

**INSTITUTIONAL COMPLIANCE AGREEMENT  
BETWEEN THE  
OFFICE OF INSPECTOR GENERAL  
OF THE  
DEPARTMENT OF HEALTH AND HUMAN SERVICES  
AND  
UNIVERSITY OF FLORIDA COLLEGE OF MEDICINE**

**I. PREAMBLE**

The University of Florida College of Medicine (“University”) hereby enters into this Institutional Compliance Agreement (“ICA” or the “Agreement”) with the Office of Inspector General (“OIG”) of the United States Department of Health and Human Services (“HHS”). The ICA is intended to ensure compliance by University’s Department of Obstetrics and Gynecology, Pensacola Division (“Residency Program”) and all physician faculty, residents, ancillary health providers, and staff who are employees of the University in connection with the Residency Program (“Covered Persons”)<sup>1</sup> with the requirements of Medicare, Medicaid and all other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f))(hereinafter collectively referred to as the “Federal health care programs.”) Contemporaneously with this ICA, University is entering into a Settlement Agreement with the United States, and this ICA is incorporated by reference into the Settlement Agreement.

---

<sup>1</sup> Currently, the Residency Program does not submit claims to Federal health care programs for services provided by the Covered Persons. Rather, that billing function is performed by Sacred Heart Hospital under a contract with the Residency Program. If, during the term of this ICA, that billing arrangement changed and the Residency Program began doing its own billing, the definition of Covered Persons in this ICA would expand to include the individuals performing that billing function.

Prior to the execution of this ICA, University voluntarily established its own corporate compliance program (known as the “University of Florida College of Medicine Billing Compliance Program” or “BCP”) that applies to all College of Medicine divisions, including the Residency Program. In addition to corporate integrity policies and procedures, the BCP provides for a Director of Compliance, Compliance Leaders, a compliance committee, a training and educational program, ongoing compliance auditing and a hotline. University represents that the BCP is aimed at ensuring that the University’s billing activities are in conformity with all statutes, regulations and guidelines applicable to billing to and reimbursement from the Federal health care programs for services rendered (the “Regulations”). University agrees to continue the operation of its BCP for the Residency Program in accordance with the provisions set forth below for the term of this ICA. University may modify the BCP as appropriate, but at a minimum, University shall ensure that it complies with the integrity obligations for the Residency Program that are enumerated in this ICA.

## **II. TERM OF THE ICA**

The effective date of this ICA will be the date on which the final signatory of this ICA executes this ICA (the “Effective Date”). The period of the compliance obligations assumed by University under this ICA shall be five (5) years from the Effective Date. The obligations in Sections VI, VII, VIII, IX, and X shall remain in effect until University submits all information required by the OIG as part of the final Annual Report required by Section IV below (unless otherwise agreed to in writing by the parties). The parties agree that if University decides to discontinue operation of the Residency Program, it will notify the OIG, in writing, thirty (30) days prior to the date of discontinuance. If University discontinues operation of the Residency Program, and notifies the OIG as specified above, the compliance obligations assumed by University under this ICA shall terminate after University submits a final Annual Report and submits all information

required by the OIG as part of a final Annual Report. Provided, however, as indicated in Section X, all obligations under this ICA shall be binding on all successors, assigns and transferees of the Residency Program.

### **III. CORPORATE INTEGRITY OBLIGATIONS**

Within ninety (90) days of the Effective Date, University agrees to implement any provisions of this ICA which have not already been accomplished with respect to the Residency Program pursuant to the BCP.

**A. Compliance Officer.** University has represented to OIG that, pursuant to the BCP, it has appointed a Departmental Compliance Leader for the Residency Program (“Compliance Leader”) and has appointed an individual to serve in that capacity. Accordingly, for the term of this ICA, University shall formally maintain the appointment of an individual to serve as the Compliance Leader. At a minimum, the Compliance Leader must continuously be charged with the responsibility for the day-to-day activities for the Residency Program in furtherance of the integrity obligations assumed in this ICA and with any reporting obligations created under this ICA. It is understood, however, that the Compliance Leader will have other responsibilities in connection with the Residency Program.

The Compliance Leader reports directly to the Director of Compliance for the College of Medicine. The Director of Compliance is appointed by and reports directly to the Dean of the College of Medicine. The Compliance Leader shall make regular (at least quarterly) reports regarding compliance matters affecting the Residency Program directly to the Director of Compliance and shall be authorized to report to the President and Dean of the College of Medicine at any time.

Any actions that would change the identity of the Director of Compliance or the Compliance Leader or materially change the responsibilities of these positions, as

outlined in the BCP, must be reported to OIG within thirty (30) days of the effective date of the action.

**B. Office of Compliance and Compliance Committee**

University has represented to OIG that, pursuant to the BCP, it has created an Office of Compliance and a Compliance Committee. Accordingly, for the term of this ICA, University shall formally maintain an Office of Compliance which, at a minimum, shall be responsible for monitoring overall compliance with the integrity obligations of the BCP and of this Agreement. As a function of the Office of Compliance, the Compliance Committee shall meet regularly to address compliance issues and shall consist of: 1) any appointed representatives from the Dean's office; 2) the Director of Compliance; 3) the Compliance Leaders of each College of Medicine clinical department; 4) the Compliance Leader of the Residency Program and 5) any appointed representatives of University billing entities. The Director of Compliance shall chair the Compliance Committee. The Office of Compliance shall support and assist the Director of Compliance in fulfilling his/her responsibilities (e.g., shall assist in the analysis of the organization's risk areas and shall oversee monitoring of internal and external audits and investigations).

**C. Written Standards.**

1. *Code of Conduct.* University has represented to OIG that it has established a Code of Conduct that is integrated as part of the BCP and that will be maintained in effect for the duration of this Agreement. To the extent not already distributed, the Code of Conduct shall be distributed to all Covered Persons within ninety (90) days of the Effective Date of this ICA. The Code of Conduct shall also be readily accessible to Covered Persons through means University considers effective. New Covered Persons shall receive the Code of Conduct within thirty (30) days after the

commencement of their association with the Residency Program. Adherence to the Code of Conduct shall be an element in evaluating the performance of Covered Persons.

The Code of Conduct shall, at a minimum, set forth:

- a. University's commitment to compliance with all Federal health care program requirements, including its commitment to prepare and submit accurate billings consistent with the Regulations;
- b. University's requirement that Covered Persons shall comply with all requirements of the Federal health care programs, the BCP, and the requirements of this Agreement;
- c. the requirement that Covered Persons shall report to the Office of Compliance or to the telephone hotline any suspected violations of the Federal health care program requirements, including the Regulations, or the BCP;
- d. the potential consequences to both University and to any Covered Person of any failure to comply with the applicable Federal health care programs requirements and with the BCP or any failure to report such non-compliance; and
- e. the right of all Covered Persons to use the Confidential Disclosure Program required by Section III.F, as well as University's commitment to confidentiality and non-retaliation with respect to disclosures.

Within ninety (90) days of the effective date of the ICA, each Covered Person shall certify, in writing, that he or she has received, read, understood, and will abide by the University's Code of Conduct. New Covered Persons shall receive the Code of Conduct and shall complete the required certification within thirty (30) days after the commencement of their association with the Residency Program or within ninety (90) days of the effective date of the ICA, whichever is later. University shall document the actions taken to distribute the Code of Conduct to Covered Persons. Such documentation shall be produced to the OIG upon request.

University will annually review the Code of Conduct and will make any necessary revisions. If revised, the Code of Conduct shall be distributed to Covered Persons within thirty (30) days of initiating such a change, unless the nature of the revision is such that it warrants earlier notice. Covered Persons shall certify that they have received, read, understood and will abide by the revised Code of Conduct within thirty (30) days of the finalization of such revisions.

2. *Policies and Procedures.* The University has represented to the OIG that it has developed and placed into effect written Policies and Procedures regarding the operation of the BCP and University's compliance with the requirements of the Federal health care programs as they relate to Residency Program operations. Accordingly, for the term of this ICA, University shall formally maintain these written policies and procedures as part of the BCP that specifically address, at a minimum: (1) compliance with all applicable requirements for the proper documentation of medical services rendered and (2) compliance with the Regulations as they relate to billing for services rendered through the Residency Program. In addition, the Policies and Procedures shall continue to include disciplinary guidelines and methods for Covered Persons to make disclosures or otherwise report on compliance issues to University through the Confidential Disclosure Program required by section III.F.

At least annually (and more frequently if appropriate), University shall assess the Policies and Procedures and will update them as necessary. Within thirty (30) days of the effective date of any revisions, the relevant portions of any such revised Policies and Procedures shall be distributed to the appropriate Covered Persons. The Policies and Procedures will be available to OIG upon request.

University has provided and shall continue the practice of providing the Policies and Procedures to each Covered Person. To the extent not already distributed, within

ninety (90) days of the Effective Date of the ICA, the relevant portions of the Policies and Procedures shall be distributed to all Covered Persons. Each Covered Person shall certify that he/she has received, read, and understood the material in the applicable policies and procedures. Compliance staff or supervisors shall be duly identified and made continuously available to explain any and all Policies and Procedures.

**D. Information and Education Program.**

University shall continue to maintain an information and education program for the benefit of the Residency Program. The program shall have two components consisting of general and specific training requirements.

1. *General Training.* To the extent not already provided, University shall provide general training to each Covered Person within ninety (90) days of the Effective Date of this ICA. This training shall cover: 1) the ICA requirements and 2) the BCP, including the Code of Conduct.

Those Covered Persons who have received general training on the BCP within the one year period prior to the Effective Date of this ICA need only be trained about the existence and requirements of this ICA and the Code of Conduct.

This general training shall be included in the orientation of new Covered Persons. New employees shall receive the general training described above within thirty (30) days of the beginning of their employment or within one hundred and twenty (120) days after the effective date of this ICA, whichever is later. After receiving the initial training described above, each of the Covered Persons shall receive this general training annually.

2. *Specific Training.* Within one hundred and twenty (120) days of the effective date of this ICA, each Covered Person who is responsible for generating, preparing and/or submitting (including, but not limited to, coding and billing) requests for reimbursement from any Federal health care programs for services provided through the Residency Program (“Covered Billing Individuals”) shall receive specific training in addition to the

general training required above. University's training program shall be a substantive and thorough program that provides meaningful training on the topics specified herein.

This specific training shall include a discussion of: a) the submission of accurate requests for reimbursement for services rendered to beneficiaries of the Federal health care programs; b) the policies, procedures and other requirements applicable to the documentation of medical records, especially as it pertains to the provision of physician and other medical services; c) the personal obligation of each individual involved in the billing process to ensure that such billings are accurate; d) all applicable reimbursement rules and statutes; e) the legal sanctions for improper billings; and f) examples of proper and improper billing practices.

Materials for this specific training shall be made available to OIG, upon request. Persons providing the training must be knowledgeable about the subject areas outlined above.

Affected new Covered Billing Individuals shall receive the training within thirty (30) days of the beginning of their employment or association with the program or within one hundred and twenty (120) days of the effective date of this ICA, whichever is later. If any new Covered Billing Individual has any responsibility for preparation or submission of claims and/or the assignment of procedure codes prior to completing this training, a Covered Billing Individual who has completed the training shall review all of the untrained person's work regarding the preparation or submission of claims for reimbursement from Federal health care programs until such time as the new Covered Billing Individual is trained.

After the first year of this ICA, each of the Covered Billing Individuals shall receive this specific training on an annual basis.

If, pursuant to the BCP, University has provided training to Covered Billing Individuals that satisfies the requirements set forth above in Section III.D.2 within the one



year prior to the Effective Date of this ICA, OIG shall credit that training for purposes of satisfying University's specific training obligations for the first year of this ICA.

3. *Certification.* Each of the Covered Persons and Covered Billing Individuals shall certify, in writing, that he or she has attended the required training. The certification shall specify the date the training was received. The Compliance Leader shall retain the certifications, along with specific course materials. These shall be made available to OIG upon request.

**E. Annual Reviews.** University has developed a protocol, attached hereto as Attachment 1, for reviewing, on an annual basis, a sample of claims for all professional services rendered by physician faculty, residents, and ancillary health providers who are employees of University in connection with the Residency Program. An objective of the annual review is to verify compliance with the Federal and state reimbursement requirements for the Federal health care programs. Implementation of the agreed-upon procedures set forth in the protocol shall be an obligation of this Agreement.

For the yearly period ending August 31, 2001 and annually thereafter, University shall contract with an independent entity (the "Annual Reviewer") with expertise in the reimbursement requirements of the Federal health care programs to verify whether University is implementing the agreed-upon procedures set forth in Attachment 1. The Annual Reviewer shall be required to issue a report concerning its work, its findings, conclusions and recommendations and that report shall be included with the Annual Reports submitted to the OIG. In addition, if the University undertakes additional audits as specified in Attachment 1, the results of those follow-up audits shall be included with the Annual Reports.

1. *Reporting of Overpayments.* If, at any time, University identifies or learns of any overpayment,<sup>2</sup> University shall notify the payor (e.g., Medicare or Medicaid fiscal intermediary or carrier) and repay any overpayment within 30 days (or such additional time as may be agreed to by the payor) and take remedial steps within 60 days (or such additional time as may be agreed by the payor) of discovery to correct the problem, including preventing the underlying problem and the overpayments from recurring. Notification and repayment to the contractor shall be made in accordance with the contractor policies, and for Medicare contractors, must include the information contained on the Overpayment Refund Form, provided as Attachment 2 to this ICA.

2. *Definition of "Material Deficiency."* For purposes of this ICA, a "material deficiency" means anything that involves:

- (a) a substantial overpayment relating to any Federal health care program;
- (b) a matter that a reasonable person would consider a probable violation of criminal, civil, or administrative laws applicable to any Federal health care program for which penalties or exclusion are authorized.

A material deficiency may be the result of an isolated event or a series of occurrences.

3. *Reporting of Material Deficiencies.* If University determines that there is a material deficiency, University shall notify the OIG within 30 days of making the determination that the material deficiency exists. Unless otherwise applicable as specified below, the report to the OIG shall include the following information:

---

<sup>2</sup> An "overpayment" shall mean the amount of money University has received in excess of the amount due and payable under the Federal health care requirements. University may not subtract any underpayments for purposes of determining the amount of relevant "overpayments."

(a) If the material deficiency results in an overpayment, the report to the OIG shall be made at the same time as the notification to the payor pursuant to Section III.E.1 and shall include all of the information on the Overpayment Refund Form as well as:

(i) the payor's name, address, and contact person to whom the overpayment was sent; and

(ii) the date of the check and identification number (or electronic transaction number) on which the overpayment was repaid/refunded.

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

(c) University's actions to correct the material deficiency; and

(d) any further steps University plans to take to address such material deficiency and prevent it from recurring.

To the extent University has not quantified and repaid any overpayment and/or completed its corrective actions at the time of any initial material deficiency notice pursuant to this subsection, it shall notify the OIG in writing after such corrective actions are undertaken and/or refunds are paid.

4. *Validation Review.* In the event the OIG determines that it is necessary to conduct an independent review to determine whether or the extent to which University is complying with its obligations under this ICA, University agrees to pay for the reasonable cost of any such review or engagement by the OIG or any of its designated agents so long as it is initiated before one year after the final report is submitted. Prior to proceeding with such an independent review, the OIG shall notify University of its intent to do so and its reasons for believing such a review is necessary, and shall in good faith attempt to resolve any Annual Review issues without proceeding with an independent review.

**F. Confidential Disclosure Program.** The University has represented to the OIG that it has established and will continue to maintain a confidential disclosure program that includes, but is not limited to, its toll-free telephone hotline. This confidential disclosure program will continue to allow individuals to disclose, to the Director of Compliance or some other person not in the reporting individual's chain of command, any identified issues or questions associated with the University's policies, practices or procedures with respect to the Federal health care program, believed by the individual to be inappropriate.

The University's disclosure program shall emphasize a non-retribution, non-retaliation policy, and shall include a reporting mechanism, to the extent permitted by law, for anonymous, confidential communication. Upon receipt of a complaint, the Director of Compliance (or designee) shall gather the information in such a way as to elicit all relevant information from the individual reporting the alleged misconduct. The Director of Compliance (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 University shall conduct an internal review of the allegations set forth in such a disclosure and ensure that proper follow-up is conducted.

The Director of Compliance (or designee) shall oversee the maintenance of a confidential disclosure log and relevant supporting documents, 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. The confidential disclosure log shall be available to OIG, upon request.

**G. Ineligible Persons.**

1. *Definition.* For purposes of this ICA, an “Ineligible Person” shall be any individual or entity who: (i) is currently excluded, suspended, debarred or otherwise ineligible to participate in the Federal health care programs; or (ii) has been convicted of a criminal offense related to the provision of health care items or services and has not been reinstated in the Federal health care programs after a period of exclusion, suspension, debarment, or ineligibility. A “contractor,” as used in this subsection III.G. shall mean an individual or entity engaged by University or its agents for the purpose of rendering health care items or services or for the processing, generation and/or submission of reimbursement claims to the Federal health care programs; provided that this term shall not include any individual or entity employed or engaged by a contractor. However, University shall demand assurances from its prospective contractors, or from contractors with which it renews contracts, that such contractors will not utilize any Ineligible Person related to its engagement with University.

2. *Screening Requirements.* University shall examine its Residency Program hiring policies to ensure that University shall not knowingly employ, with or without pay, any Ineligible Persons. Nor shall University hire or engage as contractors for the Residency Program any Ineligible Person. To avoid such occurrence, the University shall screen all prospective Covered Persons and contractors prior to engaging their services or permitting them to provide Federal health care services 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/epl>) 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 ICA, University will review its list of current Covered Persons and contractors against the Exclusion Lists. Thereafter, University will review the list semi-annually. If University has notice that any Covered Person or contractor has become an Ineligible Person, University will remove such person from responsibility for, or involvement with, the University's business operations related to the Federal health care programs 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, by Federal health care programs or otherwise with Federal funds at least until such time as the person is reinstated into participation in the Federal health care programs.

4. *Pending Charges and Proposed Exclusions.* If University has notice that any Covered Person or contractor is charged with a criminal offense related to any Federal health care program, or is proposed for exclusion during his or her employment or contract, University shall take all appropriate actions to ensure that the responsibilities of that individual do not adversely affect the quality of care rendered to any patient, or the accuracy of any claims submitted to any Federal health care program.

**H. Notification of Government Proceedings.** Within thirty (30) days of discovery, University shall notify OIG, in writing, of any ongoing investigation or legal proceeding conducted or brought by a governmental entity or its agents involving an allegation that the Residency Program 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. University shall also provide written notice to OIG within thirty (30) days of the resolution of the matter, and shall provide OIG with a description of the findings and/or results of the proceedings, if any.

#### **IV. IMPLEMENTATION AND ANNUAL REPORTS**

**A. Implementation Report.** Within one hundred and twenty (120) days after the effective date of this ICA, the University shall submit a written report to OIG summarizing the status of its implementation of the requirements of this ICA. This Implementation Report shall include:

1. the name, address, phone number and position description of the Compliance Leader required by section III.A;
2. the names and positions of the members of the Compliance Committee referenced in section III.B;
3. a copy of the University Code of Conduct required by section III.C.1;
4. the summary of the Policies and Procedures required by section III.C.2;
5. a description of the training programs required by section III.D including a description of the targeted audiences and a schedule of when the training sessions were held;
6. a certification by the Compliance Leader that:
  - a. the Policies and Procedures required by section III.C have been developed, are being implemented, and have been distributed to all pertinent Covered Persons;
  - b. all Covered Persons have completed the Code of Conduct certification required by section III.C.1; and
  - c. all Covered Persons have completed the training and executed the certification required by section III.D.
7. a description of the confidential disclosure program required by section III.F;
8. the identity of the Annual Reviewer and the proposed start and completion date of the first audit; and

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

If any of the above-reference materials were provided to the OIG prior to the submission of the Implementation Report, and the materials have not changed since the time they were supplied, the Implementation Report may so indicate and the materials need not be supplied again.

**B. Annual Reports.** The University shall submit to OIG annual reports (each one of which is referred to as an “Annual Report”) describing the status and findings regarding University’s compliance activities relating to the Residency Program in accordance with the terms of this ICA.

The Annual Reports shall include the following information:

1. any changes in the identity or position or any material change in the duties of the Compliance Leader or the Director of Compliance;
2. a certification by the Compliance Leader that:
  - a. all Covered Persons have completed the annual Code of Conduct certification required by section III.C.1; and
  - b. all Covered Persons have completed the training and executed the certification required by section III.D.
  - c. University has complied with its obligations under the Settlement Agreement: (i) not to resubmit to any Federal health care program payors any previously denied claims related to the Covered Conduct addressed in the Settlement Agreement, and not to appeal any such denials of claims; and (ii) not to charge to or otherwise seek payment from Federal or state payors for unallowable costs (as defined in the Settlement Agreement) and to identify and adjust any past charges or claims for unallowable costs;
3. notification of and a summary of any significant changes or amendments to the Code of Conduct or of the Policies and Procedures required by



section III.C that were made during the period covered by the Annual Report and the reasons for such changes;

4. a description of the training and education activities required by section III.D conducted during the time covered by the Annual Report, including a description of the targeted audiences, length of sessions, which sessions were mandatory and for whom, percentage of attendance, and a schedule of when the training sessions were held;

5. a summary of the findings made during the reviews conducted pursuant to Section III.E of the Agreement relating to the year covered by the Annual Report; copies of any disclosures or notices prepared by University pursuant to that section; a copy of the Annual Reviewer's report required under Section III.E; a copy of all reports from follow-up audits; a description of the corrective steps taken in response to any audit findings; and a description of all refunds made to all pertinent payors as a result of audit findings (where applicable);

6. University's response/corrective action plan to any issues raised by the Annual Reviewer;

7. a summary of material deficiencies identified and reported throughout the course of the previous twelve (12) months pursuant to Section III.E and the status of any corrective and preventative action relating to such material deficiencies;

8. a report of the aggregate overpayments that have been returned to the Federal health care programs that were discovered as a direct or indirect result of implementing this ICA. Overpayment amounts should be broken down into the following categories: Inpatient Medicare, outpatient Medicare, Medicaid (report each applicable state separately) and other Federal health care programs;

9. a summary of the disclosures received through mechanisms established pursuant to section III.F that: (a) relate to Federal health care programs; or (b) allege abuse or neglect of patients as well as a summary of the University's follow up on any such disclosures;

10. a description of any personnel actions (other than hiring) taken by the University as a result of the obligations in section III.G, and the name, title and responsibilities of any person that falls within the ambit of section III.G.4, and the actions taken in response to the obligations set forth in that section; and

11. a summary describing any ongoing investigation or legal proceeding required to have been reported pursuant to section III.H. The statement shall include a description of the allegation, 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 be received by the OIG no later than one year and sixty (60) days after the effective date of this ICA. Subsequent Annual Reports shall be submitted no later than the anniversary date of the due date of the first Annual Report.

**C. Certifications.** The Implementation Report and Annual Reports shall include a certification by the Compliance Leader that: (1) except as otherwise described in the applicable report, University is in compliance with all of the requirements of this ICA, to the best of his or her knowledge; and (2) the Compliance Leader has reviewed the Report and has made reasonable inquiry regarding its content and believes that, upon such inquiry, the information is accurate and truthful.

**D. Designation of Information:** University shall clearly identify any portions of its submissions that it believes are trade secrets, or information that is commercial or financial and privileged or confidential, and therefore exempt from disclosure under the Freedom of Information Act ("FOIA"), 5 U.S.C. § 552. University shall refrain from identifying any information as exempt from disclosure if that information does not meet the criteria for exemption from disclosure under FOIA.

V. NOTIFICATIONS AND SUBMISSION OF REPORTS

Unless otherwise stated in writing subsequent to the effective date of this ICA, all notifications and reports required under this ICA shall be submitted to the entities listed below:

OIG:

Civil Recoveries Branch - Compliance Unit  
Office of Counsel to the Inspector General  
Office of Inspector General  
U.S. Department of Health and Human Services  
Cohen Building, Room 5527  
330 Independence Avenue, SW  
Washington, DC 20201  
Phone 202.619.2078  
Fax 202.205.0604

The University:

Pamela J. Bernard, Esq.  
General Counsel  
University of Florida  
123 Tigert Hall  
P.O. Box 113125  
Gainesville, FL 32611-3125  
Ph. 352.392.1358  
Fax 352.392.4387

Unless otherwise specified, all notifications and reports required by this ICA may be made by certified mail, overnight mail, hand delivery or other means, provided that there is proof that such notification was received. For purposes of this requirement, internal facsimile confirmation sheets do not constitute proof of receipt

## **VI. OIG INSPECTION, AUDIT AND REVIEW RIGHTS**

In addition to any other rights OIG may have by statute, regulation, or contract, OIG or its duly authorized representative(s), may examine the University's books, records, and other documents and supporting materials relating to the Residency Program and/or conduct an onsite review of the University's operations for the purpose of verifying and evaluating: (a) the University's compliance with the terms of this ICA; and (b) the University's compliance with the requirements of the Federal health care programs in which it participates. The documentation described above shall be made available by the University to OIG or its duly authorized representative(s) at all reasonable times for inspection, audit or reproduction. Furthermore, for purposes of this provision, OIG or its duly authorized representative(s) may interview any of the University's employees or Covered Persons who consent to be interviewed at that individual's place of business during normal business hours or at such other place and time as may be mutually agreed upon between the individual and OIG. The University agrees to assist OIG in contacting and arranging interviews with such individuals upon OIG's request. The University's employees may elect to be interviewed with or without a representative of the University present. The University's employees shall have the right to request the presence of a University representative at such interviews.

## **VII. DOCUMENT AND RECORD RETENTION**

The University and Residency Program shall maintain for inspection all documents and records relating to reimbursement from the Federal health care programs or to compliance with this ICA, one year longer than the term of this ICA (or longer if otherwise required by law).

## **VIII. DISCLOSURES AND PRIVILEGES**

Subject to HHS's Freedom of Information Act ("FOIA") procedures, set forth in 45 C.F.R. Part 5, the OIG shall make a reasonable effort to notify the University prior to

any release by OIG of information submitted by the University pursuant to its obligations under this ICA and identified upon submission by the University as trade secrets, commercial or financial information and privileged and confidential under the FOIA rules. With respect to such releases, University shall have the rights set forth at 45 C.F.R. § 5.65(d). University shall refrain from identifying any information as exempt from release if that information does not meet the criteria for exemption from disclosure under FOIA.

Nothing in this ICA, or any communication or report made pursuant to this ICA, shall constitute or be construed as a waiver by University of its attorney-client, work product or other applicable privileges. Notwithstanding that fact, the existence of any such privilege does not affect University's obligation to comply with the provisions of this ICA. The confidentiality of all documents and other information provided by University in connection with its obligations under this Agreement shall be maintained by the OIG except to the extent disclosure is required by law.

**IX. BREACH AND DEFAULT PROVISIONS**

The University is expected to fully and timely comply with all of the obligations herein throughout the term of this ICA or other time frames herein agreed to.

**A. Stipulated Penalties for Failure to Comply with Certain Obligations.** As a contractual remedy, the University and OIG hereby agree that failure to comply with certain obligations set forth in this ICA may lead to the imposition of the following monetary penalties (hereinafter referred to as "Stipulated Penalties") in accordance with the following provisions.

1. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day, beginning one hundred and twenty (120) days after the effective date of this ICA and concluding at the end of the term of

this ICA, the University fails to have in place any of the following, as described in this ICA, for the Residency Program:

- a. a Compliance Leader;
- b. written Code of Conduct;
- c. written Policies and Procedures;
- d. a training program; and
- e. a Confidential Disclosure Program;

2. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day the University fails meet any of the deadlines to submit the Implementation Report or the Annual Reports to the OIG.

3. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day University fails to retain an Annual Reviewer, as required in section III.E.

4. A Stipulated Penalty of \$2,000 (which shall begin to accrue on the date the failure to comply began) for each day University employs or contracts with an Ineligible Person and that person: (i) has responsibility for, or involvement with, University's business operations related to the Federal health care programs; 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 part, directly or indirectly, by Federal health care programs or otherwise with Federal funds (the Stipulated Penalty described in this paragraph shall not be demanded for any time period during which University can demonstrate that it did not discover the person's exclusion or other ineligibility after making a reasonable inquiry (as described in section III.G) as to the status of the person).

5. A Stipulated Penalty of \$1,500 (which shall begin to accrue on the date the University fails to grant access) for each day the University fails to grant access to the information or documentation as required in section VI of this ICA.

6. A Stipulated Penalty of \$1,000 (which shall begin to accrue ten (10) days after the date that OIG provides notice to the University of the failure to comply) for each day the University fails to comply fully and adequately with any obligation of this ICA not already covered by paragraphs IX.A.1-5. In its notice to the University, the OIG shall state the specific grounds for its determination that the University has failed to comply fully and adequately with the ICA obligation(s) at issue and the steps University must take to comply with the ICA.

**B. Payment of Stipulated Penalties.**

1. *Demand Letter.* Upon a finding that the University has failed to comply with any of the obligations described in section IX.A and determining that Stipulated Penalties are appropriate, OIG shall notify the University of (a) the University's failure to comply; and (b) the OIG's exercise of its contractual right to demand payment 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, the University shall either (a) cure the breach to the OIG's satisfaction and pay the applicable stipulated penalties; or (b) request a hearing before an HHS administrative law judge ("ALJ") to dispute the OIG's determination of noncompliance, pursuant to the agreed upon provisions set forth below in section IX.D. In the event the University elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until the University cures, to the OIG's satisfaction, the alleged breach in dispute. Failure to respond to the Demand Letter in one of these two manners within the allowed time period shall be considered a material breach of this ICA and shall be grounds for exclusion under section IX.C.

2. *Timely Written Requests for Extension.* The University may submit a timely written request for an extension of time to perform any act or file any notification or report required by this ICA. Notwithstanding any other provision in this section, if OIG 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 begin to accrue until one day after the University fails to meet the revised deadline as agreed to by the OIG-approved extension. Notwithstanding any other provision in this section, if OIG denies such a timely written request, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until two (2) business days after the University receives OIG's written denial of such request. A "timely written request" is defined as a request in writing received by OIG 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. *Form of Payment.* Payment of the Stipulated Penalties shall be made by certified or cashier's check, payable to "Secretary of the Department of Health and Human Services," and submitted to OIG at the address set forth in section V.

4. *Independence from Material Breach Determination.* Except as otherwise noted, these provisions for payment of Stipulated Penalties shall not affect or otherwise set a standard for the OIG's determination that the University has materially breached this ICA, which decision shall be made at the OIG's discretion and governed by the provisions in section IX.C, below.

### **C. Remedies for Material Breach of this ICA**

1. *Notice of Material Breach and Intent to Exclude.* The parties agree that a material breach of this ICA by the University constitutes an independent basis for the University's exclusion from participation in the Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)). Upon a determination by OIG that the University has materially breached this ICA and that exclusion should be imposed, the OIG shall notify the University of (a) the University's material breach; and (b) OIG's intent to exercise its contractual right to impose exclusion (this notification is hereinafter referred to as the "Notice of Material Breach and Intent to Exclude").



2. *Opportunity to cure.* The University shall have thirty five (35) days from the date of the Notice of Material Breach and Intent to Exclude Letter to demonstrate to the OIG's satisfaction that:

- a. there was no material breach of this ICA;
- b. the alleged material breach has been cured; or
- c. the alleged material breach cannot be cured within the 35-day period, but that: (i) the University has begun to take action to cure the material breach, (ii) the University is pursuing such action with due diligence, and (iii) the University has provided to OIG a reasonable timetable for curing the material breach.

3. *Exclusion Letter.* If at the conclusion of the thirty five (35) day period, the University fails to satisfy the requirements of section IX.C.2, OIG may exclude the University from participation in the Federal health care programs. OIG will notify the University in writing of its determination to exclude the University (this letter shall be referred to hereinafter as the "Exclusion Letter"). Subject to the Dispute Resolution provisions in section IX.D, below, the exclusion shall go into effect thirty (30) days after the date of the Exclusion Letter. The exclusion shall have national effect and will also apply to all other federal procurement and non-procurement programs. If the University is excluded under the provisions of this ICA, it may seek reinstatement pursuant to the provisions at 42 C.F.R. §§ 1001.3001-.3004.

4. *Material Breach.* A material breach of this ICA means:

- a. a failure by the University to report a material deficiency, take corrective action and pay the appropriate refunds, as provided in section III.E;
- b. repeated or flagrant violations of the obligations under this ICA, including, but not limited to, the obligations addressed in section IX.A of this ICA;

c. a failure to respond to a Demand letter concerning the payment of Stipulated Penalties in accordance with section IX.B above; or

d. a failure to retain and use an Annual Reviewer for review purposes in accordance with section III.E.

#### **D. Dispute Resolution**

1. *Review Rights.* Upon the OIG's delivery to the University of its Demand Letter or of its Exclusion Letter, and as an agreed-upon contractual remedy for the resolution of disputes arising under the obligation of this ICA, the University 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. § 1005 as if they applied to the Stipulated Penalties or exclusion sought pursuant to this ICA. Specifically, the OIG's determination to demand payment of Stipulated Penalties or to seek exclusion 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 exclusion shall be made within thirty (30) days of the date of the Exclusion 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 ICA shall be (a) whether the University was in full and timely compliance with the obligations of this ICA for which the OIG demands payment; and (b) the period of noncompliance. The University shall have the burden of proving its full and timely compliance and the steps taken to cure the noncompliance, if any. If the ALJ finds for the OIG with regard to a finding of a breach of this ICA and orders the University to pay Stipulated Penalties, such Stipulated

Penalties shall become due and payable twenty (20) days after the ALJ issues such a decision unless University requests review of the ALJ decision by the DAB. If the ALJ decision is properly appealed to the DAB and the DAB upholds the determination of OIG, the Stipulated Penalties shall become due and payable twenty (20) days after the DAB issues its decision.

3. *Exclusion 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 exclusion based on a material breach of this ICA shall be (a) whether the University was in material breach of this ICA; (b) whether such breach was continuing on the date of the Exclusion Letter; and (c) whether the alleged material breach could not be cured within the 35 day period, but that (i) the University had begun to take action to cure the material breach, (ii) the University is pursuing such action with due diligence, and (iii) the University has provided to OIG a reasonable timetable for curing the material breach. For purposes of the exclusion herein, exclusion shall take effect only after an ALJ decision that is favorable to the OIG or, if the ALJ rules for University, only after a DAB decision in favor of OIG. The University's election of its contractual right to appeal to the DAB shall not abrogate the OIG's authority to exclude the University upon the issuance of the ALJ's decision in favor of the OIG. If the ALJ sustains the determination of the OIG and determines that exclusion is authorized, such exclusion shall take effect twenty (20) days after the ALJ issues such a decision, notwithstanding that the University may request review of the ALJ decision by the DAB. If the DAB finds in favor of OIG after an ALJ decision adverse to OIG, the exclusion shall take effect twenty (20) days after the DAB decision.

**X. EFFECTIVE AND BINDING AGREEMENT**

Consistent with the provisions in the Settlement Agreement pursuant to which this ICA is entered, and into which this ICA is incorporated, the University and OIG agree as follows:

A. This ICA shall be binding on the successors, assigns and transferees of the Residency Program.

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

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

D. The undersigned University signatories represent and warrant that they are authorized to execute this ICA. The undersigned OIG signatory represents that he is signing this ICA in his official capacity and that he is authorized to execute this ICA.

**ON BEHALF OF THE UNIVERSITY**

CHARLES E. YOUNG  
President

DATE

*Kenneth I Berns*  
KENNETH I. BERNS, M.D., Ph.D.  
Vice President for Health Affairs  
Dean, College of Medicine

8/11/00  
DATE

CLYDE H. DORR II, M.D., FACOG  
Associate Chair, Program Director  
Pensacola Ob/Gyn Division

DATE

**ON BEHALF OF THE UNIVERSITY**

CHARLES E. YOUNG  
President

DATE \_\_\_\_\_

KENNETH I. BERNS, M.D., Ph.D.  
Vice President for Health Affairs  
Dean, College of Medicine

DATE \_\_\_\_\_

*Clyde H. Dorr II MD*  
CLYDE H. DORR II, M.D., FACOG  
Associate Chair, Program Director  
Pensacola Ob/Gyn Division

DATE *11 Aug 00*

ON BEHALF OF THE OFFICE OF INSPECTOR GENERAL  
OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES

*Lewis Morris*

LEWIS MORRIS

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

*8/11/00*

DATE