AND JEFFERSON HEALTH ENTERPRISE RESEARCH COMPLIANCE PROGRAM

## I. OVERVIEW

Thomas Jefferson University and Jefferson Health's ("Jefferson's") Enterprise Research Compliance Program demonstrates Jefferson's commitment to ethical conduct and compliance in research by setting forth guidelines for conduct designed to prevent and detect violations of law related to research, uphold accreditation standards, comply with Jefferson policies, and encourage research compliance by providing support, training, and educational resources. The Enterprise Research Compliance Program is designed to assist Jefferson in fulfilling its compliance responsibilities by creating an operational structure that outlines and documents Jefferson's research compliance efforts and is designed to work in conjunction with other Jefferson compliance plans. Jefferson's research compliance activities rely on the combined efforts of researchers, support staff, and others, as well as collaboration among its departments. Jefferson has designed its Enterprise Research Compliance Program to be proactive, transparent, and integrated to prevent problems before they happen without impairing research. Jefferson's Enterprise Research Compliance Program complements, but does not replace or supersede any other policy applicable at Jefferson.

## II. CORE ACTIVITIES

Jefferson's Enterprise Research Compliance Program is founded upon the following core activities:

### **Program Oversight**

Assuring compliance through senior leadership and independent oversight

### **Roles and Responsibilities**

Maintaining clear roles and compliance responsibilities for all parties; using due care and appropriate oversight when assigning compliance responsibilities and coordinating Jefferson and departmental-level compliance efforts

### **Communication**

Developing and maintaining effective systems of communication, including resources for promptly responding to compliance questions or concerns

### **Policies and Procedures**

Designing standards and policies that effectively enable researchers and others to meet compliance requirements

### **Awareness, Education, and Training**

Communicating standards, procedures, and responsibilities to researchers, administrators, and others through timely and appropriate education and training

### **Monitoring and Audits**

Implementing monitoring and auditing systems to assure compliance, detect breakdowns, and identify potential problem areas

### **Enforcement and Corrective Action**

Enforcing standards fairly and consistently; promptly investigating and resolving compliance breakdowns; evaluating and modifying the compliance program where appropriate to prevent similar problems

### **Risk Assessment**

Examining research activities regularly to identify and reduce potential compliance breakdowns

### III. RESEARCH COMPLIANCE PROGRAM DESCRIPTION

#### 3.1 Program Oversight; Roles and Responsibilities; Communication

3.1-1 Enterprise Research Compliance Officer. Jefferson has created an Enterprise Research Compliance Officer position and has appointed an individual to serve in that capacity. Jefferson shall formally maintain the appointment of such individual to serve as the Enterprise Research Compliance Officer. At a minimum, the Enterprise Research Compliance Officer shall be continuously charged with the responsibility to work with the Enterprise Research Compliance Committee in the development and implementation of policies, procedures, and practices designed to ensure compliance with legal requirements. The Enterprise Research Compliance Officer shall make regular reports regarding research compliance matters directly to the designated Jefferson Senior Official, and shall be authorized to report to the designated committee of the Jefferson Board and the Jefferson Board of Trustees, at any time. The Enterprise Research Compliance Officer shall be responsible for monitoring the day-to-day activities engaged in by Jefferson to further its research compliance objectives as well as any reporting obligations created under this Section.

3.1-2 Enterprise Research Compliance Committee. Jefferson has created and shall maintain an Enterprise Research Compliance Committee, which shall be responsible for, at a minimum, supporting the Enterprise Research Compliance Officer in fulfilling his/her responsibilities. The Enterprise Research Compliance Committee shall include members from Jefferson's research community, Jefferson's research offices and other Jefferson offices that impact the research community as more fully described in Section 3.1-3 below. The Enterprise Research Compliance Officer shall chair the Enterprise Research Compliance Committee.

3.1-3 Roles and Responsibilities. The Enterprise Research Compliance Committee shall expect the members of Jefferson's research community ("Covered Individuals") and Jefferson's research offices, other Jefferson offices, departments and committees that impact the research community, and other offices that serve as advisors to the Enterprise Research Compliance Program to be responsible for the Enterprise Research Compliance Program activities specific to the area of responsibilities within each of their respective offices.

The following are Jefferson's **Research Offices**:

- Office of Human Research (OHR) including its Institutional Review Boards (IRB);
- Office of Research Administration (ORA);
- Jefferson Clinical Research Institute (JCRI),
- Research Administration Center of Excellence (RACE);
- Office of Animal Resources (OAR);
- Institutional Animal Care and Use Committee (IACUC);
- Office of Research Conduct and Compliance (ORCC); and
- Liaisons within Research Offices to include, but not be limited to liaisons from Abington – Jefferson Health campus, Jefferson Health – Northeast campus, East Falls campus and Jefferson Health New Jersey campus:

(collectively, the "Research Offices")

The following are Jefferson **offices, departments and committees impacting the research community**:

- Innovation Management (IM);
- Department of Environmental Health and Safety;

- Institutional Biosafety Committee;
- Sponsored Programs Accounting Office (SPA0);
- Conflicts of Interest (COI) Committee;
- Office of International Affairs (OIA);
- Office of Corporate Compliance;
- HIPAA Privacy Office;
- HIPAA Security Office; and
- Clinical Trial Billing Committee.

(collectively, “Impacting Research Offices”)

The following are other Jefferson offices that serve as *advisors* to the Enterprise Research Compliance Committee and Research Offices to include:

- Office of Legal Affairs (OLA),
- Internal Audit,
- Human Resources, and
- Enterprise Risk.

(collectively, “Research Advisors”)

3.1-4 Communication. Jefferson, through its Enterprise Research Compliance Officer, Enterprise Research Compliance Committee and Research Offices, shall maintain an effective system of communication and provide resources to respond to Covered Individuals’ compliance questions or concerns.

### 3.2 Code of Conduct.

Jefferson has created and distributed a Code of Conduct with provisions applicable to research. The Code of Conduct shall continue to be distributed to all Covered Individuals. Jefferson shall maintain its Code of Conduct and make the promotion of, and adherence to, the Code of Conduct an element in evaluating the conduct of research. The Code of Conduct shall continue to maintain the following elements:

- Jefferson's commitment to full compliance with all federal statutes, regulations and policies applicable to Sponsored Agreements;
- Jefferson's requirement that all of its Covered Individuals shall be expected to comply with all ethical and legal obligations, contractual agreements, and Jefferson's policies and procedures;
- the requirement that all of Jefferson's Covered Individuals shall be expected to report to the Enterprise Research Compliance Officer or other appropriate persons at Jefferson suspected violations of any statute, regulation, policy or guideline applicable to Sponsored Agreements or of Jefferson's policies and procedures;
- the possible consequences, including disciplinary actions against individuals, to both Jefferson and to any Covered Individual of failure to comply with all statutes, regulations, policies and guidelines applicable to Sponsored Agreements and with Jefferson's policies and procedures or of failure to report such non-compliance; and
- the right of all Covered Individuals to use the Confidential Reporting Alertline described below, as well as Jefferson's commitment to confidentiality and non-retaliation with respect to disclosures.

Jefferson shall document the actions taken to distribute the Code of Conduct to all Covered Individuals. The Enterprise Research Compliance Committee will periodically review the Code of Conduct and will forward any necessary revisions to the Enterprise Chief Compliance Officer

for consideration. Revisions to the Code of Conduct shall be communicated to Covered Individuals, as appropriate.

### 3.3 Policies and Procedures.

Jefferson, through the appropriate Research Offices, shall develop, initiate and maintain the implementation of written policies and procedures regarding the operation of its Enterprise Research Compliance Program (the “Policies and Procedures”) and its compliance with all federal statutes, regulations, and guidelines applicable to research. At a minimum, the Policies and Procedures shall specifically address the submission of accurate and appropriate claims and other reports relating to Sponsored Agreements and data retention requirements under federal law e.g., Research Misconduct, Integrated Clinical Trials Billing; Costing Guidelines for Sponsored Projects; Time and Effort Reporting; and Cost Sharing. In addition, the Policies and Procedures shall include (where appropriate) disciplinary guidelines and methods for employees to make disclosures or otherwise report on compliance issues through the Confidential Disclosure Program. The Enterprise Research Compliance Officer shall, with the responsible Research Offices, assess and update as necessary the Policies and Procedures with input from the Impacting Research Offices and Research Advisors, as appropriate.

### 3.4 Awareness, Education and Training.

3.4-1 General Training. Jefferson shall provide general compliance training to each Covered Individual at the time of orientation. This general training shall explain Jefferson's Enterprise Research Compliance Program (including the Policies and Procedures) and the Code of Conduct. New Covered Individuals shall receive the general training described above within sixty (60) days of becoming a Covered Individual. Each Covered Individual shall annually receive training or updates or other relevant information with respect to the Enterprise Research Compliance Program and Code of Conduct in a manner calculated to stress the continued importance of compliance with all aspects of research compliance.

3.4-2 Specific Training. Jefferson has developed and implemented a number of programs to include (i) a grants management training program which covers the following topics: the requirement to submit accurate and complete applications, requests, reports and other submissions regarding Sponsored Agreements; the personal obligation of each individual involved in the Sponsored Agreements process to ensure that submissions to federal agencies are accurate and complete and all material information is provided to the federal agencies; applicable statutes, regulations, and guidelines; the legal sanctions and possible Jefferson actions for improper acts or omissions pertaining to Sponsored Agreements; and examples of proper and improper practices, and (ii) required modules from the CITI course that cover biomedical research responsible conduct of research, which will be required to be completed every four (4) years. Additionally, Jefferson may provide specific training to Covered Individuals with respect to other research-related areas such as human subjects protections, clinical trials, and research integrity. Jefferson represents that all of its training programs are presented by persons knowledgeable about the subject area.

3.4-3 Verification. Jefferson shall maintain documents that reflect attendance/participation at both general and specific training sessions. Jefferson may choose the format of these documents.

3.5 Risk Assessment.

The Enterprise Research Compliance Officer and the Enterprise Research Compliance Committee in consultation with Jefferson's Enterprise Risk shall conduct annual risk assessments to evaluate and prioritize the risks facing Jefferson's research community, including the more heavily regulated areas of research. Each risk assessment shall measure the magnitude of applicable events of noncompliance in light of the likelihood of occurrence for each such event under existing Jefferson Policies and Procedures.

The Enterprise Research Compliance Officer shall communicate the research risk assessments with Jefferson's Offices of Internal Audit, Enterprise Risk, and Corporate Compliance (collectively known as the "ARC Team") and shall provide input in the ARC Team risk assessment process in developing the annual ARC Work Plan, described below.

It is the responsibility of each of the Research Offices' to continually assess research-related risks and establish procedures and controls to minimize the risk of non-compliance in their Research Office. The Research Offices shall be responsible to address the results of the risk assessments. The Enterprise Research Compliance Officer and the Enterprise Research Compliance Committee shall oversee the development and implementation of appropriate corrective action plans to address significant risks identified by the Research Offices and/or the members of the ARC Team.

3.6 Monitoring and Auditing.

3.6-1 Monitoring Program. Each of the Research Offices identified in 3.1-3 will establish effective internal control procedures that include review and monitoring procedures for all compliance requirements that impact the Research Offices or functions.

3.6-2 Auditing Program. In addition to the single audit requirements contained in the Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards from the OMB (2 C.F.R. Section 200) (the "Uniform Guidance"), Jefferson is also required to undergo external audits of certain State and City of Philadelphia projects.

The Internal Audit Program at Jefferson begins with an annual audit risk assessment of its research-related activities and supporting operations. This audit risk assessment, conducted jointly by the ARC Team will be the basis of establishing an annual ARC Team Work Plan ("ARC Work Plan").

In implementing the annual ARC Work Plan, Jefferson may use Jefferson's Office of Internal Audit, or employ the services of an independent service provider. Such Internal Audit projects shall review Jefferson's compliance with applicable federal laws and regulations regarding the use and expenditure of Sponsored Agreements, including the uniform administrative requirements contained in the Uniform Guidance.

If Research Offices monitoring programs or Internal Audit projects conducted at Jefferson reveal situations that might constitute or indicate non-compliance with governmental requirements for Sponsored Agreements or other research activities, the results of such reviews shall be provided to the Enterprise Research Compliance Officer and the Enterprise Research Compliance

Committee, who may report further, as appropriate, to the designated Jefferson Senior Official, Enterprise Chief Compliance Officer and/or the appropriate Board or Committee. Such reviews may include financial, ethical or academic issues, such as scientific misconduct or conflict of interest issues.

3.6-3 Ineligible Persons. For the purposes of this Program, an "Ineligible Person" shall be any individual or entity, who is or may be involved in Sponsored Agreements at Jefferson, who: (i) is currently excluded, suspended, debarred or otherwise ineligible to participate in any federal program; or (ii) has been convicted of a criminal offense related to a federal program. Jefferson shall not hire as an employee or engage as a contractor any Ineligible Person. To prevent hiring or contracting with any Ineligible Person, Jefferson shall screen all prospective employees or contractors prior to engaging their services as Covered Individuals by (i) requiring applicants to disclose whether they are Ineligible Persons, and (ii) reviewing the General Services Administration's System for Award Management active exclusion records (<https://www.sam.gov>) and the HHS/OIG List of Excluded Individuals/Entities (available through the Internet at <https://oig.hhs.gov/exclusions/index.asp>) (these lists and reports will hereinafter be referred to as the "Exclusion Lists"). Jefferson may also employ a third party vendor to perform such screening activities at hire, as well as facilitate the periodic review of exclusion databases. Such periodic review will be performed at least on a semi-annual basis. If Jefferson has notice that a Covered Individual has become an Ineligible Person, Jefferson, working with the Enterprise Chief Compliance Officer and Human Resources, will remove such person from responsibility for, or involvement with, Jefferson's business operations that are supported by Federal or state funds. This removal will, more than likely, result in termination from Jefferson.

### 3.7 Enforcement and Corrective Action.

3.7-1 Reporting Program. Jefferson's Confidential Reporting Program shall emphasize Jefferson's non-retribution and non-retaliation policies and shall include a reporting mechanism for anonymous or confidential communication. Jefferson has, pursuant to its Corporate Compliance Program, established the "Jefferson Alertline", a confidential reporting line comprised of a toll-free telephone line (1-888-5-COMPLY) and website at [Jefferson.Alertline.com](http://Jefferson.Alertline.com). Through the Jefferson Alertline, employees or other individuals may report actual or suspected concerns or ask questions associated with Jefferson's policies, practices or procedures, including research-related matters (e.g., Sponsored Agreements), (hereinafter "improper practices"). Jefferson shall continue to maintain the Alertline and shall continue to publicize its existence or take other measure(s) to satisfy this requirement (e.g., posting the hotline number and website in prominent areas).

The Jefferson Alertline is managed by a third-party company which receives each report and transmits each report to the Office of Corporate Compliance. Upon receipt of a complaint, the Enterprise Chief Compliance Officer (or designee) shall make a preliminary good faith review of the allegations and initiate an investigation or refer the report to the appropriate Jefferson department(s) (e.g., Office of Research Compliance, Human Resources, or Safety) for investigation, including all relevant information from the individual reporting the alleged improper practices. For any report that is sufficiently specific so that it reasonably: (1) permits a determination of the appropriateness of the alleged improper practice, and (2) provides an opportunity for taking corrective action, the assigned investigator shall conduct an internal review of the allegations set forth in such a report and ensure that proper follow-up is conducted.

The Enterprise Chief Compliance Officer shall maintain a record and summary of each allegation received, the status of the respective investigations, and any corrective action taken in response to the investigation.

3.7-2 Audits and Investigations. In the event of an outside agency review, audit and/or investigation, Jefferson's senior management shall provide leadership, coordination and assistance to the Research Offices concerning such activity.

3.7-3 Overpayments. Jefferson as a recipient of funding pursuant to Sponsored Agreements primarily conducts its financial management of these agreements through the Department of Health and Human Services Payment Management System ("PMS"), its centralized grants payment and cash management system. This system recognizes two payment methods: cash pooling (i.e., cash needs are not identified by individual awards at the time of the draw) and subaccounts to draw by individual award. PMS is moving toward subaccounts for all draws. The system also recognizes that periodically it may be necessary for a recipient to remit funds via PMS. Jefferson adheres to PMS website <https://www.dpm.psc.gov/>, which requires quarterly reconciliation of cash payments against expenditures by award. To the extent Jefferson receives an overpayment pertaining to Sponsored Agreements which is not addressed through this quarterly filing, Jefferson shall notify the grantor within thirty (30) days of discovering the overpayment and take remedial steps within sixty (60) days of discovery (or such additional time as may be agreed to by the grantor) to correct the problem, including preventing the underlying problem and the overpayments from recurring. For the purposes of this Program, an "overpayment" shall mean the amount of money Jefferson has received in excess of the amount Jefferson was entitled to pertaining to the specific Sponsored Agreement.

Enterprise Research Compliance Committee: July 1, 2018