# CORPORATE INTEGRITY AGREEMENT
# BETWEEN THE
# OFFICE OF INSPECTOR GENERAL
# OF THE
# DEPARTMENT OF HEALTH AND HUMAN SERVICES
# AND
# ADVANCED BIONICS LLC

## I. PREAMBLE

Advanced Bionics LLC (Manufacturer or "Advanced Bionics") 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, Advanced Bionics is entering into a Settlement Agreement with the United States.

## II. EFFECTIVE DATE, TERM, AND DEFINITIONS

A. Effective Date. The "Effective Date" of this CIA shall be the signature date of the final signatory of this CIA.

B. Term. The term of this CIA shall be five years from the Effective Date, except that Sections VII and X shall continue for 120 days after OIG's receipt of: (1) Advanced Bionics's final Annual Report or (2) any additional documentation relating to the final Annual Report requested by OIG, whichever is later. In addition, if OIG issues a Stipulated Penalties Demand Letter pursuant to Section X.C.1 or a Notice of Material Breach and Intent to Exclude pursuant to Section X.E.2 prior to the expiration of the 120 day period, then Section X shall remain in effect until the Stipulated Penalties Review described in Section X.E.2 or the Exclusion Review described in Section X.E.3 has been completed, and Advanced Bionics complies with the decision.

C. Definitions.

1. "Certifying Covered Persons" means the following: Senior Vice President, Global R&D; Vice President, Global Regulatory Affairs; and Vice President, Global Quality Assurance.

2. "Covered Functions" means all activities that involve the preparation or submission of Premarket Approval Applications (PMAs) to the FDA and all communications (initial and supplemental) with the FDA about PMAs and the component elements of PMAs, including but not limited to any performance standards applicable to Government Reimbursed Products Advanced Bionics relied upon in those submissions.

3. "Covered Persons" means: (a) all owners of Advanced Bionics who are

natural persons (other than shareholders who: (i) have an ownership interest of less than 5% and (ii) acquired the ownership interest through public trading); (b) all officers, board members, and employees of Advanced Bionics; and (c) all contractors who perform any of the Covered Functions on behalf of Advanced Bionics.

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 perform a Covered Function for Advanced Bionics for more than 160 hours a year, except that such individual shall become a "Covered Person" at the point when they work more than 160 hours on a Covered Function for Advanced Bionics during the calendar year.

4. "Disclosure Program" means a program that enables individuals to disclose to the Compliance Officer or some other person who is not in the disclosing individual's chain of command any potential violations of criminal, civil or administrative law related to the Federal health care programs or any issues or questions associated with Advanced Bionics's policies, conduct, practices, or procedures.

5. "Exclusion Lists" means the HHS/OIG List of Excluded Individuals/Entities (LEIE) (available at http://www.oig.hhs.gov) and State Medicaid program exclusion lists that are publicly available.

6. "Government Reimbursed Products" means all Advanced Bionics products that are: (a) marketed or sold by Advanced Bionics in the United States (or pursuant to contracts with the United States) and (b) reimbursed by Federal health care programs.

7. "Ineligible Person" means an individual or entity who: (a) is currently excluded from participation in any Federal health care program or (b) has been convicted of a criminal offense that falls within the scope of 42 U.S.C. § 1320a-7(a) (mandatory exclusion) but has not yet been excluded from participation in any Federal health care program.

8. "Reportable Event" means: (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 criminal or civil monetary penalties under Section 1128A or 1128B of the Social Security Act (the "Act") or exclusion under Section 1128 of the Act may be authorized; (b) a matter that a reasonable person would consider a probable violation of FDA requirements relating to any published PMA-related performance standard as referenced in 21 C.F.R. § 814.20(b)(5), including compliance with or deviation from such performance standards; (c) the employment of or contracting with a Covered Person who is an Ineligible Person; or (d) the filing of a bankruptcy petition by Advanced Bionics.

9. "Reporting Period" means each one-year period during the term of this CIA, beginning with the one-year period following the Effective Date.

10. "Training Plan" means a written plan that outlines the steps Advanced Bionics will take to ensure that Covered Persons receive training on a periodic basis during the term of the CIA regarding Advanced Bionics's CIA requirements and compliance program, and that all Covered Persons who engage in Covered Functions receive training on a periodic basis

during the term of the CIA regarding: (a) all applicable Federal health care program and FDA requirements relating to Covered Functions and (b) all Advanced Bionics Policies and Procedures and other requirements applicable to Covered Functions.

11. "Transition Plan" means a plan to address whether and how Advanced Bionics's compliance program will continue to include the compliance program requirements set forth in Section III of the CIA, following the end of the CIA's term.

## III. COMPLIANCE PROGRAM REQUIREMENTS

Advanced Bionics shall establish and maintain a compliance program that includes the following elements:

A. Compliance Officer, Compliance Committee, Board Oversight, and Management Certifications.

1. *Compliance Officer*. Within 90 days after the Effective Date, Advanced Bionics shall appoint a Compliance Officer who is an employee and a member of senior management of Advanced Bionics. The Compliance Officer shall report directly to the President of Advanced Bionics and shall not be or be subordinate to the General Counsel or Chief Financial Officer or have any responsibilities that involve acting in any capacity as legal counsel or supervising legal counsel functions for Advanced Bionics. The Compliance Officer shall be authorized to report to the Board of Managers of Advanced Bionics (Board) regarding compliance matters at any time. The Compliance Officer shall be responsible for, without limitation:

a. 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;

b. making at least quarterly reports regarding compliance matters to the Board;

c. monitoring the day-to-day compliance activities engaged in by Advanced Bionics; and

d. all reporting requirements of this CIA.

The Compliance Officer shall not have any noncompliance job responsibilities that, in OIG's discretion, may interfere or conflict with the Compliance Officer's ability to perform the duties outlined in this CIA.

Advanced Bionics shall report to OIG, in writing, any changes in the identity, duties, or job responsibilities of the Compliance Officer within five business days after such a change.

2. *Compliance Committee*. Within 90 days after the Effective Date, Advanced Bionics shall appoint a Compliance Committee that is chaired by the Compliance

Officer. The Compliance Committee shall include, at a minimum, the members of senior management necessary to meet the requirements of this CIA. The Compliance Committee shall be responsible for, among other things, reviewing the policies and procedures required by Section III.B below at least annually, reviewing the training required by Section III.C below at least annually, implementation and oversight of the risk assessment and internal review process required by Section III.E below, and the development and implementation of the Transition Plan required by Section III.K below. The Compliance Committee shall meet at least quarterly.

Advanced Bionics shall report to OIG, in writing, any changes to the membership of the Compliance Committee within 15 business days after such a change.

3. *Board Oversight*. The Board shall be responsible for the review and oversight of Advanced Bionics's compliance with Federal health care program requirements, FDA requirements, and the requirements of this CIA. The Board must include at least one independent (i.e., non-employee and non-executive) member.

The Board shall, at a minimum, be responsible for the following:

a. meeting at least quarterly to review and oversee Advanced Bionics's compliance program, including but not limited to the performance of the Compliance Officer and Compliance Committee;

b. submitting to OIG a description of the materials it reviewed and any additional steps taken, such as the engagement of an independent advisor or other third party resources, in its oversight of the compliance program and in support of making the resolution below during each Reporting Period; and

c. for each Reporting Period of the CIA, adopting a resolution, approved by each member of the Board regarding its review and oversight of Advanced Bionics's compliance with Federal health care program requirements, FDA requirements, and the requirements of this CIA.

At minimum, the resolution shall include the following language:

> "The Board has made a reasonable inquiry into the operations of Advanced Bionics'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, Advanced Bionics has implemented an effective compliance program to meet Federal health care program requirements, FDA requirements, and the requirements of Advanced Bionics's Corporate Integrity Agreement with the Office of Counsel to the Inspector General for the Department of Health and Human Services."

If the Board is unable to adopt such a resolution, the Board shall provide a written explanation of the reasons why it is unable to adopt the resolution and the steps it is taking to implement an effective compliance program at Advanced Bionics.

Advanced Bionics shall report to OIG, in writing, any changes to the membership of the Board, within 15 business days after such a change.

4. *Management Certifications*. The Certifying Covered Persons shall monitor compliance within the business unit for which they are responsible and annually certify that the applicable Advanced Bionics business unit is in compliance with applicable Federal health care program and FDA requirements and with the requirements of this CIA. For each Reporting Period, each Certifying Covered Person shall certify as follows:

> "I have been trained on and understand the compliance requirements and responsibilities as they relate to [insert name of business unit ], an area under my supervision. My job responsibilities include ensuring [business unit]'s compliance with all applicable Federal health care program requirements, FDA requirements, requirements of the Corporate Integrity Agreement, and Advanced Bionics's policies and procedures. To the best of my knowledge, the [insert name of business unit] of Advanced Bionics is in compliance with all applicable Federal health care program requirements, FDA requirements, and the requirements of the Corporate Integrity Agreement. I understand that this certification is being provided to and relied upon by the United States."

If any Certifying Covered Person is unable to provide such a certification, the Certifying Covered Person shall provide a written explanation of the reasons why he or she is unable to provide the certification.

Within 90 days after the Effective Date, Advanced Bionics shall develop and implement a written process for Certifying Covered Persons to follow for the purpose of completing the certification required by this section (e.g., reports that must be reviewed, assessments that must be completed, sub-certifications that must be obtained, etc. prior to the Certifying Covered Person making the required certification).

B. Written Standards. Within 90 days after the Effective Date, Advanced Bionics shall develop and implement written policies and procedures (Policies and Procedures) that address the following: (1) the operation of its compliance program, including the compliance program requirements outlined in this CIA and (2) Advanced Bionics's compliance with Federal health care program and FDA requirements. Advanced Bionics shall enforce its Policies and Procedures and shall make compliance with its Policies and Procedures an element of evaluating the performance of all Covered Persons. The Policies and Procedures shall be made available to all Covered Persons. At a minimum, the Policies and Procedures shall address the following:

1. appropriate ways to conduct Covered Functions in compliance with all: (a) applicable Federal health care program requirements, including, but not limited to the Federal

Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b), and the False Claims Act, 31 U.S.C. §§ 3729-3733, and (b) all applicable FDA requirements;

2. the materials and information that may be distributed by Advanced Bionics (including any contract sales force) about Government Reimbursed Products and the manner in which Advanced Bionics responds to requests for information about uses of Government Reimbursed Products that are not FDA approved, cleared or exempt ("non-FDA approved uses"), and the internal review process for the information disseminated;

3. financial arrangements entered into with health care professionals (HCPs) or health care institutions (HCIs) (including but not limited to speaker programs, speaker training programs, training and education services, product development activities, presentations, consultant task force meetings, advisory boards, ad hoc advisory activities, research and research-related activities, grant-related activities, authorship activities, and any other financial engagement or arrangement with an HCP or HCI) and all events and expenses relating to such engagements or arrangements;

4. review of promotional, reimbursement-related, and disease state materials and information intended to be disseminated outside Advanced Bionics 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 Advanced Bionics's review and approval process and are elevated when appropriate; and

5. disciplinary policies and procedures for violations of Advanced Bionics's Policies and Procedures, including policies relating to Federal health care program and FDA requirements.

The Compliance Committee shall review the Policies and Procedures at least annually and update the Policies and Procedures, as necessary. Any new or revised Policies and Procedures shall be made available to all Covered Persons. All Policies and Procedures shall be made available to OIG upon request.

C. Training and Education

1. *Covered Persons Training.* Within 90 days after the Effective Date, Advanced Bionics shall develop a Training Plan that includes the following information: (a) training topics; (b) categories of Covered Persons required to attend each training session; (c) length of the training session(s); (d) schedule for training; and (e) format of the training. The Compliance Committee shall review the Training Plan at least annually and update the Training Plan as necessary.

2. *Board Training*. Within 90 days after the Effective Date, members of the Board shall receive training regarding their responsibilities for corporate governance and review and oversight of the compliance program. The training shall address the specific responsibilities of health care board members, including the risks, oversight areas, and approaches to conducting effective oversight of a health care entity and shall include a discussion of OIG's guidance on

board member responsibilities. Each member of the Board also shall receive the training described in Section III.C.1.

New members of the Board shall receive the training described in this Section III.C. 2 above within 30 days after becoming a member or within 90 days after the Effective Date, whichever is later. The Compliance Committee shall review the Board training at least annually and update the Board training as necessary.

3. *Training Records*. Advanced Bionics shall make available to OIG, upon request, training materials and records verifying that the training described in Sections III.C.1 and III.C.2 has been provided.

D. Review Procedures.

1. *General Description.*

a. *Engagement of Independent Review Organization*. Within 90 days after the Effective Date, Advanced Bionics shall engage an entity ("Independent Review Organization" or "IRO") that meets the qualifications outlined in Appendix A to this CIA, which is incorporated by reference, to perform the reviews described in this Section III.D.

b. *Retention of Records*. The IRO and Advanced Bionics shall retain and make available to OIG, upon request, all work papers, supporting documentation, correspondence, and draft reports exchanged between the IRO and Advanced Bionics related to the reviews described in this Section III.D.

c. *Access to Records and Personnel*. Advanced Bionics shall ensure the IRO has access to all records and personnel necessary to complete the reviews listed in this Section III.D, and that all records furnished to the IRO are accurate and complete.

2. *Systems Review and Transactions Review, and Additional Item Review.* The IRO shall perform a Systems Review and a Transactions Review relating to the Covered Functions, and (if required) an Additional Item Review, and shall prepare a Systems Review Report and a Transactions Review Report, as outlined in Appendix B to this CIA, which is incorporated by reference.

3. *Independence and Objectivity Certification*. The IRO shall include in its report(s) to Advanced Bionics a certification that the IRO has: (a) evaluated its professional independence and objectivity with respect to the reviews required 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 to this CIA. The IRO's certification shall include a summary of current and prior engagements between Advanced Bionics and the IRO.

E. Risk Assessment and Internal Review Process. Within 90 days after the Effective Date, Advanced Bionics shall develop and implement a centralized annual risk assessment and internal review process to identify and address risks associated with each Government Reimbursed Product, including risks associated with the Covered Functions. The risk assessment and internal review process shall include pre-submission reviews for all PMA-related submissions to the FDA. The Compliance Committee shall be responsible for implementation and oversight of the risk assessment and internal review process. The risk assessment and internal review process shall be conducted annually and shall require Advanced Bionics to: (1) identify and prioritize risks, (2) develop work plans or internal audit plans (as appropriate) related to the identified risk areas, (3) implement the work plans and internal audit plans, (4) develop corrective action plans in response to the results of any internal audits performed, and (5) track the implementation of the work plans and any corrective action plans and assess the effectiveness of such plans.

F. Disclosure Program. Within 90 days after the Effective Date, Advanced Bionics shall establish a Disclosure Program. Advanced Bionics shall appropriately publicize the existence of the Disclosure Program and the disclosure mechanism (e.g., via periodic e-mails to employees, or by posting the information in prominent common areas). The Disclosure Program shall include a reporting mechanism for anonymous communications for which appropriate confidentiality shall be maintained. The Disclosure Program shall prohibit retaliation against Covered Persons relating to the use of the Disclosure Program and Advanced Bionics shall not retaliate against Covered Persons for use of the Disclosure Program. The Compliance Officer (or designee) shall conduct a review of each disclosure received through the Disclosure Program, including gathering all relevant information from the disclosing individual, and ensure that appropriate follow-up is conducted.

The Compliance Officer (or designee) shall record all disclosures (whether or not related to a potential violation of criminal, civil or administrative law related to Federal health care programs or FDA requirements) in a written disclosure log within two business days of receipt of the disclosure. The disclosure log shall include the following information: (1) a summary of each disclosure received (whether anonymous or not), (2) the date the disclosure was received, (3) the individual or department responsible for reviewing the disclosure, (4) the status of the review, (5) any corrective action taken in response to the review, and (6) the date the disclosure was resolved.

G. Ineligible Persons.

1. *Screening Requirements.* Advanced Bionics shall:

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

b. screen all current Covered Persons against the Exclusion Lists within 90 days after the Effective Date and on a monthly basis thereafter; and

c. require all Covered Persons to disclose immediately to the Compliance Officer (or designee) if they become an Ineligible Person.

2. *Removal Requirement*. If Advanced Bionics has actual notice that a Covered Person has become an Ineligible Person, Advanced Bionics 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 any Federal health care program(s) from which the Covered Person has been excluded, at least until such time as the Covered Person is reinstated into participation in such Federal health care program(s). Items or services furnished, ordered, or prescribed by excluded persons are not payable by Federal health care programs and Advanced Bionics may be liable for overpayments and/or criminal, civil, and administrative sanctions for employing or contracting with an excluded person regardless of whether Advanced Bionics meets the requirements of Section III.G.

H. Notification of Government Investigation or Legal Proceeding. Advanced Bionics shall notify OIG, in writing, of any ongoing investigation or legal proceeding by a governmental entity or its agents involving an allegation that Advanced Bionics has committed a crime or has engaged in fraudulent activities, within 30 days of Advanced Bionics receiving notice of such investigation or legal proceeding. This notification shall include a description of the allegation(s), the identity of the investigating or prosecuting agency, and the status of the investigation or legal proceeding. Within 30 days after resolution of the matter, Advanced Bionics shall notify OIG, in writing, of the resolution of the investigation or legal proceeding.

I. Reportable Events. Advanced Bionics shall notify OIG, in writing, within 30 days after determining that a Reportable Event exists, as follows:

1. *Probable Violation of Law*. The report to OIG shall include:

a. a complete description of all details relevant to the Reportable Event, including, at a minimum, the types of claims, transactions or other conduct giving rise to the Reportable Event, the period during which the conduct occurred, and the names of individuals and entities believed to be implicated, including an explanation of their roles in the Reportable Event;

b. a statement of the Federal criminal, civil or administrative laws that are probably violated by the Reportable Event, if any;

c. the Federal health care programs affected by the Reportable Event, if any; and

d. a description of Advanced Bionics's actions taken to correct the Reportable Event and prevent it from recurring.

2. *Probable Violation of FDA Requirements.* The report to OIG shall include:

a. a complete description of all details relevant to the Reportable Event, including, at a minimum, the types of claims, transactions or other conduct giving rise to the Reportable Event, the period during which the conduct occurred, and the names of individuals and entities believed to be implicated, including an explanation of their roles in the Reportable Event;

b. a statement of the FDA requirements probably violated by the Reportable Event, if any; and

c. a description of Advanced Bionics's actions taken to correct the Reportable Event and prevent it from recurring.

3. *Ineligible Person.* The report to OIG shall include:

a. the identity of the Ineligible Person and the job duties performed by that individual;

b. the dates of the Ineligible Person's employment or contractual relationship;

c. a description of the Exclusion Lists screening that Advanced Bionics completed before and/or during the Ineligible Person's employment or contract and any flaw or breakdown in the screening process that led to the hiring or contracting with the Ineligible Person;

d. a description of how the Ineligible Person was identified; and

e. a description of any corrective action implemented to prevent future employment or contracting with an Ineligible Person.

4. *Bankruptcy.* The report to OIG shall include documentation of the bankruptcy filing and a description of any Federal health care program or FDA requirements implicated.

J. Notification of Communications with FDA. Within 30 days after the date of any written report, correspondence, or communication between Advanced Bionics and the FDA that materially discusses Advanced Bionics's or a Covered Person's actual or potential unlawful or improper PMA-related activities involving performance standards (including without limitation any false, misleading, or materially incomplete statements), Advanced Bionics shall provide a

copy of the report, correspondence, or communication to OIG. Within 30 days after resolution of the matter, Advanced Bionics shall notify OIG, in writing, of the resolution.

K. Transition Plan. Prior to the end of the fourth Reporting Period, Advanced Bionics shall develop a Transition Plan that is reviewed and approved by the Board. The Transition Plan shall be implemented following the end of the CIA's term. A copy of Advanced Bionics's approved Transition Plan shall be included in Advanced Bionics's fourth Annual Report.

## IV. SUCCESSOR LIABILITY

If, after the Effective Date, Advanced Bionics proposes to (a) sell any or all of its business, business units or locations (whether through a sale of assets, sale of stock or other type of transaction) that engage in any of the Covered Functions; or (b) purchases or establishes a new business, business unit or location relating to or that will engage in any of the Covered Functions, the CIA shall be binding on the purchaser of any business, business unit or location and any new business, business unit or location (and all Covered Persons at each new business, business unit or location) shall be subject to the requirements of this CIA, unless otherwise determined and agreed to in writing by OIG. Advanced Bionics shall notify OIG, in writing, of such sale or purchase within 30 days following the closing of the transaction and shall notify OIG, in writing, within 30 days of establishing such new business, business unit or location.

If Advanced Bionics wishes to obtain a determination by OIG that a proposed purchase or proposed acquisition will not be subject to the CIA requirements, Advanced Bionics must notify OIG in writing at least 30 days in advance of the proposed sale or purchase. This notification shall include a description of the business, business unit, or location to be sold or purchased, a brief description of the terms of the transaction and, in the case of a proposed sale, the name and contact information of the prospective purchaser.

## V. IMPLEMENTATION REPORT AND ANNUAL REPORTS

A. Implementation Report. Within 120 days after the Effective Date, Advanced Bionics shall submit a written report (Implementation Report) to OIG that includes, at a minimum, the following information:

1. the name, business address, business phone number, and position description of the Compliance Officer required by Section III.A.1, and a detailed description of any noncompliance job responsibilities;

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

3. the names of the Board members who are responsible for satisfying the Board compliance requirements described in Section III.A.3;

4. the names and positions of the Certifying Covered Persons required by Section III.A.4 and a copy of the written process for Certifying Covered Persons to follow in order to complete the certification required by Section III.A.4;

5. a list of the Policies and Procedures required by Section III.B;

6. the Training Plan required by Section III.C.1 and a description of the Board training required by Section III.C.2 (including a summary of the topics covered, the length of the training and when the training was provided);

7. the following information regarding the IRO(s): (a) identity, address, and phone number; (b) a copy of the engagement letter; (c) information to demonstrate that the IRO has the qualifications outlined in Appendix A to this CIA; and (d) a certification from the IRO regarding its professional independence and objectivity with respect to Advanced Bionics that includes a summary of all current and prior engagements between Advanced Bionics and the IRO;

8. a description of the risk assessment and internal review process required by Section III.E;

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

10. a description of the Ineligible Persons screening and removal process required by Section III.G;

11. a list of all of Advanced Bionics's locations (including mailing addresses); the corresponding name under which each location is doing business; and the locations' Medicare and state Medicaid provider number and/or supplier number(s), if any;

12. a description of Advanced Bionics's corporate structure, including identification of any parent and sister companies, subsidiaries, and their respective lines of business; and

13. a certification by the Compliance Officer and President that:

    a. to the best of his or her knowledge, except as otherwise described in the report, Advanced Bionics has implemented and is in compliance with all requirements of this CIA;

    b. 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

    c. he or she understands that the certification is being provided to and relied upon by the United States.

B. Annual Reports. Advanced Bionics shall submit a written report (Annual Report) to OIG for each of the five Reporting Periods that includes, at a minimum, the following information:

1. any change in the identity, position description, or noncompliance job responsibilities of the Compliance Officer; a current list of the Compliance Committee members; a current list of the Board members who are responsible for satisfying the Board compliance requirements; and a current list of the Certifying Covered Persons, along with the identification of any changes made during the Reporting Period to the Compliance Committee, Board, or Certifying Covered Persons;

2. the dates of each meeting of the Compliance Committee (copies of the meeting minutes shall be made available to OIG upon request);

3. the dates of each report made by the Compliance Officer to the Board (written documentation of such reports shall be made available to OIG upon request);

4. the Board resolution required by Section III.A.3, a description of the materials reviewed by the Board and any additional steps taken in its oversight of the compliance program and in support of making the resolution;

5. a description of any changes to the written process for Certifying Covered Persons to follow in order to complete the certification required by Section III.A.4;

6. the certifications of Certifying Covered Persons required by Section III.A.4;

7. a list of any new or revised Policies and Procedures required by Section III.B developed during the Reporting Period;

8. a description of any changes to the Training Plan required by Section III.C and a summary of all training furnished to Covered Persons and Board members during the Reporting Period;

9. a complete copy of all reports prepared pursuant to Section III.D and Advanced Bionics' response to the reports, along with corrective action plan(s) related to any issues raised by the reports;

10. a certification from the IRO regarding its professional independence and objectivity with respect to Advanced Bionics, including a summary of all current and prior engagements between Advanced Bionics and the IRO;

11. a description of any changes to the risk assessment and internal review process required by Section III.E, including the reason(s) for such changes;

12. a summary of the following components of the risk assessment and internal review process during the Reporting Period: (a) risk areas identified, (b) work plans and

internal audit plans developed, (b) internal audits performed, (c) corrective action plans developed in response to internal audits, and (d) steps taken to track the implementation of the work plans and any corrective action plans. Copies of any work plans, internal audit reports, and corrective action plans shall be made available to OIG upon request;

13. 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, including at least the following information: (a) a description of the disclosure, (b) the date the disclosure was received, (c) the resolution of the disclosure, and (d) the date the disclosure was resolved. The complete disclosure log shall be made available to OIG upon request;

14. a description of any changes to the Ineligible Persons screening and removal process required by Section III.G, including the reason(s) for such changes;

15. a summary describing any ongoing investigation or legal proceeding required to have been reported pursuant to Section III.H that includes a description of the allegation(s), the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding;

16. a summary of all Reportable Events required to have been reported pursuant to Section III.I during the Reporting Period;

17. a summary describing any written communication with the FDA required to have been reported pursuant to Section III.J that includes a description of each matter and the status of each matter;

18. (in the fourth Annual Report), a copy of the Transition Plan required by Section III.K;

19. a description of all changes to the most recently provided list of Advanced Bionics's locations (including addresses) as required by Section V.A.11;

20. a description of any changes to Advanced Bionics's corporate structure, including any parent and sister companies, subsidiaries, and their respective lines of business; and

21. a certification by the Compliance Officer and President that:

a. to the best of his or her knowledge, except as otherwise described in the report, Advanced Bionics has implemented and is in compliance with all requirements of this CIA;

b. 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

c. he or she understands that the certification is being provided to and relied upon by the United States.

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. Designation of Information. Advanced Bionics 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. Advanced Bionics 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 using the following contact information:

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
Email Address: officeofcounsel@oig.hhs.gov

Advanced Bionics:

Dawn Sorensen
Vice President, Global Legal Affairs
28515 Westinghouse Place
Valencia, CA 91355
Telephone: 661.362.1400

Unless otherwise requested by OIG, all notifications and reports required by this CIA shall be submitted electronically. OIG shall notify Advanced Bionics in writing of any changes to the OIG contact information listed above. Advanced Bionics shall notify OIG in writing within two business days of any changes to the Advanced Bionics contact information listed above.

## 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 conduct interviews, examine and/or request copies of or copy Advanced Bionics's books, records, and other documents and supporting materials, and conduct on-site reviews of any of Advanced Bionics's locations, for the purpose of evaluating: (a) Advanced Bionics's compliance with the terms of this CIA and (b) Advanced Bionics's compliance with Federal health care program requirements and with all applicable FDA requirements. The documentation described above shall be made available by Advanced Bionics to OIG or its duly authorized representative(s) at all reasonable times for inspection, audit, and/or reproduction. For purposes of this provision, OIG or its duly authorized representative(s) may interview any of Advanced Bionics's owners, employees, contractors and Board members 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. Advanced Bionics shall assist OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon OIG's request. Advanced Bionics's owners, employees, contractors and Board members may elect to be interviewed with or without a representative of Advanced Bionics present.

## VIII. DOCUMENT AND RECORD RETENTION

Advanced Bionics 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 Advanced Bionics prior to any release by OIG of information submitted by Advanced Bionics pursuant to its requirements under this CIA and identified upon submission by Advanced Bionics as trade secrets, or information that is commercial or financial and privileged or confidential, under the FOIA rules. With respect to such releases, Advanced Bionics shall have the rights set forth at 45 C.F.R. § 5.42(a).

## X. BREACH AND DEFAULT PROVISIONS

A. Stipulated Penalties. OIG may assess:

1. A Stipulated Penalty of up to $2,500 for each day Advanced Bionics fails to comply with Section III.A;

2. A Stipulated Penalty of up to $2,500 for each day Advanced Bionics fails to comply with Section III.B;

3. A Stipulated Penalty of up to $2,500 for each day Advanced Bionics fails to comply with Section III.C;

4. A Stipulated Penalty of up to $2,500 for each day Advanced Bionics fails to comply with Section III.D;

5. A Stipulated Penalty of up to $2,500 for each day Advanced Bionics fails to comply with Section III.E;

6. A Stipulated Penalty of up to $2,500 for each day Advanced Bionics fails to comply with Section III.F;

7. A Stipulated Penalty of up to $2,500 for each day Advanced Bionics fails to comply with Section III.G;

8. A Stipulated Penalty of up to $2,500 for each day Advanced Bionics fails to comply with Section III.H;

9. A Stipulated Penalty of up to $2,500 for each day Advanced Bionics fails to comply with Section III.I;

10. A Stipulated Penalty of up to $2,500 for each day Advanced Bionics fails to comply with Section III.J;

11. A Stipulated Penalty of up to $2,500 for each day Advanced Bionics fails to comply with Section III.K;

12. A Stipulated Penalty of up to $2,500 for each day Advanced Bionics fails to comply with Section IV;

13. A Stipulated Penalty of up to $2,500 for each day Advanced Bionics fails to comply with Section V;

14. A Stipulated Penalty of up to $2,500 for each day Advanced Bionics fails to comply with Section VII;

15. A Stipulated Penalty of up to $2,500 for each day Advanced Bionics fails to comply with Section VIII; or

16. A Stipulated Penalty of up to $50,000 for each false certification or false statement made to OIG by or on behalf of Advanced Bionics under this CIA.

B. Timely Written Requests for Extensions. Advanced Bionics 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. 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 Advanced Bionics fails to meet the revised deadline set by OIG. 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 Advanced Bionics 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*. If OIG determines that a basis for Stipulated Penalties under Section X.A exists, OIG shall notify Advanced Bionics of: (a) Advanced Bionics's failure to comply and (b) OIG's demand for payment of Stipulated Penalties (this notification is referred to as the "Demand Letter").

2. *Response to Demand Letter.* Within 15 business days after the date of the Demand Letter, Advanced Bionics shall either: (a) 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.

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.

D. Exclusion for Material Breach

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

a. failure to comply with any of the requirements of this CIA for which OIG has previously issued a demand for Stipulated Penalties under Section X.C, unless such Stipulated Penalty was overturned by an ALJ on appeal pursuant to the procedures described in Section X.E below;

b. failure to comply with Section III.A.1;

c. failure to comply with Section III.D;

d. failure to comply with Section III.I;

e. failure to comply with Section V;

f. failure to respond to a Demand Letter in accordance with Section X.C;

g. a false statement or false certification made to OIG by or on behalf of Advanced Bionics under this CIA;

h. failure to pay Stipulated Penalties within 20 days after an ALJ issues a decision ordering Advanced Bionics to pay the Stipulated Penalties or within 20 days after the HHS Departmental Appeals

Board (DAB) issues a decision upholding the determination of OIG; or

i. failure to come into compliance with a requirement of this CIA for which OIG has demanded Stipulated Penalties, pursuant to the deadlines listed in Section X.E.2.

2. *Notice of Material Breach and Intent to Exclude*. The parties agree that a material breach of this CIA by Advanced Bionics constitutes an independent basis for Advanced Bionics's exclusion from participation in the Federal health care programs. The length of the exclusion shall be in OIG's discretion, but not more than five years for each material breach. Upon a preliminary determination by OIG that Advanced Bionics has materially breached this CIA, OIG shall notify Advanced Bionics of: (a) Advanced Bionics's material breach and (b) OIG's intent to exclude Advanced Bionics (this notification is hereinafter referred to as the "Notice of Material Breach and Intent to Exclude").

3. *Response to Notice*. Advanced Bionics shall have 30 days from the date of the Notice of Material Breach and Intent to Exclude to submit any information and documentation for OIG to consider before it makes a final determination regarding exclusion.

4. *Exclusion Letter*. If OIG determines that exclusion is warranted, OIG shall notify Advanced Bionics in writing of its determination to exclude Advanced Bionics (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 the Exclusion Letter. The effect of the exclusion shall be that no Federal health care program payment may be made for any items or services furnished, ordered, or prescribed by Advanced Bionics, including administrative and management services, except as stated in regulations found at 42 C.F.R. §1001.1901(c). The exclusion shall have national effect. Reinstatement to program participation is not automatic. At the end of the period of exclusion, Advanced Bionics 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 issuing a Demand Letter or Exclusion Letter, and as an agreed-upon remedy for the resolution of disputes arising under this CIA, Advanced Bionics 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. Specifically, OIG's determination to demand payment of Stipulated Penalties or to seek exclusion shall be subject to review by an HHS ALJ and, in the event of an appeal, the DAB, in a manner consistent with the provisions in 42 C.F.R. § 1005.2-1005.21, but only to the extent this CIA does not provide otherwise. Notwithstanding the language in 42 C.F.R. § 1005: (a) the request for a hearing involving Stipulated Penalties shall be made within 15 business days after the date of the Demand Letter and the request for a hearing involving exclusion shall be made within 25 days after the date of the Exclusion Letter and (b) no discovery shall be available to the parties. The procedures relating to the filing of a request for a hearing can be found at http://www.hhs.gov/dab/divisions/civil/procedures/divisionprocedures.html.

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 Advanced Bionics was in full and timely compliance with the requirements of this CIA for which OIG demands payment and (b) the period of noncompliance. Advanced Bionics shall have the burden of proving its full and timely compliance. If the ALJ upholds the OIG's determination that Advanced Bionics has breached this CIA and orders Advanced Bionics to pay Stipulated Penalties, Advanced Bionics must (a) come into compliance with the requirement(s) of this CIA that resulted in the OIG imposing Stipulated Penalties and (b) pay the Stipulated Penalties within 20 days after the ALJ issues a decision, unless Advanced Bionics properly and timely requests review of the ALJ decision by the DAB. If the ALJ decision is properly and timely appealed to the DAB and the DAB upholds the determination of OIG, Advanced Bionics must (a) come into compliance with the requirement(s) of this CIA that resulted in the OIG imposing Stipulated Penalties and (b) pay the Stipulated Penalties within 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 whether Advanced Bionics was in material breach of this CIA. If the ALJ sustains the OIG's determination of material breach, the exclusion shall take effect 20 days after the ALJ issues the decision. 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. Advanced Bionics shall waive its right to any notice of such exclusion if a decision upholding the exclusion is rendered by the ALJ or DAB. If the DAB finds in favor of Advanced Bionics, Advanced Bionics shall be reinstated effective on the date of the 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. 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 and Advanced Bionics agrees not to seek additional review of the DAB's decision (or the ALJ's decision if not appealed) in any judicial forum.

## XI. EFFECTIVE AND BINDING AGREEMENT

Advanced Bionics and OIG agree as follows:

A. This CIA constitutes the complete agreement between the parties and may not be amended except by written consent of the parties to this CIA.

B. All requirements and remedies set forth in this CIA are in addition to and do not affect (1) Advanced Bionics's responsibility to follow all applicable Federal health care program and FDA requirements or (2) the government's right to impose appropriate remedies for failure to follow applicable Federal health care program or FDA requirements.

C. The undersigned Advanced Bionics signatories represent and warrant that they are authorized to execute this CIA. The undersigned OIG signatories represent that they are signing this CIA in their official capacity and that they are authorized to execute this CIA.

D. This CIA may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same CIA. Electronically transmitted copies of signatures shall constitute acceptable, binding signatures for purposes of this CIA.

**ON BEHALF OF ADVANCED BIONICS**

/Dawn Sorensen/ 12/16/22
DAWN SORENSEN DATE
Vice President, Global Legal Affairs
Advanced Bionics LLC

/Matthew J. O'Connor/ 12/16/22
MATTHEW O'CONNOR DATE
Covington & Burling LLP
Counsel for Advanced Bionics LLC

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

/Lisa M. Re/ 12/14/2022
LISA M. RE DATE
Assistant Inspector General for Legal Affairs
Office of Inspector General
U.S. Department of Health and Human Services

/Gregory J. Wellins/ 12/19/2022
GREGORY J. WELLINS DATE
Senior Counsel

## APPENDIX A

## INDEPENDENT REVIEW ORGANIZATION

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

A. IRO Engagement

1. Advanced Bionics 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 E. Within 30 days after OIG receives the information identified in Section V.A.7 of the CIA or any additional information submitted by Advanced Bionics in response to a request by OIG, whichever is later, OIG will notify Advanced Bionics if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, Advanced Bionics may continue to engage the IRO.

2. If Advanced Bionics engages a new IRO during the term of the CIA, that IRO must also meet the requirements of this Appendix. If a new IRO is engaged, Advanced Bionics shall submit the information identified in Section V.A.7 of the CIA to OIG within 30 days of engagement of the IRO. Within 30 days after OIG receives this information or any additional information submitted by Advanced Bionics at the request of OIG, whichever is later, OIG will notify Advanced Bionics if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, Advanced Bionics may continue to engage the IRO.

B. IRO Qualifications

The IRO shall:

1. assign individuals to conduct the Systems Review and Transactions Review who have expertise in the medical device industry and FDA requirements relating to the Covered Functions (as defined in Section II.C of the CIA), including but not limited to expertise relating to the preparation and submission of Premarket Approval Applications (PMAs) to the FDA; and

2. 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 Systems Review and Transactions Review in accordance with the specific requirements of the CIA;

2. follow all applicable FDA requirements in making assessments in the Systems Review and Transactions Review;

3. respond to all OIG inquires in a prompt, objective, and factual manner; and

4. prepare timely, clear, well-written reports that include all the information required by Appendix B to the CIA.

D. Advanced Bionics' Responsibilities

Advanced Bionics shall ensure that the IRO has access to all records and personnel necessary to complete the reviews listed in III.D of this CIA and that all records furnished to the IRO are accurate and complete.

E. IRO Independence and Objectivity

The IRO must perform each component of the Systems Review and Transactions Review in a professionally independent and objective fashion, as defined in the most recent Government Auditing Standards issued by the U.S. Government Accountability Office.

F. IRO Removal/Termination

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

2. *OIG Removal of IRO*. In the event OIG has reason to believe the IRO does not possess the qualifications described in Paragraph B, is not independent and objective as set forth in Paragraph E or has failed to carry out its responsibilities as described in Paragraph C, OIG shall notify Advanced Bionics in writing regarding OIG's basis for determining that the IRO has not met the requirements of this Appendix. Advanced Bionics shall have 30 days from the date of OIG's written notice to provide information regarding the IRO's qualifications, independence or performance of its responsibilities in order to resolve the concerns identified by OIG. If, following OIG's review of any information provided by Advanced Bionics regarding the IRO, OIG determines that the IRO has not met the requirements of this Appendix, OIG shall notify Advanced Bionics in writing that Advanced Bionics shall be required to engage a new IRO in accordance with Paragraph A of this Appendix. Advanced Bionics must engage a new IRO within 60 days of its receipt of OIG's written notice. The final determination as to whether or not to require Advanced Bionics to engage a new IRO shall be made at the sole discretion of OIG.

## APPENDIX B

## INDEPENDENT REVIEW ORGANIZATION REVIEWS

The IRO shall perform a Systems Review and a Transactions Review relating to the Covered Functions (as defined in Section II.C of the CIA). If there are no material changes in Advanced Bionics's systems, processes, policies, and procedures relating to the Covered Functions, the IRO shall perform the Systems Review for the first and fourth Reporting Periods. If Advanced Bionics materially changes its systems, processes, policies, and procedures relating to Covered Functions, the IRO shall perform an additional Systems Review for the Reporting Period(s) in which such changes were made that identifies the material changes and reviews the systems, processes, policies, and procedures that materially changed. The IRO shall conduct the Transactions Review for the second through fifth Reporting Periods of the CIA.

A. Systems Review. For the Systems Review, the IRO shall review Advanced Bionics's systems, processes, policies, and procedures associated with the following (hereafter "Reviewed Policies and Procedures"):

1. Advanced Bionics's organizational structure as it relates to Covered Functions, including the identification of those individuals, departments, or groups within Advanced Bionics responsible for the preparation or submission of PMAs to the FDA and communications with FDA about PMAs and the component elements of PMAs;

2. The systems, processes, policies, and procedures that Advanced Bionics uses or follows in connection with performance standards related to PMAs including:

a. the individuals, departments, or groups authorized to approve the selection of performance standards to be used in connection with a Government Reimbursed Product or to approve policies and procedures relating to performance standards;

b. the information and factors to be considered in connection with the selection of performance standards and the establishment of performance standards policies and procedures; and

c. the types and sources of information (both internal and external) used to make decisions about performance standards.

3. The systems, processes, policies, and procedures that Advanced Bionics uses or follows in connection with testing or evaluating whether Advanced Bionics's Government Reimbursed Products meet performance standards and for justifying or evaluating any deviation from such performance standards; and

4. Advanced Bionics's systems, policies, processes, and procedures relating to disciplinary policies and procedures for violations of Advanced Bionics's Policies and Procedures relating to the Covered Functions.

B. Systems Review Report. The IRO shall prepare a Systems Review Report for each Systems Review that includes the following information:

1. a description of the documentation (including policies) reviewed and any personnel interviewed;

2. a detailed description of Advanced Bionics's systems, policies, processes, and procedures relating to the items identified in Sections A.1-4 above, including a general description of Advanced Bionics'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 A.1-4 above are made known or disseminated within Advanced Bionics;

4. findings and supporting rationale regarding any material differences between published PMA-related performance standards applicable to Government Reimbursed Products and the systems, processes, policies, and procedures relating to the Reviewed Policies and Procedures, if any; and

5. recommendations to improve material compliance with PMA-related performance standards applicable to Government Reimbursed Products and the systems, policies, processes, or procedures relating to the Reviewed Policies and Procedures, if any.

C. Transactions Review. The Transactions Review shall include a review of performance standards applicable to Government Reimbursed Products for which PMAs or supplements to PMAs were submitted to FDA and may also include a review of an Additional Item.

1. *Review of Performance Standards*.

a. For each Reporting Period, the IRO shall review information relating to the performance standards (as referenced in 21 C.F.R. § 814.20(b)(5)) applicable to Government Reimbursed Products included or referenced in PMAs or PMA-related submissions or supplements submitted to FDA during the applicable Reporting Period. The IRO shall conduct this review (Performance Standards Review) by reviewing configurations, results, and descriptions of the performance standards applicable to the Government Reimbursed Product and any results of testing the Government Reimbursed Products against the performance standards. If the PMAs or PMA-related submissions or supplements to be reviewed by the IRO include multiple performance standards referenced by or relied on by Advanced Bionics, or a performance standard has multiple subparts, the IRO or Advanced Bionics may propose to OIG that the IRO review a sample of performance standards or performance standard subparts. Any such proposal must be reviewed and approved in advance by the OIG and such approval shall be in the OIG's discretion.

b. For purposes of conducting its review of performance standards, the IRO shall have access to all records and personnel necessary to complete the review described below. This shall include access to internal Advanced Bionics documents and information relating to: i) the Government Reimbursed Products for which PMAs or PMA-related submissions or supplements were submitted to FDA during the applicable Reporting Period, ii) performance standards applicable to each of the Government Reimbursed Products; iii) test reports evaluating the Government Reimbursed Products against the performance standards; and iv) descriptions of performance standard test reports for the Government Reimbursed Products intended for submission to the FDA.

c. For each Government Reimbursed Product reviewed the IRO shall:

i. identify the configurations, results, and descriptions of tests of the Government Reimbursed Product against the applicable performance standards during the Reporting Period;

ii. evaluate whether the testing was conducted in a manner consistent with Advanced Bionics's Policies and Procedures relating to Covered Functions, including whether all required approvals were obtained, whether the decision-making process was consistent with Advanced Bionics's Policies and Procedures, and whether all required documentation pertaining to performance standards testing was retained; and

iii. verifying that the documentation pertaining to performance standards testing maintained by Advanced Bionics is consistent with the documentation of performance standards testing submitted to the FDA.

2. *Review of Additional Item*. As set forth in Section III.D of the CIA, for each Reporting Period, the OIG at its discretion may identify an additional item for the IRO to review (hereafter "Additional Item").

a. No later than 120 days prior to the end of the applicable Reporting Period, the OIG shall notify Advanced Bionics of the nature and scope of the IRO review to be conducted for the Additional Item. Prior to undertaking the review of the Additional Item, the IRO and/or Advanced Bionics shall submit an audit work plan to the OIG for approval and the IRO shall conduct the review of the Additional Item based on a work plan approved by the OIG. The IRO shall include information about its review of the Additional Item in the Transactions Review Report (including a description of the review conducted; the IRO's findings based on its review; and the IRO's recommendations for any changes in Advanced Bionics's systems, policies, and procedures based on its review).

b. Advanced Bionics may propose to the OIG that its internal audit(s), reviews, or monitoring activities, be substituted, for the Additional Item that would otherwise be reviewed by the IRO for the applicable Reporting Period. The OIG retains sole discretion over whether, and in what manner, to allow Advanced Bionics's internal audit work to be substituted for the Additional Item review conducted by the IRO.

D. Transactions Review Report. The IRO shall prepare a Transactions Review Report for each Transactions Review that includes the following information:

1. *Transactions Review Methodology.*

a. Review Objective: A statement of the objective intended to be achieved by each part of the Transactions Review;

b. Review Protocol: A detailed narrative description of how the Transactions Review was performed and what was evaluated; and

c. Sources of Data: A description of the documentation and other information relied on by the IRO in performing the Transactions Review.

2. *Transactions Review Findings.*

a. Relating to the Review of Performance Standards. The following results shall be included in each Transaction Review Report:

i. a description of each Government Reimbursed Product reviewed, including the name of the product, a description of the product (including the approved indications for the product), and a description of when Advanced Bionics began to sell the product;

ii. for each Government Reimbursed Product, a description of the performance standards applicable to the product during the Reporting Period;

iii. for each Government Reimbursed Product, a description of the testing against the applicable performance standard that was conducted by Advanced Bionics and submitted to FDA for the product during the Reporting Period;

iv. the IRO's findings and supporting rationale as to:

(a) whether the performance standard testing was conducted in a manner consistent with Advanced Bionics's Policies and Procedures relating to Covered Functions, including whether all required approvals were obtained, whether the

decision-making process was consistent with Advanced Bionics's Policies and Procedures, and whether all required documentation pertaining to performance standard testing decisions was retained;

(b) whether the documentation pertaining to performance standards testing maintained by Advanced Bionics is consistent with the documentation of performance standards testing submitted to the FDA;

(c) if the performance standard testing was not conducted for the Government Reimbursed Product in a manner consistent with Advanced Bionics's Policies and Procedures, the IRO's findings about Advanced Bionics's deviations from those Policies;

(d) if the documentation pertaining to performance standards testing maintained by Advanced Bionics is not consistent with the documentation of performance standards testing submitted to the FDA, the IRO's findings relating to such inconsistencies;

(e) whether the IRO identified any weaknesses in Advanced Bionics's systems, processes, policies, procedures and/or practices relating to Covered Functions; and

(f) whether the IRO has recommendations for improvements to Advanced Bionics's systems, processes, policies, procedures and/or practices relating to Covered Functions.

b. <u>Relating to the Review of Additional Item</u>

i. a description of the review conducted;

ii. the IRO's findings based on its review;

iii. the IRO's findings and supporting rationale regarding any weaknesses in Advanced Bionics's systems, processes, policies, procedures, and practices relating to the Additional Item, if any; and

iv. the IRO's recommendations, if any, for changes in Advanced Bionics's systems, processes, policies, and procedures that would correct or address any weaknesses or deficiencies uncovered during the review.