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Policy Title: Integrity Code for Interactions with Healthcare Professionals and Government Officials ("Integrity Code")

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Purpose and Background

As a company that manufactures and sells products and services for medical and research use globally, Illumina is subject to laws, regulations and rigorous standards of conduct governing its interactions with Healthcare Professionals and Government Officials. Examples of these laws and regulations include, the United States False Claims Act, United States Federal, State, and international anti-kickback laws, physician gift ban laws, laws regulating government payment systems for healthcare, as well as the U.S. Foreign Corrupt Practices Act, the UK Bribery Act and other local anti-bribery and anti-corruption laws.

Repercussions for violating these laws and regulations can include multi-million dollar civil penalties, criminal penalties, government imposed oversight and monitoring of our activities, disrupted relationships with regulators such as the U.S. Food and Drug Administration, which could impair our ability to obtain necessary regulatory clearance or approval of our in vitro diagnostic products, disruptions in our relationships with medical professionals, as well as reputational harm to the Company.

This Code establishes standards on how we at Illumina must conduct business with Healthcare Professionals and Government Officials in support of our business objectives while simultaneously ensuring our compliance with applicable laws, regulations, and standards of conduct. This Code also adheres to the principles found in various national and international medical device industry codes of conduct, including but not limited to, those of the Advanced Medical Technology Association ("AdvaMed") and MedTech Europe.

Employees that fail to comply with this Code may be subject to disciplinary action up to, and including, termination of employment in accordance with Illumina's Disciplinary Guidelines.

Scope

This Code applies to Illumina, Inc. and its subsidiaries and affiliates globally (collectively referred to as "**Illumina**"), including all of the following.

- Employees of Illumina,
- Temporary workers of Illumina, and
- Third parties working on behalf of Illumina, including for example, contractors, consultants, distributors, resale agents, marketing agencies, and meeting/event planners.

This Code applies to interactions with Healthcare Professionals ("HCPs") and Government Officials. Interactions with third parties that do not qualify as HCPs or Government Officials are governed by Illumina's *Providing and Receiving Business Courtesies Policy (CP 500.13)*.



Definitions

Term	Definition		
Entertainment	Means "an event or activity intended to entertain others."		
	Examples of entertainment include, but are not limited to, recreational activities, live music or concerts, sporting events, golf, theater, going out for drinks separate from a meal, and providing alcoholic drinks beyond a two-drink limit at any business event.		
Gift	Means "any item or in-kind benefit that is provided as an expression of appreciation or goodwill, without the obligation or expectation of anything in return."		
	Gifts are usually capable of personal use and include tangible items such as gift baskets and wine, as well as in-kind benefits such as travel and entertainment offered as a personal benefit. Travel, hotel accommodations, and meals provided as business courtesies in furtherance of legitimate business activities are not considered gifts.		
Government Official	Means "any officer or employee of a foreign government or any department agency, or instrumentality thereof, or of a public international organization, or an person acting in an official capacity for or on behalf of any such government department, agency, or instrumentality, or for or on behalf of any such pub international organization."		
	Examples of Government Officials include, but are not limited to:		
	 HCPs and non-HCPs employed by a hospital, clinic, university, research center, or other entity or institution that is fully or partially owned or funded by a government, 		
	 Elected or appointed government legislators and members of a government ministry, 		
	Political party officers and candidates for public office,		
	 Employees or individuals acting on behalf of a public international organization (e.g., IOC, World Health Organization, United Nations), 		
	Member of the military, and		
	Members of a royal family.		
Healthcare Organization	Means "any legal entity or body that is a healthcare, medical or scientific association or organization which may have a direct or indirect influence on the prescription, recommendation, purchase, order, supply, utilization, sale or lease of medical technologies or related services such as a hospital or group purchasing organization, clinic, laboratory, pharmacy, research institution, foundation, university or other teaching institution or learned or professional society (except for patient organizations); or through which one or more Healthcare Professionals provide services."		

Term	Definition		
Healthcare Professional or HCP	Is defined in the Regional Addendum for the country where the HCP is licensed or employed. For countries without a Regional Addendum , HCP means "anyone that is:		
	 Authorized or licensed to provide healthcare services to patients (e.g., physicians, nurses, pharmacists, etc.), 		
	 Involved in providing healthcare services to patients (e.g., laboratory personnel, allied health professionals such as genetic counselors, etc.), 		
	 Involved in using a medical device for human use, or 		
	 Involved in the decision to purchase, prescribe, order, use or recommend medical devices, technologies, or related services." 		
	For clarity: (1) PhDs and other academics working at an institution or university with a hospital or medical center are HCPs because they are in a position to recommend Illumina products to their clinical colleagues; and (2) patient advocates are HCPs because they are engaged by Illumina to recommend our products.		
	For purposes of this Integrity Code: (1) Any employee or temporary worker through an employment agency hired by Illumina is not considered an HCP; and (2) Except for purposes of tracking and disclosure of transfers of value, any person that is a Member of the Board of Directors of Illumina, Inc., is not considered an HCP.		
Legitimate Business Purpose	Means "a presentation, discussion, activity or event for the purpose of: (1) the exchange of scientific, technical, or educational information related to Illumina products and services, (2) promotion, demonstration or explanation of Illumina products and services, or (3) the negotiation, execution, or performance of a contract between Illumina and a third party."		
Educational Item or Medical Educational Item	Means "an item that serves a genuine educational function for an HCP or is intended for a patient, and is not capable of a non-educational, non-patient related purpose." Examples of Medical Educational Items include medical or genomics textbooks, journal reprints, and prenatal due date and screening test calculators. Examples of items that do not qualify as Medical Educational Items include office supplies, headphones, scrubs, and iPads.		
Promotional Item	Means "a professional-use item that is intended for the promotion of Illumina's products (e.g., Illumina branded items used in an office setting such as pens, mugs, backpacks, phone cases, notepads, calendars, diaries, and computer accessories for business use) or relates to an HCP's practice" (e.g., clinical items such as wipes, nail brushes, surgical gloves).		
Transfer of Value	Means "a transfer of any form of value or benefit, tangible or intangible, from Illumina to a Healthcare Professional, Healthcare Organization, or Government Employee." A Transfer of Value can be made directly from Illumina or indirectly via an intermediary and can be monetary (such as a fee for service) or non-monetary (such as a gift, meal, travel/accommodations, and no charge products or services).		

References and Related Policies

Policy or Document Title	Policy or Document Number
Illumina Code of Conduct	CP 500.01
Anti-Bribery and Anti-Corruption Policy	CP 500.05
Providing and Receiving Business Courtesies Policy	CP 500.13
Grants and Collaborations Policy	CP 500.14
Global Travel and Expense Reimbursement Policy	CP 200.14
Sponsorship Policy	CP 600.03
Corporate Donations Policy	CP 900.01

Policy

- **1** General Requirements for all Interactions with and Transfers of Value to HCPs and Government Officials
 - When interacting with HCPs and Government Officials, Illumina employees must follow this Code, as well as any requirements, limitations, or prohibitions contained in the Regional Addenda for Interactions with HCPs and Government Officials ("Regional Addenda") for the countries where the HCPs/Government Officials are licensed or employed. If a requirement in the applicable Regional Addendum conflicts with the requirements in this Code, the requirement in the Regional Addendum applies. The Regional Addenda are attached as <u>Appendix 1</u> to this Code.
 - All Transfers of Value to HCPs and Government Officials must serve or be directly related to a Legitimate Business Purpose. Transfers of Value may not be solely intended for relationship building or "goodwill."
 - Illumina may not provide a Transfer of Value that is intended to be, or that could reasonably be interpreted as, a reward for business or an attempt to gain preferential treatment or an unmerited or unfair advantage.
 - Illumina may not provide a Transfer of Value to anyone in order to induce to them to use, purchase, prescribe, or recommend the use, purchase, or prescription of Illumina' products or services.
 - All Transfers of Value to HCPs and Government Officials must be permitted by the policies of the recipient's employer or organization.
 - Illumina employees may not provide/receive cash or cash equivalents to/from HCPs or Government Officials (e.g., gifts certificates, gift cards, traveler's checks, etc.).
 - Illumina may not provide any Transfers of Value to spouses or guests of an HCP or Government Official without written approval from the Corporate Compliance Department.
 - If you are interacting with an HCP or Government Official that is licensed or employed outside of your country or region, you must follow all Illumina compliance policies and local laws applicable to that individual, including following the **Regional Addenda** for the country in which the individual is licensed

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or employed. If you are unsure of these requirements, you must consult the applicable Regional Compliance Officer.

- Applicable law, including the U.S. Sarbanes Oxley Act, requires that Illumina keep accurate books and records of all transactions. This means that everyone at Illumina is required to report all transactions with HCPs and Government Officials truthfully and accurately using the categorizations and processes established by Illumina. Transactions must <u>never</u> be misreported or disguised under any circumstances.
- Interactions with Government Officials are also governed by Illumina's *Anti-Bribery and Anti-Corruption Policy (CP 500.05*).
- All Transfers of Value to HCPs and Government Officials must also comply with Illumina's *Travel and Expense Policy (CP 200.14)*, where applicable.

If you have any doubt about whether an interaction with or Transfer of Value to an HCP or Government Official is appropriate in any situation, contact the Corporate Compliance Department at <u>compliance@illumina.com</u>.

2 Meals and Refreshments

Meals and refreshments may be provided to HCPs and Government Officials as long as all of the following conditions are met:

- Meals and refreshments must be subordinate in time and ancillary to a Legitimate Business Purpose. Meals may not be the main focus of the interaction and at least 70% of the time must be spent on the Business Purpose.
- If meals limits are not included in a **Regional Addendum** for the country where the recipient is licensed or employed, meal limits¹ should be based on the limits listed in the **United States Regional Addendum**, taking into consideration the current exchange rate and the relative cost of living.
- Meals and refreshments must occur at venues conducive to the exchange of information between the attendees. The meal location and venue should not become the main attraction of the business interaction. Home delivery of meals or refreshments is not permitted (i.e., for virtual meetings).
- Refreshments worth a maximum value of USD 10 per person (or the equivalent in local currency) may be provided to HCPs and Government Officials at congress and tradeshow booths.
- The provision of alcoholic drinks beyond a two-drink limit per person is not conducive to meaningful business or educational discussion and is therefore considered Entertainment. Entertainment is addressed in Section 8 of this Policy.

¹ All meal limits include the cost of any drinks consumed with the meal.

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• Illumina should not provide a meal to an individual HCP or Government Official more than six (6) times per calendar year.²

3 Travel and Accommodations

Travel and accommodations may be provided to or reimbursed for HCPs and Government Officials as long as all of the following conditions are met:

- Legitimate Business Purpose: All travel and accommodations must directly support a Legitimate Business Purpose. There should be an objective, legitimate reason that supports the recipient's inperson attendance, rather than virtual or remote attendance.
- If a **Regional Addendum** exists for the country where the recipient is licensed or employed, any travel and accommodation requirements contained the **Regional Addendum** must be followed.
- Airfare:³ All airfare for trips of a duration of less than 5 hours (one-way) must be coach/economy class, even if this is more stringent than Illumina's *Travel and Expense Policy* (CP 200.14). Airfare for trips of a duration of 5 hours or more (one-way) may be premium economy, comfort, or business class. First class is prohibited without approval from Illumina's Chief Compliance Officer. Flights should be booked on the most direct route and arrival and departure dates may not allow for additional days at the event location unrelated to a Legitimate Business Purpose.
- **Ground Transportation:** All ground transportation must be reasonable and not luxury. Train travel may be business class, and first class train travel is permitted where there is no designated business class option.
- Lodging/Hotels Accommodations: Lodging venues should be commonly used by industry for business travel. Luxury, vacation/resort, and "5-star" venues are inappropriate in most circumstances and may not be provided without approval from Corporate Compliance. Incidental expenses may not be reimbursed. Lodging must be directly related in time and proximity to the Legitimate Business Purpose for which the lodging is being provided. In particular:
 - Hotel accommodations should only be provided for the duration of the business event. If the HCP/Government Official will be traveling long distance, it may be appropriate to provide accommodations the night before the event and/or the night that the event concludes, but accommodations should not be provided beyond that timeframe.
 - Hotel accommodations should be within close proximity and easily accessible to the business event.
- **Special Rules for HCPs:** Travel and accommodations may be provided to HCPs provided that the general requirements listed above in this section and the following conditions are met:

² This limit does not apply to meals provided in furtherance of services an HCP or Government Official provides to Illumina pursuant to a written fee-for-service agreement (e.g., speaker agreement, consulting agreement, etc.).

³ Illumina may not pay any expenses related to air travel class upgrades, schedule changes due to personal preferences or circumstances, or non-commercial air travel.



- The HCP will speak at an Illumina or third-party event or provide consulting services to Illumina that require travel, subject to a written speaking or consulting agreement,
- The HCP will attend an Illumina-conducted training or education program concerning Illumina's products and/or services, or
- The HCP will attend another type of *non-promotional* event that requires in-person attendance and written Corporate Compliance guidance is obtained prior to providing the travel and/or accommodations.

Unless explicitly permitted under the applicable **Regional Addendum** for the country where the recipient is licensed or employed, travel and accommodations <u>may not</u> be provided to HCPs to support promotional, sales, or commercial business meetings, except where the demonstration of non-portable equipment is necessary.

4 Gifts, Promotional Items, and Medical Educational Items

HCPs: Unless explicitly permitted under the applicable **Regional Addendum** for the country where the recipient is licensed or employed, Gifts and Promotional Items may not be provided to HCPs.⁴

Medical Educational Items valued at less than USD \$100 (or the equivalent in local currency) may be provided to HCPs.

Government Officials: Gifts and Promotional Items may be provided to Government Officials that are not HCPs, provided that the following conditions are met:

- The Gift or Promotional Item must be associated with a Legitimate Business Purpose and provided to the recipient at the time of the business meeting or event.
- Any local law limits on gifts to Government Officials set forth in the **Regional Addenda** are followed; In the absence of local law limits, the Gift or Promotional Item does not exceed the following values per gift/occasion:
 - USD \$100 (or equivalent in local currency) if the item contains an Illumina logo, or
 - USD \$25 (or equivalent in local currency) if the item has no Illumina logo.
- Gifts and Promotional Items may not be given to an individual Government Official more than once a quarter.⁵
- Gifts of cash or cash equivalents (e.g., gifts certificates, gift cards, traveler's checks, etc.) are strictly prohibited.

Drawings and contests are only allowed when the "prize" is an item that all potential winners are permitted to receive under this section of the Code and all applicable Regional Addenda.

⁴ This prohibition applies even if personal funds are used.

⁵ This once per quarter limit does not apply to Gifts and Promotional Items made available at tradeshow/congress booths.

5 Entertainment

Illumina may not provide Entertainment to HCPs or Government Officials.

The provision of spirts/hard alcohol is prohibited. The provision of beer or wine beyond a two-drink limit per person is not conducive to meaningful business or educational discussion and is therefore considered Entertainment. For purposes of this Code, one bottle of wine equals four glasses of wine.

6 No Charge Products and Services

All no-charge product and services given to HCPs, HCOs, Government Officials, or other third parties must be consistent with Illumina's *No-Charge Product Framework*, attached as <u>Appendix 2</u> to this Code.⁶

7 Educational Grants, Research Grants, and Research Collaborations

Educational Grants (Continuing Medical Education and other Professional Education): Continuing Medical Education and other professional education sponsored by Illumina is managed by Illumina's Medical Affairs department. All educational grants must comply with Illumina's *Grants and Collaborations Policy (CP 500.14),* the *No Charge Product Framework,* and be approved by Illumina's Medical Education Review Committee.

Research Grants: All Research Grants (i.e., Illumina support of independent, third party investigatorinitiated research) must comply with Illumina's *Grants and Collaborations Policy (CP 500.14)* and the *No Charge Product Framework*. Research grants to HCPs or HCOs, or otherwise involving research related to human health, must be approved by Illumina's Medical Research Review Committee.

Research Collaborations: All Research Collaborations (i.e., joint research between Illumina and a third party researcher) must comply with Illumina's *Grants and Collaborations Policy (CP 500.14)* and the *No Charge Product Framework*. Research Collaborations with HCPs or HCOs, or otherwise involving research related to human health, must be approved by Illumina's Medical Research Review Committee.

8 Sponsorships

All Sponsorships must comply with Illumina's Sponsorship Policy (CP 600.03).

9 Charitable Donations

All charitable donations must comply with Illumina's *Corporate Donations Policy (CP 900.01)* and be approved by Illumina's Corporate Social Responsibility department.

⁶ Additional resources can be found on the "No-Charge Product Framework" section of the Corporate Compliance Insider Page.

10 Consulting, Speaking, Advisory and Other Services Provided by HCPs and Government Officials

All consulting, speaking, and advisory engagements with HCPs, HCOs, and Government Officials must be based on a legitimate need, compensated with fair market value payments, and comply with Illumina's *Engagement of Healthcare Professionals and Government Officials and Fair Market Value Policy* (CP 500.17).

11 All Other Transfers of Value to HCPs

Other than the Transfers of Value described in Sections 2 through 10 of this Code, Illumina may not provide any other Transfer of Value⁷ to HCPs, HCOs, Government Officials, or government entities or institutions for which Illumina will not receive fair market value compensation in return unless prior review and approval from Legal and Corporate Compliance has been obtained.

12 Vendors and Other Third Parties that Interact with or Pay HCPs or Government Officials on Behalf of Illumina

Illumina is ultimately responsible for interactions with and payments to HCPs and Government Officials made by third parties on behalf of Illumina. Prior to committing to engage a new vendor that will interact with and/or pay HCPs or Government Officials on Illumina's behalf, the Illumina business activity owner proposing to engage the vendor must:

- (1) Conduct third party due diligence on the third party to determine whether there are any compliancerelated red flags. The due diligence, at a minimum, should be comprised of:
 - Name searches (including name variations and dba names) of the entity, owners, and principals
 against relevant watchlists, blacklists, sanctions lists, Politically Exposed Persons lists, state owned
 enterprise lists and adverse media, and
 - An open source investigation (e.g., search of open records such as Linked In, Dunn and Bradstreet, etc.).
- (2) Notify the relevant Regional Compliance Officer ("RCO"). The RCO will review the terms of engagement and due diligence results and determine whether further due diligence or risk mitigation measures are required prior to engagement.
- (3) Enter into a written, fully-executed contract that remains in effect during the entire engagement and requires the vendor or other third party to:
 - Comply with all applicable anti-corruption and anti-kickback laws;
 - Ensure that any payments made by the vendor to HCPs on behalf of Illumina are at fair market value and consistent with the principles set forth in this Code and Illumina's **Engagement of**

⁷ Examples of other Transfers of Value include but are not limited to consulting services, assistance with setting up labs or workflows, support related to customer resource and capacity needs, etc.



Healthcare Professionals and Government Officials and Fair Market Value Policy (CP 500.17);⁸ and

- Provide Illumina with data on all HCP Transfers of Value in a format provided by Illumina.
- (4) Ensure that all payments to the vendor or other third party are consistent with the terms of the executed service contract with the vendor. Receipts are required for reimbursement of expenses.

13 Meetings and Events

Illumina may hold or participate in the following types of meetings and events:

- Educational Event and Product Training An educational event or training organized by Illumina and intended to provide education on genomics or training on the safe and effective use of Illumina products;
- Promotional/Sales Meeting or Event A meeting or event organized by Illumina and intended to promote or discuss features, specifications, and/or pricing related to Illumina products and services;
- Advisory Board A meeting convened by Illumina to obtain a third party expert's feedback, insights, or guidance on a product need, or medical, scientific, or business discipline;
- Illumina Internal Meeting or Event A meeting targeted to Illumina employees in which HCPs and/or Government Officials may be engaged to present about Illumina's products and services, genomics, and/or the life sciences industry generally;
- Third-Party Organized Events Educational or scientific meetings, congresses, tradeshows, academies, conferences, or any other forums for HCPs and/or Government Officials, that are not run or organized by Illumina which address genomics, medical conditions, disease states, therapies, or treatments for which Illumina's products may be used; and
- Satellite Symposium an Illumina-organized and funded program that is appended to a Third-Party Organized Event agenda. These programs often take place during meal breaks at the Third-Party Event and may address education and training topics that coincide with the Third-Party Event's focus.

Illumina may invite HCPs and Government Officials to attend or participate in Illumina organized meetings and events (including satellite symposia), provided that:

• All venues for Illumina-organized events and meetings must be conducive to the effective exchange of information and may not be luxury, tourist, or entertainment oriented. The event location and venue should not become the main attraction of the event. Venues should be located at or reasonably near the HCP's or Government Official's place of business, an Illumina facility, or central location given the place of residence of the majority of participants invited;

⁸ If Illumina identifies the HCP(s) to be engaged and/or paid by a third party on Illumina's behalf, all payments to the HCP(s) must be consistent with Illumina's Fair Market Value Guidelines and rates.

- All HCPs and Government Officials are required to either sign-in or badge-in to the meeting;
- All Transfers of Value to attendees (e.g., meals, travel, accommodations, gifts, etc.)⁹ are documented, reported according to Illumina's transparency reporting requirements, and consistent with the requirements of this Code and any appliable **Regional Addenda**;
- All payments made to HCPs and Government Officials for services provided in relation to the meeting or event are in compliance with Illumina's *Engagement of Healthcare Professionals and Government Officials Policy and Fair Market Value Guidelines*; and
- The event-specific requirements contained in the *Meeting and Event Compliance Checklists* which can be found on the **Corporate Compliance Insider Page** are followed.

14 Authorship

Illumina follows the authorship credit criteria laid out by the International Committee of Medical Journal Editors.

Illumina may not contribute to an independent third party publication for the purpose of (1) alleviating a financial burden on the third party, or (2) inducing or rewarding the purchase of Illumina products and services. Any Illumina contribution to an independent third party publication must follow Illumina's *Procedure, Global Medical Affairs Organization Scientific Publications Approval* and be documented in a written agreement clearly describing the contribution and the legitimate purpose for which it is being provided (e.g., how Illumina will use the data presented in the publication).

15 Joining Industry Associations

Corporate Compliance must be notified in advance of Illumina joining any medical technology or other industry association so that Compliance can evaluate whether Illumina will be subject to any new compliance-related obligations as a condition of membership. Compliance and Regional Leadership must confirm availability of resources to meet any new obligations prior to Illumina becoming a member.

16 Transparency Reporting and "Sunshine Act" Requirements (Tracking and Disclosure of Interactions with HCPs and HCOs)

It is Illumina's policy to track and report payments or other transfers of value or benefits made to certain HCPs and HCOs ("**Covered HCPs/HCOs**") in order to comply with all applicable global transparency laws (e.g., the United States Sunshine Act, France's Loi Bertrand, Massachusetts, Vermont, Connecticut, and other U.S. State and international disclosure laws).

All personnel are required to report all TOVs provided to HCPs and HCOs in compliance with the Sunshine Act and other applicable global transparency reporting requirements. For more information visit the

⁹ Illumina may not compensate third parties in any way for attendance at a meeting or event. Compensation may only be provided to third parties in return for legitimately needed services provided in relation to the meeting or event, consistent with Illumina's *Engagement of Healthcare Professionals and Government Officials Policy and Fair Market Value Guidelines.*



"Transparency Reporting" section of the **Corporate Compliance Insider Page** or send questions to <u>sunshineact@illumina.com</u>.

Remember, for purposes of this Code, the scope of and type of people and institutions that are considered HCPs and HCOs is very broad, even though the types of HCPs and HCOs that we have transparency reporting obligations for may be narrower.

17 Reporting Potential Compliance Violations or Concerns

Everyone has an obligation to promptly report violations of this Code. Not reporting a violation that you are aware of may result in discipline up to and including termination of employment.

You have several options to report potential violations:

- Speak with your manager or the Human Resources department. Managers and Human Resources department personnel that become aware of conduct that may violate this Code are responsible for conveying the compliance concern to the Chief Compliance Officer or other senior member of the Corporate Compliance Department within forty-eight (48) hours.
- You may submit concerns to the Corporate Compliance Department via email at compliance@illumina.com.
- You may submit concerns directly to the Chief Compliance Officer or other senior member of the Corporate Compliance Department.
- You may also submit a concern via the third-party managed Compliance and Fraud Prevention Hotline via the internet through the hotline link found on the Corporate Compliance Insider Page or by calling one of the global toll-free phone numbers available on the Hotline website. Reports made through the Compliance and Fraud Prevention Hotline may be made anonymously unless prohibited by local law.

Generally speaking, every effort will be made to maintain the confidentiality of reports about potential violations; however, depending on the circumstances, it may not be possible in all cases to protect the identity of the person making the report.

18 Who to Contact if You Have Questions About This Code

Send questions to: <u>compliance@illumina.com.</u>

Release History

Version	Version Date	Policy Owner	Description of Change
00	April 14, 2023	Gwen Chapman	Initial Release.