INSTITUTIONAL INTEGRITY AGREEMENT
BETWEEN THE
UNITED STATES
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
THOMAS JEFFERSON UNIVERSITY

I. PREAMBLE

Thomas Jefferson University ("TJU") hereby enters into this Institutional Integrity Agreement ("IIA") with the United States Department of Health and Human Services ("HHS"). Pursuant to this IIA, TJU agrees to undertake the compliance obligations outlined below. TJU agrees to implement a compliance program to prevent fraud, false statements or misspending of funds related to HHS grants, contracts and cooperative agreements (hereafter referred to collectively as "Sponsored Agreements") by TJU, its officers, faculty, independent contractors who conduct research related to Sponsored Agreements or whose costs are charged to Sponsored Agreements, and other employees who perform work related to Sponsored Agreements or whose direct costs are charged to Sponsored Agreements (collectively "Covered Individuals"). "Faculty," for purposes of this agreement, are defined as individuals employed by TJU and who hold TJU faculty appointments. "Independent contractors," for purposes of this agreement, are defined as persons performing personal research services at TJU at TJU's direction in relation to Sponsored Agreements, and whose costs are charged to Sponsored Agreements. Independent contractors do not include vendors, suppliers or other entities or persons not under TJU's control such as contractors performing work for TJU at other sites. The compliance program shall be maintained so as to ensure that TJU and each of its Covered Individuals maintain the integrity required of a recipient of HHS funds, and that TJU is in compliance with all statutes and regulations applicable to such awards and with the terms of the IIA set out below. Contemporaneously with this IIA, TJU is entering into a Settlement Agreement and Release with the United States, and this IIA is incorporated by reference into the Settlement Agreement and Release.

As part of its compliance efforts in the areas of scientific research and grants administration prior to the execution of this IIA, TJU represents the following. TJU adopted and implemented new policies and procedures for cost transfers, non-reimbursable expenditures for federally-funded programs, costing guidelines for sponsored projects, cost sharing and matching grants, emergency use of investigational drugs and biologicals, review of adverse events and a new Code of Conduct and conflict of interest statements, and maintains a variety of websites to provide research-related personnel with information about these policies and procedures and TJU's research compliance program. In April of 1998, TJU implemented a training program for all responsible staff, including all Jefferson Medical College faculty and key administrative personnel involved in supported research. Since April of 1998, over 550 of TJU's research staff

GOVERNMENT EXHIBIT
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have attended presentations on this training program.

II. TERM OF THE IIA

The period of the compliance obligations assumed by TJU under this IIA shall be three (3) years from the Effective Date (as defined below) of this IIA. The Effective Date of this IIA will be the date on which the final signatory to this IIA executes this IIA.

III. COMPLIANCE OBLIGATIONS

TJU's Compliance Program includes, or shall be amended to include, the following elements:

A. Compliance Officer/Compliance Committee.

1. Compliance Officer. TJU has represented to HHS that pursuant to its existing Compliance Program, it has created a Compliance Officer position and appointed an individual to serve in that capacity. Accordingly, TJU shall formally maintain the appointment of an individual to serve as the Compliance Officer. At a minimum, the Compliance Officer must continuously be charged with the responsibility for developing and implementing policies, procedures, and practices designed to ensure compliance with the requirements set forth in the IIA and with the requirements of Sponsored Agreements. The Compliance Officer shall make regular (at least quarterly) reports regarding compliance matters directly to the President of TJU, and shall be authorized to report to the Audit Committee and the Board of Trustees at any time. The Compliance Officer shall be responsible for monitoring the day-to-day activities engaged in by TJU to further its compliance objectives as well as any reporting obligations created under this IIA. In the event a new Compliance Officer is appointed during the term of this IIA, TJU shall notify HHS, in writing, within fifteen (15) days of such a change.

2. Compliance Committee. TJU has represented to HHS that pursuant to its existing Compliance Plan, it has created a Compliance Committee. Accordingly, TJU shall formally maintain a Compliance Committee, which shall be responsible for, at a minimum, compliance with the obligations in this IIA. The Compliance Committee shall, at a minimum, include the Chief Financial Officer of TJU, the Associate Dean for Research, the Manager of Research Administration, and the Compliance Officer. The Compliance Officer shall chair the Compliance Committee and the Compliance Committee shall support the Compliance Officer in fulfilling his/her responsibilities.

B. Written Standards.

1. Code of Conduct. TJU has represented to HHS that pursuant to its existing Compliance Program, it has created and distributed a Code of Conduct with provisions

applicable to Sponsored Agreements. The Code of Conduct shall continue to be distributed to all Covered Individuals, but any Covered Individual who has not previously received it shall receive the Code of Conduct within ninety (90) days of the Effective Date of this IIA. TJU shall maintain its Code of Conduct and make the promotion of, and adherence to, the Code of Conduct an element in evaluating the performance of all Covered Individuals. The Code of Conduct shall continue to maintain the following elements:

a. TJU's commitment to full compliance with all federal statutes, regulations and policies applicable to Sponsored Agreements;

b. TJU's requirement that all of its Covered Individuals shall be expected to comply with all statutes, regulations, policies and guidelines applicable to Sponsored Agreements and with TJU's own Policies and Procedures (including the requirements of this IIA);

c. the requirement that all of TJU's Covered Individuals shall be expected to report to the Compliance Officer or other appropriate persons at TJU suspected violations of any statute, regulation, policy or guideline applicable to Sponsored Agreements or of TJU's own Policies and Procedures;

d. the possible consequences, including disciplinary actions against individuals, to both TJU and to any Covered Individual of failure to comply with all statutes, regulations, policies and guidelines applicable to Sponsored Agreements and with TJU's own Policies and Procedures or of failure to report such non-compliance; and

e. the right of all Covered Individuals to use the Confidential Disclosure Program, as well as TJU's commitment to confidentiality and non-retaliation with respect to disclosures.

TJU shall document the actions taken to distribute the Code of Conduct to all Covered Individuals. New Covered Individuals shall receive the Code of Conduct within thirty (30) days after the commencement of their employment or contract, or within ninety (90) days of the Effective Date of this IIA, whichever is later.

The Compliance Committee will annually review the Code of Conduct and will make any necessary revisions. These revisions shall be communicated by the Compliance Officer to Covered Individuals on TJU's research website and broadcast e-mail within thirty (30) days of initiating such a change, unless the nature of the revision is such that it warrants earlier notice.

2. Policies and Procedures. Within ninety (90) days of the Effective Date of this

IIA, TJU shall develop, initiate and maintain the implementation of written Policies and Procedures regarding the operation of its Compliance Program and its compliance with all federal statutes, regulations, and guidelines applicable to Sponsored Agreements. 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 and this IIA. In addition, the Policies and Procedures shall include disciplinary guidelines and methods for employees to make disclosures or otherwise report on compliance issues through the Confidential Disclosure Program required by section III.E, below. The Compliance Officer shall assess and update as necessary the Policies and Procedures at least annually and, when appropriate, more frequently. A summary of the Policies and Procedures will be provided to HHS in the Implementation Report. The Policies and Procedures will be available to HHS at any time upon request.

Within ninety (90) days of the Effective Date of this IIA, the relevant portions of the Policies and Procedures shall be communicated to all Covered Individuals. Compliance staff or supervisors should be available to explain to Covered Individuals any and all policies and procedures.

C. Training and Education.

1. General Training. Within one hundred and twenty (120) days of the Effective Date of this IIA, TJU shall provide at least one (1) hour of general compliance training to each Covered Individual. This general training shall explain TJU's:

a. Institutional Integrity Agreement requirements;

b. Compliance Program (including the Policies and Procedures as they pertain to general compliance issues); and

c. Code of Conduct.

These training materials shall be made available to HHS upon request.

New Covered Individuals shall receive the general training described above within sixty (60) days of becoming a Covered Individual, or within one hundred and twenty (120) days after the Effective Date of this IIA, whichever is later. Each Covered Individual shall annually receive at least one hour of training or updates or other relevant information with respect to this IIA, Compliance Program and Code of Conduct in a manner calculated to stress the continued importance of compliance with all aspects of this IIA.

2. Specific Training. TJU has represented to HHS that it has developed and implemented a grants management training program which covers the following topics:

a. the requirement to submit accurate and complete applications, requests, reports and other submissions regarding Sponsored Agreements;

b. 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;

c. applicable statutes, regulations, and guidelines;

d. the legal sanctions and possible university actions for improper acts or omissions pertaining to Sponsored Agreements; and

e. examples of proper and improper practices.

Additionally, TJU may provide training to Covered Individuals with respect to other research-related areas such as human subjects' protections, clinical trials, and research integrity. TJU represents that all of its training programs are presented by persons knowledgeable about the subject area. Within one hundred fifty (150) days of the Effective Date of this IIA, each Covered Individual with responsibility for applying for, administering, or submitting reports regarding Sponsored Agreements (hereafter referred to as "Covered Reporting Individuals") shall receive at least one (1) hour of this specific training in addition to the general training required above. This shall be an annual requirement during the term of this IIA. The training materials shall be made available to HHS upon request.

New Covered Reporting Individuals shall receive this training within ninety (90) days of the beginning of their employment, or within one hundred and fifty (150) days of the Effective Date of this IIA, whichever is later. If a new Covered Reporting Individual has any responsibility for the preparation or submission of requests for Sponsored Agreements funds prior to completing this specific training, then a Covered Reporting Individual who has completed the substantive training shall review all of the untrained Covered Reporting Individual's work pertaining to these responsibilities.

3. Verification. TJU shall maintain documents that reflect attendance at both general and specific training sessions. TJU may choose the exact format of these documents, but these materials shall include, at a minimum, dated sheets with the attendees' signatures attesting to their attendance at the sessions. Information concerning the format, dates, and copies of the materials provided will be made available, upon request, for review by HHS. TJU shall certify that such training has been provided to all Covered Individuals in its Annual Reports to HHS in accordance with section IV below.

D. Audit Procedures.

In addition to the single audit requirements contained in OMB Circular A-133, TJU on an annual basis shall conduct a comprehensive audit of randomly selected Sponsored Agreements as provided for in the TJU Audit Program attached as Exhibit A. Implementation of the agreed-upon procedures set forth in Exhibit A shall be an element of this Agreement throughout its term. The annual internal review shall cover each of the three (3) consecutive one-year periods immediately following the execution of this IIA.

TJU shall retain an entity, such as an accounting, auditing or consulting firm (hereinafter "Independent Review Organization"), to review whether TJU has performed the TJU Audit Program in conformance with the agreed-upon procedures set forth in Exhibit A. The Independent Review Organization must have expertise in the applicable standards related to Sponsored Agreements reviewed under the TJU Audit Program. TJU shall require the Independent Review Organization to produce reports on its findings, which reports shall be included in TJU's Annual Reports to HHS. The Independent Review Organization must be retained to perform these functions for the first year within one hundred and twenty (120) days of the effective date of this IIA. A complete copy of the Independent Review Organization's reports shall be included in each of TJU's Annual Reports to HHS. After the submission of the first Annual Report, external review by the Independent Review Organization for years two and/or three will be conducted if HHS has a reasonable basis for questioning TJU's internal audit procedures.

In implementing the audit, TJU at its option may use TJU's Department of Internal Audit, develop a separate internal audit function for the purposes of this IIA, or employ the services of an IRO. The audit shall review TJU's compliance with applicable federal laws and regulations regarding the use and expenditure of Sponsored Agreements, including the uniform administrative requirements contained in 45 C.F.R. Part 74, the Federal Acquisition Regulations, regulations governing grants for research projects contained in 42 C.F.R. Part 52, and the cost principles contained in OMB Circular A-21. Such audits shall be performed with respect to each department of TJU as specified in TJU's Audit Program methodology and will be conducted in accordance with Generally Accepted Auditing Practices. All audit workpapers or supporting documents for audits or reviews of federal compliance relating to Sponsored Agreements and undertaken pursuant to this IIA shall be made available to HHS upon request.

If other reviews conducted at TJU reveal situations that might constitute or indicate noncompliance with HHS requirements for Sponsored Agreements, the results of such reviews shall be provided to the Compliance Officer. Such reviews may include financial, ethical or academic issues, such as scientific misconduct or conflict of interest problems.

E. Confidential Disclosure Program. TJU has, pursuant to its existing Compliance Program, established a Confidential Disclosure Program, ComplyLine, which includes measures

(e.g., a toll-free compliance telephone line) to enable employees or other individuals to disclose, to the Compliance Officer or some other person who is not in the reporting individual's chain of command, any identified issues or questions associated with TJU's policies, practices or procedures with respect to Sponsored Agreements, believed by the individual to be inappropriate (hereinafter "improper practices"). TJU shall continue to maintain ComplyLine and shall continue to publicize its existence or take other measure(s) to satisfy the requirement of this section (e.g., e-mail to employees or posting the hotline number in prominent areas).

The Confidential Disclosure Program shall continue to emphasize a non-retribution, non-retaliation policy, and shall include a reporting mechanism for anonymous, confidential communication. Pursuant to TJU's existing Compliance Program, upon receipt of a complaint, the Compliance Officer (or designee) shall gather the information in such a manner as to elicit all relevant information from the individual reporting the alleged improper practices. The Compliance Officer (or designee) shall make a preliminary good faith inquiry into the allegations set forth in every disclosure to ensure that he or she has obtained all of the information necessary to determine whether a further review should be conducted. For any disclosure 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 Compliance Officer shall conduct an internal review of the allegations set forth in such a disclosure and ensure that proper follow-up is conducted.

The Compliance Officer shall maintain a confidential disclosure log, which shall include a record and summary of each allegation received, the status of the respective investigations, and any corrective action taken in response to the investigation.

F. Ineligible Persons.

1. Definition. For the purposes of this IIA, an "Ineligible Person" shall be any individual or entity, who is or may be involved in Sponsored Agreements at TJU, 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 federal programs.

2. Screening Requirements. TJU shall not hire as an employee or engage as contractors any Ineligible Person. To prevent hiring or contracting with any Ineligible Person, TJU 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 List of Parties Excluded from Federal Programs (available through the Internet at http://www.arnet.gov/epls) and the HHS/OIG List of Excluded Individuals/Entities (available through the Internet at http://www.dhhs.gov/oig) (these lists and reports will hereinafter be referred to as the "Exclusion Lists").

3. Review and Removal Requirement. Within ninety (90) days of the Effective

Date of this IIA, TJU will review its list of Covered Individuals against the Exclusion Lists. Thereafter, TJU will review the Exclusion Lists at least on a semi-annual basis. If TJU has notice that a Covered Individual has become an Ineligible Person, TJU, working with the Compliance Officer, will remove such person from responsibility for, or involvement with, TJU's business operations related to Sponsored Agreements and shall remove such person from any position for which the person's salary or the items or services rendered, ordered, or prescribed by the person are paid in whole or part, directly or indirectly, through Sponsored Agreements or otherwise with federal funds at least until such time as the person is no longer debarred from participation in the federal programs.

G. Notification of Proceedings. Within thirty (30) days of discovery, TJU shall provide written notice to HHS of any ongoing investigation or legal proceeding conducted or brought by a governmental entity or its agents involving an allegation that TJU, as a corporate entity, has committed a crime or has engaged in fraudulent activities. This notification shall include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding. TJU shall also provide written notice to HHS within thirty (30) days of the resolution of the matter, and shall provide HHS with a description of the findings and results of the proceedings, if any.

H. Reporting.

1. Reporting of Overpayments. TJU as a recipient of funding pursuant to Sponsored Agreements conducts its financial management of these agreements through the Department of Health and Human Services Payment Management System ("PMS"). This system recognizes the concept of cash pooling (i.e., cash needs are not identified by individual awards at the time of the draw) as the basis for drawing down funds on a regular basis. The system also recognizes that periodically it may be necessary for a recipient to remit funds via PMS. TJU adheres to the standards for financial management systems of recipients set forth in the DHHS Manual for Recipients Financed Under the Payment Management System. This process requires quarterly reconciliation of cash advances against expenditures by project.

To the extent TJU receives an overpayment pertaining to Sponsored Agreements which is not addressed through this quarterly filing, TJU 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. If the overpayment is discovered as the result of any of the activities required by this IIA, the notice to the grantor shall include:

a. a statement that the refund is being made pursuant to this IIA;

b. a description of the complete circumstances surrounding the overpayment;

c. the methodology by which the overpayment was determined;

d. the amount of the overpayment;

e. any Sponsored Agreement-specific information used to determine the overpayment; and

f. any applicable overpayment refund form provided and required by the grantor.

2. Reporting of Material Deficiencies. If TJU determines that there is a material deficiency, TJU shall notify HHS within thirty (30) days of discovering the material deficiency. If the material deficiency results in an overpayment, the report to HHS shall be made at the same time as the report to the grantor and shall include all of the information required by section III.H.1 plus: (i) the grantor's name, address, and contact person where the overpayment was sent; and (ii) the date of the check and identification number (or electronic transaction number) on which the overpayment was repaid. Regardless of whether the material deficiency resulted in an overpayment, the report to HHS shall include:

a. a complete description of the material deficiency, including the relevant facts, persons involved, and legal and program authorities;

b. TJU's actions to correct the material deficiency; and

c. any further steps TJU plans to take to address such material deficiency and prevent it from recurring.

3. Definition of "Overpayment." For the purposes of this IIA, an "overpayment" shall mean the amount of money TJU has received in excess of the amount TJU was entitled to pertaining to the specific Sponsored Agreement.

4. Definition of "Material Deficiency." For the purposes of this IIA, a "material deficiency" means anything that involves: (i) a substantial overpayment relating to any Sponsored Agreement; or (ii) a matter that a reasonable person would consider a violation of criminal, civil, or administrative laws applicable to Sponsored Agreements for which penalties or debarment may be authorized; or (iii) one that has a significant adverse impact on HHS research or administration of projects supported by HHS Sponsored Agreements. A material deficiency may be the result of an isolated event or a series of occurrences.

IV. IMPLEMENTATION AND ANNUAL REPORTS

A. Implementation Report. Within one hundred and eighty (180) days after the Effective Date of this IIA, TJU shall submit a written report to HHS summarizing the status of its implementation of the requirements of this IIA. This Implementation Report shall include:

1. the name, address, phone number and position description of the Compliance Officer required by section III.A;

2. the names and positions of the members of the Compliance Committee required by section III.A;

3. a copy of TJU's Code of Conduct required by section III.B.1;

4. the summary of the Policies and Procedures required by section III.B.2;

5. a description of the training programs required by section III.C, including a description of the targeted audiences and a schedule of when the training sessions were held;

6. a certification by the Compliance Officer that to the best of the Compliance Officer's knowledge and upon reasonable efforts and inquiry:

   a. the Policies and Procedures required by section III.B.2 have been developed, are being implemented, and have been distributed to all appropriate Covered Individuals;

   b. all Covered Individuals have received the Code of Conduct required by section III.B.1; and

   c. all Covered Individuals have completed the training required by section III.C.

7. a description of the Confidential Disclosure Program required by section III.E;

8. if applicable, the identity of the IRO; and

9. a summary of personnel actions taken pursuant to section III.F.

B. Annual Reports. TJU shall submit to HHS an Annual Report with respect to the status and findings of its compliance activities.

The Annual Reports shall include:

1. any change in the identity or position description of the Compliance Officer or members of the Compliance Committee described in section III.A;

2. a certification by the Compliance Officer that to the best of the Compliance Officer's knowledge and upon reasonable efforts and inquiry:

a. all Covered Individuals have received the Code of Conduct required by section III.B.1; and

b. all Covered Individuals have completed the applicable training required by section III.C.

3. notification of any changes or amendments to the Policies and Procedures required by section III.B and the reasons for such changes (e.g., change in grantor policy);

4. where applicable, a complete copy of the report(s) prepared pursuant to the Independent Auditor's audit for the relevant one-year period;

5. TJU's response and corrective action plan to any issues raised by the IRO or the annual audit conducted pursuant to section III.D;

6. a summary of Material Deficiencies reported to HHS throughout the course of the previous twelve (12) months pursuant to section III.H, and the status of any corrective and preventative action relating to all such Material Deficiencies;

7. a report of the aggregate overpayments that have been returned to the federal programs that were discovered as a direct or indirect result of implementing this IIA. Overpayment amounts should be broken down by the specific grant, contract or cooperative agreement and grantor agency to which the improper payment relates;

8. a copy of the confidential disclosure log required by section III.E;

9. a description of any personnel action (other than hiring) taken by TJU as a result of the obligations in section III.F; and

10. a summary describing any ongoing investigation or legal proceeding conducted or brought by a governmental entity involving an allegation that TJU, as a corporate entity, has committed a crime or has engaged in fraudulent activities, which is required to be reported pursuant to section III.G. The summary shall include a description of the allegation(s), the identity of the investigating or prosecuting agency, and the status of such investigation, legal

proceeding or requests for information.

The first Annual Report shall cover the period of time from the effective date of this IIA through June 30, 2001, and shall be received by HHS no later than October 31, 2001. Subsequent Annual Reports shall cover the subsequent one year periods and shall be received no later than October 31 of the appropriate years.

C. Certifications. The Implementation Report and Annual Reports shall include a certification by the Compliance Officer to the best of the Compliance Officer's knowledge and upon reasonable efforts and inquiry that (1) TJU is in compliance with all of the requirements of this IIA; and (2) the Compliance Officer has reviewed the Report and has made reasonable inquiry regarding its content and believes that, upon such inquiry, the information is accurate and truthful.

V. NOTIFICATIONS AND SUBMISSION OF REPORTS

Except as noted in section IV.D, above and unless otherwise stated in writing subsequent to the Effective Date of this IIA, all notifications and reports required under this IIA shall be submitted to the entities listed below:

If to HHS:

Attn: Terrence J. Tychan
Deputy Assistant Secretary for Grants and Acquisition Management
U.S. Department of Health and Human Services
Humphrey Building, Room 517D
200 Independence Avenue, S.W.
Washington, DC 20201
Phone 202.690.6901

If to TJU:

Attn: Joanne Rosenthal, Esq.
Compliance Officer
Thomas Jefferson University
Room 626, Scott Building
1020 Walnut Street
Philadelphia, PA 19107
Phone 215.955.8585

VI. HHS INSPECTION, AUDIT AND REVIEW RIGHTS

In addition to any other rights HHS may have by statute, regulation, or agreement, HHS or its duly authorized representative(s) may examine TJU's books, records, and other documents and supporting materials for the purpose of verifying and evaluating: (a) TJU's compliance with the terms of this IIA; and (b) TJU's compliance with the requirements related to Sponsored Agreements. The documentation described above shall be made available by TJU to HHS or its duly authorized representative(s) at all reasonable times for inspection, audit or reproduction. Furthermore, for purposes of this provision, HHS or its duly authorized representative(s) may interview any of TJU's employees who consent to be interviewed at that person's place of business during normal business hours or at such other place and time as may be mutually agreed upon between that person and HHS. However, if an employee, consistent with the rights and privileges of such individual, refuses to be interviewed based upon an individual decision and/or advice of counsel, TJU will not be in breach of this IIA if the interview does not occur. TJU agrees to assist HHS in contacting and arranging interviews with such employees. Counsel for TJU may be present during the interview if TJU counsel is representing the interviewee.

VII. DOCUMENT AND RECORD RETENTION

TJU shall maintain for inspection all documents and records relating to Sponsored Agreements or to compliance with this IIA, for four (4) years from the effective date of this IIA (or longer if otherwise required by law).

VIII. BREACH AND DEFAULT PROVISIONS

TJU is expected to fully and timely comply with all of the obligations herein throughout the term of this IIA or other time frames herein agreed to. Nothing in this IIA affects the rights of the United States or HHS to exercise any criminal, civil, or administrative authority.

A. Stipulated Penalties for Failure to Comply with Certain Obligations. As a contractual remedy, TJU and HHS hereby agree that failure to comply with certain obligations set forth in this IIA may lead to the imposition of certain penalties (hereinafter referred to as "Stipulated Penalties") in accordance with this section VIII. HHS, at its option, may impose the following types of Stipulated Penalties: (i) the withholding of a percentage of funds pertaining to Sponsored Agreements; (ii) the withholding or disallowance of overhead costs (also known as indirect costs) pertaining to Sponsored Agreements; (iii) the suspension of payments on Sponsored Agreements; and (iv) the termination of Sponsored Agreements. Unless otherwise noted, the Stipulated Penalties shall accrue for the time period during which TJU did not comply with any of the obligations set forth below until TJU has established its compliance with the obligation. Any or all of these Stipulated Penalties may be imposed if any of the following occurs:

1. Stipulated Penalties may be imposed if TJU fails to have in place one or more of the following:

a. a Compliance Officer;

b. a Compliance Committee;

c. a written Code of Conduct;

d. written Policies and Procedures;

e. a training program; or

f. a Confidential Disclosure Program.

2. Stipulated Penalties may be imposed if TJU fails to meet any of the deadlines to submit the Implementation Report or the Annual Reports to HHS.

3. Stipulated Penalties may be imposed for each day TJU:

a. hires or enters into a contract with an Ineligible Person after that person has been listed by a federal agency as debarred, excluded, suspended or otherwise ineligible for participation in federal programs (this Stipulated Penalty shall not be imposed for any time period during which TJU can demonstrate that it did not discover the person's exclusion, debarment or other ineligibility after making a reasonable inquiry (as described in section III.F) as to the status of the person);

b. employs or contracts with an Ineligible Person and that person: (i) has responsibility for, or involvement with, TJU's business operations related to Sponsored Agreements or (ii) is in a position for which the person's salary or the items or services rendered, ordered, or prescribed by the person are paid in whole or in part, directly or indirectly, by federal programs or otherwise with federal funds (this Stipulated Penalty shall not be imposed for any time period during which TJU can demonstrate that it did not discover the person's exclusion, debarment or other ineligibility after making a reasonable inquiry (as described in section III.F) as to the status of the person); or

c. employs or contracts with a person who: (i) has been charged with a criminal offense related to any federal program, or (ii) is suspended,

debarred or proposed for exclusion, and that person has responsibility for, or involvement with, TJU's business operations related to Sponsored Agreements (this Stipulated Penalty shall not be imposed before ten (10) days after TJU received written notice of the relevant matter or after the resolution of the matter).

4. Stipulated Penalties (which shall begin to accrue on the date TJU fails to grant access) may be imposed for each day TJU fails to grant access to the information or documentation as required in section VI of this IIA.

5. Stipulated Penalties (which shall begin to accrue ten (10) days after the date that HHS provides written notice to TJU of the failure to comply) may be imposed for each day TJU fails to comply fully and adequately with any obligation of this IIA. In its written notice to TJU, HHS shall fully state the specific facts, circumstances, and reasons for its determination that TJU has failed to comply fully and adequately with the IIA obligation(s) at issue.

B. Imposition of Stipulated Penalties.

1. Demand Letter. Upon a finding that TJU has failed to comply with any of the obligations described in section VIII.A and a determination that a Stipulated Penalty is appropriate, HHS shall notify TJU by personal service or certified mail of (a) TJU's failure to comply; and (b) HHS's exercise of its contractual right to demand imposition of the Stipulated Penalties (this notification is hereinafter referred to as the "Demand Letter").

Within fifteen (15) days of the date of the Demand Letter, TJU may request a hearing before an HHS administrative law judge ("ALJ") to dispute HHS's determination of noncompliance, pursuant to the agreed upon provisions set forth below in section VIII.D. In the event TJU elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until cured but shall not be collected or withheld until a final decision is reached in accordance with section VIII.D.4. In the event TJU elects to forego its right to an ALJ hearing, Stipulated Penalties shall begin at the expiration of the fifteen (15) days.

2. Timely Written Requests for Extensions. TJU may submit a timely written request (as defined below) for an extension of time to perform any act or file any notification or Report required by this IIA. Notwithstanding any other provision in this section, if HHS grants the timely written request with respect to an act, notification, or report, Stipulated Penalties for failure to perform the act or file the notification or report shall not go into effect until one (1) business day after TJU fails to meet the revised deadline as agreed to by the HHS-approved extension. Notwithstanding any other provision in this section, if HHS denies such a timely written request, Stipulated Penalties for failure to perform the act or file the notification or report shall not become effective until two (2) business days after TJU receives HHS's written denial of such request. A "timely written request" is defined as a request in writing received by HHS at

least five (5) business days prior to the date by which any act is due to be performed or any notification or report is due to be filed.

3. Independence from Material Breach Determination. Except as otherwise noted, these provisions for Stipulated Penalties shall not affect or otherwise set a standard for HHS's determination that TJU has materially breached this IIA, which decision shall be made at HHS's discretion and is governed by the provisions in section VIII.C, below.

C. Debarment or Suspension for Material Breach of this IIA.

1. Notice of Material Breach and Intent to Debar or Suspend. The parties agree that a material breach of this IIA by TJU constitutes an independent basis for TJU's debarment or suspension. Upon a determination by HHS that TJU has materially breached this IIA and that debarment or suspension should be imposed, HHS shall notify TJU by certified mail of (a) TJU's material breach; and (b) HHS's intent to exercise its contractual right to impose debarment or suspension (this notification is hereinafter referred to as the "Notice of Material Breach and Intent to Debar or Suspend").

2. Opportunity to Cure. TJU shall have thirty-five (35) days from the date of the Notice of Material Breach and Intent to Debar or Suspend to demonstrate to HHS's satisfaction that:

a. TJU is in full compliance with this IIA;

b. the alleged material breach has been cured; or

c. the alleged material breach cannot be cured within the thirty-five (35) day period, but that: (i) TJU has begun to take action to cure the material breach, (ii) TJU is pursuing such action with due diligence, and (iii) TJU has provided to HHS a reasonable timetable for curing the material breach.

3. Debarment or Suspension Letter. If, at the conclusion of the thirty-five (35) day period, TJU fails to satisfy the requirements of section VIII.C.2, HHS may debar or suspend TJU unless TJU exercises its rights under section VIII.D, below. HHS will notify TJU in writing of its determination to debar or suspend TJU (this letter shall be referred to hereafter as the "Debarment Letter" or the "Suspension Letter"). Subject to the Dispute Resolution provisions in section VIII.D, below, the debarment or suspension shall go into effect thirty (30) days after the date of the Debarment Letter or the Suspension Letter. The debarment or suspension shall have national effect and will also apply to all other federal Sponsored Agreements.

4. Material Breach. A "material breach" of this IIA means:

a. a failure by TJU, acting through its Compliance Officer, to report a

material deficiency, take corrective action and pay the appropriate refunds, as provided in section III.H, above;

b. repeated or flagrant violations of the obligations under this IIA, including, but not limited to, the obligations addressed in section VIII.A, above;

c. a failure to respond to a Stipulated Penalty Letter concerning the imposition of Stipulated Penalties in accordance with section VIII.B, above; or

d. if applicable, a failure to retain and use an IRO in accordance with section III.D, above.

D. Dispute Resolution.

1. Review Rights. Upon HHS's delivery to TJU of its Demand Letter or of its Debarment Letter or Suspension Letter, and as an agreed-upon contractual remedy for the resolution of disputes arising under the obligations of this IIA, TJU shall be afforded certain review rights comparable to the ones that are provided in 42 U.S.C. § 1320a-7(f) and 42 C.F.R. Part 1005 as if they applied to the Stipulated Penalty, debarment or suspension sought pursuant to this IIA. Specifically, HHS's determination to impose Stipulated Penalties or debarment or suspension shall be subject to review by an ALJ and, in the event of an appeal, the Departmental Appeals Board ("DAB"), in a manner consistent with the provisions in 42 C.F.R. §§ 1005.2-1005.21. Notwithstanding the language in 42 C.F.R. § 1005.2(c), the request for a hearing involving Stipulated Penalties shall be made within fifteen (15) days of the date of the Demand Letter and the request for a hearing involving debarment or suspension shall be made within thirty (30) days of the date of the Debarment Letter or the Suspension Letter.

2. Stipulated Penalties Review. Notwithstanding any provision of Title 42 of the United States Code or Chapter 42 of the Code of Federal Regulations, the only issues in a proceeding for Stipulated Penalties under this IIA shall be (a) whether TJU was in full and timely compliance with the obligations of this IIA for which HHS demands imposition of Stipulated Penalties; and (b) the period of noncompliance.

In accordance with 42 C.F.R. § 1005.15, TJU shall have the burden of going forward and the burden of persuasion with respect to affirmative defenses and any mitigating circumstances, including, but not limited to proving its full and timely compliance and the steps taken to cure the noncompliance, if any. In addition, HHS shall have the burden of going forward and burden of persuasion with regard to TJU's noncompliance and all other issues. The burden of persuasion will be judged by a preponderance of the evidence. After both parties have presented their cases, evidence may be admitted on rebuttal even if not previously exchanged, subject to the provisions

of 42 C.F.R. § 1005.8.

3. Debarment or Suspension Review. Notwithstanding any provision of Title 42 of the United States Code or Chapters 42, 45 and 48 of the Code of Federal Regulations, the only issues in a proceeding for debarment or suspension based on a material breach of this IIA shall be: (a) whether TJU was in material breach of this IIA; (b) whether such breach was continuing on the date of the Debarment Letter or the Suspension Letter; and (c) the alleged material breach cannot be cured within the thirty-five (35) day period, but that (i) TJU has begun to take action to cure the material breach, (ii) it is pursuing such action with due diligence, and (iii) TJU has provided to HHS a reasonable timetable for curing the material breach.

In accordance with 42 C.F.R. § 1005.15, TJU shall have the burden of going forward and the burden of persuasion with respect to affirmative defenses, including but not limited to proving that it was not in material breach of this IIA and/or that the material breach has been cured or can be cured within the reasonable timetable proposed by TJU. In addition, HHS shall have the burden of going forward and burden of persuasion with regard to all other issues, including whether TJU was in material breach of this IIA, whether such breach was continuing and that the material breach cannot be cured as provided by TJU. The burden of persuasion will be judged by a preponderance of the evidence. After both parties have presented their cases, evidence may be admitted on rebuttal even if not previously exchanged, subject to the provisions of 42 C.F.R. § 1005.8.

For purposes of the Stipulated Penalties, debarment or suspension pursuant to this IIA, the Stipulated Penalties, debarment or suspension shall be effective immediately upon the ALJ's decision supporting the HHS determination.

IX. DISCLOSURES

Subject to HHS's Freedom of Information Act ("FOIA") procedures, set forth in 45 C.F.R. Part 5, HHS shall make a reasonable effort to notify TJU prior to any release by HHS of information submitted by TJU pursuant to its obligations under this IIA and identified upon submission by TJU as trade secrets, commercial or financial information and privileged and confidential under the FOIA rules. TJU shall refrain from identifying any information as trade secrets, commercial or financial information and privileged and confidential that does not meet the criteria for exemption from disclosure under FOIA. Nothing in this IIA shall constitute or be construed as a waiver by TJU of its Attorney-Client or other applicable privileges. Notwithstanding that fact, the existence of any such privilege does not affect TJU's obligation to comply with the provisions of this IIA.

X. EFFECTIVE AND BINDING AGREEMENT

Consistent with the provisions in the Settlement Agreement and Release pursuant to which this IIA is entered, and into which this IIA is incorporated, TJU and HHS agree as follows:

A. This IIA shall be binding on the successors, assigns and transferees of TJU;

B. This IIA shall become final and binding on the date the final signature is obtained on the IIA;

C. Any modifications to this IIA shall be made with the prior written consent of the parties to this IIA; and

D. The undersigned TJU signatories represent and warrant that they are authorized to execute this IIA. The undersigned HHS signatories represents that they are signing this IIA in their official capacity and that they are authorized to execute this IIA.

ON BEHALF OF TJU

Paul C. Brucker

PAUL C. BRUCKER, MD
President

5/19/00
DATE

ON BEHALF OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES

L Morris

LEWIS MORRIS
Assistant Inspector General for Legal Affairs
Office of Inspector General
U. S. Department of Health and Human Services

5/18/00
DATE

for Charles Gale

TERRENCE J. TYCHAN
Deputy Assistant Secretary for Grants and
Acquisition Management
U. S. Department of Health and Human Services

5/18/00
DATE