

CORPORATE INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
BAXANO SURGICAL, INC.

I. PREAMBLE

Baxano Surgical, Inc. (“Baxano Surgical”) hereby enters into this Corporate Integrity Agreement (CIA) with the Office of Inspector General (OIG) of the United States Department of Health and Human Services (HHS) to promote compliance with the statutes, regulations, and written directives of Medicare, Medicaid, and all other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) (Federal health care program requirements) and with the statutes, regulations, and written directives of the Food and Drug Administration (FDA requirements).

Contemporaneously with this CIA, Baxano Surgical is entering into a Settlement Agreement with the United States.

Prior to the Effective Date of this CIA (as defined below), Baxano Surgical established a voluntary compliance program applicable to Baxano Surgical directors, officers, managers, and employees (Compliance Program). Baxano Surgical’s Compliance Program includes, among other features, a Chief Compliance Officer; an executive level compliance committee and a compliance committee of the Board of Directors; a code of conduct and written policies and procedures; educational and training initiatives; and a disclosure program.

Baxano Surgical shall continue its Compliance Program throughout the term of this CIA and shall do so in accordance with the terms set forth below. Baxano Surgical may modify its Compliance Program as appropriate, but, at a minimum, Baxano Surgical shall ensure that during the term of this CIA, it shall comply with the obligations set forth herein.

II. TERM AND SCOPE OF THE CIA

A. The period of the compliance obligations assumed by Baxano Surgical under this CIA shall be five years from the effective date of this CIA, unless otherwise specified. The “Effective Date” shall be the date on which the final signatory of this CIA executes this CIA, unless otherwise specified. Each one-year period, beginning with the one-year period following the Effective Date, shall be referred to as a “Reporting Period.”

B. Sections VII, X, and XI shall expire no later than 120 days after OIG’s receipt of: (1) Baxano Surgical’s final Annual Report; or (2) any additional materials submitted by Baxano Surgical pursuant to OIG’s request, whichever is later.

C. The scope of this CIA shall be governed by the following definitions:

1. “Covered Persons” includes:

a. all owners of Baxano Surgical who are natural persons (other than shareholders who: (1) have an ownership interest of less than 5% and (2) acquired the ownership interest through public trading) and all officers and directors of Baxano Surgical;

b. all employees of Baxano Surgical; and

c. all contractors, subcontractors, agents, and other persons who perform any of the Promotional and Product Services Related Functions on behalf of Baxano Surgical, and who in that capacity either (1) interact directly with health care professionals (HCPs), healthcare institutions (HCIs), or consumers in the United States; or (2) perform activities, provide services, or create materials relating to the Promotional and Product Services Related Functions and those activities, services, or materials are not reviewed or supervised by a Covered Person prior to execution or dissemination.

Notwithstanding the above, the term Covered Persons does not include part-time or per diem employees, contractors, subcontractors, agents, and other persons who are not reasonably expected to work more than 160 hours per

year, except that any such individuals shall become “Covered Persons” at the point when they work more than 160 hours during the calendar year.

2. “Relevant Covered Persons” includes all Covered Persons who engage in any of the Promotional and Product Services Related Functions or who supervise Covered Persons who engage in any of the Promotional and Product Services Related Functions.
3. “Government Reimbursed Products” refers to all Baxano Surgical drugs, devices, and biologics that are marketed or sold by Baxano Surgical in the United States that are reimbursed by Federal health care programs or sold pursuant to contracts with the United States.
4. “Promotional and Product Services Related Functions” includes: (a) the selling, detailing, marketing, advertising, promoting, or branding of Government Reimbursement Products; (b) the development, approval, preparation, or dissemination of materials or information about, or the provision of services relating to, Government Reimbursed Products including those functions relating to review committees and Clinical Affairs; (c) the dissemination of information and/or advice about coding and reimbursement; and (d) contracting with HCPs or HCIs in the United States to be speakers, consultants, or to conduct post-marketing and other clinical studies of Government Reimbursed Products and all other types of post-marketing research, and the authorship, publication, and disclosure of results relating to such studies or research.
5. The term “Third Party Educational Activity” shall mean any continuing medical education (CME), disease awareness, or other scientific, educational, or professional program, meeting, or event supported by Baxano Surgical, including but not limited to, sponsorship of symposia at medical conferences.
6. The term “Third Party Personnel” shall mean personnel of the entities with which Baxano Surgical has entered or may in the future (during the term of this CIA) enter into agreements to promote or co-promote a Government Reimbursed Product or to engage in joint promotional activities relating to such a product. Baxano Surgical represents that: (1) Third Party Personnel are employed by entities independent of Baxano

Surgical; (2) Baxano Surgical does not control Third Party Personnel; and (3) it would be commercially impractical to compel the compliance of Third Party Personnel with the requirements set forth in this CIA. Baxano Surgical agrees to promote compliance by Third Party Personnel with Federal health care program and FDA requirements by complying with the provisions set forth below in Sections III.B.2, V.A.7, and V.B.4. Provided that Baxano Surgical complies with the requirements of Sections III.B.2, V.A.7, and V.B.4, Baxano Surgical shall not be required to fulfill the other CIA obligations that would otherwise apply to Third Party Personnel who meet the definitions of Covered Persons.

III. CORPORATE INTEGRITY OBLIGATIONS

Baxano Surgical shall establish and maintain a Compliance Program that includes the following elements:

A. Compliance Responsibilities of Certain Baxano Surgical Employees and the Board of Directors.

1. *Compliance Officer.* Prior to the Effective Date, Baxano Surgical appointed an individual to serve as its compliance officer (known as the Vice President of Regulatory, Quality and Compliance and Chief Compliance Officer) and Baxano Surgical shall maintain a compliance officer for the term of the CIA. The Compliance Officer is, and shall continue to be, responsible for developing and implementing policies, procedures, and practices designed to ensure compliance with the requirements set forth in this CIA and with Federal health care program and FDA requirements. The Compliance Officer shall be a member of senior management of Baxano Surgical, shall report directly to the Chief Executive Officer of Baxano Surgical, shall make periodic (at least quarterly) reports regarding compliance matters directly to the Board of Directors of Baxano Surgical, and shall be authorized to report on such matters to the Board of Directors at any time. The Compliance Officer shall not be or be subordinate to the General Counsel or Chief Financial Officer. The Compliance Officer shall be responsible for monitoring the day-to-day compliance activities engaged in by Baxano Surgical as well as for any reporting obligations created under this CIA. Any noncompliance job responsibilities of the Compliance Officer shall be limited and must not interfere with the Compliance Officer's ability to perform the duties outlined in this CIA.

Baxano Surgical shall report to OIG, in writing, any change in the identity of the Compliance Officer, or any actions or changes that would affect the Compliance Officer's ability to perform the duties necessary to meet the obligations in this CIA, within five days after such a change.

2. *Compliance Committee.* Prior to the Effective Date, Baxano Surgical appointed a Compliance Committee. Baxano Surgical shall continue the Compliance Committee during the term of this CIA. The Compliance Committee shall, at a minimum, include the Compliance Officer and other members of senior management necessary to meet the requirements of this CIA (e.g., senior executives of relevant documents, such as legal, clinical affairs, regulatory affairs, professional affairs, sales, marketing, human resources, audit, research and development, and operations). The Compliance Officer shall chair the Compliance Committee and the Compliance Committee shall support the Compliance Officer in fulfilling his/her responsibilities (e.g., shall assist in the analysis of the Baxano Surgical's risk areas and shall oversee monitoring of internal and external audits and investigations). The Compliance Committee shall meet at least quarterly.

Baxano Surgical shall report to OIG, in writing, any changes in the composition of the Compliance Committee, or any actions or changes that would affect the Compliance Committee's ability to perform the duties necessary to meet the obligations in this CIA, within 15 days after such a change.

3. *Board of Directors Compliance Obligations.* The Board of Directors (Board) shall be responsible for the review and oversight of matters related to compliance with Federal health care program requirements, FDA requirements, and the obligations of this CIA. The Board must include independent (i.e., non-executive) members. The Board shall, at a minimum, be responsible for the following:

a. The Board shall meet at least quarterly to review and oversee Baxano Surgical's Compliance Program, including but not limited to evaluating its effectiveness and receiving updates about the activities and performance of the Compliance Officer and Compliance Committee; and

b. For each Reporting Period of the CIA, the Board shall adopt a resolution, signed by each individual member of the Board, summarizing its review and oversight of Baxano Surgical's compliance with Federal health care program requirements, FDA requirements, and the obligations of this CIA.

At a minimum, the resolution shall include the following language:

“The Board of Directors has made a reasonable inquiry into the operations of Baxano Surgical's Compliance Program, including the performance of the Compliance Officer and the Compliance Committee. Based on its inquiry and review, the Board has concluded that, to the best of its knowledge, Baxano Surgical has implemented an effective Compliance Program to meet Federal health care program requirements, FDA requirements, and the obligations of the CIA.”

If the Board is unable to provide such a conclusion in the resolution, the Board shall include in the resolution a written explanation of the reasons why it is unable to provide the conclusion and the steps it is taking to implement an effective Compliance Program at Baxano Surgical.

Baxano Surgical shall report to OIG, in writing, any changes in the composition of the Board, or any actions or changes that would affect the Board's ability to perform the duties necessary to meet the obligations in this CIA, within 15 days after such a change.

4. *Management Accountability and Certifications:* In addition to the responsibilities set forth in this CIA for all Covered Persons, certain Baxano Surgical officers or employees (Certifying Employees) are specifically expected to monitor and oversee activities within their areas of authority and shall annually certify that the applicable Baxano Surgical business unit is compliant with applicable Federal health care program and FDA requirements and with the obligations of this CIA. These Certifying Employees shall include, at a minimum, the following: President and Chief Executive Officer; and executives in Marketing; Sales; Regulatory; Clinical Affairs; Professional Affairs; Research and Development; Business Development; and similar business units; Commercial; and to the extent that any business unit performs Promotional and Product Services Related Functions and is not covered by the certifications of one of the above-listed individuals, such other executives, vice-presidents, and/or leaders/heads of business units as would be necessary to ensure that there is a Certifying Employee from each such business unit.

For each Reporting Period, each Certifying Employee shall sign a certification that states:

“I have been trained on and understand the compliance requirements and responsibilities as they relate to [department or functional area], an area under my

supervision. My job responsibilities include ensuring compliance with regard to the _____ [insert name of the department or functional area] with all applicable Federal health care program requirements, FDA requirements, obligations of the Corporate Integrity Agreement, and Baxano Surgical policies, and I have taken steps to promote such compliance. To the best of my knowledge, except as otherwise described herein, the _____ [insert name of department or functional area] of Baxano Surgical is in compliance with all applicable Federal health care program requirements, FDA requirements, and the obligations of the CIA. I understand that this certification is being provided to and relied upon by the United States.”

If any Certifying Employee is unable to provide such a conclusion in the certification, the Certifying Employee shall provide a written explanation of the reasons why he or she is unable to provide the certification outlined above and the steps being taken to address the issue(s) identified in the certification.

B. Written Standards.

1. *Code of Conduct.* Prior to the Effective Date, Baxano Surgical developed, implemented, and distributed a written code of conduct to all Covered Persons who are Baxano Surgical employees. This code is known as Baxano Surgical’s Code of Business Conduct and Ethics (Code of Conduct). Baxano Surgical makes, and shall continue to make, the promotion of, and adherence to, the Code of Conduct an element in evaluating the performance of all employees who are Covered Persons. The Code of Conduct includes, or within 120 days after the Effective Date, shall be revised to address or include the following:

- a. Baxano Surgical’s commitment to full compliance with all Federal health care program requirements and FDA requirements, including its commitment to comply with all requirements relating to the Promotional and Product Services Related Functions;
- b. Baxano Surgical’s requirement that all of its Covered Persons shall be expected to comply with all applicable Federal health care program requirements, FDA Requirements, and with Baxano Surgical’s own Policies and Procedures;
- c. the requirement that all of Baxano Surgical’s Covered Persons shall be expected to report to the Compliance Officer, or other

appropriate individual designated by Baxano Surgical, suspected violations of any Federal health care program requirements, FDA requirements, or of Baxano Surgical's own Policies and Procedures;

d. the personal obligations of each Covered Person to comply with Federal health care program requirements, FDA requirements, and Baxano Surgical's Policies and Procedures; and

e. the right of all individuals to use the Disclosure Program described in Section III.E, and Baxano Surgical's commitment to nonretaliation and to maintain, as appropriate, confidentiality and anonymity with respect to such disclosures.

Within 120 days after the Effective Date, each Covered Person shall certify, either in writing or in electronic form, that he or she has received, read, understood, and shall abide by Baxano Surgical's Code of Conduct. New Covered Persons shall receive the Code of Conduct and shall complete the required certification within 30 days after becoming a Covered Person or within 120 days after the Effective Date, whichever is later.

Baxano Surgical shall periodically review the Code of Conduct to determine if revisions are appropriate and shall make any necessary revisions based on such review. Any revised Code of Conduct shall be distributed within 30 days after any revisions are finalized. Each Covered Person shall certify, in writing, that he or she has received, read, understood, and shall abide by the revised Code of Conduct within 30 days after the distribution of the revised Code of Conduct.

2. *Third Party Personnel.* Within 120 days after the Effective Date, and annually thereafter by the anniversary of the Effective Date, Baxano Surgical shall send a letter, either in hard copy or electronic form, to each entity employing Third Party Personnel. The letter shall outline Baxano Surgical's obligations under the CIA and its commitment to full compliance with all Federal health care program and FDA requirements. The letter shall include a description of Baxano Surgical's Compliance Program. Baxano Surgical shall attach a copy of its Code of Conduct to the letter and shall request the entity employing Third Party Personnel to either: (a) make a copy of Baxano Surgical's Code of Conduct and a description of Baxano Surgical's Compliance Program available to its Third Party Personnel; or (b) represent to Baxano Surgical that it

has and enforces a substantially comparable code of conduct and compliance program for its Third Party Personnel.

3. *Policies and Procedures.* To the extent not already accomplished, within 120 days after the Effective Date, Baxano Surgical shall implement written Policies and Procedures regarding the operation of Baxano Surgical's Compliance Program and Baxano Surgical's compliance with Federal health care program and FDA requirements. At a minimum, the Policies and Procedures must address the following:

- a. the subjects relating to the Code of Conduct identified in Section III.B.1;
- b. appropriate ways to conduct Promotional and Product Services Related Functions in compliance with all applicable Federal healthcare program requirements, including, but not limited to the Federal anti-kickback statute (codified at 42 U.S.C. § 1320a-7b(b)), and the False Claims Act (codified at 31 U.S.C. §§ 3729-3733) and in compliance with all applicable FDA requirements;
- c. consultant or other fee-for-service arrangements entered into with HCPs or HCIs (including, but not limited to speaker programs, speaker training programs, presentations, consultant task force meetings, advisory boards, and ad hoc advisory activities, and any other financial engagement or arrangement with an HCP or HCI) and all events and expenses relating to such engagements or arrangements. These Policies and Procedures shall be designed to ensure that the arrangements and related events are used for legitimate and lawful purposes in accordance with applicable Federal health care program and FDA requirements. The Policies and Procedures shall include requirements about the content and circumstances of such arrangements and events;
- d. programs to educate sales representatives, including but not limited to presentations by HCPs at sales meetings, preceptorships, tutorials, and experience-based learning activities, if any. These Policies and Procedures shall be designed to ensure that the programs are used for legitimate and lawful purposes in accordance with applicable Federal health care program and FDA

requirements. The Policies shall include requirements about the content and circumstances of such arrangements and events;

- e. sponsorship or funding of grants (including educational grants) or charitable contributions. These Policies and Procedures shall be designed to ensure that Baxano Surgical's funding and/or sponsorship complies with all applicable Federal health care program and FDA requirements;
- f. funding of, or participation in, any Third Party Educational Activity as defined in Section II.C.5 above. These Policies and Procedures shall be designed to ensure that Baxano Surgical's funding and/or sponsorship of such programs complies with all applicable Federal health care program and FDA requirements;

The Policies and Procedures shall require that: 1) Baxano Surgical disclose its financial support of the Third Party Educational Activity and, to the extent feasible consistent with subsection III.B.3.h.4 below, any financial relationships with faculty, speakers, or organizers at such Activity; 2) as a condition of funding, the third party shall agree to disclose Baxano Surgical's financial support of the Third Party Educational Activity and to require faculty, speakers, or organizers at such Activity to disclose any financial relationship with Baxano Surgical; 3) the Third Party Educational Activity have an educational focus; 4) the content, organization, and operation of the Third Party Educational Activity be independent of Baxano Surgical's control; 5) Baxano Surgical support only Third Party Educational Activity that is non-promotional in tone/nature; and 6) Baxano Surgical's support of a Third Party Educational Activity shall be contingent on the provider's commitment to provide information at the Third Party Educational Activity that is fair, balanced, accurate and not misleading;

- g. review of promotional materials and information intended to be disseminated outside Baxano Surgical by appropriate qualified personnel (such as regulatory, medical, and/or legal personnel) in a manner designed to ensure that legal, regulatory, and medical

concerns are properly addressed during Baxano Surgical's review and approval process and are elevated when appropriate. The Policies and Procedures shall be designed to ensure that such materials and information comply with all applicable Federal health care program and FDA requirements. The Policies and Procedures shall require that: 1) applicable review committees review all promotional materials prior to the distribution or use of such materials; and 2) deviations from the standard review committee practices and protocols (including timetables for the submission of materials for review) shall be documented and referred for appropriate follow-up;

- h. compensation (including through salaries, bonuses, or other means) for Relevant Covered Persons. These Policies and Procedures shall: 1) be designed to ensure that financial incentives do not inappropriately motivate such individuals to engage in improper promotion, sales, and marketing of Baxano Surgical's Government Reimbursed Products; and 2) include mechanisms, where appropriate, to exclude from incentive compensation sales that may indicate improper or off-label promotion of Government Reimbursed Products;
- i. sponsorship or funding of clinical trials, investigator-initiated studies (IISs), and all other types of post-marketing research (collectively "Research") by Baxano Surgical, including the decision to provide financial or other support for Research; the manner in which Research support is provided; the publication of information about the Research, including the publication of information about the Research results and trial outcomes; and uses made of publications relating to Research;
- j. the materials and information that may be distributed by Baxano Surgical sales representatives about Government Reimbursed Products and the manner in which Baxano Surgical sales representatives respond to requests for information about non-FDA approved (or "off-label") uses, coding, and reimbursement of Government Reimbursed Products. These Policies and Procedures shall require that sales representatives refer all

requests for information about non-FDA approved (or “off-label) uses of Government Reimbursed Products to the Clinical Affairs and refer requests for information about coding and reimbursement to a third party designated by Baxano Surgical to receive such requests or a specified Baxano Surgical department.

- k. the materials and information that may be distributed by Baxano Surgical’s Clinical Affairs Department and the mechanisms through, and manner in which, Baxano Surgical’s Clinical Affairs Department receives and responds to requests for information from an HCP or another individual or entity about off-label uses of Baxano Surgical’s Government Reimbursed Products; the form and content of information disseminated by Baxano Surgical in response to such requests; and the internal review process for the information disseminated.

The Policies and Procedures shall include a requirement that Baxano Surgical use a database (“Off-Label Inquiries Database”) to track all requests for information about Government Reimbursed Products. The Off-Label Inquiries Database shall include the following items of information for each unique inquiry (Inquiry) received for information about Baxano Surgical’s products: (1) date of Inquiry; (2) form of Inquiry (e.g., fax, phone, etc.); (3) name of the requesting HCP, HCI, or other individual or entity; (4) nature and topic of request (including exact language of the Inquiry if made in writing); (5) an evaluation of whether the Inquiry relates to information about an off-label use for the product (on-label, off-label, or unable to determine); (6) nature/form of the response from Baxano Surgical (including a record of the materials provided to the HCP or HCI in response to the request); and (7) the name of the Baxano Surgical representative or agent who called on or interacted with the HCP, customer, or HCI, if known;

- l. the materials and information that may be distributed by Baxano Surgical or a third party working on behalf of Baxano Surgical and the mechanisms through, and manner in which, Baxano Surgical receives and responds to requests for information from

an HCP or another individual or entity about coding and reimbursement of Baxano Surgical's Government Reimbursed Products; the form and content of information disseminated in response to such requests; and the internal review process for the information disseminated.

The Policies and Procedures shall include a requirement that Baxano Surgical use a database ("Reimbursement Inquiries Database") to track all requests for information about coding and reimbursement of Government Reimbursed Products. The Inquiries Database shall include the following items of information for each unique inquiry (Inquiry) received for information about Baxano Surgical's products: (1) date of Inquiry; (2) form of Inquiry (e.g., fax, phone, etc.); (3) name of the requesting HCP, HCI, or other individual or entity; (4) nature and topic of request (including exact language of the Inquiry if made in writing); (5) an evaluation of whether the Inquiry relates to information about coding and reimbursement; (6) nature/form of the response from Baxano Surgical (including a record of the materials provided to the HCP or HCI in response to the request); and (7) the name of the Baxano Surgical representative or agent who called on or interacted with the HCP, customer, or HCI, if known. Baxano Surgical shall review the information in the Reimbursement Inquiries Database and take appropriate corrective action;

- m. authorship of journal articles or other publications about Government Reimbursed Products or about therapeutic areas or disease states that may be treated with Government Reimbursed Products, including, but not limited to, the disclosure of any and all relationships between the author and Baxano Surgical, the identification of all authors or contributors (including professional writers) associated with a given publication, and the scope and breadth of research results made available to each author or contributor; and

- n. disciplinary policies and procedures for violations of Baxano Surgical's Policies and Procedures, including policies relating to Federal health care program and FDA requirements.

To the extent not already accomplished, within 120 days after the Effective Date, the Policies and Procedures shall be made available to all Covered Persons whose job functions relate to those Policies and Procedures. Appropriate and knowledgeable staff shall be available to explain the Policies and Procedures.

At least annually (and more frequently, if appropriate), Baxano Surgical shall assess and update, as necessary, the Policies and Procedures. Within 30 days after the effective date of any revisions, any such revised Policies and Procedures shall be made available to all Covered Persons whose job functions relate to those Policies and Procedures.

C. Training and Education.

1. *General Training.* Within 120 days after the Effective Date, Baxano Surgical shall provide at least two hours of General Training to each Covered Person. This training, at a minimum, shall explain Baxano Surgical's:

- a. CIA requirements; and
- b. Baxano Surgical's Compliance Program (including the Code of Conduct and the Policies and Procedures as they pertain to general compliance issues).

New Covered Persons shall receive the General Training described above within 30 days after becoming a Covered Person or within 90 days after the Effective Date, whichever is later. After receiving the initial General Training described above, each Covered Person shall receive at least one hour of General Training in each subsequent Reporting Period.

2. *Specific Training.* Baxano Surgical shall provide annual training to each Relevant Covered Person relating to his or her specific job responsibilities. This training shall be known as Specific Training.

Within 120 days after the Effective Date, each Relevant Covered Person shall receive at least three hours of Specific Training in addition to the General Training required above.

This Specific Training shall include a discussion of:

- a. all applicable Federal health care program requirements relating to Promotional and Product Services Related Functions;
- b. all applicable FDA requirements relating to Promotional and Product Services Related Functions;
- c. all Baxano Surgical Policies and Procedures and other requirements applicable to Promotional and Product Services Related Functions;
- d. the personal obligation of each individual involved in Promotional and Product Services Related Functions to comply with all applicable Federal health care program and FDA requirements and all other applicable legal requirements;
- e. the legal sanctions for violations of the applicable Federal health care program and FDA requirements; and
- f. examples of proper and improper practices related to Promotional and Product Services Related Functions.

New Relevant Covered Persons shall receive their Specific Training within 30 days after the beginning of their employment or becoming Relevant Covered Persons, or within 120 days after the Effective Date, whichever is later.

After receiving the initial Specific Training described in this Section, each Relevant Covered Person shall receive at least three hours of Specific Training in each subsequent Reporting Period.

3. *Board Member Training.* Within 120 days after the Effective Date, Baxano Surgical shall provide at least two hours of training to each member of the Board of Directors, in addition to the General Training. This training shall address the responsibilities of board members and corporate governance.

New members of the Board of Directors shall receive the Board Member Training described above within 30 days after becoming a board member or within 90 days after the Effective Date, whichever is later.

4. *Certification.* Each Covered Person who is required to complete training shall certify, in writing or in electronic form, if applicable, that he or she has received such training. The certification shall specify the type of training received and the date received. The Compliance Officer (or designee) shall retain these certifications, along with all course materials. These shall be made available to OIG, upon request.

5. *Qualifications of Trainer.* Persons responsible for providing the General and Specific Training shall be knowledgeable about the subject area of the training, including about applicable Federal health care program and FDA requirements.

6. *Update of Training.* Baxano Surgical shall review its training annually, and, where appropriate, shall update the training to reflect changes in Federal health care program requirements, FDA requirements, any issues discovered during internal audits or the IRO Reviews, and any other relevant information.

7. *Computer-based Training.* Baxano Surgical may provide the training required under this CIA through appropriate computer-based training approaches. If Baxano Surgical chooses to provide computer-based training, it shall make available appropriately qualified and knowledgeable staff or trainers to answer questions or provide additional information to the individuals receiving such training.

D. Risk Assessment and Mitigation Process.

Prior to the Effective Date of the CIA, Baxano Surgical implemented an Enterprise Risk Management (ERM) process. Within 120 days after the Effective Date, Baxano Surgical shall modify the ERM process as necessary to meet the requirements of the CIA and Appendix C by developing a standardized, centralized process to allow Baxano Surgical in-house or outside legal counsel, compliance, and other personnel to identify and assess risks associated with the marketing and promotion of Government Reimbursed

Products, and to devise and implement specific measures to mitigate the identified risks. This process shall focus on the risks associated with Government Reimbursed Products, including the areas of: safety, marketing, sales, promotion issues (including the risk of off-label promotion), reimbursement, and healthcare compliance risks. Based on the outcomes of the risk identification and assessment process, Baxano Surgical in-house or outside legal counsel, compliance and other personnel shall centrally develop and implement specific plans designed to mitigate or reduce the identified risks. The IRO review of the ERM process is described in more detail in Appendix C. Baxano Surgical shall maintain the ERM process for the duration of the CIA.

E. Review Procedures.

1. *General Description.*

a. *Engagement of Independent Review Organization.* Within 120 days after the Effective Date, Baxano Surgical shall engage an entity (or entities), such as an accounting, auditing, or consulting firm (hereinafter “Independent Review Organization” or “IRO”), to perform reviews to assist Baxano Surgical in assessing and evaluating its Promotional and Product Services Related Functions. More specifically, the IRO(s) shall conduct reviews that assess Baxano Surgical’s systems, processes, policies, procedures, and practices relating to the Promotional and Product Services Related Functions and the ERM process (IRO Reviews).

The applicable requirements relating to the IRO are outlined in Appendix A to this CIA, which is incorporated by reference. Each IRO engaged by Baxano Surgical shall have expertise in applicable Federal health care program and FDA requirements as may be appropriate to the Review for which the IRO is retained. Each IRO shall assess, along with Baxano Surgical, whether it can perform the engagement in a professionally independent and objective fashion, as appropriate to the nature of the review, taking into account any other business relationships or other engagements that may exist.

b. *Frequency and Brief Description of Reviews.*

(i) System, Transaction, and Additional Items Reviews. As set forth more fully in Appendices B and C, the IRO Reviews shall consist of two components: Systems Reviews and Transactions Reviews relating to the Promotional and Product Services Related Functions and the ERM Program. The Systems Reviews shall assess Baxano Surgical's systems, processes, policies, and procedures relating to the Promotional and Product Services Related Functions and ERM Program. If there are no material changes in Baxano Surgical's relevant systems, processes, policies, and procedures, the Systems Reviews shall be performed for the periods covering the first and fourth Reporting Periods. If Baxano Surgical materially changes its relevant systems, processes, policies, and procedures, the IRO shall perform a Systems Review for the Reporting Period in which such changes were made in addition to conducting the Systems Review for the first and fourth Reporting Periods, as set forth more fully in Appendices B and C.

The Transactions Reviews shall be performed annually and shall cover each of the five Reporting Periods. The IRO(s) shall perform all components of each annual Transaction Review. As set forth more fully in Appendices B and C, the Transactions Review shall include several components.

c. *Retention of Records.* The IRO and Baxano Surgical shall retain and make available to OIG, upon request, all work papers, supporting documentation, correspondence, and draft reports (those exchanged between the IRO and Baxano Surgical) related to the IRO Reviews.

2. *IRO Review Reports.* The IRO shall prepare a report based upon each IRO Review performed (IRO Review Report). Information to be included in the IRO Review Report is described in Appendices B and C.

3. *Validation Review.* In the event OIG has reason to believe that: (a) any of Baxano Surgical's IRO Reviews fails to conform to the requirements of this CIA; or (b) the IRO's findings or Review results are inaccurate, OIG may, at its sole discretion,

conduct its own review to determine whether the applicable IRO Review complied with the requirements of the CIA and/or the findings or Review results are inaccurate (Validation Review). Baxano Surgical shall pay for the reasonable cost of any such review performed by OIG or any of its designated agents. Any Validation Review of Reports submitted as part of Baxano Surgical's final Annual Report shall be initiated no later than one year after Baxano Surgical's final submission (as described in Section II) is received by OIG.

Prior to initiating a Validation Review, OIG shall notify Baxano Surgical of its intent to do so and provide a written explanation of why OIG believes such a review is necessary. To resolve any concerns raised by OIG, Baxano Surgical may request a meeting with OIG to: (a) discuss the results of any IRO Review submissions or findings; (b) present any additional information to clarify the results of the IRO Review or to correct the inaccuracy of the IRO Review; and/or (c) propose alternatives to the proposed Validation Review. Baxano Surgical agrees to provide any additional information as may be requested by OIG under this Section III.E.3 in an expedited manner. OIG will attempt in good faith to resolve any IRO Review issues with Baxano Surgical prior to conducting a Validation Review. However, the final determination as to whether or not to proceed with a Validation Review shall be made at the sole discretion of OIG.

4. *Independence and Objectivity Certification.* The IRO shall include in its report(s) to Baxano Surgical a certification that the IRO has: (a) evaluated its professional independence and objectivity with respect to the reviews conducted under this Section III.D; and (b) concluded that it is, in fact, independent and objective in accordance with the requirements specified in Appendix A.

F. Disclosure Program.

Prior to the Effective Date, Baxano Surgical established a Disclosure Program that includes a mechanism (e.g., a toll free Compliance telephone line) to enable individuals to disclose, to the Compliance Officer or some other person who is not in the disclosing individual's chain of command, any identified issues or questions associated with Baxano Surgical's policies, conduct, practices, or procedures with respect to a Federal health care program or an FDA requirement believed by the individual to be a potential violation of criminal, civil, or administrative law. Baxano Surgical shall maintain such a Disclosure Program throughout the term of the CIA. Baxano Surgical shall appropriately publicize the existence of the Disclosure Program and the Compliance telephone line (e.g., via

periodic e-mails to employees and/or by posting the information in prominent common areas).

The Disclosure Program shall emphasize a nonretribution, non-retaliation policy and shall include a reporting mechanism for anonymous communications for which appropriate confidentiality shall be maintained. Upon receipt of a disclosure, the Compliance Officer (or designee) shall gather all relevant information from the disclosing individual. 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 necessary information 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, Baxano Surgical shall conduct an internal review of the allegations set forth in the disclosure and ensure that proper follow-up is conducted.

The Compliance Officer (or designee) shall maintain, a disclosure log, which includes a record and summary of each disclosure received (whether anonymous or not), the status of the respective internal reviews, and any corrective action taken in response to the internal reviews. This disclosure log shall be made available to OIG upon request.

G. Ineligible Persons.

1. *Definitions.* For purposes of this CIA:

- a. an “Ineligible Person” shall include an individual or entity who:
 - i. is currently excluded, debarred, suspended, or otherwise ineligible to participate in the Federal health care programs or in Federal procurement or nonprocurement programs; or
 - ii. has been convicted of a criminal offense that falls within the scope of 42 U.S.C. § 1320a-7(a), but has not yet been excluded, debarred, suspended, or otherwise declared ineligible.

b. "Exclusion Lists" include:

i. the HHS/OIG List of Excluded Individuals/Entities (available through the Internet at <http://www.oig.hhs.gov>); and

ii. the General Services Administration's List of Parties Excluded from Federal Programs (available through the Internet at <http://www.epls.gov>).

2. *Screening Requirements.* Baxano Surgical shall ensure that all prospective and current Covered Persons are not Ineligible Persons, by implementing the following screening requirements.

a. as part of the hiring or contracting process, Baxano Surgical shall require all prospective and current Covered Persons to disclose whether they are Ineligible Persons and shall screen potential Covered Persons against the Exclusion Lists prior to engaging their services.

b. Baxano Surgical shall screen all Covered Persons against the Exclusion Lists within 120 days after the Effective Date and on an annual basis thereafter.

c. Baxano Surgical shall implement and maintain a policy requiring all Covered Persons to disclose immediately any debarment, exclusion, suspension, or other event that makes that person an Ineligible Person.

Nothing in this Section III.G affects Baxano Surgical's responsibility to refrain from (and liability for) billing Federal health care programs for items or services furnished, ordered, or prescribed by excluded persons. Baxano Surgical understands that items or services furnished by excluded persons are not payable by Federal health care programs and that Baxano Surgical may be liable for overpayments and/or criminal, civil, and administrative sanctions for employing or contracting with an excluded person regardless of whether Baxano Surgical meets the requirements of Section III.G.

3. *Removal Requirement.* If Baxano Surgical has actual notice that a Covered Person has become an Ineligible Person, Baxano Surgical shall remove such Covered Person from responsibility for, or involvement with, Baxano Surgical's business operations related to the Federal health care programs and shall remove such Covered Person from any position for which the Covered Person's compensation or the items or services furnished, ordered, or prescribed by the Covered 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 Covered Person is reinstated into participation in the Federal health care programs.

4. *Pending Charges and Proposed Exclusions.* If Baxano Surgical has actual notice that a Covered Person is charged with a criminal offense that falls within the scope of 42 U.S.C. §§ 1320a-7(a), 1320a-7(b)(1)-(3), or is proposed for exclusion during the Covered Person's employment or contract term, Baxano Surgical shall take all appropriate actions to ensure that the responsibilities of that Covered Person have not and shall not adversely affect the quality of care rendered to any beneficiary, patient, or resident, or the accuracy of any claims submitted to any Federal health care program.

H. Notification of Government Investigation or Legal Proceedings.

Within 30 days after discovery, Baxano Surgical shall notify OIG, in writing, of any ongoing investigation or legal proceeding known to Baxano Surgical conducted or brought by a governmental entity or its agents involving an allegation that Baxano Surgical 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. Baxano Surgical shall also provide written notice to OIG within 30 days after the resolution of the matter, and shall provide OIG with a description of the findings and/or results of the investigation or proceedings, if any.

I. Reportable Events.

1. *Definition of Reportable Event.* For purposes of this CIA, a "Reportable Event" means anything that involves:

- a. 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 may be authorized;

b. a matter that a reasonable person would consider a probable violation of criminal, civil, or administrative laws applicable to any FDA requirements relating to the promotion of Government Reimbursed Products (including an FDA Warning Letter issued to Baxano Surgical);

c. the employment of or contracting with a Covered Person who is an Ineligible Person as defined by Section III.G.1.a; or

d. the filing of a bankruptcy petition by Baxano Surgical.

A Reportable Event may be the result of an isolated event or a series of occurrences.

2. *Reporting of Reportable Events.* If Baxano Surgical determines (after a reasonable opportunity to conduct an appropriate review or investigation of the allegations) through any means that there is a Reportable Event, Baxano Surgical shall notify OIG, in writing, within 30 days after making the determination that the Reportable Event exists.

3. *Reportable Events under Sections III.I.1.a-c.* For Reportable Events under Sections III.H.1.a-c, the report to OIG shall include:

a. a complete description of the Reportable Event, including the relevant facts, persons involved, and legal and Federal health care program or FDA authorities implicated;

b. a description of Baxano Surgical's actions taken to correct the Reportable Event;

c. any further steps Baxano Surgical plans to take to address the Reportable Event and prevent it from recurring; and

4. *Reportable Events under Section III.I.1.d.* For Reportable Events under Section III.I.1.a, the report to the OIG shall include documentation of the bankruptcy filing and a description of any Federal health care program and/or FDA authorities implicated.

J. Notification of Communications with FDA. Within 30 days after the date of any written report, correspondence, or communication between Baxano Surgical and the FDA that materially discusses Baxano Surgical's or a Covered Person's actual or potential unlawful or improper promotion of Baxano Surgical's products (including any improper dissemination of information about off-label indications), Baxano Surgical shall provide a copy of the report, correspondence, or communication to the OIG. Baxano Surgical shall also provide written notice to the OIG within 30 days after the resolution of any such disclosed off-label matter, and shall provide the OIG with a description of the findings and/or results of the matter, if any.

K. Field Force Monitoring and Review Efforts.

To the extent not already established, within 120 days after the Effective Date, Baxano Surgical shall establish a comprehensive Field Force Monitoring Program (FFMP) to evaluate and monitor its sales representatives' interactions with HCPs and HCIs. The FFMP shall be a formalized process designed to directly and indirectly observe the appropriateness of sales representatives' interactions with HCPs and HCIs and to identify potential off-label promotional activities or other improper conduct. As described in more detail below, the FFMP shall include: 1) a Speaker Monitoring Program; 2) direct field observations (Observations) of sales representatives; and 3) the monitoring and review of other records relating to sales representatives' interactions with HCPs and HCIs (Records Reviews).

1. *Speaker Program Activities.* With regard to speaker programs, Baxano Surgical shall maintain processes to require all speakers to complete training and enter written agreements that describe the scope of work to be performed, the speaker fees to be paid, and compliance obligations for the speakers (including requirements that the speaker may only use Baxano Surgical approved materials and may not directly or indirectly promote the product for off-label, investigational, or unapproved uses). Baxano Surgical shall maintain a centralized electronic system through which all speaker programs are administered. This system shall establish controls regarding eligibility and qualifications of speakers and venues for the programs and require that speakers are paid according to a centrally managed, pre-set rate structure determined based on a fair-market value analysis conducted by Baxano Surgical. Baxano Surgical shall maintain a comprehensive list of speaker program attendees through its centralized system. In addition, Baxano Surgical shall track and review the aggregate amount (including speaker fees, travel, and other expenses) paid to each speaker in connection with speaker

programs conducted during each Reporting Period. Baxano Surgical shall require the completion of monitoring forms by sales representatives or other Baxano Surgical personnel regarding whether a speaker program complied with Baxano Surgical requirements, and in the event of non-compliance, Baxano Surgical shall require the identification of the policy violation and ensure appropriate follow up activity to address the violation.

To the extent not already accomplished, Baxano Surgical shall institute a Speaker Monitoring Program under which Baxano Surgical compliance or other appropriately trained Baxano Surgical personnel who are independent from the functional area being monitored shall attend speaker programs during each Reporting Period and conduct live audits at least 10 percent of such programs (“Speaker Program Audits”). If Baxano Surgical does not conduct any speaker programs during a Reporting Period, Baxano Surgical monitoring personnel are not required to conduct audits of speaker programs during that Reporting Period. If Baxano Surgical conducts 10 or fewer speaker programs in a Reporting Period, Baxano Surgical shall audit at least half of the performed Speaker Programs in that Reporting Period. For each program reviewed, personnel conducting the Speaker Program Audits shall review slide materials and other materials used as part of the speaker program, speaker statements made during the program, and Baxano Surgical representative activities during the program to assess whether the programs were conducted in a manner consistent with Baxano Surgical’s Policies and Procedures. Baxano Surgical shall maintain the controls around speaker programs as described above, and shall conduct its Speaker Program Audits as described above throughout the term of the CIA.

2. *Observations.* As a component of the FFMP, Baxano Surgical compliance personnel and/or other appropriately trained Baxano Surgical personnel who are not currently working in the marketing or field sales organization (“Monitoring Personnel”) shall conduct observations of sales representatives to assess whether the messages delivered and materials distributed to HCPs are consistent with applicable legal requirements and with Baxano Surgical’s Policies and Procedures. These observations shall be full day ride-alongs with sales representatives (Observations), and each Observation shall consist of directly observing all meetings between a sales representative and HCPs during the workday. The Observations shall be scheduled throughout the year, selected by Baxano Surgical compliance personnel both on a risk-based targeting approach and on a sampling approach, include each therapeutic area and actively promoted product, and be conducted across the United States. At the completion of each

Observation, Baxano Surgical compliance personnel shall prepare a report which includes:

- 1) the identity of the sales representative;
- 2) the identity of the Baxano Surgical Monitoring Personnel;
- 3) the date and duration of the Observation;
- 4) the product(s) promoted during the Observation;
- 5) an overall assessment of compliance with Baxano Surgical policy; and
- 6) the identification of any potential off-label promotional activity or other improper conduct by the sales representative.

Baxano Surgical compliance or other appropriately trained Monitoring Personnel shall conduct Observations of at least 20 percent of the sales representatives during each Reporting Period.

3. *Records Reviews.* As a component of the FFMP, Baxano Surgical shall also review various types of records to assess sales representatives' interactions with HCPs and HCIs in order to identify potential or actual compliance violations. For each Reporting Period, Baxano Surgical shall develop and implement a plan for conducting Records Reviews associated with up to three Government Reimbursed Products and a sampling of the representatives promoting those products in every separate region. The OIG shall have the discretion to identify the three Government Reimbursed Products to be reviewed for each Reporting Period. The OIG will select the products based on information about Baxano Surgical's products provided by Baxano Surgical, upon request by the OIG no later than 60 days prior to the beginning of the Reporting Period, and other information known to the OIG. If the OIG does not identify the Government Reimbursed Products to be reviewed within the first 30 days of the Reporting Period, Baxano Surgical shall select up to three products to be reviewed.

These Records Reviews shall include the monitoring and review of the following records, to the extent that the records exist: 1) records and systems relating to sales representatives' interactions with HCPs and HCIs (including records from the electronic detailing system for the particular sales representative, sales communications from managers, and expense reports); 2) requests for medical information about, or inquiries relating to, Government Reimbursed Products; 3) tutorials and preceptorships; 4) message recall studies or other similar records (such as Verbatims) purporting to reflect the details of sales representatives' interactions with HCPs and HCIs; 5) sales representative call notes; 6) sales representatives' e-mails and other electronic records; and 7) recorded

results of the Observations of sales representatives and applicable notes or information from the sales representatives' managers.

4. *Reporting and Follow-up.* Personnel conducting the Speaker Program Audits, Observations, and Records Reviews shall have access to all relevant records and information necessary to assess potential or actual compliance violations. Results from the FFMP audits, including the identification of potential violations of policies and/or legal requirements, shall be compiled and reported to the Compliance Department for review and follow-up as appropriate. In the event that a potential violation of Baxano Surgical's Policies and Procedures or of legal or compliance requirements, including but not limited to potential off-label promotion, is identified during any aspect of the FFMP, Baxano Surgical shall investigate the incident consistent with established policies and procedures for the handling of investigations and shall take all necessary and appropriate responsive action (including disciplinary action) and corrective action, including the disclosure of Reportable Events pursuant to Section III.I above, if applicable. Any compliance issues identified during a Speaker Program Audit, Observation and/or Records Review and any corrective action shall be recorded in the files of the Compliance Department.

Baxano Surgical shall include a summary of the FFMP and the results of the FFMP as part of each Annual Report. As part of each Annual Report, Baxano Surgical also shall provide the OIG with copies of the Observation report for any instances in which it was determined that improper promotion occurred and a description of the action(s) that Baxano Surgical took as a result of such determinations. Baxano Surgical shall make the Observation reports for all other Observations available to the OIG upon request.

L. Monitoring of Non-Promotional Activities.

To the extent not already accomplished, within 120 days after the Effective Date Baxano Surgical shall develop and implement a monitoring program for the following types of activities: 1) consultant arrangement activities; 2) medical education grants; and 3) publications. This program shall be referred to as the Non-Promotional Monitoring Program.

1. *Consultant Arrangement Activities.* To the extent that Baxano Surgical engages U.S.-based HCPs or HCIs for services that relate to Promotional and Product Services Related Functions other than for speaker programs (e.g., as a member of an

advisory board or to attend consultant meetings), such HCPs or HCIs shall be referred to herein as “Consultants.” Baxano Surgical shall require all Consultants to enter written agreements describing the scope of work to be performed, the fees to be paid, and compliance obligations for the Consultants. Consultants shall be paid according to a centrally managed, pre-set rate structure that is determined based on a fair-market value analysis conducted by Baxano Surgical.

Within 120 days after the Effective Date, Baxano Surgical shall establish a process to develop annual budgeting plans that identify the business needs for, and the estimated numbers of, various Consultant engagements and activities to occur during the following year. The Consultant budgeting plans shall also identify the budgeted amounts to be spent on Consultant-related activities. Baxano Surgical’s compliance personnel shall be involved in the review and approval of such budgeting plans, including any subsequent modification of an approved plan. The purpose of this review shall be to ensure that Consultant arrangements and related events are used for legitimate purposes in accordance with applicable Baxano Surgical Policies and Procedures and Federal health care program and FDA requirements.

Within 120 days after the Effective Date, Baxano Surgical shall establish a process to ensure that a needs assessment has been completed to justify the retention of a Consultant prior to the retention of the Consultant. The needs assessment shall identify the business need for the retention of the Consultant and provide specific details about the consulting arrangement (e.g., information about the numbers and qualifications of the HCPs or HCIs to be engaged, the agenda for the proposed meeting, and a description of the proposed work to be done and type of work product to be generated.) Any deviations from the Consultant budgeting plans shall be documented in the needs assessment form and shall be subject to review and approval by Baxano Surgical compliance personnel.

Within 120 days after the Effective Date, Baxano Surgical shall amend its policies and procedures in a manner designed to ensure that each Consultant performed the work for which the Consultant was engaged and that, as applicable, Baxano Surgical received the work product generated by the Consultant.

Within 120 days after the Effective Date, Baxano Surgical shall establish a Consultant Monitoring Program through which it shall conduct audits for each Reporting Period (Consultant Program Audits) of at least 10 percent of Consultant arrangements with HCPs. The Consultant Monitoring Program shall review Consultant arrangements both on a risk-based targeting approach and on a sampling approach. Baxano Surgical

compliance personnel conducting the Consultant Program Audits shall review needs assessment documents, consultant contracts, and materials relating to the program or work of the Consultant (including work product resulting from any program or event), in order to assess whether the programs and arrangements were conducted in a manner consistent with Baxano Surgical's Policies and Procedures. Results from the Consultant Program Audits, including the identification of potential violations of policies, shall be compiled and reported to the Compliance Department for review and follow-up as appropriate.

2. *Medical Education Grant Activities.* Within 120 days after the Effective Date, Baxano Surgical shall establish a grants management system as the exclusive mechanism through which requestors may seek or be awarded grants for independent medical education activities.

The grants management system shall ensure that the Baxano Surgical sales and marketing departments have no involvement in, or influence over, the review and approval of medical education grants. To the extent not already accomplished, within 120 days after the Effective Date, Baxano Surgical shall develop a system for grant submission and processing by a centralized office which is not part of the sales or marketing divisions. Baxano Surgical shall continue the medical education grant process described above (or an equivalent process) throughout the term of the CIA, and shall notify the OIG in writing at least 60 days prior to the implementation of any new system subsequent to the Effective Date.

Within 120 days after the Effective Date, Baxano Surgical shall establish a Grants Monitoring Program through which it shall conduct audits for each Reporting Period of at least 10 percent of medical education grants. The Grants Monitoring Program shall select grants for review both on a risk-based targeting approach and on a sampling approach. Baxano Surgical compliance personnel conducting the Grants Monitoring Program shall review proposal documents (including grant requests), approval documents, contracts, payments and materials relating to the grant office's review of the requests, and documents and materials relating to the grants and any events or activities funded through the grants in order to assess whether the activities were conducted in a manner consistent with Baxano Surgical's Policies and Procedures. Results from the Grant Monitoring Programs, including the identification of potential violations of policies, shall be compiled and reported to the Ethics and Compliance Department for review and follow-up as appropriate.

3. *Publication Controls.* To the extent that Baxano Surgical engages HCPs or HCIs as authors for articles or other publications relating to research involving Government Reimbursed Products (Publications), such HCPs or HCIs shall be referred to as “Authors.”

Within 120 days after the Effective Date, Baxano Surgical shall establish compliance controls for publications. These controls shall ensure, among other factors, that: (i) prior to the beginning of drafting a Publication manuscript, Authors confirm in writing that they will participate in a manner consistent with Baxano Surgical’s requirements for Authors; (ii) during the Final Publication Approval process, Publications are reviewed and approved by non-commercial Baxano Surgical personnel with relevant expertise prior to submission to a journal or congress; (iii) Publications are developed in a transparent and collaborative manner in accordance with principles of scientific exchange; (iv) with certain limited exceptions, no compensation is paid to Authors for their time spent drafting or revising Publications; and (v) Authors confirm that they satisfy International Committee of Medical Journal Editors (ICMJE) authorship criteria, including providing final approval of the version of the Publication to be published (collectively, “Publication Control”).

4. *Follow Up Reviews and Reporting.* In the event that a potential violation of Baxano Surgical’s Policies and Procedures or of legal or compliance requirements, including but not limited to potential improper promotion, are identified during any aspect of the Non-Promotional Monitoring Program, Baxano Surgical shall investigate the incident consistent with established Policies and Procedures for the handling of investigations and shall take all necessary and appropriate responsive action (including disciplinary action) and corrective action, including the disclosure of Reportable Events pursuant to Section III.I above, if applicable. Any compliance issues identified during any Non-Promotional Monitoring Program referenced above, and any corrective action, shall be recorded in the files of the Compliance Department.

Baxano Surgical shall include a summary of the Non-Promotional Monitoring Program and the results of the Non-Promotional Monitoring Program as part of each Annual Report. As part of each Annual Report, Baxano Surgical also shall provide the OIG with descriptions of any instances identified through the Non-Promotional Monitoring Program in which it was determined that improper promotion of Government Reimbursed Products occurred or the activities violated Baxano Surgical’s requirements or Policies and Procedures, and a description of the action(s) that Baxano Surgical took as

a result of such determinations. Baxano Surgical shall make the documents relating to the Non-Promotional Monitoring Program available to the OIG upon request.

M. Reporting of Physician Payments.

Prior to the Effective Date, Baxano Surgical voluntarily disclosed physician consultants and payments on its website.

1. *Reporting of Payment Information.* Quarterly Reporting: To the extent not already accomplished, on or before January 1, 2014, Baxano Surgical shall post in a prominent position on its website an easily accessible and readily searchable listing of all U.S.-based physicians and Related Entities who or which received Payments (as defined in Section III.M.2) directly or indirectly from Baxano Surgical during the third quarter of 2013 and the aggregate value of such Payments. Thereafter, 60 days after the end of each calendar quarter, Baxano Surgical shall post on its website a report of the cumulative value of the Payments provided to each physician and Related Entity during the preceding calendar quarter.

Annual Reporting: On or before March 31, 2014, and 90 days after the end of each subsequent calendar year, Baxano Surgical shall post on its website a report of the cumulative value of the Payments provided to all U.S.-based physicians and Related Entities directly or indirectly from Baxano Surgical during the prior applicable calendar year. Each quarterly and annual report shall be easily accessible and readily searchable.

Each listing made pursuant to this Section III.M shall include a complete list of all individual physicians or Related Entities to whom or which Baxano Surgical made Payments in the preceding quarter or year (as applicable). Each listing shall be arranged alphabetically according to the physicians' last name or name of Related Entity. The Payment amounts in the lists shall be reported in the actual amount paid for all physicians or Related Entity on the listing. For each physician, the applicable listing shall include the following information: i) physician's full name; ii) name of any Related Entities (if applicable); iii) city and state that the physician has provided to Baxano Surgical for contact purposes; and (iv) the aggregate value of the payment(s) in the preceding quarter or year (as applicable). If payments for multiple physicians have been made to one Related Entity, the aggregate value of all payments to the Related Entity will be the reported amount.

2. *Definitions and Miscellaneous Provisions.*

(i) Baxano Surgical shall continue to make each annual listing and the most recent quarterly listing of Payments available on its website during the term of the CIA. Baxano Surgical shall retain and make available to OIG, upon request, all supporting documentation, correspondence, and records related to all applicable Payments and to the annual and/or quarterly listings of Payments. Nothing in this Section III.M affects the responsibility of Baxano Surgical to comply with (or liability for noncompliance with) all applicable Federal health care program requirements and state laws as they relate to all applicable Payments made to physicians or Related Entity.

(ii) For purposes of Section III.M.1, “Payments” is defined to include all “payments or other transfers of value” as that term is defined in § 1128G(e)(10) under Section 6002 of the Patient Protection and Affordable Care Act (Public Law 111-148) (Affordable Care Act) and any regulations promulgated thereunder. The term Payments includes, by way of example, the types of payments or other transfers of value enumerated in § 1128G(a)(1)(A)(vi) of the Affordable Care Act. The term includes all payments or transfers of value made to Related Entities on behalf of, at the request of, for the benefit or use of, or under the name of a physician for whom Baxano Surgical would otherwise report a Payment if made directly to the physician. The term Payments also includes any payments or transfers of value made, directly by Baxano Surgical or by a vendor retained by Baxano Surgical to a physician or Related Entity in connection with, or under the auspices of, a co-promotion arrangement.

(iii) For purposes of its annual and quarterly website postings as described above, and only with regard to payments made pursuant to product research or development agreements and clinical investigations as set forth in § 1128G(c)(E) of the Affordable Care Act and any subsequent regulations promulgated thereunder, Baxano Surgical may delay the inclusion of such payments on its website listings consistent with § 1128G(c)(E) of the Act and any subsequent regulations promulgated thereunder.

(iv) The term “Payments” does not include transfers of value or other items that are not included in or are excluded from the definition of “payment” as set forth in § 1128G(e)(10) under Section 6002 of the Affordable Care Act and any regulations promulgated thereunder.

(v) For purposes of this Section III.M, the term “Related Entity” is defined to be any entity by or in which any physician receiving Payments is employed, has tenure, or has an ownership interest.

IV. CHANGES TO BUSINESS UNITS OR LOCATIONS

A. Change or Closure of Unit or Location. In the event that, after the Effective Date, Baxano Surgical changes locations or closes a business unit or location related to or engaged in any of the Promotional and Product Services Related Functions, Baxano Surgical shall notify OIG of this fact as soon as possible, but no later than within 30 days after the date of change or closure of the location.

B. Purchase or Establishment of New Unit or Location. In the event that, after the Effective Date, Baxano Surgical purchases or establishes a new business unit or location related to or engaged in any of the Promotional and Product Services Related Functions, Baxano Surgical shall notify OIG no later than five days after the date that the purchase or establishment of the new business unit or location is publicly disclosed by Baxano Surgical. This notification shall include the address of the new business unit or location, phone number, fax number, the location's Federal health care program provider number and/or supplier number(s) (if applicable); and the name and address of each Federal health care program contractor to which Baxano Surgical currently submits claims (if applicable). Each new business unit or location and all Covered Persons at each new business unit or location shall be subject to the applicable requirements of this CIA.

C. Sale of Unit or Location. In the event that, after the Effective Date, Baxano Surgical proposes to sell any or all of its business units or locations that are subject to this CIA, Baxano Surgical shall notify OIG of the proposed sale at no later than five days after the sale is publicly disclosed by Baxano Surgical. This notification shall include a description of the business unit or location to be sold, a brief description of the terms of the sale, and the name and contact information of the prospective purchaser. This CIA shall be binding on the purchaser of such business unit or location, unless otherwise determined and agreed to in writing by the OIG.

V. IMPLEMENTATION AND ANNUAL REPORTS

A. Implementation Report. Within 150 days after the Effective Date, Baxano Surgical shall submit a written report to OIG summarizing the status of its implementation of the requirements of this CIA (Implementation Report). The Implementation Report shall, at a minimum, include:

1. the name, address, phone number, and position description of the Compliance Officer required by Section III.A.1, and a summary of other noncompliance job responsibilities the Compliance Officer may have;
2. the names and positions of the members of the Compliance Committee required by Section III.A.2;
3. the names of the members of the Board of Directors referenced in Section III.A.3;
4. the names and positions of the Certifying Employees required by Section III.A.4;
5. a copy of Baxano Surgical's Code of Conduct required by Section III.B.1;
6. the number of individuals required to complete the Code of Conduct certification required by Section III.B.1, the percentage of individuals who have completed such certification, and an explanation of any exceptions (the documentation supporting this information shall be available to OIG, upon request);
7. (a) a copy of the letter (including all attachments) required by Sections II.C.6 and III.B.2 sent to each party employing Third Party Personnel; (b) a list of all such existing co-promotion and other applicable agreements with the party employing the Third Party Personnel; and (c) a description of the entities' response to Baxano Surgical's letter;
8. a summary of all Policies and Procedures required by Section III.B.3 (a copy of such Policies and Procedures shall be made available to OIG upon request);
9. the following information regarding each type of training required by Section III.C:
 - a. a description of such training, including a summary of the topics covered, the length of sessions, and a schedule of training sessions; and

- b. the number of individuals required to be training, percentage of individuals actually trained, and an explanation of any exceptions.

A copy of all training materials and the documentation supporting this information shall be available to OIG, upon request.

10. the following information regarding the IRO(s): (a) identity, address, and phone number; (b) a copy of the engagement letter; and (c) information to demonstrate that the IRO has the qualifications outlined in Appendix A; (d) a summary and description of any and all current and prior engagements and agreements between Baxano Surgical and the IRO; and (e) a certification from the IRO regarding its professional independence and objectivity with respect to Baxano Surgical;

11. a description of the Disclosure Program required by Section III.F;

12. a description of the process by which Baxano Surgical fulfills the requirements of Section III.G regarding Ineligible Persons;

13. a certification from the Compliance Officer that, if required under Section III.M and to the best of his/her knowledge, information regarding Payments has been posted on Baxano Surgical's website as required by Section III.M;

14. a list of all of Baxano Surgical's locations (including locations and mailing addresses); the corresponding name under which each location is doing business; the corresponding phone numbers and fax numbers; each location's Federal health care program provider number and/or supplier number(s) (if applicable); and the name and address of any each Federal health care program contractor to which Baxano Surgical currently submits claims (if applicable);

15. a description of Baxano Surgical's corporate structure, including identification of any parent and sister companies, subsidiaries, and their respective lines of business; and

16. the certifications required by Section V.C.

B. Annual Reports. Baxano Surgical shall submit to OIG annually a report with respect to the status of, and findings regarding, Baxano Surgical's compliance activities for each of the five Reporting Periods (Annual Report).

Each Annual Report shall include, at a minimum:

1. any change in the identity, position description, or other noncompliance job responsibilities of the Compliance Officer and any change in the membership of the Compliance Committee, the Board of Directors, or the group of Certifying Employees described in Sections III.A.1-4;
2. a copy of the resolution by the Board required by Section III.A.3;
3. the number of individuals required to review Baxano Surgical's Code of Conduct and complete the certifications required by Section III.B.1, the percentage of individuals who have completed such certifications, and an explanation of any exceptions (the documentation supporting this information shall be available to OIG, upon request);
4. (a) a copy of the letter (including all attachments) required by Sections II.C.6 and III.B.2 sent to each party employing Third Party Personnel; (b) a list of all such existing co-promotion and other applicable agreements with the party employing the Third Party Personnel; and (c) a description of the entities' response to Baxano Surgical's letter;
5. a summary of any significant changes or amendments to the Policies and Procedures required by Section III.B.3 and the reasons for such changes (e.g., change in applicable requirements);
6. the following information regarding each type of training required by Section III.C:
 - a. a description of the initial and annual training, including a summary of the topics covered, the length of sessions, and a schedule of training sessions; and
 - b. the number of individuals required to complete the initial and annual training, percentage of individuals who completed the training, and an explanation of any exceptions.

A copy of all training materials and the documentation supporting this information shall be available to OIG, upon request.

7. a summary of any significant changes to the ERM Program required by Section III.D;
8. a complete copy of all reports prepared pursuant to Sections III.E, along with a copy of the IRO's engagement letter;
9. Baxano Surgical's response to the reports prepared pursuant to the reviews outlined in Sections III.E, along with corrective action plan(s) related to any issues raised by the reports;
10. a summary and description of any and all current and prior engagements and agreements between Baxano Surgical and the IRO (if different from what was submitted as part of the Implementation Report);
11. certifications from the IRO regarding its professional independence and objectivity with respect to Baxano Surgical;
12. a summary of the disclosures in the disclosure log required by Section III.F that relate to Federal health care programs, FDA requirements, or Government Reimbursed Products;
13. any changes to the process by which Baxano Surgical fulfills the requirements of Section III.G regarding Ineligible Persons;
14. a summary describing any ongoing investigation or legal proceeding required to have been reported pursuant to Section III.H. The summary shall include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding;
15. a summary of Reportable Events (as defined in Section III.I) identified during the Reporting Period and the status of any corrective and preventative action relating to all such Reportable Events;
16. a summary describing any written communication with the FDA required to have been reported pursuant to Section III.J. This summary shall include a description of the matter and the status of the matter;

17. a summary of the FFMP and the results of the FFMP required by Section III.K, including copies of the Observation report for any instances in which it was determined that improper promotion occurred and a description of the action(s) that Baxano Surgical took as a result of such determinations;

18. a summary of the Non-Promotional Monitoring Program and the results of the program described in Section III.L, including detailed description of any identified instances in which it was determined that the activities violated Baxano Surgical's policies or that improper promotion of Government Reimbursed Products occurred and a description of the action(s) Baxano Surgical took as a result of such determinations;

19. a certification from the Compliance Officer that to the best of his/her knowledge, information regarding Payments has been posted on Baxano Surgical's website as required by Section III.M;

20. a description of all changes to the most recently provided list of Baxano Surgical's locations (including addresses) as required by Section V.A.14; the corresponding name under which each location is doing business; and the corresponding phone numbers and fax numbers;

21. the certifications required by Section V.C.

The first Annual Report shall be received by OIG no later than 60 days after the end of the first Reporting Period. Subsequent Annual Reports shall be received by OIG no later than the anniversary date of the due date of the first Annual Report.

C. Certifications.

1. Certifying Employees: In each Annual Report, Baxano Surgical shall include the certifications of Certifying Employees as required by Section III.A.4;

2. Compliance Officer: In each Implementation Report and Annual Report, Baxano Surgical shall include the following individual certification by the Compliance Officer:

1. to the best of his or her knowledge, except as otherwise described in the report, Baxano Surgical is in compliance with in compliance the requirements of this CIA;

2. he or she has reviewed the report and has made reasonable inquiry regarding its content and believes that the information in the report is accurate and truthful; and

3. Baxano Surgical's: 1) Policies and Procedures as referenced in Section III.B.3 above; 2) templates for standardized contracts and other similar documents; and 3) the training materials used for purposes of Section III.C all have been reviewed by competent legal counsel and have been found to be in compliance with all applicable Federal health care program and FDA requirements. In addition, Baxano Surgical's promotional materials containing claims or information about Government Reimbursed Products and other materials and information intended to be disseminated outside Baxano Surgical have been reviewed by competent regulatory, medical, or, as appropriate, legal counsel in accordance with applicable Policies and Procedures to ensure that legal, medical, and regulatory concerns have been addressed by Baxano Surgical and brought to the attention of the appropriate individuals when required, and that the materials and information when finally approved are in compliance with all applicable Federal health care program and FDA requirements. If the applicable legal requirements have not changed, after the initial review of the documents listed above, only material changes to the documents must be reviewed by competent legal counsel. The certification shall include a description of the document(s) reviewed and approximately when the review was completed. The documentation supporting this certification shall be available to OIG, upon request.

D. Designation of Information. Baxano Surgical 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 potentially exempt from disclosure under the Freedom of Information Act (FOIA), 5 U.S.C. § 552. Baxano Surgical shall refrain from identifying any information as exempt from disclosure if that information does not meet the criteria for exemption from disclosure under FOIA.

VI. NOTIFICATIONS AND SUBMISSION OF REPORTS

Unless otherwise stated in writing after the Effective Date, all notifications and reports required under this CIA shall be submitted to the following entities:

OIG: Administrative and Civil Remedies Branch
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, S.W.
Washington, DC 20201
Telephone: 202.619.2078
Facsimile: 202.205.0604

Baxano Surgical: Stephanie Fitts
Vice President of Regulatory, Quality and Compliance
and Chief Compliance Officer
110 Horizon Drive
Raleigh, NC 27615
Telephone: 919-825-2709
Facsimile: 919-926-1185

Unless otherwise specified, all notifications and reports required by this CIA 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. Upon request by OIG, Baxano Surgical may be required to provide OIG with an electronic copy of each notification or report required by this CIA in searchable portable document format (pdf), either instead of or in addition to, a paper copy.

VII. 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 or request copies of Baxano Surgical's books, records, and other documents and supporting materials and/or conduct on-site reviews of any of Baxano Surgical's locations for the purpose of verifying and evaluating: (a) Baxano Surgical's compliance with the terms of this CIA; and (b) Baxano Surgical's compliance with the requirements of the Federal health care programs in which it participates and with all applicable FDA requirements. The documentation described above shall be made available by Baxano Surgical 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 Baxano Surgical's employees, contractors, or agents who consent to be interviewed at the 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. Baxano Surgical shall assist OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon OIG's request. Baxano Surgical's employees may elect to be interviewed with or without a representative of Baxano Surgical present.

VIII. DOCUMENT AND RECORD RETENTION

Baxano Surgical shall maintain for inspection all documents and records relating to reimbursement from the Federal health care programs and to compliance with this CIA for six years (or longer if otherwise required by law) from the Effective Date.

IX. DISCLOSURES

Consistent with HHS's FOIA procedures, set forth in 45 C.F.R. Part 5, OIG shall make a reasonable effort to notify Baxano Surgical prior to any release by OIG of information submitted by Baxano Surgical pursuant to its obligations under this CIA and identified upon submission by Baxano Surgical as trade secrets, or information that is commercial or financial and privileged or confidential, under the FOIA rules. With respect to such releases, Baxano Surgical shall have the rights set forth at 45 C.F.R. § 5.65(d).

X. BREACH AND DEFAULT PROVISIONS

Baxano Surgical is expected to fully and timely comply with all of its CIA obligations.

A. Stipulated Penalties for Failure to Comply with Certain Obligations. As a contractual remedy, Baxano Surgical and OIG hereby agree that failure to comply with certain obligations as set forth in this CIA 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 Baxano Surgical fails to establish and implement any of the following obligations as described in Section III:

- a. a Compliance Officer;
- b. a Compliance Committee;
- b. the Board of Directors compliance obligations, including the resolution from the Board;
- c. Management certifications;
- d. a written Code of Conduct;
- e. written Policies and Procedures;
- f. the training of Covered Persons, Relevant Covered Persons, and Board Members;
- g. an ERM Process;
- h. a Disclosure Program;
- i. Ineligible Persons screening and removal requirements;
- j. notification of Government investigations or legal proceedings;
- k. reporting of Reportable Events;
- l. notification of written communications with FDA as required by Section III.J;
- m. a program for FFMP as required by Section III.K;
- n. a program for Monitoring Non-Promotional Activities as required by Section III.L; and
- o. posting of any Payments as required by Section III.M.

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 Baxano Surgical fails to engage and use an IRO as required in Sections III.E and Appendices A-C.

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 Baxano Surgical fails to submit the Implementation Report or any Annual Reports to OIG in accordance with the requirements of Section V by the deadlines for submission.

4. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Baxano Surgical fails to submit any IRO Review report in accordance with the requirements of Sections III.E and Appendices B and C.

5. A Stipulated Penalty of \$1,500 for each day Baxano Surgical fails to grant access as required in Section VII. (This Stipulated Penalty shall begin to accrue on the date Baxano Surgical fails to grant access.)

6. A Stipulated Penalty of \$5,000 for each false certification submitted by or on behalf of Baxano Surgical as part of its Implementation Report, Annual Report, additional documentation to a report (as requested by the OIG), or otherwise required by this CIA.

7. A Stipulated Penalty of \$1,000 for each day Baxano Surgical fails to comply fully and adequately with any obligation of this CIA. OIG shall provide notice to Baxano Surgical stating the specific grounds for its determination that Baxano Surgical has failed to comply fully and adequately with the CIA obligation(s) at issue and steps Baxano Surgical shall take to comply with the CIA. (This Stipulated Penalty shall begin to accrue 10 days after Baxano Surgical receives this notice from OIG of the failure to comply.) A Stipulated Penalty as described in this Subsection shall not be demanded for any violation for which OIG has sought a Stipulated Penalty under Subsections 1- 6 of this Section.

B. Timely Written Requests for Extensions. Baxano Surgical may, in advance of the due date, submit a timely written request for an extension of time to perform any act or file any notification or report required by this CIA. 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 Baxano Surgical fails to meet the revised deadline set by OIG. 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 three business days after Baxano Surgical receives OIG's written denial of such request or the original due date, whichever is later. A "timely written request" is defined as a request in writing received by OIG at least five 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.

C. Payment of Stipulated Penalties.

1. *Demand Letter.* Upon a finding that Baxano Surgical has failed to comply with any of the obligations described in Section X.A and after determining that Stipulated Penalties are appropriate, OIG shall notify Baxano Surgical of: (a) Baxano Surgical's failure to comply; and (b) OIG's exercise of its contractual right to demand payment of the Stipulated Penalties (this notification is referred to as the "Demand Letter").

2. *Response to Demand Letter.* Within 10 days after the receipt of the Demand Letter, Baxano Surgical shall either: (a) cure the breach to OIG's satisfaction and pay the applicable Stipulated Penalties or (b) request a hearing before an HHS administrative law judge (ALJ) to dispute OIG's determination of noncompliance, pursuant to the agreed upon provisions set forth below in Section X.E. In the event Baxano Surgical elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until Baxano Surgical cures, to 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 CIA and shall be grounds for exclusion under Section X.D.

3. *Form of Payment.* Payment of the Stipulated Penalties shall be made by electronic funds transfer to an account specified by OIG in the Demand Letter.

4. *Independence from Material Breach Determination.* Except as set forth in Section X.D.1.d, these provisions for payment of Stipulated Penalties shall not affect or otherwise set a standard for OIG's decision that Baxano Surgical has materially breached this CIA, which decision shall be made at OIG's discretion and shall be governed by the provisions in Section X.D, below.

D. Exclusion for Material Breach of this CIA.

1. *Definition of Material Breach.* A material breach of this CIA means:

- a. a repeated or flagrant violation of the obligations under this CIA, including, but not limited to, the obligations addressed in Section X.A;
- b. a failure by Baxano Surgical to report a Reportable Event and take corrective action as required in Section III.I;
- c. a failure to engage and use an IRO in accordance with Section III.E and Appendices A-C;
- d. a failure to respond to a Demand Letter concerning the payment of Stipulated Penalties in accordance with Section X.C; or
- e. a failure of the Board to issue a resolution in accordance with Section III.A.3.

2. *Notice of Material Breach and Intent to Exclude.* The parties agree that a material breach of this CIA by Baxano Surgical constitutes an independent basis for Baxano Surgical's exclusion from participation in the Federal health care programs. Upon a determination by OIG that Baxano Surgical has materially breached this CIA and that exclusion is the appropriate remedy, OIG shall notify Baxano Surgical of: (a) Baxano Surgical'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").

3. *Opportunity to Cure.* Baxano Surgical shall have 30 days from the date of receipt of the Notice of Material Breach and Intent to Exclude to demonstrate to OIG's satisfaction that:

- a. Baxano Surgical is in compliance with the obligations of the CIA cited by OIG as being the basis for the material breach;
- b. the alleged material breach has been cured; or

c. the alleged material breach cannot be cured within the 30 day period, but that: (i) Baxano Surgical has begun to take action to cure the material breach; (ii) Baxano Surgical is pursuing such action with due diligence; and (iii) Baxano Surgical has provided to OIG a reasonable timetable for curing the material breach.

4. *Exclusion Letter.* If, at the conclusion of the 30 day period, Baxano Surgical fails to satisfy the requirements of Section X.D.3, OIG may exclude Baxano Surgical from participation in the Federal health care programs. OIG shall notify Baxano Surgical in writing of its determination to exclude Baxano Surgical (this letter shall be referred to hereinafter as the “Exclusion Letter”). Subject to the Dispute Resolution provisions in Section X.E, below, the exclusion shall go into effect 30 days after the date of Baxano Surgical’s receipt of the Exclusion Letter. The exclusion shall have national effect and shall also apply to all other Federal procurement and nonprocurement programs. Reinstatement to program participation is not automatic. After the end of the period of exclusion, Baxano Surgical may apply for reinstatement by submitting a written request for reinstatement in accordance with the provisions at 42 C.F.R. §§ 1001.3001-.3004.

E. Dispute Resolution

1. *Review Rights.* Upon OIG’s delivery to Baxano Surgical of its Demand Letter or of its Exclusion Letter, and as an agreed-upon contractual remedy for the resolution of disputes arising under this CIA, Baxano Surgical 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 Penalties or exclusion sought pursuant to this CIA. Specifically, OIG’s determination to demand payment of Stipulated Penalties or to seek exclusion shall be subject to review by an HHS Administrative Law Judge and, in the event of an appeal, the HHS 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 10 days after receipt of the Demand Letter and the request for a hearing involving exclusion shall be made within 25 days after receipt of the Exclusion Letter.

2. *Stipulated Penalties Review.* Notwithstanding any provision of Title 42 of the United States Code or Title 42 of the Code of Federal Regulations, the only issues in a proceeding for Stipulated Penalties under this CIA shall be: (a) whether Baxano

Surgical was in full and timely compliance with the obligations of this CIA for which OIG demands payment; and (b) the period of noncompliance. Baxano Surgical shall have the burden of proving its full and timely compliance and the steps taken to cure the noncompliance, if any. OIG shall not have the right to appeal to the DAB an adverse ALJ decision related to Stipulated Penalties. If the ALJ agrees with OIG with regard to a finding of a breach of this CIA and orders Baxano Surgical to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless Baxano Surgical 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 20 days after the DAB issues its decision.

3. *Exclusion Review.* Notwithstanding any provision of Title 42 of the United States Code or Title 42 of the Code of Federal Regulations, the only issues in a proceeding for exclusion based on a material breach of this CIA shall be:

- a. whether Baxano Surgical was in material breach of this CIA;
- b. whether such breach was continuing on the date of the Exclusion Letter; and
- c. whether the alleged material breach could not have been cured within the 30-day period, but that: (i) Baxano Surgical had begun to take action to cure the material breach within that period; (ii) Baxano Surgical has pursued and is pursuing such action with due diligence; and (iii) Baxano Surgical provided to OIG within that period a reasonable timetable for curing the material breach and Baxano Surgical has followed the timetable.

For purposes of the exclusion herein, exclusion shall take effect only after an ALJ decision favorable to OIG, or, if the ALJ rules for Baxano Surgical, only after a DAB decision in favor of OIG. Baxano Surgical's election of its contractual right to appeal to the DAB shall not abrogate OIG's authority to exclude Baxano Surgical upon the issuance of an ALJ's decision in favor of OIG. If the ALJ sustains the determination of OIG and determines that exclusion is authorized, such exclusion shall take effect 20 days after the ALJ issues such a decision, notwithstanding that Baxano Surgical 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 20 days after the DAB

decision. Baxano Surgical shall waive its right to any notice of such an exclusion if a decision upholding the exclusion is rendered by the ALJ or DAB. If the DAB finds in favor of Baxano Surgical, Baxano Surgical shall be reinstated effective on the date of the original exclusion.

4. *Finality of Decision.* The review by an ALJ or DAB provided for above shall not be considered to be an appeal right arising under any statutes or regulations. Consequently, the parties to this CIA agree that the DAB's decision (or the ALJ's decision if not appealed) shall be considered final for all purposes under this CIA.

XI. EFFECTIVE AND BINDING AGREEMENT

Baxano Surgical and OIG agree as follows:

- A. This CIA shall be binding on the successors, assigns, and transferees of Baxano Surgical;
- B. This CIA shall become final and binding on the date the final signature is obtained on the CIA;
- C. This CIA constitutes the complete agreement between the parties and may not be amended except by written consent of the parties to this CIA;
- D. The undersigned Baxano Surgical signatories represent and warrant that they are authorized to execute this CIA. The undersigned OIG signatory represents that he is signing this CIA in his official capacity and that he is authorized to execute this CIA.
- E. This CIA may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same CIA. Facsimiles of signatures shall constitute acceptable, binding signatures for purposes of this CIA.

ON BEHALF OF BAXANO SURGICAL, INC.

\Ken Reali\

Ken Reali, President and CEO, Baxano Surgical

6/10/13
DATE

\Stephanie Fitts\

Stephanie Fitts, Vice President, Regulatory, Quality
and Compliance

10-JUN-2013
DATE

\Peter Spivack\

Peter Spivack
Magdalena Grossman
Hogan Lovells
Counsel to Baxano Surgical, Inc

6.10.13
DATE

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

\Robert K. DeConti\

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

6/24/13
DATE

\Maame Gyamfi\

MAAME GYAMFI
Senior Counsel
Office of Inspector General
U. S. Department of Health and Human Services

6/24/13
DATE

APPENDIX A

INDEPENDENT REVIEW ORGANIZATION

This Appendix contains the requirements relating to the Independent Review Organization (IRO) required by Section III.E of the CIA.

A. IRO Engagement

1. Baxano Surgical shall engage an IRO that possesses the qualifications set forth in Paragraph B, below, to perform the responsibilities in Paragraph C, below. The IRO shall conduct the review in a professionally independent and objective fashion, as set forth in Paragraph D. Within 30 days after OIG receives the information set forth in Section V.A.10 of the CIA, OIG will notify Baxano Surgical if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, Baxano Surgical may continue to engage the IRO.

2. If Baxano Surgical engages a new IRO during the term of the CIA, this IRO shall also meet the requirements of this Appendix. If a new IRO is engaged, Baxano Surgical shall submit the information identified in Section V.A.10 of the CIA to OIG within 30 days of engagement of the IRO. Within 30 days after OIG receives written notice of the identity of the selected IRO, OIG will notify Baxano Surgical if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, Baxano Surgical may continue to engage the IRO.

B. IRO Qualifications.

The IRO shall:

1. assign individuals to conduct the IRO Reviews who have expertise in all applicable Federal health care program and FDA requirements relating to Promotional Functions and Product Related Functions. The assigned individuals shall also be experienced in risk identification and mitigation in relation to medical device marketing and promotion. The assigned individuals shall also be knowledgeable about the general requirements of the Federal health care program(s) under which Baxano Surgical products are reimbursed;

2. assign individuals to design and select the samples for the Transaction Reviews who are knowledgeable about the appropriate statistical sampling techniques; and

3. have sufficient staff and resources to conduct the reviews required by the CIA on a timely basis.

C. IRO Responsibilities.

The IRO shall:

1. perform each component of the IRO Review in accordance with the specific requirements of the CIA;

2. follow all applicable Federal health care program and FDA requirements in making assessments in each IRO Review;

3. if in doubt of the application of a particular Federal health care program or FDA requirement, policy, or regulation, request clarification from the appropriate authority (e.g., CMS or FDA);

4. respond to all OIG inquiries in a prompt, objective, and factual manner; and

5. prepare timely, clear, well-written reports that include all the information required by Appendices B and C to the CIA.

D. IRO Independence and Objectivity.

The IRO must perform the IRO Review in a professionally independent and objective fashion, as appropriate to the nature of the engagement, taking into account any other business relationships or engagements that may exist between the IRO and Baxano Surgical.

E. IRO Removal/Termination.

1. *Baxano Surgical and IRO.* If Baxano Surgical terminates its IRO or if the IRO withdraws from the engagement during the term of the CIA, Baxano Surgical must submit a notice explaining its reasons for termination or the reason for withdrawal to OIG no later than 30 days after termination or withdrawal. Baxano Surgical must engage a new IRO in accordance with Paragraph A of this Appendix and within 60 days of termination or withdrawal of the prior IRO.

2. *OIG Removal of IRO.* In the event OIG has reason to believe that the IRO does not possess the qualifications described in Paragraph B, is not independent and/or

objective as set forth in Paragraph D, or has failed to carry out its responsibilities as described in Paragraph C, OIG may, at its sole discretion, require Baxano Surgical to engage a new IRO in accordance with Paragraph A of this Appendix. Baxano Surgical must engage a new IRO within 60 days of termination of the prior IRO.

Prior to requiring Baxano Surgical to engage a new IRO, OIG shall notify Baxano Surgical of its intent to do so and provide a written explanation of why OIG believes such a step is necessary. To resolve any concerns raised by OIG, Baxano Surgical may present additional information regarding the IRO's qualifications, independence or performance of its responsibilities. OIG will attempt in good faith to resolve any differences regarding the IRO with Baxano Surgical prior to requiring Baxano Surgical to terminate the IRO. However, the final determination as to whether or not to require Baxano Surgical to engage a new IRO shall be made at the sole discretion of OIG.

Appendix B to CIA Independent Review Organization Reviews

I. General Description

As specified more fully below, Baxano Surgical shall retain an Independent Review Organization (IRO) to perform reviews to assist Baxano Surgical in assessing and evaluating its systems, processes, policies, procedures, and practices related to Baxano Surgical's Promotional and Product Services Related Functions and Risk Assessment and Monitoring Process (IRO Reviews). The IRO Review shall consist of two components - a systems review (Systems Review) and a transactions review (Transactions Review) as described more fully below. Baxano Surgical may engage, at its discretion, a single IRO to perform both components of the IRO Review provided that the entity has the necessary expertise and capabilities to perform both.

If there are no material changes in Baxano Surgical's systems, processes, policies, and procedures relating to Promotional and Product Services Related Functions, the IRO shall perform the Systems Review for the first and fourth Reporting Periods. If Baxano Surgical materially changes its systems, processes, policies, and procedures relating to Promotional and Product Services Related Functions, the IRO shall perform a Systems Review for the Reporting Period(s) in which such changes were made in addition to conducting the Review for the first and fourth Reporting Periods. The additional Systems Review(s) shall consist of: 1) an identification of the material changes; 2) an assessment of whether other systems, processes, policies, and procedures previously reported did not materially change; and 3) a review of the systems, processes, policies, and procedures that materially changed. The IRO shall conduct the Transactions Review for each Reporting Period of the CIA.

II. IRO Systems Reviews

A. Description of Policies and Procedures Systems Review

The Policies and Procedures Systems Review shall be a review of Baxano Surgical's systems, processes, policies, and procedures (including the controls on those systems, processes, policies, and procedures) relating to certain aspects of the Promotional and Product Services Related Functions. Where practical, Baxano Surgical personnel may compile documentation, schedule and organize interviews, and undertake other efforts to assist the IRO in performing the Systems Review. The IRO is not required to undertake a de novo review of the information gathered or activities undertaken by Baxano Surgical pursuant to the preceding sentence.

Specifically, the IRO shall review Baxano Surgical's systems, processes, policies, and procedures associated with the following (hereafter "Reviewed Policies and Procedures"):

- 1) Baxano Surgical's systems, policies, processes, and procedures applicable to the manner in which Baxano Surgical sales representatives and/or Clinical Affairs personnel and Clinical Affairs agents handle requests or inquiries relating to information about the uses of Government Reimbursed Products (including non-FDA-approved (*i.e.*, off-label) uses) and the dissemination of materials and information relating to off-label uses, coding, and reimbursement of products. This review includes:
 - a) the manner in which Baxano Surgical sales representatives handle requests for information about off-label uses of Government Reimbursed Products (e.g., by referring all such requests to Clinical Affairs and/or a third party designated by Baxano Surgical);
 - b) the manner in which Clinical Affairs personnel and Clinical Affairs agents handle and respond to requests for information about off-label uses of Government Reimbursed Products (including tracking the requests and using pre-approved materials for purposes of responding to the request);
 - c) the manner in which Baxano Surgical and/or its designees handle and respond to requests for information about coding and reimbursement of Government Reimbursed Products (including tracking the requests and using pre-approved materials for purposes of responding to the request);
 - d) the form and content of information and materials related to Government Reimbursed Products disseminated to physicians, pharmacists, or other health care professionals (collectively "HCPs") or health care institutions ("HCIs") by Baxano Surgical;
 - e) Baxano Surgical's systems, processes, and procedures (including the Inquiries Databases) to track requests for information about off-label uses, coding, and reimbursement of products and responses to those requests;
 - e) the manner in which Baxano Surgical collects and supports information reported in any systems used to track and respond

to requests for product information, including its Inquiries Databases;

- f) the processes and procedures by which Clinical Affairs and its agents, or other appropriate individuals or their designees within Baxano Surgical identify situations in which it appears that off-label or other improper promotion may have occurred;
- g) the processes and procedures by which Baxano Surgical and its agents, or other appropriate individuals or their designees within Baxano Surgical identify situations in which it appears that improper conduct regarding coding and reimbursement may have occurred; and
- h) Baxano Surgical's processes and procedures for investigating, documenting, resolving, and taking appropriate disciplinary action for potential situations involving improper conduct;

2) Baxano Surgical's systems, policies, processes, and procedures relating to Baxano Surgical's internal review and approval of information and materials related to Government Reimbursed Products disseminated to HCPs or HCIs by Baxano Surgical;

3) Baxano Surgical's systems, policies, processes and procedures relating to incentive compensation for Relevant Covered Persons who are sales representatives, with regard to whether the systems, policies, processes, and procedures are designed to ensure that financial incentives do not inappropriately motivate such individuals to engage in the improper promotion, sales, and marketing of Government Reimbursed Products. This shall include a review of the bases upon which compensation is determined and the extent to which compensation is based on product performance. To the extent that Baxano Surgical establishes different methods of compensation for different Government Reimbursed Products, the IRO shall review each type of compensation arrangement separately;

4) Baxano Surgical's systems (including any centralized electronic systems), processes, policies, and procedures relating to speaker programs, speaker training programs, and all events and expenses relating to such engagements or arrangements;

5) Baxano Surgical's systems, processes, policies, and procedures relating to non-speaker related consultant or other fee-for-service

arrangements entered into with HCPs or HCIs (including, but not limited to, presentations, consultant task force meetings, advisory boards, preceptorships, mentorships, ad hoc advisory activities, and any other financial engagements or arrangements with an HCP or HCI, if any) and all events and expenses relating to such engagements or arrangements.

B. IRO Policies and Procedures Systems Review Report

The IRO shall prepare a report based upon Policies and Procedures Systems Review. For each of the Reviewed Policies and Procedures identified in Section II.A above, the report shall include the following items:

- 1) a description of the documentation (including policies) reviewed and any personnel interviewed;
- 2) a detailed description of Baxano Surgical's systems, policies, processes, and procedures relating to the items identified in Sections II.A.1-6 above, including a general description of Baxano Surgical's control and accountability systems (e.g., documentation and approval requirements, and tracking mechanisms) and written policies regarding the Reviewed Policies and Procedures;
- 3) a description of the manner in which the control and accountability systems and the written policies relating to the items identified in Sections II.A.1-6 above are made known or disseminated within Baxano Surgical;
- 4) a detailed description of any system(s) used to track and respond to requests for information about Government Reimbursed Products (including the Inquiries Databases);
- 5) a detailed description of Baxano Surgical's incentive compensation system for Relevant Covered Persons who are sales representatives, including a description of the bases upon which compensation is determined and the extent to which compensation is based on product performance. To the extent that Baxano Surgical may establish compensation differently for individual Government Reimbursed Products, the IRO shall report separately on each such type of compensation arrangement;
- 6) findings and supporting rationale regarding any weaknesses in Baxano Surgical's systems, processes, policies, and procedures relating to the Reviewed Policies and Procedures, if any; and

- 7) recommendations to improve any of the systems, policies, processes, or procedures relating to the Reviewed Policies and Procedures, if any.

III. IRO Transaction Review

As described more fully below in Sections III.A-D, the Transactions Review shall include a review of: (1) Baxano Surgical's Inquiries and Inquires Database; (2) records relating to a sample of the Payments that are reported by Baxano Surgical pursuant to Section III.M of the CIA; and (3) Risk Assessment and Monitoring Process. The IRO shall report on all aspects of its reviews in the Transactions Review Reports.

A. Review of Inquiries and Inquiries Database

1) Description of Inquiries Database

As set forth in Section III.B.2.e of the CIA, Baxano Surgical shall use databases to track information relating to requests for information received by Baxano Surgical about its Government Reimbursed Products (hereafter "Inquiries"). Specifically, Baxano Surgical shall document and record all Inquiries received from HCPs or HCIs regarding Government Reimbursed Products in databases (the "Inquiries Databases"). Baxano Surgical shall record in the Inquiries Databases the following information for each Inquiry received: 1) date of Inquiry; 2) form of Inquiry (e.g., fax, phone, etc.); 3) name of requesting HCP or HCI or other individual or entity; 4) nature and topic of request (including exact language of the Inquiry if made in writing); 5) an evaluation of whether the Inquiry relates to information about an off-label use for the product (on-label, off-label, or unable to determine), coding or reimbursement; 6) nature/form of the response from Baxano Surgical (including a record of any materials provided in response to the request); and 7) the name of the Baxano Surgical representative who called on or interacted with the HCP, customer, or HCI, if known.

2) Internal Review of the Inquiries Databases

On a semi-annual basis, the Compliance Officer shall review the Inquiries Databases and related information, as appropriate, and shall generate a report summarizing the items of information outlined in Section III.A.1 above for each Inquiry received during the preceding two quarters ("Inquiry Report"). The Compliance Officer shall review the Inquiry Reports to assess whether the information contained in the report suggests that improper conduct regarding off-label promotion, coding, or reimbursement may have occurred in connection with any Inquiry(ies). If the Compliance Officer, in consultation with other appropriate Baxano Surgical personnel,

suspects that improper conduct may have occurred in connection with any Inquiry, the Compliance Officer shall undertake a follow-up review of the Inquiry (“Inquiry Review”), make specific findings based on his/her Inquiry Review, and take all appropriate responsive action (including disciplinary action of the Covered Person and reporting of the conduct, including disclosing Reportable Events pursuant to Section III.I of the CIA, if applicable).

3) IRO Review of Inquiries Reflected in Inquiries Database

The IRO shall select and review a random sample of at least 10 percent but not more than 50 Inquiries from among the Inquiries reflected in the Inquiries Database for each Reporting Period. Seventy percent of the Inquiries reviewed by the IRO shall be Inquiries for which Baxano Surgical conducted a review related to off-label promotion (“Off-label Review”), and the remainder of the random sample shall be Inquiries for the review related to coding and reimbursement and other issues. For each Inquiry reviewed, the IRO shall determine:

- a) Whether each item of information listed above in Section III.A.1 is reflected in the Inquiries Database for each reviewed Inquiry;
- b) For each Inquiry for which the Compliance Officer conducted an Off-Label Review, the basis for suspecting that improper off-label promotion may have occurred; the steps undertaken as part of the Off-Label Review; the findings of the Compliance Officer as a result of the Off-Label Review; and any follow-up actions taken by Baxano Surgical based on the Off-Label Review findings; and
- c) For each Inquiry for which the Compliance Officer conducted a review of coding and reimbursement, the basis for suspecting that improper conduct may have occurred; the steps undertaken as part of the review; the findings of the Compliance Officer as a result of the review; and any follow-up actions taken by Baxano Surgical based on the review findings.

B. IRO Review of Physician Payment Listings

1) Information Contained in Physician Payment Listings

As set forth in Section III.M of the CIA, Baxano Surgical shall post quarterly and annual listings of physicians and Related Entities who received Payments, as defined in

the CIA, directly or indirectly from Baxano Surgical during the prior calendar year or quarter as applicable. For purposes of the IRO review as set forth in this Section III.C, each annual listing shall be referred to as the “Physician Payment Listing” or “Listing.” For each physician and Related Entity, each Physician Payment Listing shall include the following information: i) physician’s full name; ii) name of Related Entity (if applicable); iii) city and state of the physician’s practice or the Related Entity; and iv) the aggregate value of the Payment(s) in the preceding year.

For purposes of this IRO review, the term “Control Documents” shall include all documents or electronic records associated with each Payment reflected in the Physician Payments Listing for the sampled physician and/or Related Entity. For example, the term “Control Documents” includes, but is not limited to, documents relating to the nature, purpose, and amount of all Payments reflected in the Listing; contracts relating to the Payment(s) reflected in the Listing; documents relating to the occurrence of Payment(s) reflected in the Listing; documents reflecting any work product generated in connection with the Payment(s); documents submitted by sales representatives or headquarters personnel to request approval for the Payment(s); and business rationale or justification forms relating to the Payment(s).

2) Selection of Sample for Review

For each Reporting Period, the OIG shall have the discretion to identify at least 10 percent but no more than 40 physicians or Related Entities from the applicable Physician Payment Listing that will be subject to the IRO review described below. If the OIG elects to exercise this discretion, it shall notify the IRO, at least 90 days prior to the end of the Reporting Period, of the physicians and/or Related Entities subject to the IRO review. If the OIG elects not to exercise its discretion as described above, the IRO shall randomly select at least 10 percent but no more than 40 physicians and/or Related Entities to be included in the review. For each selected physician and/or Related Entity, the IRO shall review the entry in the Physician Payment Listing and the Control Documents relating to Payments reflected in Listing identified by the IRO as necessary and sufficient to validate the Payment information in the Listing.

3) IRO Review of Control Documents for Selected Physicians and/or Related Entities

For each physician and/or Related Entity selected as part of the sample, the IRO shall review the Control Documents identified by the IRO as necessary and sufficient to validate each Payment reflected in the Listing to evaluate the following:

- a) Whether Control Documents are available relating to each Payment reflected in the Listing for the sampled physician and/or Related Entity;

- b) Whether the Control Documents were completed and archived in accordance with the requirements set forth in Baxano Surgical's policies;
- c) Whether the aggregate value of the Payment(s) as reflected in the Listing for the sampled Physician is consistent with the value of the Payments(s) reflected in the Control Documents; and
- d) Whether the Control Documents reflect that Baxano Surgical's policies were followed in connection with Payment(s) reflected in the Listing (e.g., all required written approvals for the activity were obtained in accordance with Baxano Surgical's policies.)

4) Identification of Material Errors and Additional Review

A Material Error is defined as any of the following:

- a) A situation in which all required Control Documents relating to Payments reflected in the Listing for the sampled physician and/or Related Entity do not exist and:
 - i. no corrective action was initiated prior to the selection of the sampled physicians and/or Related Entities; or
 - ii. the IRO cannot confirm that Baxano Surgical otherwise followed its policies and procedures relating to the entry in the Listing for the sampled physician or Related Entity, including its policies and procedures relating to any Payment(s) reflected in the Listing; or
- b) Information or data is omitted from key fields in the Control Documents that prevents the IRO from assessing compliance with Baxano Surgical's policies and procedures, and the IRO cannot obtain this information or data from reviewing other Control Documents.

If a Control Document does not exist, but Baxano Surgical has initiated corrective action prior to the selection of the sampled physicians and/or Related Entities, or if a Control Document does not exist but the IRO can determine that Baxano Surgical

otherwise followed its policies and procedures with regard to each entry in the Listing for a sampled physician or Related Entity, the IRO shall consider such a situation to be an exception (rather than a Material Error) and the IRO shall report the situation as such. Similarly, the IRO shall note as exceptions any Control Documents for which non-material information or data is omitted.

If the IRO identifies any Material Errors, the IRO shall conduct such Additional Review of the underlying Payment associated with the erroneous Control Documents as may be necessary to determine the root cause of the Material Errors. For example, the IRO may need to review additional documentation and/or conduct interviews with appropriate personnel to identify the root cause of the Material Error(s) discovered.

C. Transactions Review Report

For each Reporting Period, the IRO shall prepare a report based on its Transactions Review. The report shall include the following:

- 1) General Elements to Be Included in Report
 - a) Review Objectives: A clear statement of the objectives intended to be achieved by each part of the review;
 - b) Review Protocol: A detailed narrative description of the procedures performed and a description of the sampling unit and universe utilized in performing the procedures for each sample reviewed; and
 - c) Sources of Data: A full description of documentation and other information, if applicable, relied upon by the IRO in performing the Transactions Review.
- 2) Results to be Included in Report

The following results shall be included in each Transaction Review Report:

(Relating to the Review of Inquiries)

- a) in connection with the review of Inquiries, a description of each type of sample unit reviewed, including the number of each type of sample units reviewed (e.g., the number of Inquiries) and an identification of the types of documents and information reviewed for the Inquiries;

- b) for each Inquiry sample unit, the IRO shall summarize the information about the Inquiry contained in the Inquiries Database;
- c) for each Inquiry sample unit, findings and supporting rationale as to whether: (i) each item of information listed in Section III.A.1 is reflected in the Inquiries Database; and (ii) for each Inquiry for which an Off-Label Review was conducted, the basis for suspecting that improper off-label promotion may have occurred; the steps undertaken as part of the Off-Label Review; the findings of the Compliance Officer as a result of the Off-Label Review; and any follow-up actions taken by Baxano Surgical as a result of the Compliance Officer's findings;
- d) the findings and supporting rationale regarding any weaknesses in Baxano Surgical's systems, processes, policies, procedures, and practices relating to the Inquiries, and the Inquiries Database, if any;
- e) recommendations for improvement in Baxano Surgical's systems, processes, policies, procedures, and practices relating to the Inquiries and the Inquiries Database, if any;

(Relating to the Physician Payment Listing Reviews)

- f) a description of the entries in the Physician Payment Listing for each physician or Related Entity sampled and a description of Control Documents reviewed in connection with each selected physician or Related Entity;
- g) for each sampled physician or Related Entity, findings and supporting rationale as to whether: i) all required Control Documents exist; ii) each Control Document was completed in accordance with all of the requirements set forth in the applicable Baxano Surgical policy; iii) the aggregate value of the Payment(s) as reflected in the Listing for the sampled physician or entity is consistent with the value of the Payment(s) reflected in the Control Documents; iv) each Control Document reflects that Baxano Surgical's policies were followed in connection with the underlying activity reflected in the document (e.g., all required approvals were obtained); and v) any disciplinary action that was undertaken

in those instances in which Baxano Surgical policies were not followed;

- h) for each sampled physician or Related Entity unit reviewed, an identification and description of all exceptions discovered. The report shall also describe those instances in which corrective action was initiated prior to the selection of the sampled physicians or Related Entities, including a description of the circumstances requiring corrective action and the nature of the corrective action; and
- i) if any Material Errors are discovered in any sample unit reviewed, a description of the error, the Additional Review procedures performed and a statement of findings as to the root cause(s) of the Material Error.

Appendix C

IRO Reviews of Baxano Surgical's Enterprise Risk Management Process

I. General Description of the Enterprise Risk Management Process

Prior to Effective Date of the CIA, Baxano Surgical implemented an Enterprise Risk Management (ERM) process. Baxano Surgical shall modify the ERM process as necessary to assess risks associated with the marketing and promotion of each of its Government Reimbursed Products. Based on the outcomes of the risk identification and assessment process, Baxano Surgical in-house or outside legal counsel, compliance and other personnel shall centrally develop and implement specific plans designed to mitigate or reduce the identified risks. Baxano Surgical shall develop a customized risk mitigation plan for each Government Reimbursed Product.

A. Risk Identification and Evaluation

As part of the ERM process, Baxano Surgical will solicit risk information from key operating areas: (i) business operations; (ii) sales and marketing; (iii) regulatory affairs; (iv) quality assurance/quality control; (v) research and development; (vi) legal; (vii) audit; and (viii) the Compliance Officer.

Based on inputs from these sources, Baxano Surgical's Enterprise Risk Management Committee will produce a relative risk ranking report (Risk Evaluation Report). The Risk Evaluation Report will be presented to the Compliance Committee with recommendations regarding which products may require enhanced risk mitigation plans and a copy shall be provided to the Board of Directors.

The Risk Evaluation Report will also be used by the Compliance Officer to inform the risk-based selection of products as required by the Field Force Monitoring Program described in CIA Section III.L.

B. Risk Mitigation Plans

Risk Mitigation Plans (RMPs) will be completed annually for all Baxano Surgical Government Reimbursed Products. All RMPs will outline standard risk mitigation activities that will be performed and tracked for each Baxano Surgical Government Reimbursed Product, regardless of the product's relative risk ranking (Standard RMPs). Standard risk mitigation activities will consist of the monitoring activities to be conducted for each Baxano Surgical Government Reimbursed Product in the upcoming year, such as ride-alongs with sales personnel, sampling, verbatim reviews, monitoring of speaker programs, speaker training, advisory boards, and medical information requests.

Based on the Risk Evaluation Report, Government Reimbursed Products may be selected for Enhanced RMPs by the Compliance Committee or Compliance Officer.

These RMPs will include enhanced risk mitigation activities, in addition to the standard activities (Enhanced RMPs). Enhanced RMPs will consist of activities tailored to the risks identified during the risk ranking process. For example, such activities may include increased compliance messaging, modifications to or limitations of promotional programs, or enhanced training requirements.

All RMPs (whether Standard or Enhanced) will be developed jointly by the Compliance Officer and the applicable department on an annual basis. Each RMP will specify the: (i) risk monitoring activities; (ii) metrics by which risk monitoring results will be evaluated and/or measured; (iii) risk mitigation action items, if necessary; (iv) metrics by which risk mitigation activities and results will be evaluated and/or measured; (v) responsible individual(s); and (vi) expected date(s) of monitoring and/or action item completion.

C. *Risk Mitigation Plan Tracking*

RMP activities (including risk monitoring activities, risk mitigation activities, and risk mitigation action items) will be tracked by the Compliance Officer. The Compliance Officer shall report on RMP activities specified above on at least a quarterly basis to the Board and to the Compliance Committee.

II. Enterprise Risk Management Review, General Description

A. As specified more fully below, Baxano Surgical shall retain an IRO to assist Baxano Surgical in assessing and evaluating its systems, processes, policies, procedures, and practices relating to the Enterprise Risk Management Review (ERM Review) as modified by Baxano Surgical to identify the risks associated with marketing and promotion of Government Reimbursed Products. The ERM Review shall consist of two components - a systems review (ERM Systems Review) and a transactions review (ERM Transactions Review) as described more fully below. Baxano Surgical may engage, at its discretion, a single IRO to perform both components of the ERM Review provided that the entity has the necessary expertise and capabilities to perform both.

B. If there are no material changes in Baxano Surgical's systems, processes, policies, and procedures relating to Risk Mitigation Program, the IRO shall perform the ERM Systems Review for the first and fourth Reporting Periods. If Baxano Surgical materially changes its systems, processes, policies, and procedures relating to the ERM Program, the IRO shall perform an ERM Systems Review for the Reporting Period(s) in which such changes were made in addition to conducting the Systems Review for the first and fourth Reporting Periods. The additional ERM Systems Review(s) shall consist of: (1) an identification of the material changes; (2) an assessment of whether other systems, processes, policies, and procedures previously reported did not materially change; and (3) a review of the systems, processes, policies, and procedures that materially changed. The

IRO shall conduct the ERM Transactions Review for the first through fifth Reporting Periods of the CIA.

III. ERM Systems Review

A. The ERM Systems review shall consist of the following:

1. A review of the processes by which Baxano Surgical develops and evaluates Risk Evaluation Reports and develops Standard and Enhanced RMPs, including the sources of information (e.g., the individual personnel, departments or functional areas, and/or any systems involved) used to compile the Reports and RMPs; the types of underlying data and information that are considered or evaluated during the development of the Risk Evaluation Reports and the RMPs; and the timing for development of Risk Evaluation Reports and the RMPs;
2. An assessment of whether, in developing the Risk Evaluation Reports and the RMPs: i) additional or different sources of information; ii) additional or different types of data or information; and iii) additional or different timing cycles should be utilized;
3. A review of the experience and background of the individuals responsible for development of the RMPs and an assessment of the completeness and appropriateness of the training, policies, procedures, standard operating procedures, and guidance such individuals receive regarding the development of the RMPs;
4. An assessment of whether the standard risk mitigation activities (monitoring activities) included in RMPs are designed to: (i) adequately monitor all relevant identified risks; (ii) identify any actual problems that have occurred in connection with the identified potential risk; and/or (iii) ensure that the activity associated with an identified risk does not occur in the future;
5. An assessment of whether standard risk mitigation activities (monitoring activities) that may be included in RMPs should be: (i) enhanced, revised, or refined; (ii) changed to include additional or different mitigation/monitoring options to be considered based upon specific identified risks; (iii) tracked and reviewed more frequently than prescribed by current policies to ensure that the options address all relevant risks for the specific products reviewed;

6. An assessment of whether enhanced risk mitigation activities and risk mitigation action items (and options for such activities) included in Enhanced RMPs are designed to: (i) adequately address all relevant identified risks; (ii) identify any actual problems that have occurred in connection with the identified potential risk; and/or (iii) ensure that the activity associated with an identified risk does not occur in the future;
7. An assessment of whether enhanced risk mitigation activities that may be included in RMPs should be: (i) enhanced, revised, or refined; (ii) changed to include additional or different mitigation/monitoring options to be considered based upon specific identified risks; (iii) tracked and reviewed more frequently than prescribed by current policies to ensure that the options address all relevant risks for the specific products reviewed; and
8. A review of the systems, policies, procedures, and processes by which Baxano Surgical tracks and manages RMP activities and an assessment of whether the systems, policies, procedures and processes ensure that the RMPs are appropriately implemented (including by identifying individuals responsible for the follow-up or action items).

B. The IRO shall prepare a report based upon each ERM Systems Review performed (ERM System Review Report). The ERM Systems Review Report will include the IRO's findings, recommendations, observations, and comments on items 1-8 above and, to the extent not otherwise addressed, an assessment of the following: (i) whether the Risk Evaluation Reports and RMPs identify and prioritize relevant risks; (ii) whether the risk monitoring activities, risk mitigation activities and any risk mitigation action items identified in RMPs address identified risks; (iii) whether sufficient controls exist to ensure that all risk mitigation steps (including monitoring activities and risk mitigation activities) are completed in accordance with the RMPs; iv) whether the options for risk monitoring activities and risk mitigation activities identified in the RMPs address and potentially mitigate identified risks; and (v) whether sufficient controls exist to ensure that all agreed-upon risk monitoring activities and risk mitigation activities are completed in accordance with the RMPs.

IV. ERM Transactions Review

A. At least thirty (30) days prior to the end of the first through fifth Reporting Periods, Baxano Surgical shall submit to OIG a list of all Baxano Surgical Government Reimbursed Products for which RMPs were developed. Baxano Surgical shall notify the OIG about which products had Standard RMPs and which products had Enhanced RMPs. Prior to the end of the applicable Reporting Period, OIG shall select up to 3 Baxano

Surgical Government Reimbursed Products (each a “Selected Product” and together the “Selected Products”) to be reviewed in connection with the ERM Transactions Review.

B. For each Reporting Period and for each Selected Product, the IRO shall conduct a review of: i) the applicable Risk Evaluation Report entry and RMP; ii) documents and materials related to the development of the RMP; and iii) documents and materials relating to the implementation of the RMP. The IRO shall also interview the individual(s) responsible for the development of the RMP and the individual(s) responsible for the implementation of the risk monitoring and risk mitigation activities specified in the RMP.

The objective of the IRO shall be to: (i) understand the processes followed by Baxano Surgical in developing the RMP for each Selected Product, including the underlying bases for Baxano Surgical’s decision to develop either a Standard RMP or an Enhanced RMP for the Selected Product; (ii) determine whether, based on the information contained in the Risk Evaluation Report, an appropriate RMP (including as to the included risk monitoring activities, risk mitigation activities, and risk mitigation action items) was developed for the Selected Product; and (iii) assess Baxano Surgical’s implementation and tracking of the implementation of the RMP for the Selected Product.

C. The IRO will prepare a report based on each ERM Transactions Review performed (ERM Transaction Review Report). The Transactions Review Report shall include the following:

1. an identification of the Selected Products and a description of the documents and information reviewed in connection with each Selected Product, including a description of whether the RMP for each Selected Product was a Standard RMP or an Enhanced RMP;
2. for each Selected Product, a description of: i) the process followed in developing the RMP; and ii) the types of identified risks associated with the Selected Product;
3. for each Selected Product, an assessment of whether it was appropriate for Baxano Surgical to develop, as applicable, an Enhanced or a Standard, RMP for the product;
4. for each Selected Product, an assessment of whether, based on the information contained in the Risk Evaluation Report, an appropriate RMP was developed for the Selected Product;

5. for each Selected Product, a description of the expertise and backgrounds of the individuals who were responsible for the development of the RMP;
6. for each Selected Product, a description of the following items set forth in the RMP: (i) risk monitoring activities; (ii) metrics by which the risk monitoring activities and results will be evaluated and/or measured; (iii) risk mitigation activities, including any risk mitigation action items; (iv) metrics by which the risk mitigation activities and results will be evaluated and/or measured; (v) responsible individual(s); (vi) expected date(s) of completion for each risk monitoring activity and risk mitigation activity; and (vii) if the RMP did not specify each of the items set forth above, a description of any deficiencies;
7. for each Selected Product, a description of whether risk monitoring activities specified in the RMP were implemented and tracked in accordance with the RMP and Baxano Surgical's policies and procedures, and a description of any deficiencies;
8. for each Selected Product, a description of whether risk mitigation activities (including any action items) specified in the RMP were implemented and tracked in accordance with the RMP and Baxano Surgical's policies and procedures, and a description of any deficiencies;
9. for each Selected Product a description of: (i) any recommendations made by the IRO regarding the RMP or any risk monitoring activities and risk mitigation activities included in the RMP; (ii) whether, and in what manner, Baxano Surgical implemented the recommendations from the IRO; and (iii) if Baxano Surgical did not implement the IRO recommendations, a description of the rationale for Baxano Surgical's decision not to implement the recommendations; and
10. the IRO's findings and supporting rationale regarding any weaknesses or deficiencies in Baxano Surgical's systems, processes, policies, procedures, and practices relating to the ERM program, if any; and recommendations, if any, for changes in Baxano Surgical's systems, processes, policies, procedures, and practices that would correct or address any weaknesses or deficiencies uncovered during the Transactions Review with respect to the ERM program.