

BIOCEPT COMPLIANCE AND ETHICS PROGRAM

I. <u>Introduction</u>:

Biocept, Inc. ("Company") recognizes that it has an affirmative obligation to ensure that it complies with all international, federal, state and local laws and regulations as they pertain to all aspects of Company's operations and corporate existence. Such obligation includes full compliance with those laws and regulations related to the medical device and healthcare industry, such as the Anti-Kickback Statute in the United States that prohibits remuneration in exchange for referrals. Understanding this obligation, Company, by resolution of its Board of Directors authorized the creation of *The Biocept Compliance and Ethics Program* (the "Program"), a compliance program containing the seven elements of an effective compliance program as described in the United States Federal Sentencing Guidelines and consistent with the draft compliance program issued by the Office of Inspector General of the Department of Health and Human Services in 1998.

This Program applies to the following individuals: (i) all officers, directors, and employees of Company; and (ii) all contractors, subcontractors, agents, and other persons who, on behalf of Company, perform functions related to Company's business but excluding vendors whose sole connection with Company is selling or otherwise providing medical supplies or equipment to Company and who do not bill any government health care program for such items ("collectively "Employees"). Notwithstanding the above, this term does not include part-time or per diem contractors, subcontractors, agents, and other persons who are not reasonably expected to work more than 160 hours per year, except that any such individuals shall be deemed an Employee for the purposes of this Program at the point when they work more than 160 hours during the calendar year.

The Company has invested, and continues to invest, the necessary time, energy, and resources in maintaining this Program and Company's Board of Directors, executive and senior management and all other officers and managers provide the appropriate ethical leadership to Company and its Employees.

II. <u>Designation of a Compliance Officer and a Compliance Committee:</u>

A. <u>Compliance Officer</u>. Company has selected a specific individual within high-level personnel to oversee the implementation of the Program. This individual is designated as the Compliance Officer ("CCO") and has direct access to Company's Chief Executive Officer, Board of Directors and other senior management. The CCO, or his or her designee, shall chair the Compliance Committee.

The primary responsibilities of the CCO, which may be performed by the CCO or his or her designee, include, but not be limited to, (i) overseeing and monitoring the implementation of the Program; (ii) reporting on a regular basis to Company's Board of Directors ("Board"), Chief Executive Officer and Compliance Committee on the implementation of the Program, recommendations regarding methods to improve Company's efficiency and quality of services

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and to reduce Company's vulnerability to non-compliance such as fraud and abuse; (iii) periodically revising the Program in light of changes in Company's needs, and in the law and policies and procedures of government and other applicable organizations; (iv) reviewing employees' certifications that they have received, read and understood the Code; (v) developing, coordinating, and participating in a training and education program that focuses on the elements of the Program, and will ensure that all relevant Employees are knowledgeable of, and comply with, pertinent international, federal, state and local standards; (vi) ensuring that independent contractors and agents who furnish products or services to Company are aware of the requirements of the Program; (vii) coordinating personnel issues with Company's Human Resources and Sales/Marketing Departments to ensure that the Cumulative Sanction Report and the General Services Administration's list of debarred contractors have been checked with respect to all Employees; (viii) assisting Company's financial management in coordinating internal compliance review and monitoring activities, including annual or periodic reviews of appropriate departments; (ix) independently investigating and acting upon matters related to compliance, including the coordination of internal investigations and any resulting corrective actions; (x) developing policies and procedures that encourage Employees to report suspected fraud and other improprieties without fear of retaliation; and (xi) continuing the momentum of the Program and the accomplishment of its objectives long after the initial years of implementation.

The CCO, or his or her designee, is authorized to review all documents and other information relevant to compliance activities, including but not limited to, patient records, product records, financial records, the records concerning the sales/marketing efforts of Company, all arrangements between Company and Employees, suppliers and agents.

The existence of a CCO does not diminishes or vitiates the responsibility of all Employees to comply with all applicable laws, rules and regulations or Company's policies and procedures, nor does it diminish each manager's responsibility to ensure that those persons for whom he or she has responsibility comply as well.

Compliance Committee. The Board of Directors has appointed appropriate senior executives, including the CCO, or his or her designee, to sit on a Compliance Committee (the "Committee"). The members of the Committee include individuals from the each business unit, the Legal Department and such other departments as deemed necessary. All individuals appointed to the Committee have been educated as to the requirements of the Program. The Committee's primary responsibilities include, but not be limited to, (i) analyzing Company's regulatory environment, the legal requirements with which Company must comply and specific risk areas; (ii) assessing Company's existing policies and procedures that address these risk areas for possible incorporation into the Program; (iii) working with the various departments within Company to develop standards of conduct and policies and procedures to promote compliance with legal and ethical requirements; (iv) recommending, in conjunction with the relevant departments, internal systems of control to carry out Company's standards, policies and procedures as a part of Company's daily operations; (v) determining the appropriate strategy/approach to promote compliance with the Program and detection of any potential violations, including but not limited to, Hotlines and other fraud reporting mechanisms; (vi) developing an appropriate system to solicit, evaluate, and respond to complaints and problems; and (vii) monitoring internal and external audits and investigations for the purpose of identifying



problematic and deficient areas experienced by Company and implementing appropriate corrective action and preventive action.

- C. Medical Director. Company shall appoint, and shall maintain for the term of this Program, a pathologist who is certified by the American Board of Pathology in pathology to serve as the Medical Director for the Company. The Medical Director shall be responsible for the clinical management and quality of care oversight of the Company's laboratory and any other locations affiliated with Company where pathology procedures are performed, including but not limited to performance improvement, quality assessment, safety, clinical efficacy, utilization, staff training and discipline. The Medical Director shall be a member of senior management of Company, shall make periodic (at least quarterly) reports regarding quality of care matters directly to the Board and shall be authorized to report on such matters to the Board at any time. The total amount of time devoted by the Medical Director to these tasks shall be, at a minimum, the equivalent of one full-time employee.
- Obligations of Board. The Board shall review and oversee matters related to compliance with the obligations of this Program, including compliance with U.S. federal health care program requirements At a minimum, the Board shall: (i) have a meeting at least quarterly to review and oversee the Program, including but not limited to the performance of the Compliance Officer and Compliance Committee and that the obligations of this Program are being met; and (iii) adopt a resolution, signed by each member of the Board summarizing its review and oversight of the Company's obligations under this Program At minimum, the resolution shall include the following language: "The Board of Directors has made a reasonable inquiry into the operations of the Company'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, the Company has implemented an effective Compliance Program to meet Federal health care program requirements and the obligations of the Company's Compliance Program." If the Board is unable to provide such a conclusion in the resolution, the Board shall include in the resolution a written explanation of the reasons why it is unable to provide the conclusion and the steps it is taking to revised or amend the Program to be able to make such statement.

III. Adoption of Written Standards:

A. <u>Code of Conduct</u>. Company has developed a code of ethical business conduct (the "Code") which clearly delineates Company's commitment to compliance and sets forth Company's mission, goals and the ethical standard of conduct expected from each Employee and, where appropriate, contractors and other agents.

The Code specifically informs all individuals covered by this Program regarding (i) Company's commitment to full compliance with all applicable laws, rules and regulations, including any federal health care program requirements; (ii) the requirement that all individuals covered by this Program shall be expected to comply with all applicable laws, rules and regulations, including those related to healthcare fraud and abuse, and Company policies and procedures; (iii) the requirement that all individuals covered by this Program shall be expected to report to the CCO, or his or her designee, suspected violations of any applicable law, rule or regulations, including



those related to healthcare fraud, or Company policy or procedure; and (iv) the possible consequences to both Company and those individuals covered by this Program of failure to comply with applicable laws, rules and regulations, including the federal health care program requirements and with Company's own policies and procedures and the failure to report such noncompliance; and (v) the right of all individuals to use the confidential disclosure program described in Section V of this Program, and Company's commitment to non-retaliation and to maintain, as appropriate, confidentiality and anonymity with respect to such disclosures.

The Code also includes written standards and procedures addressing a range of issues including, but not limited to, (i) healthcare fraud and abuse and dealing with healthcare professionals; (ii) prohibition of bribes, kickbacks, unlawful payments and other corrupt practices; (iii) conflicts of interest; (iv) confidential use of information; (v) employment practices; (vi) fair competition and antitrust (vii) trade compliance; (viii) environment, health and safety; (ix) sales and marketing practices; and (x) responsible use of Company assets.

The Code applies to all Employees and, when appropriate, independent contractors and agents of Company and its subsidiaries. A copy of the Code is distributed to each Employee and appropriate independent contractor who is required to acknowledge they have read it and agree to comply with its standards. Compliance with the Code is an element in the performance evaluation of all Employees.

The Code is periodically reviewed (at least annually) to determine if revisions are appropriate and is revised as necessary based on such review. Any revision of the Code is distributed within 30 days after any revisions are finalized. Each Employee is required to certify, in writing, that he or she has received, read, understood, and shall abide by the revised Code within thirty (30) days after the distribution of the revised Code.

B. <u>Policies and Procedures</u>. Company has implemented written policies and procedures regarding the operation of this Program. At a minimum, the policies and procedures address (i) the subjects discussed in the Code; (ii) appropriate documentation of medical records and billing records; (iii). quality assessment and performance improvement program, including but not limited to: (i) measuring, analyzing, and tracking quality indicators; (ii) setting priorities for performance improvement activities; (iii) tracking medical errors and adverse patient events; (iv) management and oversight of the Company's pathology service; and (v) the requirements addressed in this Program.

The policies and procedures shall be periodically reviewed (at least annually) to determine if revisions are appropriate and are revised as necessary based on such review. Any revisions to the policies and procedures are made available to the appropriate Employees within thirty (30) days after such revisions are finalized.

IV. Training and Education:

Company has instituted and maintains training and education programs designed to ensure that each appropriate Employee, including each member of the Board, is aware of all applicable international, federal and state statutes, rules, regulations, and guidelines, Company's policies and procedures and Company's commitment to compliance with these requirements.



Such training and education includes, depending upon the position and responsibilities of the individuals being trained, (i) highlights of the Program, including the duty to report misconduct; (ii) summary of the applicable fraud and abuse laws, including general prohibitions on paying or receiving remuneration to induce referrals; (iii) federal healthcare program requirements for US employees; (iv) appropriate documentation of medical and billing records; (v) quality assessment and performance improvement activities; (vi) management and oversight of pathology laboratory procedures; and (vii) other applicable rules and regulations.

Participation in such training and education programs is a condition of employment at Company and failure to comply with the training requirements results in appropriate disciplinary action, up to and including termination. The Committee has determined the minimum amount of training necessary for appropriate Employees, which is no less than one hour of training annually. All instructors are qualified to present the training and experienced enough to answer questions and coordinate discussion among those being trained. All training materials are designed to take into account the skills, experience and knowledge of the individual being trained. The CCO or his or her designee ensures that all formal training undertaken by Company is properly documented as a part of the Program. Each individual who is required to attend training shall certify, in writing, or in electronic form, if applicable, that he or she has received the required training. The certification shall specify the type of training received and the date received. Copies of certifications, along with all course materials shall be retained.

Training and education programs are conducted through live lecture, CD/DVD, video conference, computer-based or other comparable training methods. All training and education programs are periodically reviewed (at least annually) to ensure they represent the current applicable laws, rules and regulations, any issues discovered during any internal audits, and any other relevant information.

V. Confidential Communication and Disclosure Process:

Company has developed independent reporting mechanisms for Employees to report actual or suspected illegal or unethical action, such as fraud and abuse, so that Employees can feel comfortable reporting outside the normal chain of command and so supervisors or other personnel cannot conceal, divert or cover-up such reports. Company has established a confidential disclosure system ("Hotline") for use as a confidential reporting system to enable Employees or others to disclose to the CCO, or his or her designee, any practices deemed inappropriate or seek information or advice on compliance matters. Company has published such information to its Employees. The Hotline functions as an anonymous method for (i) reporting actual, potential, or suspected violations of any law, regulation, the Code or the Program; or (ii) obtaining information, or answering questions. Company maintains the anonymity of any caller, should the caller choose not to voluntarily reveal his/her identity, within the limits of the law. Callers who chose to reveal their identity are protected by Company's non-retaliation policy.

All matters reported through the Hotline or other communication sources are documented and investigated promptly. The Hotline is staffed by the CCO, or his or her designee, who are



trained in compliance issues, Company's policies and general Hotline skills and techniques. At the discretion of the CCO the Hotline may be contracted to a third party qualified to provide such services. If the information gathered, permits a determination of the appropriateness of the alleged improper practice; and provides an opportunity for taking corrective action, the CCO, or his or her designee, conducts an internal review of the allegations set forth in the disclosure and ensures proper follow-up is conducted. The CCO, or his or her designee, maintain a confidential log that records all such communications, including a summary of the matter, the status of any internal review or investigation and any corrective action taken. Such information is included in reports to the Board of Directors, the Chief Executive Officer and the Committee. The Company shall ensure that the non-retribution, non-retaliation of this Confidential Disclosure policy is emphasized to all Employees and shall ensure the reporting mechanism for anonymous communications is maintained. The Compliance Officer (or designee) shall maintain a disclosure log, which shall include a record and summary of each disclosure received (whether anonymous or not), the status of the respective internal reviews, and any corrective action taken in response to the internal reviews. The disclosure log shall be made available to OIG upon request.

VI. Enforcement and Discipline Guidelines:

Company has adopted a written policy statement included in the Code, setting forth the disciplinary action for Employees who fail to comply with the (i) Code; (ii) any international, federal, state or local law or regulation; or (iii) who have otherwise engaged in wrongdoing, which has the potential to impair Company's status as a reliable, honest and trustworthy medical device manufacturer.

The CCO, or his or her designee, in conjunction with the Human Resources Department, has developed appropriate sanctions and disciplinary guidelines setting forth the degrees of disciplinary action that may be imposed upon Employees for failing to comply with the Code. Intentional or reckless noncompliance subjects the transgressor to significant sanctions, ranging from oral warnings to suspension, financial penalties or termination, as appropriate. Disciplinary action is warranted in situations where, due to an Employee's negligence or reckless disregard, the Employee fails to detect a violation. The consequences of noncompliance is consistently applied and enforced.

VII. Dealing with Excluded or Convicted Persons or Entities:

Company does not knowingly employ or contract with, with or without compensation, an individual or entity who (i) is listed by a US governmental agency as debarred, suspended, excluded or otherwise ineligible to participate in government healthcare programs or non-procurement programs; (ii) has been convicted of a criminal offense that falls within the ambit of 42 U.S.C. § 1320a-7(a), but has not yet been excluded, debarred, suspended, or otherwise declared ineligible; (iii) appears on an exclusion lists" include, including but not limited to, the HHS/OIG List of Excluded Individuals/Entities (available through the Internet at http://www.oig.hhs.gov); or the General Services Administration's List of Parties Excluded from Federal Programs (available through the Internet at http://www.epls.gov); or (iv) Company is otherwise prohibited from employing due to any applicable law, rule or regulation.



For all new Employees who have discretionary authority to make decisions that may involve compliance with the law or compliance oversight, Company conducts a reasonable reference check, as a part of every employment application. The employment application specifically requires the applicant to disclose any criminal conviction, as defined by 42 U.S.C. Section 1320a-7(i), or exclusion action. Pending the resolution of any criminal charges or proposed debarment or exclusion, any individual who is the subject of such actions is removed from direct responsibility for or involvement in any government healthcare or procurement program. Company terminates the employment of any current Employee, or terminates its contractual arrangement with any individual or contractor, who is convicted, debarred, suspended or excluded.

Company shall verify the information contained herein prior to the hire or engagement of any Employee, within ninety (90) after hire and/or engagement and shall verify such information on an annual basis.

Should an Employee that, subsequent to employment or engagement, becomes ineligible or face pending charges that may result in an Employee becoming ineligible as described above, the Company shall remove such Employee from responsibility for, or involvement with, Company's business operations related to the government health care programs and shall remove such Employee from any position for which the Employee's compensation or the items or services furnished, ordered, or prescribed by the Employee are paid in whole or part, directly or indirectly, by a government health care programs or otherwise with government funds at least until such time as the Employee is reinstated into participation in the government health care programs.

VIII. Monitoring and Auditing of the Program:

Company conducts regular audits of the Program using appropriate personnel. The CCO, or his or her designee, has determined the frequency, scope and manner of such audits. Compliance reports created by these audits, including those reports of suspected noncompliance, are maintained by the CCO, or his or her designee, and shared with Company's Board of Directors, Chief Executive Officer, senior management and the Committee. The audits focus on the Program, including the external relationships with third-party contractors, specifically those with substantial exposure to government enforcement actions and, at a minimum, address Company's compliance with the laws governing kickback arrangements, physician self-referral prohibition, and marketing. In addition, such audits focus on any area of concern that has been identified by any entity, whether international, federal, state or internal.

As a part of the monitoring and audit process, the CCO, or his or her designee, utilize such techniques as (i) assessment of existing relationships with physicians, hospitals and other potential referral sources; (ii) unannounced surveys, audits or investigations; (iii) reevaluations of deficiencies cited in past surveys/audits; (iv) review and examination of the compliance logs; (v) interviews with personnel involved with management, operations, sales and other related activities; and (vi) review of expense reports and accounts payables.



On an annual basis certain Employees annually certify, in writing or electronically, that to the best of the Employee's knowledge, Company is compliant with applicable laws, rules, regulations, the Code and Company's policies and procedures.

IX. Responding to Detected Matters and Developing Corrective Action Initiatives:

Upon receipt of a disclosure or other information of an actual or suspected violation, the CCO, or his or her designee, shall gather all relevant information from the disclosing individual or other sources. The Compliance Officer (or designee) shall make a preliminary, good faith inquiry into the allegations set forth in every disclosure to ensure that he or she has obtained all of the information necessary to determine whether a further review should be conducted. For any disclosure or information that is sufficiently specific so that it reasonably: (i) permits a determination of the appropriateness of the alleged improper practice; and (ii) provides an opportunity for taking corrective action, the CCO, or his or her designee, promptly investigates the conduct in question to determine whether a material violation of applicable law or the requirements of the Program has occurred. If a determination is made that such a violation has occurred, the CCO, or his or her designee, takes all appropriate steps, which may include an immediate referral to criminal and/or civil law enforcement authorities, a corrective action plan, a report to the government, if applicable.

Upon completion of the investigation of any detected matter, should the CCO have reason to believe that Company has materially violated any criminal, civil or administrative law, Company promptly reports the existence of such noncompliance to the appropriate governmental authorities within a reasonable time, but not more than sixty (60) days.

Records of any investigation include documentation of the alleged violation, a description of the investigative process (including the objectivity of the investigators and methodologies used), copies of interview notes and key documents, a log of the witnesses interviewed and the documents reviewed, the results of the investigation and any corrective action taken. The CCO, or his or her designee, takes all necessary action to maintain the integrity of any investigation and prevent the destruction of documents or other evidence relevant to the investigation.