



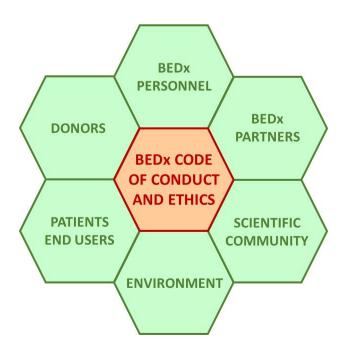
#### **STATEMENT**

Big Eye Diagnostics' MISSION is to discover new treatments and develop new diagnostics for neglected tropical diseases and other diseases that affect impoverished populations, all of which have typically been neglected by pharmaceutical research and development due to the perceived lack of profitability. To achieve this mission, Big Eye Diagnostics relies on grants and donations. This requires that the organization maintain a spotless reputation at any time and under all circumstances.

Consistent with this, the responsibility to behave in a manner that supports the achievement of our mission, and even enhances Big Eye Diagnostics' reputation, lies with all those associated with Big Eye Diagnostics and its work. In pursuing its mission, Big Eye Diagnostics is being guided by unconditional transparency, respect, accountability, integrity, and open communication.

All of us working at Big Eye Diagnostics (BEDx) have a duty of care to ensure that we always behave honestly and ethically. Any intentionally inappropriate, especially unethical, behavior has the potential to tarnish BEDx' character and reputation and thereby its mission.

" What we do is important - How we do it is just as important!"





# **SUMMARY**

We have developed this Code of Conduct and Ethics (the Code) to assist all of us working at Big Eye Diagnostics (BEDx) in fulfilling our ethical obligations. The standards in this Code call upon us to reach deep within ourselves and act with integrity, to put service before self, and to achieve excellence in all we do. It provides a strong and disciplined set of standards and guidelines to help us do the right thing. We are committed to ensuring that these standards reflect and define the operating culture within BEDx and in all interactions of BEDx with its Partners. The Code applies to all of us - please embrace the letter and spirit of the Code.

Specifically, the Code defines our best behavior in the following areas:

- 1. **Integrity:** We will fulfil our tasks with impartiality, honesty, and with personal and professional integrity at all times
- 2. **Compliance:** We will comply with our Code, the rules, and regulations of BEDx, as well as federal, state, and local laws.
- 3. **Conflict of Interest:** We will always act in the best interests of BEDx, rather than being guided by personal interest, relationship, pressure, or gain.
- 4. Transparency and Information: We will be open and candid about our activities and operations.
- 5. **Confidentiality:** We will be 100% trustworthy in protecting confidential information.
- 6. **Equality and Respect:** We will respect others and support and protect diversity. We will not tolerate any discrimination on the basis of gender identity, race, ethnicity, national origin, religion, disability status, sex, sexual orientation, marital status, pregnancy, political affiliation, or age.
- 7. **Harassment:** We will ensure that our workplace remains free from any form of harassment, and we encourage each employee to immediately report any suspected or real cases of harassment.
- 8. **Safeguarding:** We will not tolerate any form of abuse, neglect, exploitation, or violence against vulnerable groups such as children, women, and adults who are unable to protect themselves.
- 9. **Health and Safety:** We will conduct our work in a manner that protects the health and safety of all staff members, partners, visitors, and any other people with whom we interact.
- 10. **Partners:** We expect our Partners to embrace the same principles as BEDx when it comes to respecting the human rights of workers and treating employees with dignity and respect.
- 11. **Responsibility:** We will manage our resources in a responsible manner maximizing our ability to advance the mission of the organization.
- 12. **Governance and Duty:** We will govern carefully and honestly to advance the mission of BEDx and, in doing so, will unwaveringly adhere to, and report breaches of, our Code.

#### Our Commitment to Integrity

Integrity is a central value for any person or entity and means to act ethically. It is an inner compass that helps to steer each of us in the appropriate and ethical direction. It is a matter of character that helps us personally and professionally make use of such core values as honesty and apply the morals we learned when we were young. It is an organizing force that organizes and helps to regulate our impulses and appetites. It is an inner voice that urges us to act with conviction and courage even in the face of adversity.

#### Our Commitment to Excellence

Excellence is about maintaining high standards and a passion for constantly seeking to improve everything we do on behalf of BEDx. It is about personal, professional, organizational, operational, and service excellence on behalf of the communities we serve. It is about a process of improving our efforts — both



individual and collective — on an ongoing basis.



## 1. Guiding Principles, Scope, and Purpose

- 1.1. The purpose of this Code (the "Code") is to establish principles and standards of conduct that our donors¹, partners, patients and end users, members of the scientific community, and other stakeholders expect of us, and that we as BEDx Personnel should expect of ourselves. This Code helps define and understand legal issues and ethical dilemmas we may face in our work with, or on behalf of, BEDx.
- 1.2. Who has to follow this Code?
  - BEDx Personnel. This Code applies to all members of the BEDx Board of Directors, its
    officers, and its employees including affiliated offices around the world ("BEDx Personnel").
  - **Partners**. In addition, BEDx requires that third parties who work with or on its behalf, *i.e.*, consultants, agents, interns, volunteers, representatives, service providers, collaborating partners, and independent contractors (collectively, "Partners"), will meet the standards embodied in this Code or sufficiently similar codes of conduct and/or ethics of their own.
- 1.3. <u>Individual responsibilities</u>. In all our activities in support of BEDx, each of us must
  - understand this Code and become thoroughly familiar with the policies and procedures that are relevant to our individual responsibilities
  - follow these policies and procedures because compliance is the responsibility of each one of us
  - be aware of developments around us
  - promptly and appropriately raise concerns, and cooperate fully and honestly in any potential investigation
  - avoid retaliating against another person for raising an integrity concern
- 1.4. <u>Management responsibilities</u>. Managers need to embody the Code and always demonstrate appropriate conduct. They must
  - ensure that their staff understand the Code and their responsibilities
  - reinforce behaviors that reflect BEDx values and never encourage those that do not
  - create a team environment where issues can be discussed and where staff feel comfortable with raising concerns
  - ensure that communicated concerns receive proper attention, response, documentation, and are managed as described in section 12
- 1.5. <u>Collective responsibility</u>. Adherence to this Code is a matter of collective responsibility of all BEDx Personnel and Partners. As a result, when using the words "we", "us" or "our" in this Code, BEDx is referring to all persons to whom this Code applies.
- 1.6. Obligations. Each member of BEDx Personnel and Partners is required to agree to comply with this Code by signing a copy in the space provided at the end of this document and returning their signed copy to Big Eye Diagnostics' CEO. In addition, BEDx Personnel must ensure that the provisions of this Code have been communicated to, and accepted by, all Partners who receive BEDx resources. If a Partner already has a sufficiently similar code of conduct or ethics of its own, or is part of a national or international organization with its own applicable rules of conduct, BEDx will expect it to adhere to, and comply with, its own set of rules instead of this Code for as long as BEDx is collaborating with this Partner.

<sup>&</sup>lt;sup>1</sup> Many BEDx donors have policies and guidelines that are complementary to Big Eye Diagnostics' Code. Partners who are sub- recipients of BEDx grants are to consult these as well



# 2. Integrity and Ethical Standards

- 2.1. We assume professional responsibility for our actions and decisions. All BEDx Personnel and Partners must fulfil their tasks with impartiality, honesty, and integrity at all times. We must apply our professional knowledge and skills toward achieving Big Eye Diagnostics' mission and meeting Big Eye Diagnostics' objectives. In doing so, we will always:
  - be honest and impartial in our work, acting fairly, ethically, and with integrity in all dealings
  - ensure that decisions regarding individual or organizational activities are fair and transparent, and that they will be implemented in an ethical manner
  - seek expert guidance if in doubt about the propriety of a situation
  - engage only in activities or practices that support the welfare of individuals and people
  - · avoid committing any form of scientific or research misconduct
  - strive to contribute to the field of public health by providing universal access to results and information arising from Big Eye Diagnostics' work

## 3. Legal Compliance

- 3.1. All BEDx Personnel and Partners must be fully compliant with all local applicable laws. In all activities related to BEDx, we shall:
  - comply with all laws and regulations in the countries in which we operate and travel
  - never engage in, or support any form of bribery, corruption, extortion, or embezzlement
  - refrain from offering or accepting gifts and from offering or accepting entertainment (hospitality) other than of minimal value when engaging directly or indirectly in business activities relating to BEDx
  - not engage (whether directly or indirectly, or through an agent or other intermediary) in any corrupt, fraudulent, collusive, anti-competitive, or coercive practices.

#### 4. Conflicts of Interest

- 4.1. The integrity of all BEDx Personnel and Partners must always be maintained. Conflicts of interest arise when we place personal, social, financial, or political interests before those of BEDx. While we respect the right to privacy, BEDx Personnel and Partners, in their personal activities, political interests, and financial affairs, are responsible for avoiding situations that present or create the appearance of a conflict between their interests and those of the organization. Whether on the job or otherwise, nothing should conflict with our responsibilities to BEDx. By avoiding actual or apparent conflicts of interest we will be able to act according to sound judgment in the best interests of BEDx, rather than being guided by personal interest, relationship, pressure, or gain.
- 4.2. <u>Examples of potential conflicts of interest</u>. It is difficult to address every situation in which a conflict of interest may arise, but here are some that are indicative of conflictual situations:
  - Engaging in an external business activity that is detrimental to, or morally incompatible with, Big Eye Diagnostics' objectives, vision, mission, and by-laws
  - Being bound by any external employment or activity that calls into question the loyalty of the BEDx staff member or Partner, or that may prevent him/her from being able to devote appropriate time and attention to his/her responsibilities and obligations to BEDx
  - Receiving any amount of cash or anything of significant value (including inappropriate or undue entertainment beyond a normal business meal), whether as a gift or otherwise, from any individual or company with which BEDx has dealings
  - Taking advantage of or seeking to obtain personal gain from any opportunity learned of while doing any work for BEDx that could have benefited BEDx



#### 5. Accurate and Complete Information

- 5.1. In all our BEDx-related activities, we shall:
  - record and report information, including financial and non-financial information honestly, accurately, and objectively
  - accurately reflect transactions and events in any information we provide, including financial data and other information
  - create, retain, or destroy paper and electronic information in line with the applicable laws and BEDx requirements
  - not falsify records or misrepresent facts; BEDx does not tolerate any kind of fraud

#### 6. Proprietary and Confidential Information

- 6.1. We may receive access to confidential or proprietary information that is not generally known or available to the public. Neither during, nor subsequent to, our employment or collaboration with BEDx will we be permitted to disclose to any third parties any confidential or proprietary information, or any information regarding any organizational operations, projects, or activities, unless the Chief Executive Officer of BEDx authorizes such disclosure in writing. Hence, each of us must:
  - respect and protect confidential, proprietary, and/or sensitive business information and avoid divulging such information to any third party that is not bound by a written confidentiality agreement with BEDx
  - always keep confidential or proprietary information secure at our workstation and ensure the security of such information
- 6.2. How to tell if information is confidential:
  - If it is obviously marked as such: for documents or e-mails, there will typically be an indication that it is "confidential"
  - for electronically shared data: the "confidential" mark may be in the filename, and it is our responsibility to notice these things
  - If we have been told that information being shared with us is confidential: this includes phrases such as: "I am telling you this in confidence/private", or "Please do not share this information with anybody"
  - If in doubt, ask the "owner" of the information whether it can be shared or not

# 7. Equality and Respect as Core Principles

- 7.1. BEDx holds the principles and practices of Equal Employment Opportunity (EEO) and Workforce Diversity high on its corporate agenda. EEO means freedom from discrimination on the basis of protected classes such as race, color, sex, national origin, religion, age, disability, or genetic information. EEO rights are guaranteed by federal and state fair employment laws and are enforced by the Equal Employment Opportunity Commission (EEOC) and its state counterparts. The value of diversity is achieved through awareness, education, and positive recognition of the qualities, experiences and work styles that make individuals unique (e.g., age, race, religion, disability, ethnicity) within the workplace. The management of diversity establishes a business case that is closely aligned with an employer's organizational goals.
- 7.2. BEDx has an equal employment opportunity and non-discriminatory policy regarding the recruitment and treatment of all BEDx Personnel and Partners. BEDx selects staff candidates based on merit only.



- 7.3. BEDx conducts salary benchmarking and ensures external validation of merit awards, including of its CEO.
- 7.4. BEDx values the richness that diversity brings to the organization and does not abide by discrimination on the basis of gender identity, race, ethnicity, national origin, religion, disability status, sex, sexual orientation, marital status, pregnancy, political affiliation, or age. A work environment that openly values diversity and supports the full contribution of each staff member leads to increased productivity, tolerance, and mutual respect. No staff member or Partner may discriminate against any other staff member, Partner, or beneficiary of the work of BEDx.

#### 8. Harassment

- 8.1. Harassment is formally defined as "aggressive pressure or intimidation". Essentially, it is any conduct toward another person (verbal, physical, written) that makes them feel discriminated against, belittled, pressured, or threatened amongst others. Harassment is a behavior that BEDx will not tolerate and for which BEDx encourages and protects any attempt or means to report, regardless of whether it is
  - individually perpetrated or pervasive
  - a one-off event or a persistent attack
  - conducted based on race, religion, national origin, age, disability, gender or sex, amongst other "drivers".
- 8.2. BEDx does not tolerate persecution in any form. It is expected that each of us will strive to ensure that the workplace remains free from any form of harassment, and shall not subject any person to any physical, verbal, or sexual abuse, mobbing, molestation, intimidation, any form of blackmail, or threat to commit any of the above.

# 9. Safeguarding

- 9.1. BEDx respects the rights of all people, and as BEDx Personnel, we have a duty of care toward others. BEDx is deeply committed to
  - Providing a safe and trusted environment for its staff
  - Providing a structure and an escalation process that ensures that secure reporting channels are available for all levels of the organizational hierarchy.
  - Nurturing an organizational culture that accepts its accountability for the safety and well-being of others.
  - Maintaining adequate policies and procedures, such as this Code, for safeguarding Personnel, Partners, and beneficiaries of its work, and ensuring that they are well communicated, understood, and accepted.
  - Safeguarding vulnerable groups (*i.e.*, children, women, and vulnerable adults, specifically those who are unable to take care of, or protect themselves). Any form of abuse, neglect, exploitation, or violence against vulnerable groups by BEDx Personnel or Partners will not be tolerated and constitutes a violation of this Code.
- 9.2. BEDx ensures that its Personnel be trained on safeguarding and encourages its Partners that they should do the same. Online training possibilities on safeguarding are available<sup>2</sup> to each member of BEDx Personnel.

<sup>&</sup>lt;sup>2</sup> for instance, at <a href="https://agora.unicef.org/course/info.php?id=7380">https://agora.unicef.org/course/info.php?id=7380</a>



## 10. Health, Safety, and Environmental Protection

10.1. BEDx Personnel and Partners are responsible for conducting their work in a manner that protects the health and safety of all staff members, partners, visitors, and any other people with whom they interact. BEDx Personnel and Partners should always act in a manner that ensures compliance with all applicable governmental and private health, safety, and environmental requirements. While the development of entirely "green" diagnostic tests is currently unfeasible, BEDx remains committed to minimizing the impact of its activities on the environment. Product specifications that are provided to development and manufacturing partners include a requirement to use biodegradable or recyclable materials where possible, and, at a minimum, products that produce the fewest waste and health hazards.

#### 11. Practices of Partners

- 11.1. <u>Labor practices</u>: Partners of BEDx shall respect the human rights of workers and treat employees with dignity and respect. Specifically, we expect our Partners to adhere to the following requirements on labor practices:
  - Partners shall pay employees at least the minimum wage required by law or the prevailing industry standard in the country, whichever is greater, and shall provide all legally mandated benefits.
  - Partners shall not directly or indirectly recruit or employ child labor in violation of international laws or national laws of the country where the partner operates.
  - Partners shall not use forced or involuntary labor (*e.g.*, forced, indentured, or involuntary prison labor).
  - Partners shall respect the rights of employees protected by local law to join, or not join, labor unions, seek representation, and join workers' organizations.
  - Workers shall be able to bargain collectively, and workers' representatives shall not be discriminated against.
- 11.2. <u>Safety and rights of clinical trial patients and/or healthy volunteers</u>: Partners shall observe external guidelines and regulations originating in the <u>Nuremberg Code</u>, the <u>Declaration of Helsinki</u>, and the principles of current <u>Good Clinical Practice (GCP)</u> and good management practice. Specifically, we require our Partners to:
  - Ensure that only Institutional Review Board (IRB) approved protocols will be followed
  - Ensure the safety, rights, integrity, confidentiality, and well-being of clinical trial patients and/or healthy volunteers by applying proper scientific and ethical values.
  - Ensure that the interests and well-being of trial patients and/or healthy volunteers shall always prevail over interests of science, society, and commerce.
  - Ensure that all trial participants enroll voluntarily in clinical trials through appropriately provided information and freely given informed consent. Clinical trial patients and/or healthy volunteers must always be able to withdraw from trials without having to give a reason.
  - Ensure that special consideration is shown to vulnerable clinical trial patients and/or healthy volunteers (including children, elderly, unconscious, or mentally incapacitated persons).
  - Ensure that staff involved in executing clinical trials are appropriately qualified.
  - Maintain a quality system that ensures compliance with the above-mentioned guidelines and principles.



# 12. Implementation of the Code

- 12.1. Other policies and procedures. In certain cases, this Code is supplemented by additional policies that cover specific topics in more detail. While this Code is designed to familiarize us with Big Eye Diagnostics' policy position on several issues, it does not supersede or act as a substitute for other more specific policies, either internal or belonging to a donor (and requiring adherence). As an organization working closely with WHO on all of its projects, BEDx works to ensure that its ethics and conduct policies are in line with those of WHO<sup>3</sup>.
- 12.2. Recognizing a potential violation of the Code. No code can anticipate every possible question in every country or culture in which we operate. Specific questions will undoubtedly arise during our activities. Taking the time and having the courage to request from BEDx management to give appropriate answers to questions that arise is not always easy, but it is essential. When faced with such questions, we must bear in mind the spirit of this Code and recognize the need to bring them to the attention of others within the organization. At times we might sacrifice some immediate gain or benefit, but in the long run, adherence to high ethical standards benefits the organization and all our stakeholders.
- 12.3. <u>Raising questions.</u> We recognize that BEDx Personnel and some of our Partners operate in different legal and cultural environments, and that interpreting and implementing these requirements may be challenging. To improve understanding and to answer any questions, BEDx provides an annual training on its policies.
- 12.4. <u>Reporting violations</u>: Violations of this Code should immediately be reported to Big Eye Diagnostics' CEO, who will personally guarantee:
  - Anonymity and confidentiality: when you report a violation or suspected violation of the Code to the CEO, your confidentiality will be respected if you request it. The information you provide will be shared only on a "need-to-know" basis with those responsible for resolving the concern.
  - <u>Prompt action and detailed feedback</u>: BEDx management will address all reports in a timely
    and confidential manner. All reports will receive an objective and complete assessment and,
    if warranted, an investigation. In addition, corrective action will be implemented when
    appropriate, and you will have the opportunity to receive feedback.
- 12.5. <u>Prohibition of retaliation.</u> Anyone who raises in good faith a concern about a possible violation of this Code will be supported and protected by Big Eye Diagnostics' CEO and management, and will not be subject to retaliation. Any act or threat of retaliation will be considered a serious violation of the Code.
- 12.6. <u>Consequences of Code violations</u>: Any BEDx Personnel or Partners who violate this Code will be held accountable and may be sanctioned accordingly by appropriate disciplinary actions including, in severe cases, termination of Big Eye Diagnostics' relationship with that person or Partner. Such disciplinary actions could be triggered by
  - · Violations of the Code
  - Asking others to violate the Code
  - Failure to promptly raise a known or suspected violation of the Code
  - Failure to cooperate in investigations of possible Code violations
  - Disclosing confidential information regarding investigations
  - Retaliation against another person for reporting a potential violation of the Code in good faith

<sup>&</sup>lt;sup>3</sup> These can be accessed at <a href="https://www.who.int/about/ethics/">https://www.who.int/about/ethics/</a>



- 12.7. <u>Continuous improvement.</u> We are continuously examining and refining this Code, our policies, and procedures, as well as our compliance with regulatory or donor requirements. If you have a suggestion as to how to improve our controls and processes in order to detect violations of the law or BEDx policies, we encourage you to bring it to the attention of Big Eye Diagnostics' CEO through any of the previously described mechanisms. The same holds true if you believe that there is a need for additional training in any particular area, or that other areas should be covered by this Code.
- 12.8. <u>Distribution and accessibility of the Code</u>. In addition to ensuring that all BEDx Personnel and Partners have access to, and can sign, a copy of this Code, BEDx management shall ensure that a copy of it shall continuously be available via the BEDx website.

READ AND AGREED TO BY:	
Name:	Signature:
Organization:	Date:
Please return a copy of the signed Code to <a href="marco.biamonte@bigeyedx.com">marco.biamonte@bigeyedx.com</a>	