



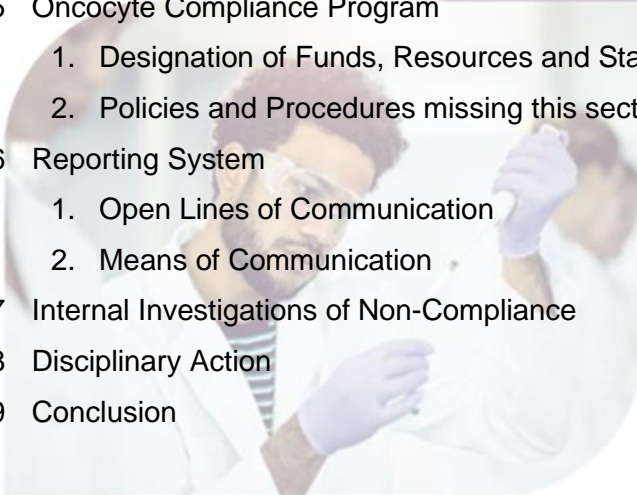
# CORPORATE COMPLIANCE CHARTER & PROGRAM

As of January 2021



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## Corporate Compliance Charter & Program

### 1. Introduction

Oncocyte Corporation (the “Company” or “Oncocyte”) is committed to compliance with all applicable laws and regulations and the highest standards of corporate integrity. The purpose of this Charter is to establish processes to ensure that there is a committed compliance organization within Oncocyte. Accordingly, Oncocyte has established and will maintain an effective compliance program (“Compliance Program”) in accordance with the “Compliance Program Guidance for Pharmaceutical Manufacturers” published by the Office of Inspector General of the US Health and Human Services (“OIG Guidance”), which has been recognized as applying in relevant part to diagnostic and other life science companies, as well as abiding by the principles set forth in the Advanced Medical Technology Association Code of Ethics (“AdvaMed Code”). The Compliance Program is a central component of the Company’s commitment to fostering a culture of compliance where integrity is the bottom line.

The Compliance Program is designed to ensure compliance with all applicable laws, regulations, mandates, and applicable industry standards. Our Board of Directors oversees and fully supports the Compliance Program and has established procedures to ensure that it will receive regular reports and updates from the Company Compliance Committee (“Compliance Committee”) regarding all compliance related matters.

The OIG Guidance sets forth the US federal government's views on the value and fundamental principles of compliance programs and is regarded as the key guidance for the life sciences industry, including diagnostic and medical technology companies such as Oncocyte. The OIG Guidance establishes specific elements that companies should consider when developing and implementing an effective compliance program, including: (1) policies and procedures; (2) compliance personnel; (3) training and education; (4) communication; (5) auditing and monitoring; (6) incentives and enforcement; (7) corrective action; and (8) Board oversight & risk assessment. The OIG Guidance is a major benchmark regarding the government's efforts to prevent and reduce fraud and abuse in the sales and marketing activities of life sciences companies.

While the primary purpose of the Compliance Program is to prevent and detect violations of applicable laws, regulations, or Company policies, implementation of such a program cannot guarantee that all improper conduct will be eliminated. However, it is the Company’s unconditional expectation that all employees will comply with applicable laws, regulations, and policies established in support of the Compliance Program. If the Company becomes aware of any violations of applicable laws, regulations, or Company policies, we will investigate the matter and, where appropriate, take disciplinary action and implement corrective measures to prevent further violations.

The fundamental elements of the Compliance Program are outlined below, which are aligned with the AdvaMed Code, policy considerations and specific requirements of the OIG Guidance and the recent Department of Justice (“DOJ”) guidance issued in



June 2020 that outlines key considerations for an “effective” compliance program. Consistent with the DOJ and OIG Guidances, the Compliance Program is tailored to fit our specific needs and environment and will be regularly reviewed and enhanced to meet evolving compliance needs.

## **2. Scope**

The Compliance Program governs all of Oncocyte’s activities and employees irrespective of jurisdiction and territory in which they may operate, as well as third parties acting on the Company's behalf. Employees are responsible for being aware of and understanding Oncocyte’s policies and procedures and are responsible for attending and completing all required training in connection with those policies and procedures.

## **3. Compliance Officer & Compliance Committee**

Oncocyte’s Code of Business Conduct & Ethics (“Code of Conduct”) represents the Company’s statement of ethical and compliance principles that guide our operations. The Code of Conduct sets forth the basic principles, values, and framework for action within the Company, and it establishes Oncocyte’s expectations that management and employees of the Company will act in accordance with all applicable laws, regulations, and Company policies and will foster a culture of compliance across the Company.

The OIG Guidance identifies several risk areas and has urged companies to develop compliance policies to address these risk areas. These risk areas include: (i) data integrity pertaining to government reimbursement practices, (ii) kickbacks and other illegal remuneration, and (iii) compliance with laws regulating drug samples. To that end, Oncocyte has adopted policies and procedures designed to address the specific risk areas identified in the OIG Guidance, as well as other risk areas relevant to our specific business activities. These policies and procedures are provided to all employees who are affected by them.

### **3.1. Chief Compliance Officer**

#### **3.1.1. Appointment**

Oncocyte has established the role of Chief Compliance Officer (“Compliance Officer”) with authority and responsibility for the development, implementation, enforcement, and monitoring of the Compliance Program. This role may be the designated person’s sole duty or in addition to other responsibilities, provided that those additional responsibilities do not materially impede the Compliance Officer's compliance responsibilities. The Compliance Officer shall have direct access to Oncocyte’s Board of Directors, CEO, other members of senior management and legal counsel.



### **3.1.2. Authority**

The Compliance Officer is authorized to recommend change within the organization as necessary and appropriate within the scope of the Compliance Program, and to exercise independent judgment in this function. The Compliance Officer has the authority to review all documents and other information relevant to compliance activities. The Compliance Officer shall serve as chair of the Compliance Committee (set forth below), and will carry out his or her responsibilities, as defined in Section 3.1.3, with the advice and input of the other members of the Compliance Committee. As the chair of the Compliance Committee, the Compliance Officer may delegate duties to individual members of the Compliance Committee or to the Compliance Committee as a whole, provided that he or she supervises the delegated responsibilities.

### **3.1.3. Responsibilities**

The Compliance Officer shall be primarily responsible for the operation of the Compliance Committee and oversight of the Oncocyte Compliance Program. The Compliance Officer, with the assistance of the Compliance Committee (as detailed in Section 3.2), shall be responsible for the development, implementation, maintenance, monitoring and promotion of compliance consistent with company policies and all laws and regulations. The specific responsibilities of the Compliance Officer include, but are not necessarily limited to, the following:

- 3.1.3.1. Overseeing, monitoring, and maintaining the implementation and effectiveness of the Compliance Program;
- 3.1.3.2. Monitoring changes, clarifications and updates to the legal and regulatory requirements and policy guidance relating to the corporate compliance aspects of marketing, sales, pricing, distribution, coverage, and reimbursement of Oncocyte products;
- 3.1.3.3. Developing, reviewing, and/or updating as necessary department-specific compliance policies and procedures to address existing and new compliance risk areas;
- 3.1.3.4. Reporting on a regular basis to the CEO and the Board of Directors on compliance matters, including corporate compliance risk areas, and establishing methods for reducing the Company's vulnerability to fraud and abuse;
- 3.1.3.5. Developing, conducting, and/or overseeing annual and as-needed compliance training for Oncocyte personnel;
- 3.1.3.6. Coordinating personnel issues with the People and Culture Department (to the extent that there is a compliance-related issue);





- 3.1.3.7. Coordinating routine and ad hoc internal and external compliance reviews and/or audits to monitor Oncocyte compliance efforts and ensure continued adherence to compliance policies, or working with consultants and/or outside vendors to ensure compliance;
- 3.1.3.8. Reviewing, in consultation with legal counsel, any new Oncocyte business arrangements, particularly those involving the commercial team and a healthcare professional and/or a federal health care program, to ensure that they comply with applicable laws, regulations, and policies;
- 3.1.3.9. Responding to – and documenting – employee and contractor corporate compliance questions and inquiries;
- 3.1.3.10. Investigating and responding to reports of non-compliance, including working with relevant members of the Compliance Committee and the People and Culture Department to implement corrective measures and take appropriate disciplinary action; and
- 3.1.3.11. Recommend modifications and amendments to the Compliance Program to Oncocyte’s CEO and Board of Directors, as appropriate, to reflect: (a) changes, clarifications, or updates in applicable laws, regulations, and policies; (b) changes in the nature or scope of Oncocyte’s business, including, but not limited to, new or expanded lines of business, new or expanded geographical presence, and new or expanded contractual obligations; or (c) if existing policies or procedures appear to have been ineffective in preventing compliance violations or where new or additional policies and procedures would be more effective in promoting best practices and preventing or avoiding future misconduct.

## **3.2. Compliance Committee**

### ***3.2.1. Creation of the Compliance Committee***

Oncocyte has also established a Compliance Committee (“Compliance Committee”). The role of the Compliance Committee is to ensure the Compliance Officer and Compliance Program are appropriately informed and take into account the specific and unique circumstances of Oncocyte’s business and risks. Accordingly, the Compliance Committee shall advise and assist the Chief Compliance Officer in the implementation of the Compliance Program. In addition to the Compliance Officer, the Compliance Committee shall be comprised of persons representing core departments and disciplines across the Company and who shall be of sufficient seniority to represent their respective departments’ views and cause change as necessary. The Compliance



Committee shall comprise representatives of the following functions or departments within the Company:

- Legal / Regulatory
- People and Culture
- Medical Affairs
- Commercial
- Finance
- Other ad hoc members as determined by the Compliance Committee

The Compliance Committee will meet quarterly, or more frequently as needed to ensure all elements of the Compliance Program are implemented and operating optimally.

Depending on the nature of the compliance matter, some Committee Members may be excluded from ad-hoc Compliance Committee meetings or compliance discussions, as determined by the Compliance Officer. The Compliance Committee reports at least semi-annually through the Compliance Officer to the Board of Directors on the state of the Compliance Program (although the Compliance Officer may report to the Board of Directors at any time as needed or as requested by the Board.).

### **3.2.2. Committee Members**

- 3.2.2.1. The members of the Compliance Committee (“Committee Members”) shall have a variety of skills and backgrounds, and may have additional responsibilities at Oncocyte; however, any additional responsibilities should not materially impede the Committee Members' compliance responsibilities. If a Committee Member reasonably believes that a potential conflict exists or may arise between the Committee Member's compliance responsibilities and his or her other responsibilities, the Committee Member must recuse himself or herself from further participation in the Compliance Committee regarding the specific matter causing the conflict. If a Committee Member recuses himself or herself, the Compliance Officer may appoint a temporary Committee Member from the recused representative's department to address the specific matter(s) requiring the recusal, provided that the Compliance Officer exercises due care in minimizing the potential for continuing conflict.
- 3.2.2.2. When necessary, the Compliance Committee may invite other employees of the Company to address particular issues on an ad hoc basis.



- 3.2.2.3. All Committee Members must be well-versed in compliance matters and must have completed training on the policies and procedures of the Oncocyte Compliance Program, as well as how to discharge their duties.

### ***3.2.3. Scope of Authority***

Committee Members are expected to exercise independent judgment and to be able to effectuate change that will further Oncocyte's compliance efforts and initiatives.

The scope of the Compliance Committee includes the authority to conduct the review of and provide advisory support for the following actions:

- Development, oversight, and maintenance of policies and procedures that directly or indirectly relate to functioning of Oncocyte's Compliance Program, including but not limited to the Compliance Policies, the Code of Conduct, and attendant Compliance Program Policies and Standard Operating Procedures;
- Oversight of investigations or allegations that may implicate federal or state fraud and abuse statutes or regulations, including but not limited to, a False Claims Act or Anti-Kickback Statute violation, or any other law or regulation;
- Development of risk assessments for the Compliance Committee;
- Evaluation of variances or exceptions to any Company policy or procedure;
- Attestations to the various states, countries, and the federal government regarding the Compliance Program, including but not limited to certain promotional and clinical spend (transfer of value) disclosures to physicians and teaching hospitals as defined by the regulations;
- Day-to-day oversight and implementation of the Oncocyte Compliance Program; and

### ***3.2.4. Responsibilities***

- 3.2.4.1. The Compliance Committee shall advise the Compliance Officer and assist in the creation, maintenance, and implementation of the Compliance Program, as necessary. The Compliance Committee is responsible for aiding the Compliance Officer, as requested, in carrying out the responsibilities outlined in this Charter.





- 3.2.4.2. Committee Members shall regularly review applicable laws and regulations, guidance documents from state and federal agencies, and recent enforcement actions that are relevant to their respective departments. When deemed warranted by a Committee Member and/or the Compliance Officer, the Committee Member shall work with the Compliance Officer to adopt, revise, and monitor procedures, policies, and protocols for the applicable Oncocyte department.
- 3.2.4.3. The Compliance Committee's duties shall also include advisory support of the Compliance Officer in:
- Understanding the regulatory environment in which Oncocyte operates, as well as the legal requirements with which the Company must comply and Corporate Compliance risk areas specific to Oncocyte's business;
  - Developing and revising documents for the Corporate Compliance Program, including corporate compliance policies that address specific risk areas;
  - Monitoring internal and external audits and investigations for the purpose of identifying Corporate Compliance concerns within Oncocyte and implementing corrective and preventive action;
  - Recommending and monitoring, in conjunction with the relevant departments, the development of internal systems and controls to carry out Oncocyte's Corporate Compliance Program;
  - Developing the appropriate strategy and approach to promote development of the Compliance Program, including the development of tools and processes to facilitate the detection of any potential compliance violations, such as hotlines and fraud reporting mechanisms; and
  - Annually updating Oncocyte's Board of Directors of Compliance Committee activities, recommendations, and any other work product or items of importance as determined by the Compliance Committee.

### **3.2.5. Committee Meetings**

- 3.2.5.1. The agenda and all associated documents for Compliance Committee meetings shall be prepared and distributed in writing or electronically in sufficient time to allow the Committee Members to read the documents prior to the meetings;
- 3.2.5.2. Each member of the Compliance Committee shall have one equal vote on all matters. The goal, though not a requirement, is to have decisions made by unanimous consent and all Committee Members shall strive



to meet this objective.

3.2.5.3. Committee Members shall treat information presented or distributed in connection with Compliance Committee meetings as confidential to the Compliance Committee and shall refrain from discussing any matter related to the Compliance Committee outside of the established process or using information obtained in their capacity as Committee Members other than for the purpose for which that information was originally collected.

3.2.5.4. The Compliance Officer shall designate a non-Committee Member to record minutes of each Compliance Committee meeting. In addition, each Committee Member shall be responsible for the following:

- Attending Compliance Program training for Committee Members;
- Reading the Compliance Committee meeting agenda and all associated documents in advance of the Compliance Committee meeting;
- Attending the Compliance Committee meetings and being prepared to discuss the agenda items based on his or her general business knowledge and area of expertise;
- Attending ad hoc meetings – either in person, via telephone and/or electronically – that are called by the Compliance Officer to address issues requiring immediate attention;
- Ensuring that the Compliance Program of the Company is being managed in a manner that is consistent with all applicable laws, regulations, and Company policies;
- Promoting an organizational culture at the Company that encourages ethical conduct and a commitment to compliance with all applicable laws, regulations, and Company policies;
- Periodically reviewing legal and regulatory developments in areas of compliance that may impact the Company;
- Reviewing, at least annually, this Charter and submitting proposed changes, if any, for approval;
- Periodically endorsing areas of focus for development of policies and procedures, training, audits, and other controls based on external trends, an annual risk assessment, and emerging audit findings; and



- Ensuring that information about the Compliance Committee and its role at the Company is adequately communicated to all employees and that relevant employees are adequately trained regarding the operations and rules of the Compliance Committee.

### **3.3. Training and Education**

#### **3.3.1. Oversight of Training**

- 3.3.1.1. The training and education of Oncocyte's employees on their legal and ethical obligations under applicable laws, regulations, and Company policies is a critical element of the Company's Compliance Program. To that end, the Company is committed to regularly communicating its standards, policies, and procedures to all affected personnel. Additionally, the Company will regularly review and update its training programs, as well as identify additional areas of training as needed based on new developments.
- 3.3.1.2. The Compliance Officer is responsible for coordinating, implementing, and monitoring the effectiveness of compliance training for Oncocyte personnel. The Compliance Committee will review and approve all training materials on a regular basis to ensure that the materials reflect any change in the US federal healthcare program requirements, and applicable federal and state laws and regulations, other countries' laws and regulations, and industry standards.
- 3.3.1.3. The Company shall keep records of all colleague training. These records shall include descriptions of the training sessions, copies of the materials distributed at the training session, and a list of Oncocyte personnel that have completed each training session.

#### **3.3.2. General Training**

The Compliance Officer, in consultation with the Compliance Committee, shall establish, and revise from time to time, as necessary, courses of compliance training for employees ("General Compliance Training"), which will include a discussion of the Oncocyte Compliance Program, written standards and codes of conduct and ethics, and applicable legal and regulatory requirements. General Compliance Training, either live or electronic, must be undertaken by each colleague no less than once per calendar year.

#### **3.3.3. Specific Training**

Oncocyte provides targeted training in key risk areas to those employees whose job functions implicate those risk areas, such as employees in medical affairs, marketing,



sales, etc. The Compliance Officer, in conjunction with applicable Committee Members, will determine if specific training is necessary for certain Oncocyte personnel based on their responsibilities and will oversee the development of training materials to address those specific needs.

### **3.4. Audits**

#### ***3.4.1. Risk Areas and Monitoring***

The Compliance Program includes ongoing efforts to monitor, assess, audit and evaluate the effectiveness of the Compliance Program itself, including the Company's policies and procedures, training programs, lines of communication and other components. The Compliance Officer, in consultation with the Compliance Committee, shall identify compliance risk areas or matters that require further investigation and ensure that those areas are subjected to internal and/or external audits. The Compliance Officer, or a Committee Member designated by the Compliance Officer, shall be responsible for overseeing all compliance audits and ensuring that all such audits are conducted in accordance with applicable Company policies and procedures.

#### ***3.4.2. Audit Policy and Procedures***

Audits and monitoring of Oncocyte policies and procedures shall be undertaken on a regular basis. The extent and/or frequency of audits may change depending on factors such as newly identified high risk areas, changes in business practices, or changes under the law. The Compliance Officer, or a designated Committee Member, shall document all ongoing monitoring. The Compliance Officer sets and executes auditing and monitoring priorities each year based on an assessment of Oncocyte departments and which practices constitute high-risk areas. All audits should determine whether Oncocyte policies cover the identified risk areas, whether appropriate policies were implemented and communicated to Oncocyte personnel, and whether those policies were followed.

#### ***3.4.3. Audit Results***

The Compliance Officer, in consultation with the Committee shall consider and respond to all results, conclusions, and reports resulting from an internal or external audit. The Compliance Committee must review the internal or external audit reports to identify problem areas or patterns that may require attention. The Compliance Officer must then present the CEO, and if appropriate the Board of Directors, with the results, conclusions, and reports resulting from any internal or external audit, as appropriate. Auditing and monitoring results may be used to recommend changes in Oncocyte's business practices or policies and procedures.

### **3.5. Compliance Program Resources**

#### ***3.5.1. Designation of Funds, Resources and Staff***



The Compliance Officer, in consultation with the Compliance Committee, shall annually prepare and submit to the CEO a proposal for funds, resources, and staff to maintain the Company's Compliance Program. The Compliance Officer is responsible for overseeing the allocation of funds, resources, and staff dedicated to the Compliance Program and its initiatives.

### **3.6. Reporting System**

#### ***3.6.1. Open Lines of Communication***

Oncocyte is committed to fostering dialogue between management and employees through multiple channels. Employees should know where and to whom to turn when they are seeking answers to ethical questions or reporting potential instances of fraud and abuse, or other potential violations of applicable law, regulations, or Company policies. Employees should feel free to make these inquiries or reports without fear of retribution.

To facilitate these goals, Oncocyte expects its managers to maintain an open-door environment, and will not tolerate retaliation by any colleague against another colleague for good faith reports of potential violations of laws, regulations, or Company policies.

#### ***3.6.2. Means of Communication***

Oncocyte adheres to an open-door policy and encourages all employees to discuss with their manager, Corporate Compliance, Legal, or People and Culture Departments any compliance issues, concerns, problems and/or suggestions without fear of retaliation and with the assurance that the matter will be kept as confidential as possible.

Each colleague has a Duty to Act – meaning, if a colleague sees, hears, or knows about a potential violation, they have a duty to report the information – by reporting suspected compliance violations to the Chief Compliance Officer, or via one of the methods listed below:

- E-mailing the Compliance Office directly at [Compliance@oncocyte.com](mailto:Compliance@oncocyte.com)
- Calling the toll-free Compliance Hotline/Helpline at 844-420-0044
- E-mail: [reports@lighthouse-services.com](mailto:reports@lighthouse-services.com) (must include company name with report)
- Website: [www.lighthouse-services.com/oncocyte](http://www.lighthouse-services.com/oncocyte)

The Compliance Hotline/Helpline allows for confidential reporting of suspected non-compliance or violations of the Oncocyte Compliance Program, Oncocyte's standards of conduct, or any other law, regulation, or Company policy. The Hotline/Helpline is staffed by independent third-party personnel and is available 24 hours a day, 7 days a week.



### **3.7. Internal Investigations of Non-Compliance**

Violations of any applicable laws, regulations, or Company policies threaten the Company's status as a reliable, honest, and trustworthy participant in the health care industry. Therefore, Oncocyte is committed to investigating any suspected violations of applicable laws, regulations, or Company policies in a manner designed to promptly, thoroughly, and accurately ascertain the facts and to determine the underlying cause or causes of any substantiated, non-compliant conduct. Such investigations will assess whether the non-compliance is due to any gaps in Oncocyte's policies or internal controls, and the Company will take appropriate action to address any gaps so as to prevent future violations. The Compliance Officer or designee, in consultation with the Compliance Committee, as appropriate, will direct investigations of suspected non-compliance and document the nature and results of such investigations

### **3.8. Disciplinary Action**

The Company is committed to taking reasonable and consistent disciplinary action to address compliance violations and deter potential future misconduct. Disciplinary action for noncompliance may include oral or written warnings, remedial compliance training, suspension or termination of employment, or other sanctions, as appropriate.

### **3.9. Conclusion**

Oncocyte's Compliance Program, including all relevant policies and procedures adopted in furtherance of the program, is part of the Company's commitment to honest and ethical business dealings and corporate responsibility. Your commitment to the letter and spirit of the Compliance Program is critical to the overall success of the Company, and your efforts in that regard are appreciated as we strive to develop innovative new tests and bring them to market to benefit the patients we serve. Together in the fight!

