

## **CORPORATE COMPLIANCE PROGRAM PLAN DESCRIPTION**

### **I. INTRODUCTION**

T2 Biosystems, Inc. (the “Company”) hereby establishes this Corporate Compliance Program (“Compliance Program”) which sets forth a code of conduct as well as standards and procedures for all facets of corporate activity. The Compliance Program applies to all Company directors, officers, employees, and agents including all directors, officers, employees and agents of subsidiaries, operating divisions, and units of the Company (collectively referred to herein as “Company Personnel”). The Company’s operations are subject to numerous federal and state laws and regulations. The Company is committed to conducting all of its business activities in compliance with all applicable laws, rules and regulations. Its management and employees are dedicated to high ethical standards and recognize the Company’s duty to conduct its affairs within the bounds of the law. This Compliance Program, is an expression of the core values that are fundamental to our business. It is intended to provide guidelines for complying with the law for all Company Personnel. This Compliance Program is subject to amendment as provided herein in Section IX. The Company’s Board of Directors adopted this Compliance Program, on February 16, 2016.

### **II. COMPLIANCE COMMITTEE AND COMPLIANCE OFFICER**

The Company has designated a Compliance Committee and Compliance Officer to oversee the implementation and operation of the Compliance Program. The Compliance Committee and Compliance Officer have the authority to report directly to the Board of Directors and/or the President/CEO of the Company.

A. The Compliance Committee shall consist of the Company’s:

1. Chief Executive Officer;
2. Chief Financial Officer;
3. General Counsel;
4. Chief Operating Officer;
5. Chief Scientific Officer;
6. Vice President of Marketing; and
7. Vice President of Sales.

B. The Compliance Officer has the authority to review all documents and information relevant to compliance activities. The Compliance Officer is responsible for the operation of the Compliance Program, including:

1. Developing, implementing, maintaining, and administering the Compliance Program;

2. Overseeing periodic review of the Compliance Program;
3. Preparing reports on the Compliance Program to the Board of Directors, Compliance Committee, and/or the President/CEO and other Company committees and management on a regular basis;
4. Overseeing educational training requirements of the Compliance Program;
5. Disseminating memoranda, news articles, or other informational materials explaining compliance requirements, compliance responsibilities or highlighting the importance of compliance to Company Personnel;
6. Ensuring that independent contractors and agents are aware of the requirements of the Company's Compliance Program;
7. Coordinating Company Personnel issues with the Company's Human Resources office to ensure that the List of Excluded Individuals/Entities has been checked with respect to all employees and independent contractors;
8. Assisting the Company's internal auditors in coordinating internal compliance review and monitoring;
9. Reviewing audits and reports prepared by auditors or investigators;
10. Reviewing and, where appropriate, acting in response to reports of noncompliance received through the hotline (or other established reporting mechanism) or otherwise brought to his or her attention;
11. Independently investigating and acting on matters related to compliance;
12. Participating with the Company's legal counsel in the appropriate reporting of any self-discovered violations of federal health care program requirements;
13. Organizing and maintaining all documentation regarding the Compliance Program;
14. Interpreting and providing guidance on any issue concerning the Compliance Program;
15. Monitoring developments relating to compliance with applicable laws, regulations, and standards of conduct;
16. Overseeing any revisions to this Compliance Program as needed in response to: (i) an identified weakness in the compliance program or identified systemic patterns of noncompliance or (ii) changes in Company's business or applicable federal, state or local statutes, regulations, or binding case law; and
17. Any other duties as may be assigned by the Board of Directors or as required, ensuring that the Compliance Program meets its objectives.

### **III. WRITTEN STANDARDS OF CONDUCT, POLICIES AND PROCEDURES**

#### **A. CODE OF CONDUCT**

All Company Personnel shall be subject to and comply with the standards set forth in the Company Code of Business Conduct and Ethics (the “Company Code of Conduct”). All current Company Personnel shall receive a copy of the Company Code of Conduct. All personnel hired shall receive a copy of the Company Code of Conduct within thirty (30) days of the beginning of their employment term. All Company Personnel shall execute a statement affirming that they have received and reviewed the Company Code of Conduct. In addition, all management personnel, officers and directors shall execute a statement once a year affirming that they have reviewed the most current version of the Company Code of Conduct. These statements shall be maintained by the Compliance Officer for a period of 5 years.

## B. COMPLIANCE PROGRAM FOR SALES AND MARKETING ACTIVITIES

The Company is committed to following the highest ethical standards as well as all legal requirements in its interactions with the medical community. It is the Company policy that all Company Personnel interactions with health care professionals that are made on behalf of the Company are consistent with ethical business practices and socially responsible industry conduct. All compensation arrangements with Company sales agents are designed to comply with all applicable laws. It is the Company policy that no grants, scholarships, subsidies, support, consulting contracts, or educational or practice related items should be provided or offered to a health care professional as an unlawful inducement in order to sell, lease, recommend, or arrange for the sale, lease or prescription of its products. It is the Company’s policy that nothing should be offered or provided in a manner or on conditions that would interfere with the independence of a health care professional’s prescribing practices. The Company has adopted policies and procedures addressing legal requirements and industry standards in connection with interactions with those individuals or entities that purchase, lease, recommend, use, arrange for the purchase or lease of, or prescribe the Company’s medical technology products in the United States (“Health Care Professionals”) including the following policies and procedures designed to ensure compliance with the guidelines set forth in the OIG Compliance Program Guidance for Pharmaceutical Manufacturers (“OIG Guidance”) and the Advanced Medical Technology Association Code of Ethics on Interactions with Health Care Professionals (the “AdvaMed Code”):

### 1. COMPANY TRAINING POLICY

- a. Member-Sponsored Product Training and Education: Consistent with the OIG Guidance and the AdvaMed Code, Company Personnel may conduct informational presentations and discussions with Health Care Professionals to provide product education and training. Company Personnel may offer such programs at centralized locations in clinical, educational, conference, or other settings that are conducive to the effective transmission of knowledge. If the product training or education requires “hands on” training, the Company shall provide the training at a training facility, medical institution, laboratory, or other appropriate facility. Company Personnel shall ensure that the training staff have the proper qualifications and expertise to conduct the training. It is the

Company's policy to provide only modest meals and receptions to Health Care Professional attendees in connection with training programs, and the Company shall only provide meals that are modest in value and subordinate in time and focus to the educational or training purpose of the meeting. The Company may pay for reasonable travel and modest lodging costs incurred by attending Health Care Professionals. Company Personnel are prohibited from offering anything of value, either directly or indirectly, to a Health Care Professional for time spent listening to marketing information. Company Personnel may not, directly or indirectly, provide meals or refreshments for any person who does not have a *bona fide* professional interest in the information being shared at a meeting. Because spouses and guests are viewed as not having a *bona fide* professional interest, meals or refreshments cannot be provided.

- b. Supporting Third Party Educational Conferences: The Company recognizes that *bona fide* independent, educational, scientific or policymaking conferences promote scientific knowledge, medical advancement and the delivery of effective health care. Accordingly, the Company may provide financial support to organizations with a genuine educational purpose or function for educational conferences, consistent with all applicable laws and regulations and industry standards and guidelines, if the conference is sponsored by a national, regional, or specialty medical association; an accredited continuing medical education provider; or is a grand round or similar event. The Company may provide financial support to such an organization for events, conferences or meetings if (i) the gathering is primarily dedicated, in both time and effort, to promoting objective scientific and educational activities and discourse, and (ii) the main incentive for bringing attendees together is to further their knowledge on the topic(s) being presented. Consistent with the AdvaMed Code and the conference sponsor's guidelines, the Company may provide financial support directly to the conference sponsor to (i) reimburse the legitimate expenses for bona fide educational activities; (ii) support the conference's meals and hospitality, (iii) reimburse the costs of reasonable honoraria, travel, lodging, and meals for bona fide conference faculty members; or (iv) fund meals and receptions that are modest in value and subordinate in time and focus to the purpose of the conference. The Company prohibits providing any financial support for non-faculty Health Care Professionals attending a conference or educational meeting.

## 2. PROMOTIONAL AND MARKETING POLICY

- a. Sales and Promotional Meetings: Consistent with the OIG Guidance and the AdvaMed Code, Company Personnel may conduct informational presentations and discussions with Health Care Professionals to discuss product features, contract negotiations, and sales terms. In connection with such presentations or discussions, Company Personnel may offer occasional, modest meals or receptions in a manner conducive to the

exchange of information. The Company may pay for reasonable travel costs of Health Care Professional attendees when travel is necessary for the presentation of the information. Company Personnel are prohibited from offering entertainment or recreational activities to a Health Care Professional in association with information or marketing presentations. Company Personnel are prohibited from offering anything of value, either directly or indirectly, to a Health Care Professional for time spent listening to marketing information. Company Personnel may not, directly or indirectly, provide meals or refreshments for any person who does not have a *bona fide* professional interest in the information being shared at the meeting. Because spouses and guests are viewed as not having a *bona fide* professional interest, meals or refreshments cannot be provided.

- b. Gifts: Company Personnel may not offer cash or cash equivalents (such as gift certificates) to Health Care Professionals either directly or indirectly, except as compensation for bona fide services provided pursuant to a written agreement. Company Personnel may occasionally provide Health Care Professionals modest gifts if the gift benefits patients or serves a genuine educational function and has a fair market value of less than \$100. The Company maintains items that Company Personnel may occasionally offer Health Care Professionals that are of minimal value and are associated with the Health Care Professional's work or for the benefit of patients. The Company prohibits any of its Personnel from offering items that are intended for the personal benefit of the Health Care Professional, or any type of non-educational, branded promotional items such as pens, notepads and mugs, even if the item is of minimal value and related to the Health Care Professional's work or for the benefit of patients.

## 2. COMPANY CONSULTANT POLICY

- a. Consultant Selection and Compensation: The Company may engage Health Care Professionals to furnish *bona fide* personal services as consultants or advisers for the Company, including research, participation on advisory boards, presentations at Member-sponsored training, and product collaboration. The Company requires that each consultant enter a written contract specifying the nature of the services to be provided and the basis for payment of the services. Further, it is the Company's policy that any contract with a consultant for research services must include a written research protocol. The Company must conduct a fair market value analysis on all consulting agreement compensation arrangements. Documentation of this analysis must be attached to the consulting agreement. The Company may enter into a royalty arrangement with a Health Care Professional only where the Health Care Professional is expected to make or has made a novel, significant or innovative contribution to, for example, the development of a product, technology, processes or method. The calculation of royalties payable to a Health Care Professional in exchange for intellectual property must be based on

factors that preserve the objectivity of medical decision-making and avoid the potential for improper influence. The Company must document any significant contribution by an individual or group if it is the basis for compensation. In addition, each consultant must document the activities he or she performs at the Company's request in advance of receiving compensation, and the Company must retain such documentation. The department requesting the engagement of a consultant must clearly identify the following items to the Legal Department: (i) the legitimate need for the consulting services in advance of requesting such services, (ii) the skills and expertise required by each consultant, (iii) the number of consultants necessary to satisfy the identified need, and (iv) the Company representatives able to select consultants on the basis of their scientific or medical expertise. It is the Company's policy to select consultants on the basis of their qualifications and expertise to address the identified purpose.

- b. Consultant Training: It is the Company's policy to provide consultants with training at venues and under circumstances appropriate to the subject matter of the consultation. The Company shall conduct consultant training meetings in clinical, educational, conference, or other settings that are conducive to the effective exchange of information. The Company may reimburse the consultant for reasonable, actual and documented travel, lodging and meal expenses that the consultant incurs in connection with training or on behalf of the Company when carrying out the subject of the consulting arrangement. The Company prohibits paying honoraria, travel or lodging expenses for any non-consultant attendee.

### 3. GRANTS AND OTHER CHARITABLE DONATIONS

- a. Charitable Donations: The Company may make donations for a charitable purpose which may include, supporting genuine independent medical research for the advancement of medical science or education, indigent care, patient education, public education, or the sponsorship of events where proceeds are intended for charitable purposes. It is the Company's policy to only make donations to charitable organizations or, in rare instances, to individuals engaged in genuine charitable missions for the support of that mission. The Company prohibits making any donations for the purpose of unlawfully inducing Health Care Professionals to purchase, lease, recommend, use, or arrange for the purchase, lease or prescription of the Company's products. It is the Company's policy to maintain accurate and appropriate documentation of all donations.
- b. Scholarships and Educational Grants: If the academic or training institution is responsible for recipient selection or if the grant is paid directly to a third party conference sponsor, then the Company may provide financial assistance for scholarships or other educational funds to permit medical students, residents, fellows, and other Health Care Professionals in training to attend bona fide educational conferences. It is

the Company's policy to only provide such grants to organizations with a genuine educational purpose or function that will use the funds for legitimate expenses for bona fide educational activities consistent with relevant guidelines established by professional societies or organizations.

- c. Research Grants: The Company may provide financial support for *bona fide*, general research grants that are intended to provide valuable scientific and clinical information, improve treatment, promote better delivery of health care, or otherwise benefit patients. The Company prohibits the funding of a research grant, in any way, expressly or implicitly, if the funding is provided for the purpose of unlawfully inducing Health Care Professionals to purchase, lease, recommend, use, or arrange for the purchase, lease or prescription of the Company's products. The Company prohibits the awarding of any restricted grants or grants conditioned with respect to content or faculty.
- d. Public Education: The Company may make grants for the purpose of supporting education of patients or the public about important health care topics.

#### 4. ANNUAL DOLLAR LIMIT ON GIFTS OR INCENTIVES PROVIDED TO MEDICAL OR HEALTH PROFESSIONALS

The Company has established an annual dollar limit on gifts, promotional materials, or items or activities that the Company may give or otherwise provide to an individual medical or health professional equal to **\$500** per such individual. This annual limit does not include any amounts the Company spends for product samples, for continuing medical education forums, or for health educational scholarships.

#### 5. PRODUCT SUPPORT

It is the Company's policy to support accurate and responsible billing to Medicare and other payors by providing coverage, reimbursement and health economic information to Health Care Professionals regarding the Company's products. The Company may provide such information if it is accurate and objective to facilitate patient access to the Company's products, identify the clinical value of the Company's products and the services and procedures in which they are used, and aid in the appropriate and efficient use or installation of the Company's products in connection with the sale of the Company's products. The Company prohibits the provision of support services for the purpose of unlawfully inducing a Health Care Professional to purchase, lease, recommend, use, or arrange for the purchase, lease or prescription of the Company's products.

#### 6. EVALUATION AND DEMONSTRATION PRODUCTS

The Company may provide single use (e.g., consumable or disposable) products and multiple use products (sometimes referred to as "capital equipment") to Health Care Professionals at no charge for evaluation or demonstration purposes to allow

Health Care Professionals to assess the appropriate use and functionality of the Company's products and determine whether and when to use, order, purchase or recommend the Company's products in the future. The Company may only provide the amount of single use products at no charge that is reasonably necessary for the adequate evaluation of the Company's products. The Company may provide multiple use products without transfer of title for evaluation purposes only for a period of time that is reasonable to allow an adequate evaluation. It is the Company's policy that it will promptly remove such multiple use products from the Health Care Professional's location at the conclusion of the evaluation period unless the Health Care Professional purchases or leases the Company's products. The Company must provide Health Care Professionals with documentation and disclosure regarding the no-charge status of evaluation and demonstration products.

#### **IV. TRAINING AND EDUCATION**

The Company will provide all Company Personnel with appropriate training, as determined to be necessary. The training will focus on this Compliance Program, including applicable federal and state laws, industry standards, and the Company's Code of Conduct. The training will include specific information pertaining to the Program's application and enforcement.

- A. The Compliance Officer shall designate Company Personnel to attend training and retraining seminars to be required as part of their employment responsibilities. Attendance at training and educational sessions shall be documented by the Officer, *e.g.*, all training and agendas and sign-in sheets will be retained. Company Personnel unable to attend sessions shall be provided follow-up training opportunities. Company Personnel are required to complete **four (4)** hours of training annually. Failure to participate in required training may result in disciplinary action.
- B. The Compliance Officer will conduct, as needed, but at least annually, general compliance seminars to discuss pertinent laws and regulatory developments. In addition, the Compliance Officer shall identify all Company Personnel with significant compliance responsibilities and ensure that appropriate training and education is provided to those Personnel. For example, in consultation with legal counsel the Compliance Officer shall conduct additional seminars as needed, but at least annually, for Personnel engaged in sales and marketing activities. The Compliance Officer shall periodically create and disseminate training materials to all Company Personnel, to ensure consistency and efficiency in training. The identity of the Compliance Officer shall be stated in training materials, manuals and presentations.
- C. The Compliance Officer shall disseminate to all Company Personnel alerts regarding new rules, regulations, fraud alerts or similar compliance notices issued by relevant government or professional entities. The alerts shall be numbered and shall be kept in a binder by the Compliance Officer at the Company's corporate offices. Such Company Personnel shall be informed that they may obtain additional information regarding the pertinent laws and regulations from the Compliance Officer and legal



counsel.

- D. The Compliance Officer shall identify all Company contractors with potential compliance responsibilities and ensure that appropriate training and education is provided to those contractors.

## **V. COMMUNICATING WITH THE COMPANY REGARDING COMPLIANCE**

The identity of the Compliance Officer shall be publicized periodically in compliance training programs, employee alerts, and other materials. In accordance with this publicity, individuals and entities which are subject to the Compliance Program shall be informed of their ability to either send written reports to the Compliance Officer, supervisors, or other appropriate Company Officers (e.g., Company legal counsel) or to use the Company's Employee Hotline regarding any activity that the employee believes may be unlawful, or an infraction of this Compliance Program, including the Company Code of Conduct. Individuals shall be informed that their report, whether written or oral, may be made anonymously without fear of repercussion. It is the Company's policy that any individual who reports a compliance concern in good faith will not be subject to retaliation or harassment as a result of the report. Company Personnel are encouraged to self-report any of their own suspected violations, although self-reporting does not necessarily shield the Company Personnel from disciplinary action resulting from his or her own violation of the Compliance Program.

The Compliance Officer shall track all reports in the following manner:

- A. Implement a confidential, sequentially numbered tracking system for reports/complaints. Number and retain the oral or written employee complaints in the compliance file. A summary of this log will be provided in the annual compliance report to the Board of Directors.
- B. In concert with legal counsel, investigate the issue raised, keeping identity of reporting individual confidential if requested.
- C. Create a detailed report to corporate management regarding the report, and file the management report in the compliance file.
- D. Track the compliance file on a monthly basis to ensure that follow-up action has been taken on all outstanding complaints and concerns.
- E. Incorporate any problems that are raised into alerts, training, education programs and revisions to the Compliance Program as necessary.

## **VI. ENFORCEMENT AND DISCIPLINE**

It is the policy of the Company that the Compliance Program and Code of Conduct shall be consistently enforced through appropriate disciplinary mechanisms. Disciplinary actions may be up to and including dismissal, and may extend, as appropriate, to individuals responsible for the failure to prevent, detect, or report an offense. The Compliance Officer shall, in consultation with Company management and supervisors as appropriate, establish and administer a company-wide disciplinary system, including written disciplinary procedures, designed to produce appropriate and consistent results in disciplinary cases. The system shall provide for the

making of disciplinary decisions by appropriate officials of the Company in consultation with the Compliance Officer.

The Company will not employ or retain individuals or entities who have been excluded from participation in federal health care programs. The Company will conduct reasonable and prudent background investigations, including a reference check and the OIG Exclusion database, to ensure that Company Personnel and consultants have not been excluded or barred from participation in a federal health care program. The annual employment review of all Company Personnel and other contract renewals shall include an assessment of adherence to the Compliance Program and the Code of Conduct. A record of any discipline resulting from noncompliance with the Compliance Program or the Code of Conduct also shall be maintained, both in the compliance file and in the personnel record. Further, the immediate supervisors shall receive notice of the discipline.

## **VII. AUDITING AND MONITORING THE COMPLIANCE PROGRAM**

A. Periodic audits of the Compliance Program shall be conducted to measure the effectiveness of the program. The following steps shall be taken to determine if the Compliance Program is being implemented and understood by all Company Personnel.

1. Conduct annual audits targeting those areas identified in Paragraph VII(B) which may include without limitation, sales and marketing activities and FDA compliance issues (e.g., GMP requirements). Audits shall be performed with external or internal audit resources under the direction of legal counsel;
2. The Company shall conduct an annual internal audit to ensure that (1) there has been appropriate dissemination of the Compliance Program's standards, training and on-going educational programs, (2) the anonymous reporting system has been implemented and is properly functioning, (3) reports and complaints have been tracked and addressed, and appropriate audits have been conducted, (4) any identified actual or suspected violation of the law has been appropriately investigated, rectified and the wrongdoer disciplined, and (5) compliance issues identified in previous reports, complaints and audits have been addressed in training programs and alerts and no longer occur.
3. All audit results shall be incorporated in the training and education programs, as appropriate.

B. The Compliance Committee will establish monitoring and auditing priorities based on factors that may include:

1. Identified risk factors;
2. Industry trends;
3. Government enforcement actions;

4. Changes in statutes, regulations, or case law; or
  5. Other relevant factors as determined by the Compliance Officer.
- C. The results of all internal and external audits will be communicated to the Compliance Committee. Any significant deficiencies in the Company's Compliance Program will be reported along with recommendations for process improvement and follow-up actions.
- D. The Compliance Officer shall, by memorandum, at least annually, advise all Personnel with supervisory responsibility of their duty to monitor all activities of their subordinates in the course of their employment with the Company to ensure that those activities are conducted in compliance with all applicable laws, regulations, and standards of conduct.

### **VIII. RESPONSE TO SUSPECTED VIOLATIONS OF THE COMPLIANCE PROGRAM**

It is the policy of the Company that, if a violation of any applicable law, regulation, or standard of conduct relating to the business of the Company is detected, the Company shall take all reasonable steps to respond appropriately to the violation and to prevent further similar violations, including any necessary modifications to this Compliance Program.

- A. Whenever the Compliance Officer receives information regarding a possible violation of any applicable law or regulation, the Compliance Officer shall take appropriate steps to examine the information and verify the factual basis of a violation or suspected violation. The Compliance Officer, in consultation with the Compliance Committee and, as necessary, with Company legal counsel, shall have the discretion to determine the appropriate scope of any investigation and the necessary response. Appropriate responses to a violation or suspected violation may include, without limitation:
1. Investigating all aspects of the alleged violation;
  2. Preparing recommendations for corrective action;
  3. Considering the advisability of disclosing the incident to government entities;
  4. Formally notifying the Company's Board of Directors of the incident and the planned response.
- B. During any stage of the investigation, the Compliance Committee may, in its discretion and at the Company's expense, seek the advice and guidance of independent legal counsel. While the Compliance Committee will strive to keep all concerns and complaints confidential to the extent possible, it may seek advice and guidance from any other Company Personnel, including outside legal counsel and, if appropriate, government enforcement authorities.
- C. Results of each investigation, including any corrective action taken, shall be documented and maintained by the Compliance Officer. Any matter that is

communicated to the Compliance Committee but which, after investigation, is determined not to be appropriate for processing through the Compliance Program will be referred to the appropriate department for resolution.

## **IX. COMPLIANCE PROGRAM REVISION**

This Compliance Program will be modified as needed to address new laws, regulations, or other binding matters that affect the Company's compliance. The Company is committed to continuous improvement of its operations to adapt to changes in the health care industry. The governmental and industry standards as well as the laws and regulations applicable to Company's operations are dynamic and complex. Moreover, the Company's business operations may change and expand in the future. The Compliance Program is designed to enable the Company to adapt to these changes and maintain constant compliance with these standards, laws and regulations. Accordingly, the Compliance Program is subject to regular review and updating as appropriate to stay abreast of these changes. The Company shall ensure that any necessary revisions are made to the Compliance Program within six months of an update or a revision to the OIG Guidance or the AdvaMed Code. All Company Personnel are responsible for complying with the most current version of the Compliance Program. Each copy of the Compliance Program will specify the version of the document and the date of the most recent revision to the Compliance Program.

## **X. COMPLIANCE PROGRAM CERTIFICATION**

It is the Company's policy to adhere to this Compliance Program. The Company shall declare, in writing, that it is the intention of the Company to operate in compliance with both this Compliance Program and the requirements of Sections 119400 to 119402 of the California Health and Safety Code. The Company shall post this statement, a copy of this Compliance Program, and its Hotline Number on its website.