

We are Otsuka.

CODE OF ETHICS AND PROFESSIONAL CONDUCT

Otsuka America Pharmaceutical, Inc. (OAPI)
Otsuka Pharmaceutical Development &
Commercialization, Inc. (OPDC)



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CODE OF ETHICS AND PROFESSIONAL CONDUCT

INNOVATING ETHICALLY AND WITH INTEGRITY

Dear Valued Colleague,

We are innovators. Every day, in every location, we strive to create industry-leading solutions while remaining mindful that each of our actions and interactions must have an ethical foundation. We innovate with integrity, never losing sight of the trust others have placed in us.

Providing new products for better health worldwide is the core of what we do. As caring corporate citizens, we take responsibility for our actions in the local, national, and international communities where we operate. This means treating one another with dignity and respect.

This *Code of Ethics and Professional Conduct* represents our commitment to always conducting business ethically and with integrity. It provides an overview of important policies, procedures, and work practices—all collectively referred to in this Code as “standards”—as well as the laws and regulations that apply to our business. It also provides many tools to assist you, including common scenarios that may arise and references to policies that contain additional guidance. We expect you to read and follow this Code and commit to conducting business in accordance with Otsuka’s high ethical standards.

You play a significant role in our success. With every action you take, in every decision you make, you represent our heritage and the reputation of our company. Together, we continue to make a difference in people’s lives. We are Otsuka.

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TAREK RABAH

President & CEO, North America
Pharmaceutical Business

CODE OF ETHICS AND PROFESSIONAL CONDUCT

CONTENTS

SHARING A COMMITMENT

1.1 Our Code

1.2 Otsuka's Compliance Program

1.3 Ethical Decision-Making

1.4 Speaking Up

1.5 Non-Retaliation Policy

1.6 Violation of Our Code or Standards

CONDUCTING BUSINESS ETHICALLY AND FAIRLY

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August 2025

Veeva 01US25IUE0337

- 2.1 Fair Competition**
- 2.2 Bribery and Corruption**
- 2.3 Insider Trading**
- 2.4 International Trade**
- 2.5 Money Laundering**
- 2.6 Relationships with Third-Parties**
- 2.7 Relationships with the Government**
- 2.8 Interactions with Healthcare Professionals**
- 2.9 Product Promotion**

DRIVING PRODUCT EXCELLENCE

- 3.1 Industry Laws and Regulations**
- 3.2 Ethical Research**
- 3.3 Product Quality and Safety**

MAINTAINING AN ETHICAL AND RESPECTFUL WORKPLACE

- 4.1 A Commitment to Diversity**
- 4.2 Preventing Harassment and Discrimination**
- 4.3 Alcohol and Drugs**
- 4.4 Health and Safety**
- 4.5 Respect for Privacy**

SAFEGUARDING OUR REPUTATION AND ASSETS

5.1 Confidential and Proprietary Information

5.2 Protecting Otsuka Assets

5.3 Accurate Recordkeeping

5.4 Records Management

5.5 Avoiding Conflicts of Interest

5.6 Gifts and Entertainment

5.7 Communicating About Otsuka

5.8 Social Media

FOCUSING ON OUR COMMUNITIES

6.1 Protecting the Environment

6.2 Promoting Human Rights

6.3 Political Involvement

6.4 Social Impact

CONCLUSION

Our Big Venture Company - Closing Thoughts

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SHARING A COMMITMENT

Our Code embodies our uncompromising commitment to high standards of integrity, ethical conduct, and professionalism.

1.1 Our Code

1.2 Otsuka's Compliance Program

1.3 Ethical Decision Making

1.4 Speaking Up

1.5 Non-Retaliation Policy

1.6 Violation of our Code or Standards

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OUR CODE

SHARING A COMMITMENT

We have a long, rich history of combining a commitment to caring with a passion for innovating and developing new products for better health worldwide. This Code frames the way we do business, our commitment to conduct business ethically and with integrity, and articulates the values we all share.

YOUR RESPONSIBILITY

The decisions you make on the job every day help to define the kind of company we are. This Code provides an overview of the standards that apply to our business, sets expectations, and directs you to the people and resources available to help you make the right choices.

- In addition to this Code, you are responsible for reading and complying with the [Otsuka Group Global Code of Business Ethics](#) (GCOBE).
- If there is any conflict between the GCOBE and this Code and associated policies, you should decide which sets forth higher standards of conduct. If one requires higher standards than the other, that Code should guide your behavior. Simply put, we must consistently follow the most stringent rules. If you are in doubt, seek guidance from your manager, U.S. E&C, or Laws, Regulations & Business Optimization (LRBO).
- You have a responsibility to understand and comply with the laws and regulations governing the life sciences industry.

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This U.S. regional Code applies equally to all employees of OAPI and OPDC. We also hold third-parties (e.g., contractors, vendors, and suppliers) who act on our behalf to the same high standards.

Know the Standards, Laws, and Regulations Where You Work

As a global company operating in a highly regulated industry, we are responsible for following the standards, laws, and regulations of the states and the countries where we work.

Be aware that the laws of some countries extend to conduct beyond their borders and can change and vary by location or job function. It is important that you know and comply with the requirements that apply to your work. Always ask for guidance if you are unsure of the proper course of action.

Your commitment to an ethical culture helps us comply with the law, protect patient safety, promote a respectful workplace, and keep us on the path to success.

Our patients, HCPs, clinical trial participants, and colleagues count on all of us to act ethically and with integrity.

MANAGERS HAVE AN ADDED RESPONSIBILITY

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Managers play a critical role in promoting an ethical culture. If you manage one person or an entire team, you are counted on to lead ethically, act with integrity, and ensure that employees understand their obligation to do the same.

Create the kind of workplace where everyone feels comfortable coming forward with questions and concerns without fear of reprisal. For more guidance on how to manage ethically and with integrity, refer to the *Supervisors' Guide to the Code of Ethics and Professional Conduct*.

When you see “Otsuka” or “company” or “we” or “our” in this Code, it means all employees of Otsuka America Pharmaceutical, Inc. (OAPI), Otsuka Pharmaceutical Development & Commercialization, Inc. (OPDC).

Find Out More

- GxP policies and procedures are in the [Otsuka Document Management System](#). These documents outline good clinical practices (GCP), laboratory practices (GLP), and manufacturing practices (GMP), as well as quality system regulation (QSR).
- Always use good judgment and make decisions that are consistent with our values. If the right course of action is ever unclear, [ask for guidance](#).

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OTSUKA'S COMPLIANCE PROGRAM

SHARING A COMMITMENT

Our comprehensive compliance program reflects our commitment to conduct business honestly, ethically, and in compliance with the laws and regulations where we operate.

U.S. ETHICS & COMPLIANCE (U.S. E&C)

U.S. E&C's mission is to promote an organizational culture integrating ethical conduct, integrity, and compliance into innovative, quality solutions for better health. We also:

- Provide the tools, guidance, and resources to help Otsuka colleagues conduct themselves in an ethical and compliant manner.
- Partner with teams to provide guidance and support for a variety of business initiatives.
- Oversee the development and implementation of our comprehensive compliance program, which includes training, auditing, and monitoring, policies and procedures, compliance committees, ongoing communications and advice, and internal investigations.

Led by the Vice President and U.S. Chief Compliance Officer, we are a dedicated resource available to support all Otsuka employees in maintaining an ethical culture.

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For questions and guidance about policies, procedures, or practices, e-mail: E&CHelpline@otsuka-us.com. (Please do not submit confidential concerns or information using this e-mail address — use the Integrity Line instead, details below).

Visit the [**U.S. E&C department page**](#) to learn more about how we assist teams throughout Otsuka and provide guidance and resources to help colleagues support job performance, remain compliant, and act with integrity.

Integrity Line
1-800-363-5670
or

[**Click here to report online**](#)

**What if there is a conflict between this Code
and the local law where you work**

Always abide by the laws of the United States unless the local law is stricter. If you have any doubts about whether an action might violate either local law or U.S. law, contact LRBO or U.S. E&C for guidance.

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- Always use good judgment and make decisions that are consistent with our values. If the right course of action is ever unclear, [ask for guidance](#).

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ETHICAL DECISION MAKING

SHARING A COMMITMENT

Each of us has a responsibility to read, understand, and follow this Code, our standards, as well as the laws and regulations that apply to our work. Together, they lay the foundation for ethical decision making, regardless of where we work or what we do.

WHEN THE ANSWER IS NOT CLEAR

This Code explores many—but not all—ethical situations you may face on the job. Always apply good judgment, make decisions that are consistent with our values, and, if the right course of action is ever unclear, ask for guidance.

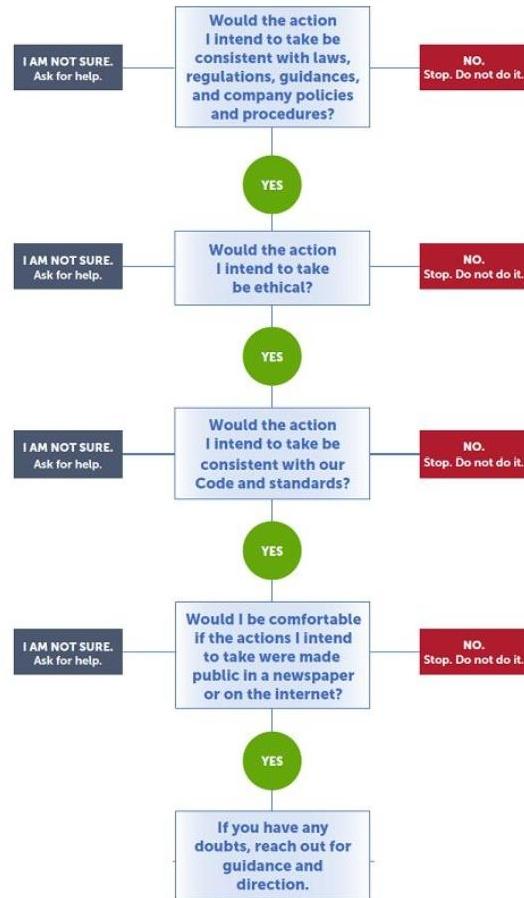
ETHICAL DECISION MAKING TREE

A decision making tree can be a useful tool when you are faced with a difficult decision.

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Find Out More

- Always use good judgment and make decisions that are consistent with our values. If the right course of action is ever unclear, [ask for guidance](#).

SPEAKING UP

SHARING A COMMITMENT

We have a responsibility to speak up if we see or suspect activity that potentially violates this Code, policies, standards, laws or regulations. Speaking up may not be easy, but it is always the right thing to do.

WHY SPEAK UP

Sometimes if you suspect illegal or unethical conduct, it may seem easier to say nothing. A violation, left unreported, can put our company, patients, clinical trial participants, and colleagues at risk. Speaking up is not just the right thing to do—it is required under this Code.

All colleagues have a duty to report potential or actual misconduct. By promptly sharing good faith concerns, you allow Otsuka to address potential issues. Speaking up:

- Helps protect patient safety and supports our mission to conduct business honestly, ethically, and with integrity.
- Allows us to take corrective and preventative action, where applicable.

Otsuka will protect the confidentiality of all involved (to the greatest extent possible) by using discretion and only sharing information as needed. Speak up when you:

- Are unsure about how to navigate a situation properly and need advice.
- Believe that you or someone acting on behalf of the company has done, is doing, or may be about to do something that violates a law, rule, regulation, Otsuka's values, policies, procedures, or Code.

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- Make a mistake (it is better to self-report than to be the subject of a report).

Resources for Reporting

You have multiple avenues to voice your concerns or ask questions.

In most cases, your manager is the best place to start. If you are not comfortable speaking with your manager (or are not satisfied with their response), you may reach out to U.S. E&C, Human Resources (HR), LRBO, or the Integrity Line. See the [Help, Reporting, and Guidance Contacts for Otsuka Colleagues](#) page in Inkling for contact information.

THE INTEGRITY LINE

- The Integrity Line can be accessed via phone or web.
- When you contact the Integrity Line, a third-party vendor documents your concern in detail and forwards the information to our company for follow-up. Reports made to the Integrity Line are never recorded or traced.
- You can report 24 hours a day, 7 days a week. You DO NOT have to give your name.

Integrity Line
1-800-363-5670
or

[**Click here to report online**](#)

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AFTER YOU SPEAK UP

All reported concerns are handled professionally, discreetly, and in accordance with our company's internal investigation procedures and applicable legal and regulatory requirements.

The information you provide is shared only with those individuals with a need to know.

Otsuka adheres to a non-retaliation policy. This means anyone who in good faith reports a violation (or potential violation) will not be subject to harassment, retaliation, or adverse employment consequences on the basis of submitting a good faith report.

Anyone who retaliates against someone who has reported a violation or potential violation in good faith is subject to discipline, up to and including termination of employment. If you suspect that you have been subject to retaliation or if you are aware of retaliatory conduct by others, you may use one of the above channels to report your concerns.

Find Out More

- The *Speak Up Policy* is [here](#).
- The *Internal Investigations of Potential Violations of Otsuka's Codes, Policies, Procedures, Laws or Regulations* SOP is [here](#).
- If you are a manager, refer to the [*Supervisors' Guide to the Code of Ethics and Professional Conduct*](#) for additional guidance.

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- Always use good judgment and make decisions that are consistent with our values. If the right course of action is ever unclear, [ask for guidance](#).

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NON-RETALIATION POLICY

SHARING A COMMITMENT

Otsuka prohibits retaliation against anyone who makes a good faith report about a known or suspected violation of this Code or standards, any law or regulation, or who engages in any other protected activity.

WHERE TO GO FOR HELP

If you suspect that you have been subject to retaliation or if you are aware of retaliatory conduct by others, immediately contact HR, U.S. E&C, LRBO, or the Integrity Line. Anyone who engages in retaliatory behavior will face disciplinary action that may include termination of employment.

When employees raise observed or suspected violations of this Code or standards or any law or regulation, managers have a responsibility to listen to their concerns and to never respond in a retaliatory manner.

Managers also have an obligation to report and prevent retaliation by others.

What if you report a concern and an investigation finds there was nothing wrong?

Any time you report a concern in good faith, you are doing the right thing. "Good faith" does not mean that you are right. It means you

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honestly believe that something is wrong and are not making a complaint for improper purposes.

We do not allow retaliation for any reports made in good faith. We may not be able to share the specifics of an investigation with you, as we respect the privacy of both the person raising the concern and the person about whom the report is being raised. We do, however, treat all reports seriously, fairly, and promptly.

Find Out More

- Search the [***Employee Handbook***](#) using the keyword: retaliation.
- Always use good judgment and make decisions that are consistent with our values. If the right course of action is ever unclear, [**ask for guidance**](#).

VIOLATION OF OUR CODE OR STANDARDS

SHARING A COMMITMENT

We are committed to complying with this Code, our policies and standards, as well as applicable laws and regulations. Anyone who violates them may be subject to disciplinary and corrective action, up to and including termination of employment.

CORRECTIVE ACTION AND INTERNAL INVESTIGATIONS

Allegations of misconduct are evaluated and investigated on a case-by-case basis. Investigative activity is conducted without regard to the potential wrongdoer's length of service, position, or relationship with Otsuka and is handled in the most discrete manner possible.

Under certain circumstances and if the facts warrant, we may report violations to the government or other third-parties, or we may report matters to law enforcement authorities for possible prosecution.

As an employee, you are obligated to cooperate in any internal investigations. As an organization, we strive to maintain your confidentiality to the greatest extent reasonably possible.

If You are a Manager

Managers are responsible for ensuring that employees know and understand what is required of them, leading with integrity, and creating an environment that promotes

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ethical conduct. Managers may face disciplinary action if they ignore reports of misconduct or fail to address them effectively and appropriately.

Compliance is critical to the safety of our patients, clinical trial participants, and colleagues – as well as our reputation and continued success. Keep in mind that no one, at any level, has the authority to tell you to do something unethical or illegal.

CONSEQUENCES OF MISCONDUCT

If misconduct is confirmed, disciplinary action(s) may include coaching, written warning, suspension, termination, referral for criminal prosecution, or reimbursement to Otsuka for any losses or damages resulting from the misconduct.

Follow not only what is written in this Code, but also the spirit of this Code.

Find Out More

- Search the [***Employee Handbook***](#) using the keywords: corrective action, discipline.
- The *Supervisors' Guide to the Code of Ethics and Professional Conduct* is [**here**](#).
- Always use good judgment and make decisions that are consistent with our values. If the right course of action is ever unclear, [**ask for guidance**](#).

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CONDUCTING BUSINESS ETHICALLY AND FAIRLY

We know and comply with the laws and regulations that affect our business and strive, in every interaction, to act professionally, ethically, and with integrity.

2.1 Fair Competition

2.2 Bribery and Corruption

2.3 Insider Trading

2.4 International Trade

2.5 Money Laundering

2.6 Relationships with Third-Parties

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2.8 Interactions with Healthcare Professionals

2.9 Product Promotion

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FAIR COMPETITION

CONDUCTING BUSINESS FAIRLY AND ETHICALLY

We compete fairly and strategically in the marketplace and in full compliance with antitrust and fair competition laws.

WHAT THIS MEANS FOR YOU

Promote Fair Business Practices

Do your part to build positive business relationships and comply with the letter and spirit of laws designed to foster competition in the country (or countries) where you do business.

You must never enter into any understanding or agreement—written or verbal—with a competitor, customer, or supplier to:

- Raise, set, or hold (i.e., “fix”) prices on our products.
- Split territories, markets, or customers.
- Participate in any kind of bid rigging.
- Prevent another company from entering the market
- Refuse to deal with a customer or supplier.
- Restrict production, sales, or output.
- Tie two products together so that customers—in order to buy a product they do want—must buy something they do not want.

Be aware that engaging in anti-competitive behavior can result in severe legal risk to you and to Otsuka.

GATHER COMPETITIVE INFORMATION LEGALLY AND ETHICALLY

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Never acquire information through improper means or enlist someone else to do so on our behalf. If you are in possession of information that may have been obtained in an illegal or unethical manner, contact LRBO immediately.

**What if an informal conversation with a competitor turns to a topic
that potentially violates our standards or the law?**

Make it clear that you will not participate in discussions regarding any competitive matters, announce why you are leaving to ensure there is no ambiguity about your intention, then promptly leave and report the incident to LRBO or U.S. E&C.

Find Out More

- The *Supplier Code of Ethics and Professional Conduct* is [here](#).
- Always use good judgment and make decisions that are consistent with our values. If the right course of action is ever unclear, [ask for guidance](#).

BRIBERY AND CORRUPTION

CONDUCTING BUSINESS FAIRLY AND ETHICALLY

We comply with anti-bribery and anti-corruption laws in all of the locations where we operate, not only because we have a legal obligation to do so, but also because it reflects our commitment to conducting business honestly, ethically, and with integrity.

WHAT THIS MEANS FOR YOU

We Are Subject to the Laws of Multiple Countries

Most countries have laws that prohibit bribery and corruption and the laws of many countries have a global reach. This is why it is critical to understand and comply with the statutory, regulatory, and contractual provisions that govern the work you do. Violating anti-bribery laws can result in lawsuits, substantial fines (for both you and Otsuka), and even jail time.

Additionally, even in the absence of laws prohibiting bribery and corruption, Otsuka people should not be engaged in this activity as it is unethical and in violation of this Code.

AVOID EVEN THE APPEARANCE OF SOMETHING IMPROPER

Never offer or accept anything of value, either directly or indirectly, to obtain an advantage for yourself or for Otsuka. Wherever you conduct business and regardless of local custom or practice, comply with U.S. law.

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Also, never offer or provide anything of value to influence someone to prescribe, purchase, recommend, or use products that are reimbursed by federal healthcare programs like Medicare and Medicaid.

ANYTHING OF VALUE INCLUDES

- Donations to charities or political parties.
- Cash equivalents, like a check, gift card, or money order.
- Discounts.
- Entertainment.
- Favors.
- Travel.

In addition to our own actions, we may be responsible for the acts of suppliers and other third-parties working on our behalf. We conduct due diligence on our vendors to help ensure they are conducting business in accordance with relevant laws, codes, and regulations.

We do not buy business under any circumstances. All fee-for-service agreements must be in writing and approved in advance through the appropriate channels.

To honor our commitment:

- Comply with our anti-fraud and anti-corruption policies.
- Know who you are working with, the business practices they employ, and the reputation they have for operating honestly and ethically.

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- Speak up if you see or suspect anything improper.
- Ask for guidance if you are unsure of the proper course of action.

FACILITATING PAYMENTS ARE PROHIBITED

The laws of some countries allow for facilitating payments (sometimes referred to as “grease payments”) to be made to government officials to expedite or to secure the performance of a routine governmental action. We prohibit facilitating payments even when permitted under local law.

KNOW YOUR OBLIGATIONS

Be aware that anti-bribery laws are especially strict when it comes to offering bribes to government officials. HCPs working in, on behalf of, or affiliated with a government healthcare facility, institution, university, or hospital are also considered government officials.

Find Out More

- The *Anti-Fraud Policy* is [here](#).
- The *Due Diligence Policy* is [here](#).
- Always use good judgment and make decisions that are consistent with our values. If the right course of action is ever unclear, [ask for guidance](#).

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INSIDER TRADING

CONDUCTING BUSINESS FAIRLY AND ETHICALLY

We do not trade in the securities of any publicly held company (including ours, our business partners, or customers) using inside information.

WHAT THIS MEANS FOR YOU

We Recognize and Protect “Inside” Information

Otsuka colleagues have a duty of trust and confidentiality to Otsuka which means that Otsuka colleagues must not use “inside” information for personal gain. Inside information is material, non-public information. Information is considered material when a reasonable investor would consider it important in deciding whether to buy, sell, or hold securities, and information is considered nonpublic up until the point it is widely communicated to the public (for example, through the issuance of a press release or public filing).

In determining whether information is inside information, it does not matter what the Otsuka colleague using the information to trade subjectively believes; the objective reasonable investor is the applied standard.

You may acquire inside information about Otsuka and about other companies that Otsuka deals with by virtue of your duties at Otsuka.

It is illegal to trade securities (e.g., stocks, bonds, and options) of any public company when you have inside information.

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While Otsuka Holdings Co., Ltd. is not listed on a U.S. securities exchange, it is a public company and its securities are listed on the Tokyo Stock Exchange.

Neither you, nor any member of your family or household, may use or disclose any inside information you acquire about Otsuka or other businesses we deal with during your relationship with Otsuka for any purpose, including trading in securities of any entity.

Anyone who acts on or shares inside information (or fails to take appropriate steps to prevent someone from acting on or sharing inside information) can be subject to penalties including termination and civil and criminal liability.

“TIPS” ARE ALSO ILLEGAL

Never disclose any confidential or proprietary information related to Otsuka's business or the business of a party we deal with. This is inside information and must be treated as confidential. For example, if you learn that Otsuka is planning to acquire a public company and reveal this to a spouse or any other outsider who then buys shares in the company before the information is publicly known, it is considered a tip. Tips are illegal and a form of insider trading.

You do not need to benefit from the other person's transaction to be held liable.

EXAMPLES OF MATERIAL, NONPUBLIC INFORMATION

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Never provide inside information to anyone who does not need it for their work at Otsuka. This applies to both verbal and written communications in any media and includes:

- Projections of future earnings or losses.
- Product safety issues or adverse events.
- Merger, acquisition, divestiture or licensing proposals.
- Changes in executive management.

- New products or discovery announcements.
- Clinical trial results.
- New projects contemplated.
- Significant developments in litigation.

Find Out More

Always use good judgment and make decisions that are consistent with our values. If the right course of action is ever unclear, [ask for guidance.](#)

INTERNATIONAL TRADE

CONDUCTING BUSINESS FAIRLY AND ETHICALLY

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As a company that conducts business around the world, we are subject to - and comply with - the international trade laws of the countries where we work.

WHAT THIS MEANS FOR YOU

Follow the Rules

We are all responsible for complying with import, export control, customs, and economic sanctions laws that govern the transfer of certain products, items, software, and technology, as well as the performance of some services and interactions with third-parties. These complex laws govern how our products move across international borders, the duties (tariffs) payable and other taxes assessed (VAT/GST). Violation of these laws can result in significant fines and penalties, as well as an inability to import or export our products.

If you are involved in the import or export of products, services, information, or technology for our company:

- U.S. export restrictions target specific countries, organizations, and even individuals.
- The complex set of rules is administered by a variety of different agencies, each with its own lists and often its own policies and procedures.
- Exporters have to check both the item and the destination and reconcile information from at least two different agencies.
- Follow all Customs rules regarding classification, valuation, country of origin markings, and documentation.
- Submit declarations and certifications to local government agencies and secure government licenses where required.
- Know and abide by:
 - All applicable Customs laws and regulations.

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- All applicable export control requirements.
- U.S. restrictions on doing business with foreign countries.
- U.S. anti-boycott law.
-

Complying with Otsuka standards will help you meet the requirements of applicable laws, regulations, and restrictions relating to the import or export of our products wherever we operate in the world.

DID YOU KNOW

Export control laws apply not only to shipments of our products, but also to where they are hand-carried during traveling.

- Digital transmissions such as email attachments, shared files, or even web-conference screen-sharing can be considered “exports” and may be controlled.
- Release of goods and technology to foreign nationals of controlled countries within the United States is considered a “deemed” export and may require a license.

[Find Out More](#)

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- To find out more about export and import requirements, seek advice from Trade Compliance (import@otsuka-us.com or export@otsuka-us.com) or LRBO.
- Always use good judgment and make decisions that are consistent with our values. If the right course of action is ever unclear, [ask for guidance](#).

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MONEY LAUNDERING

CONDUCTING BUSINESS FAIRLY AND ETHICALLY

We comply with laws designed to deter money laundering and terrorist financing.

WHAT THIS MEANS FOR YOU

Watch for Red Flags

Money laundering happens when individuals or organizations work to hide or disguise the proceeds of criminal activity (e.g., terrorism or drug dealing) through a series of legitimate business transactions.

Report any suspicious or unusual transactions or activities.

Take steps to prevent the inadvertent use of our business for this purpose. Immediately report any suspicious or unusual transactions or activities such as:

- Large payments in cash.
- Requests to transfer funds to or from countries or entities that are not related to the transaction or the customer.
- Unusual fund transfers to or from foreign countries.
- Other parties that have an unnecessarily complex corporate structure.
- Requests or instructions for Otsuka to act as a bank or escrow agent for the vendor.
- Requests or instructions to return overpayments to a third-party.

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Find Out More

- Always use good judgment and make decisions that are consistent with our values. If the right course of action is ever unclear, [ask for guidance](#).

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RELATIONSHIPS WITH THIRD-PARTIES

CONDUCTING BUSINESS ETHICALLY AND FAIRLY

We hold our suppliers to the same high standards we hold ourselves and communicate our expectation that they conduct business ethically, compliantly, and in a manner that is consistent with this Code.

WHAT THIS MEANS FOR YOU

Select Suppliers Based on Objective Criteria

We encourage fair and open competition and the selection of suppliers based on due diligence considering factors such as quality, service, price, delivery, experience, capability, and reliability. Remember, all decisions should reflect Otsuka's best interest.

Follow the procurement and sourcing procedures defined by our policies and standards and ask questions if you are ever unsure of what is required.

SUPPLIERS MUST HONOR THEIR OBLIGATIONS

We require that suppliers abide by the *[Suppliers' Code of Ethics and Professional Conduct](#)* which outlines key responsibilities, including:

- Ensuring the quality of the products and services provided.
- Protecting confidential information and Otsuka assets.
- Complying with applicable anti-bribery, anti-corruption, and other laws.

Otsuka can be held responsible for the actions of our suppliers. If your job involves working with suppliers, monitor contractual agreements to ensure suppliers are meeting their

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August 2025

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obligations and speak up about any conduct that appears to be inconsistent with our high standards.

WE MUST HONOR OUR OBLIGATIONS

Treat our suppliers with fairness and respect by honoring our commitments, ensuring timely payment, giving clear guidance as to scope of services, and protecting their confidential and proprietary information.

DUE DILIGENCE IS ONGOING

Due diligence means identifying and mitigating any potential risks throughout the lifecycle of a third-party supplier relationship. If you work with (or manage the work of) a third-party supplier, you are responsible for understanding and abiding by the assessment and screening requirements that happen during the due diligence process.

Performing due diligence throughout the lifecycle of an engagement helps determine if a reevaluation of the business relationship is necessary and reduces the risk of a violation.

Find Out More

- The *Due Diligence Policy* is [here](#).
- The *Materials, Goods, Equipment, and Services Procurement Guidelines* policy is [here](#).

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- Always use good judgment and make decisions that are consistent with our values. If the right course of action is ever unclear, [ask for guidance](#).

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INTERACTIONS WITH THE GOVERNMENT

CONDUCTING BUSINESS FAIRLY AND ACCURATELY

As a global company, we interact with individuals from government entities in the United States and around the world and understand our obligation not only to meet our legal obligations but also to conduct business fairly, honestly, and transparently.

WHAT THIS MEANS FOR YOU

Follow the Rules

If you are involved in any interaction with the government (including U.S. or non-U.S. government agencies and government-owned businesses), you are expected to understand the unique requirements that apply to these type of interactions. Promote procurement integrity by competing fairly and ethically throughout the bidding and negotiating processes.

Never:

- Seek confidential or source selection information before a contract is awarded.
- Discuss employment or business opportunities with government procurement officials.
- Provide a fee, payment, kickback, gift, or anything of value to any person.

Make sure all representations, reports, data, and other statements that you submit on behalf of our company are accurate and truthful.

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If you are responsible for administering a government contract for Otsuka, understand and abide by all applicable statutory, regulatory, and contractual provisions of the work and avoid even the appearance of anything improper.

Help us to be a responsible partner—comply with all security requirements associated with the contract and protect information from unauthorized disclosure.

COOPERATE WITH GOVERNMENT REQUESTS

Government representatives could potentially visit an Otsuka site or its employees as part of an inquiry, to issue a subpoena, or to execute a search or arrest warrant. If you are contacted, read or listen carefully to the request, then direct the individual to the proper resource.

FOR	CONTACT
GMP inspections or matters	Quality Management representative
GCP inspections or matters	Clinical Quality Management representative
Subpoenas, search or arrest warrants, visits from law enforcement	LRBO
FDA or other agency inquiries related to product filings and Risk Evaluation and Mitigation Strategies (REMS)	Regulatory Affairs

We comply and cooperate with government requests for information or facility visits related to government inspections or investigations.

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August 2025

Veeva 01US25IUE0337

If you are responsible for responding to a government request, be honest and accurate. Responses must first be vetted internally by the appropriate parties/leadership chain.

Lying to a federal official is a crime. Never conceal, destroy, alter documents, make misleading statements, or interfere with a government inspection or investigation.

Find Out More

- GxP policies and procedures are in the [Otsuka Document Management System.](#)
- Always use good judgment and make decisions that are consistent with our values. If the right course of action is ever unclear, [ask for guidance.](#)

INTERACTIONS WITH HEALTHCARE PROFESSIONALS

CONDUCTING BUSINESS FAIRLY AND ETHICALLY

In our interactions with healthcare professionals (HCPs), healthcare institutions (HCIs), and advocacy groups, we follow the law, building on our reputation as a company that operates ethically and with integrity.

WHAT THIS MEANS FOR YOU

Know our Standards

We are committed to developing and marketing our products in a way that allows patients to live longer, healthier, and more productive lives. To protect the safety of patients and consumers and prevent fraud, waste, and abuse, we abide by codes from industry organizations such as PhRMA and AdvaMed that foster compliance with laws and professional ethical standards for interactions with HCPs.

We also have established important compliant collaboration principles that help guide efficient internal collaboration across functions within the company and effective external interactions with HCPs and healthcare organizations.

Remember, what is acceptable elsewhere in the commercial marketplace may not be acceptable when interacting with HCPs.

MAINTAIN HIGH ETHICAL STANDARDS

We want our continued success to be based on the merits of the products we bring to the marketplace, never on unethical or illegal business practices. All interactions must:

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August 2025

Veeva 01US25IUE0337

- Be based on integrity and high ethical standards.
- Be conducted for a legitimate business purpose, such as fostering education, research, or scientific advancement.
- Not interfere, or give the appearance of interfering, with someone's independent judgment. Never offer or give anything of value to an HCP to induce or influence them to prescribe, use, purchase, lease, or recommend our products or to reward such use.

Find Out More

- The *Interactions With Healthcare Professionals Policy* is [here](#).
- The "*Compliant Collaboration Principles*" are contained in the CEM Playbook, [located here](#).
- Always use good judgment and make decisions that are consistent with our values. If the right course of action is ever unclear, [ask for guidance](#).

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PRODUCT PROMOTION

CONDUCTING BUSINESS FAIRLY AND ETHICALLY

We are dedicated to open and transparent communication about our products and work to ensure that all promotional materials and communications are honest, accurate, and balanced.

WHAT THIS MEANS FOR YOU

Follow the Law

Promote drugs and medical devices in accordance with FDA and other legal requirements for labeling (including information related to indications, important safety information, adverse reactions, patient population or age range, dosing strength, and phase of disease state or treatment).

Always provide fair and balanced information.

DO NOT MISLEAD OR OMIT IMPORTANT FACTS

Know our standards regarding promotional activities. All advertising, promotional labeling, and statements must:

- Be consistent with all legal and regulatory requirements.
- Be accurate, truthful, and not misleading.
- Provide fair and balanced information.

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August 2025

Veeva 01US25IUE0337

- Only make claims that are properly substantiated.
- Never promote off-label use.

PROMOTING TO HEALTHCARE PROFESSIONALS

When providing promotional materials to HCPs or HCIs, always ensure that they have a reasonable on-label use for the product. Product promotion for uses outside of the approved indications (or to a population for which the product is not indicated or intended for use) is prohibited.

APPROVAL BY PROMOTIONAL REVIEW COMMITTEE (PRC)

All promotional materials distributed to HCPs or to the public must be approved in advance by the PRC. Once approved, the materials may not be altered or modified in any way. This includes highlighting, underlining, editing, or changing the order in which the information appears.

Also, promotional materials may only be used within the period of their approved expiration dating; once expired, their use should be discontinued, and the materials must be removed from circulation/distribution and destroyed.

Find Out More

- The *Interactions With Healthcare Professionals Policy* is [here](#).

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August 2025

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- The *Review of Advertising and Promotional Material and Other Specific Internal and External Communications SOP* is [here](#).
- Always use good judgment and make decisions that are consistent with our values. If the right course of action is ever unclear, [ask for guidance](#).

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DRIVING PRODUCT EXCELLENCE

We understand that the purpose of industry laws and regulations is to protect patient safety, so we honor and follow them. This aligns with our mission of creating new products for better health worldwide.

3.1 Industry Laws and Regulations

3.2 Ethical Research

3.3 Product Quality and Safety

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INDUSTRY LAWS AND REGULATIONS

DRIVING PRODUCT EXCELLENCE

The products we discover, design, develop, manufacture, and distribute touch millions of lives around the world. We have a critical obligation to comply with all applicable industry laws and regulations to ensure the quality of our products and protect patient safety.

WHAT THIS MEANS FOR YOU

As We Work in a Regulated Industry, We Are Subject to Many Requirements

The federal, state, and local requirements that govern our industry are aimed at a single objective—to protect the health and safety of patients and consumers.

We have a duty to abide by these requirements and follow all applicable laws and regulations governing research, development, manufacturing, promotion, sales, and distribution of our products in the countries where we operate. Ensuring product quality and safety is paramount.

Some of the U.S. laws that apply to our operations include the Food, Drug, and Cosmetic Act (FDCA), the False Claims Act (FCA), the Foreign Corrupt Practices Act (FCPA), the Patient Protection and Affordable Care Act (PPACA), the Anti-Kickback Statute (AKS), and the Health Insurance Portability and Accountability Act (HIPAA).

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Our internal standards help to ensure compliance with these laws and all applicable laws and regulations.

In addition to legal and regulatory requirements, we also comply with industry codes (including PhRMA and AdvaMed) to ensure the integrity of relationships with third-parties, such as HCPs, HCIs, payers and advocacy groups.

KNOW THE REQUIREMENTS THAT APPLY TO YOUR JOB

Your understanding of—and compliance with—federal, state, and local requirements help us maintain the reputation for trust we have built within the marketplace. Refer to our policies, procedures, and standards to ensure compliance with requirements that apply to your role and responsibilities.

If you are working outside the United States, always abide by the laws of the United States unless the laws of any locale in which you work are stricter.

REPORT SUSPECTED VIOLATIONS

Non-compliance with our policies, procedures, and standards can compromise patient safety and can subject us to substantial civil and criminal penalties as well as individual liability. It can also damage the trust we have earned through ethical business dealings.

We count on you to help maintain the reputation for trust we have built within the marketplace.

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If you see or suspect violations, speak up. Your voice matters and we take concerns seriously and promptly investigate them. By speaking up, you help Otsuka do the right thing. A failure to speak up about violations can result in disciplinary action. See the “Speaking Up” section of this Code for reporting guidance.

Find Out More

- The *Speak Up Policy* is [here](#).
- Always use good judgment and make decisions that are consistent with our values. If the right course of action is ever unclear, [ask for guidance](#).

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ETHICAL RESEARCH

DRIVING PRODUCT EXCELLENCE

We are committed to innovative, quality research, conducted with the highest ethical standards and in accordance with all applicable laws, regulations, guidelines, and industry codes.

WHAT THIS MEANS FOR YOU

Safety Is Our Highest Priority

Ensure the rights, safety, and wellbeing of all research subjects in clinical trials and protect them from exposure to unnecessary risks. This means:

- Informing all participants of the nature and purpose of the research and obtaining their informed consent.
- Conducting all clinical trials under the supervision of an independent review board and in accordance with good clinical practices (GCP) and the *International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use Guidelines*.
- Carefully recording and storing all information from clinical trials in compliance with data protection laws.
- Producing clean, auditable data to support regulatory approval of new medicines, new indications, and new formulations.

Independent proposals for research grants must be scientifically reviewed in accordance with external laws and regulations and all internal standards.

PROMOTE ANIMAL WELFARE

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We continually strive to adopt new testing methods that do not require the use of animals.

When the use of laboratory animals is scientifically necessary, we ensure that research is conducted ethically, responsibly, and humanely in accordance with the law and our standards.

WE ARE COMMITTED TO TRANSPARENCY

As a company focused on innovation, we recognize that access to clinical trial data is valuable for the advancement of public health and science and that greater transparency of clinical trial data promotes better health worldwide.

We are committed to sharing clinical trial data and results through clinical trial registries in public databases, such as <https://clinicaltrials.gov/>, through publication in peer reviewed journals, as well as in accordance with evolving industry requirements to advance clinical trial data transparency.

Ensure the rights, safety, and wellbeing of all research subjects.

Our goal is to strike the necessary balance between advancing science for public health and fostering innovation with the need to protect the privacy of individual patients, who have made a selfless contribution to the advancement of medicine.

Find Out More

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- GxP policies and procedures are in the [Otsuka Document Management System.](#)
- Always use good judgment and make decisions that are consistent with our values. If the right course of action is ever unclear, [ask for guidance.](#)

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PRODUCT QUALITY AND SAFETY

DRIVING PRODUCT EXCELLENCE

Otsuka is committed to the quality, safety and efficacy of our products, as well as for the company to meet its legal obligations.

Our continued success depends on our ability to provide quality products that are both safe and effective. We all have a responsibility to ensure the safety and efficacy of our products, and to take appropriate action if they do not.

WHAT THIS MEANS FOR YOU

Take Responsibility for the Work You Do

Always carry out your work precisely, accurately, and in compliance with appropriate standards.

Do your part to ensure that, as a company, we meet or exceed requirements and customer expectations. We count on you to identify and recommend improvements in the way we do business and appreciate your feedback on new ways to deliver on our promise of safe, high-quality products.

PROMPTLY REPORT ANY SAFETY, QUALITY, OR PERFORMANCE ISSUES

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It is mandatory that safety information and product quality complaints (PQCs) related to our products be reported within 24 hours of the first Otsuka colleague being notified of the complaint.

To ensure safety and quality, we track, investigate or assess, and report safety information and PQCs. The information we collect is shared with patients, medical professionals, and regulatory authorities as well as used to continually improve our products and minimize risks to consumers.

BE ALERT TO COUNTERFEITING AND TAMPERING

Product that is fraudulently mislabeled or is tampered with can pose a serious risk to patients and consumers and harm our reputation for quality and safety. Any event involving known or suspected counterfeiting of or tampering with our products should be reported immediately via the Product Quality Complaints number.

**Product Quality Complaints
and Safety Information
1-800-438-9927**

Carry out your work precisely, accurately, and in compliance with appropriate standards.

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August 2025

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It is mandatory that product quality complaints and safety information related to our products be reported within 24 hours of receipt. Remember, reporting a safety or quality concern could help save someone's life.

Find Out More

- Safety Reporting Guidelines are [here](#).
- GxP policies and procedures are in the [Otsuka Document Management System](#).
- Always use good judgment and make decisions that are consistent with our values. If the right course of action is ever unclear, [ask for guidance](#).

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MAINTAINING AN ETHICAL AND RESPECTFUL WORKPLACE

Our success is driven by dedicated employees who are committed to acting ethically and with integrity at all times.

4.1 A Commitment to Diversity

4.2 Preventing Harassment and Discrimination

4.3 Alcohol and Drugs

4.4 Health and Safety

4.5 Respect for Privacy

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A COMMITMENT TO DIVERSITY

MAINTAINING AN ETHICAL AND RESPECTFUL WORKPLACE

The unique blending of individual skills, backgrounds, experiences, and cultures create a powerful team, a superior work experience, and a distinct advantage in driving innovation and improving patient care.

WHAT THIS MEANS FOR YOU

Each of Us Is Valued

We are proud of our diverse and inclusive workforce. Each of us has unique experiences and perspectives that together drive the creativity and ingenuity that marks our company's success. We have a responsibility to treat each other with respect and dignity as this is a fundamental aspect of how we work and our company culture.

We apply the principles of equal employment opportunity and nondiscrimination to all employment decisions, including those related to recruitment, hiring, training, and promotion; and are committed to supporting and providing a fair, equitable, and diverse workplace.

“Work up the courage and make every effort to break through the thunderclouds of unfairness.”

-Masahito Otsuka

We foster an environment that is welcoming for people inclusive of sex, gender, gender identity or gender expression, sexual or affectional orientation, religion, creed, race, color,

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August 2025

Veeva 01US25IUE0337

age, national origin, nationality, ancestry, atypical hereditary cellular or blood trait, pregnancy, genetic information, marital status, civil union or domestic partnership status, familial status, disability or disabled veteran status, service in the armed forces and veteran status, domestic or sexual violence victim status, or any other aspect of our humanity that makes us unique.

Find Out More

- Search the [***Employee Handbook***](#) using the keywords: diversity, equal opportunity, reasonable accommodation.
- Always use good judgment and make decisions that are consistent with our values. If the right course of action is ever unclear, [**ask for guidance**](#).

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PREVENTING HARASSMENT AND DISCRIMINATION

MAINTAINING AN ETHICAL AND RESPECTFUL WORKPLACE

We are committed to maintaining a respectful workplace that is free of unlawful discrimination and harassment, including sexual harassment.

WHAT THIS MEANS FOR YOU

We Insist on a Professional Atmosphere

We do not tolerate discrimination or harassment based on an individual's race, color, creed, religion, sex, gender, sexual or affectional orientation, gender identity or gender expression, age, national origin, nationality, ancestry, atypical hereditary cellular or blood trait, pregnancy, genetic information, marital status, civil union or domestic partnership status, familial status, disability or disabled veteran status, service in the armed forces and veteran status, domestic or sexual violence victim status or other characteristics protected by applicable federal, state or local laws.

Leaders set the tone for ethical and professional behavior. If you observe any inappropriate behavior among teams or in meetings —such as unprofessional conduct or comments — we expect you to address the situation in the moment and to escalate. We are responsible for promoting a work environment that fosters mutual respect, openness, and individual integrity.

Our policy prohibiting harassment and discrimination applies to all executives, managers, supervisors, employees, job applicants, independent contractors, and suppliers. It applies

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in the office, in the field, or in any other work-related settings (such as business trips and off-site company functions).

RECOGNIZE AND REPORT INAPPROPRIATE BEHAVIOR WHEN YOU SEE IT

Celebrate each individual's contributions and treat all colleagues with respect. If you experience or witness any incident of discrimination or harassment, immediately report it. See the "[**Speaking Up**](#)" section of this Code for reporting guidance.

ACTIVITIES THAT CAN CREATE A DISRESPECTFUL OR HARASSING WORK ENVIRONMENT INCLUDE

- **Physical activities** such as unwanted hugging, touching, standing too close, or blocking someone's path.
- **Verbal activities** such as making derogatory or malicious statements, using slurs, or making jokes that stereotype, demean, intimidate, or make fun of someone in a protected class.
- **Visual activities** such as displaying derogatory posters, images on computer screens, photography, cartoons or drawings or using gestures that are degrading to or reflect negatively upon any protected class.

Find Out More

- Search the [**Employee Handbook**](#) using the keywords: harassment and discrimination.

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August 2025

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- The *Supervisors' Guide to the Code of Ethics and Professional Conduct* is [here](#).
- Always use good judgment and make decisions that are consistent with our values. If the right course of action is ever unclear, [ask for guidance](#).

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ALCOHOL AND DRUGS

MAINTAINING AN ETHICAL AND RESPECTFUL WORKPLACE

We share a commitment to a drug-free workplace that allows each of us to achieve the high levels of professional performance we expect and ensure a safe working environment for everyone.

WHAT THIS MEANS FOR YOU

Comply with Company Standards

Being under the influence of alcohol or illegal drugs can impair your job performance, the job performance of those around you, and create an unsafe work environment.

This is why our standards prohibit employees and third-parties working for Otsuka from performing work or driving a vehicle for company business while under the influence of alcohol or an illegal or unauthorized drug (including a prescription medication that is not prescribed to them).

Possessing, using, selling, or offering illegal or unauthorized drugs while working, while on company premises, or while driving a vehicle for company business is also strictly prohibited.

This is not meant to prohibit the appropriate use of over-the-counter or legally prescribed medication, to the extent that it does not impair your job performance, personal safety, or the safety of others. If you take over-the-counter or legally prescribed medication, you must inform HR – before reporting to work under the influence of that medication – if you believe the medication will impair your job performance, personal safety, or the safety of others, or if you need to request a reasonable accommodation.

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You are also prohibited from consuming alcoholic beverages at work or possessing open alcoholic beverage containers on company premises, unless you are attending a company-sanctioned event at which alcohol is being served.

If you choose to drink alcoholic beverages at company functions, do so responsibly. Failure to use good judgment can lead to disciplinary action up to and including termination.

SAFEGUARDING OUR EMPLOYEES

To ensure the safety of all employees, we may require you to submit to drug and/or alcohol testing while you are employed at Otsuka under any of the following conditions:

- You are involved in an on-the-job accident or in an accident involving a company-provided vehicle and there was personal injury or damage to company property.
- It is part of a follow-up program for treatment for drug abuse.
- There is a reasonable suspicion that you are in violation of our policies regarding alcohol and drugs.

All drug and alcohol testing will be conducted in accordance with applicable law.

Employees are not guaranteed a right to testing and may be disciplined up to termination for violations of Otsuka's policies about alcohol and drugs without testing.

**If you have a question or concern about
substance dependency or abuse**

You may seek help through **Lyra Work-Life Services**,
care@lyrahealth.com, or call 877-695-2789.

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Veeva 01US25IUE0337

Find Out More

- Search the [***Employee Handbook***](#) using the keywords: alcohol, drugs.
- Always use good judgment and make decisions that are consistent with our values. If the right course of action is ever unclear, [**ask for guidance**](#).

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HEALTH AND SAFETY

MAINTAINING AN ETHICAL AND RESPECTFUL WORKPLACE

Safety is everyone's responsibility. We are each responsible for taking the necessary precautions to protect ourselves, our guests, and our work environment.

WHAT THIS MEANS FOR YOU

Observe Safe Work Practices

Take an active role in ensuring your own safety by complying with all workplace safety rules and procedures. Speak up and report all health and safety concerns, near-misses, and injuries immediately by:

Calling 911 for any life-threatening situation.

Alerting the Crisis Management Team at 609-524-6754.

Completing an [**Injury, Illness, or Incident Reporting and Investigation form**](#) within 24 hours and send to [**OtsukaHealthandSafety@otsuka-us.com**](mailto:OtsukaHealthandSafety@otsuka-us.com) (with a cc to your direct manager).

PHYSICAL SECURITY

If you have a company-issued ID badge, always keep it visible while on company business. Direct all visitors to enter through approved security points. Visitors must wear badges prominently and are not permitted to take photographs without prior written approval.

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August 2025

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Promptly report any suspicious activity. The [***Help, Reporting, and Guidance Contacts for Otsuka Colleagues***](#) page has reporting information for each home office location.

ZERO TOLERANCE FOR WORKPLACE VIOLENCE

CRISIS MANAGEMENT HOTLINE

Violence in any form is not tolerated. Report all threats, incidents of violent behavior, or any unauthorized persons that you observe in your work environment by calling the Crisis Management Hotline at **609-524-6754**, or notify your manager, another member of management, or HR.

If a situation occurs that could result in immediate danger, ensure your personal safety by following emergency procedures and, if necessary, removing yourself from the area.

Company policy prohibits you from possessing a deadly weapon while on company premises or while conducting company business.

SPEAK UP ABOUT ANY POTENTIAL RISKS

- Health or safety concerns.
- Work-related injuries or illness.
- Suspicious activity.
- Unauthorized persons in the workplace.
- Workplace threats or violence.

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August 2025

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For additional guidance on response scenarios, see the Occupational Health and Clinical Services Section of the [Occupational Health & Safety Handbook](#).

Be aware that you will never face disciplinary action for reporting a good-faith health or safety concern that you believe presents a danger to yourself or others in the workplace.

Find Out More

- The *Occupational Health & Safety Handbook* is [here](#).
- Always use good judgment and make decisions that are consistent with our values. If the right course of action is ever unclear, [ask for guidance](#).

RESPECT FOR PRIVACY

MAINTAINING AN ETHICAL AND RESPECTFUL WORKPLACE

Our employees, clinical trial participants, healthcare professionals (HCPs), patients, caregivers, and colleagues trust Otsuka to collect and process their personal information. We have an obligation to respect and keep this data private in accordance with our company standards and the law.

WHAT THIS MEANS FOR YOU

Handle Personal Information with Care

Personal information is any information that (alone or when used in combination with other data) can be used to identify, locate or contact an individual or household.

Always handle this data with care and take reasonable precautions to prevent it from coming into the hands of unintended recipients.

Personal information is confidential and must be used or disclosed for legitimate business purposes. If you handle it as part of your work at Otsuka, only share it with those who are authorized to receive it and have a need for it to do their job.

Be careful when sending or storing information via phone, e-mail, text, social media, cloud, or any other means. Always comply with all requirements related to collection, use, transmission, and retention.

We all play a part in safeguarding personal information. This means:

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August 2025

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- Protecting the confidentiality, integrity, availability, accuracy, and resilience of an individual's personal information.
- Following all applicable privacy policies and procedures. Ask your manager (or the Privacy Office) for guidance if you have a question or concern.
- Being transparent with the individual about how we are using their personal information. Collect only what is needed, use it for the purpose for which it was collected, only share it with authorized individuals, and delete it in accordance with policy.
- When possible, provide individuals appropriate choices with respect to their data.

Find Out More

- The *Corporate U.S. Privacy Policy* is [here](#).
- The *Classifying and Safeguarding Business Information Policy* is [here](#).
- The *Mobile Device Acceptable Use Policy* is [here](#).
- Always use good judgment and make decisions that are consistent with our values. If the right course of action is ever unclear, [ask for guidance](#).

SAFEGUARDING OUR REPUTATION AND ASSETS

**It is paramount that we lead with
integrity in all that we do.**

5.1 Confidential and Proprietary Information

5.2 Protecting Otsuka Assets

5.3 Accurate Recordkeeping

5.4 Records Management

5.5 Avoiding Conflicts of Interest

5.6 Gifts and Entertainment

5.7 Communicating About Otsuka

5.8 Social Media

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CONFIDENTIAL AND PROPRIETARY INFORMATION

SAFEGUARDING OUR REPUTATION AND ASSETS

We are committed to protecting confidential information about our company, employees, the companies with which we work, and the patients and consumers we serve.

WHAT THIS MEANS FOR YOU

Information Is a Critical Asset

Our knowledge base and work product (e.g., manufacturing methods, business plans, research, forecasts, budgets, and marketing strategies) are critical assets that give us a competitive advantage in the industry.

Each of us is responsible for protecting confidential and proprietary information as any unauthorized disclosure can put our company at risk. Unauthorized disclosure can also potentially violate data privacy, copyright, patent, trademark, and trade secret laws.

KNOW THE CATEGORIES OF INFORMATION THAT NEED SAFEGUARDING

Protect:

- Proprietary information. This is information that makes our company unique such as R&D information, intellectual property, and non-public financial information.

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August 2025

Veeva 01US25IUE0337

- **Personal information.** This is information that could be used to identify our customers, patients, or fellow employees such as telephone numbers, birth dates, social security numbers, or other PII.

DO YOUR PART TO PROTECT INFORMATION

Only share confidential or proprietary information if you are authorized to do so and disclose it only to those who have both a right and a business need for the information. Companies or individuals outside of Otsuka must sign a nondisclosure agreement before gaining access to our confidential or proprietary information.

Limit the information shared to only what is required. Make sure that the person receiving the information knows that it is confidential and understands any restrictions related to its use or dissemination.

Be a good steward of confidential information and observe the proper security measures when it is in your possession. Never:

- Use confidential information for personal benefit.
- Discuss it in public places.
- Disclose it to others (including family members and friends) or to anyone else within the company who does not need it for a business purpose.

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In the office, keep sensitive documents and computer media in locked cabinets. Make sure to physically secure all laptops in a locked cabinet or with security cables and lock your workstation when you step away. Always keep your user ID and passwords private.

Protect the Confidential Information of Others

You also have an obligation to protect the confidential information of others (including suppliers and third-parties). This includes pricing, strategies, and practices shared by our company and our suppliers. Never share this information outside of Otsuka, even if a non-disclosure agreement is not in place.

Do not share confidential information you have learned from previous employers and never share confidential information about Otsuka with future employers. Your obligation to protect confidential information applies even if you stop working at Otsuka.

DID YOU KNOW

We have standards that protect our intellectual property (IP). Before it is shared externally, IP is evaluated to determine whether new patent applications are possible, whether past or future activity infringes on another party's IP rights and whether there is any conflict between R&D information and previous Otsuka publications or patents.

We require pre-approval of any potential publication involving Otsuka R&D information.

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Find Out More

- The *Corporate U.S. Privacy Policy* is [here](#).
- The *Intellectual Property Protection Policy* is [here](#).
- The *Classifying and Safeguarding Business Information Policy* is [here](#).
- The *Information Security Policy* is [here](#).
- Always use good judgment and make decisions that are consistent with our values. If the right course of action is ever unclear, [ask for guidance](#).

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PROTECTING OTSUKA'S ASSETS

SAFEGUARDING OUR REPUTATION AND ASSETS

In addition to our information assets, our financial, physical and technology resources represent critical company assets and we work to safeguard them from theft, loss, waste, and abuse.

WHAT THIS MEANS FOR YOU

Use Company Assets for Company Business

Company assets, including financial resources, equipment, facilities, computer files, and programs, should only be used for business and not for personal use. This includes only seeking reimbursement for allowable and legitimate business-related expenses. Use company assets as they are intended, protect them as you would your own, and report any instances of misuse or fraud.

"Technologies are the indispensable assets of a company."

-Masahito Otsuka

Certain assets, such as phones and copiers, may occasionally be used for non-business purposes. Your use should be reasonable and infrequent and never interfere with your work.

PROTECT OUR TECHNOLOGY

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Malware, short for malicious software, can come in many forms. Some variants steal data or corrupt systems, while others cause physical damage to machines or factories. In all cases, malware can cause great harm and we are obligated to prevent it from spreading at Otsuka.

Help us reduce the risks of malware by understanding how to identify phishing e-mails, installing security updates as soon as possible, and by never installing unauthorized applications, software, hardware or storage devices on your corporate devices.

Situational awareness is a concept that focuses on minding your surroundings and staying alert for threats. Be sure to follow the *Information Security Policy* which requires you to report any security incident immediately.

Information you create, send, receive, download, or store during your employment is Otsuka property. Otsuka reserves the right to monitor, review, and disclose information as we deem appropriate, subject to applicable laws and regulations.

You should have no expectation of privacy when using company resources.

USE ELECTRONIC COMMUNICATIONS APPROPRIATELY

Make sure your use of the company intranet and internet access complies with our standards and that personal use is limited. Take care to never violate a law, harass others, divulge confidential information, or interfere with network users, services, or equipment.

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Immediately report any security concerns to:

- The Crisis Management Hotline **609-524-6754**
- Your manager
- Otsuka Information Security
- The Otsuka Service Desk-**1-877-4OTSUKA.**

SAFEGUARD THE OTSUKA BRAND

The Otsuka brand represents a rich heritage and a dedicated workforce. We have a duty to protect it, and the reputation it embodies, by following the applicable standards and reporting any misuse by either internal or external parties.

Find Out More

- The *Information Security Policy* is [here](#).
- The *North American Regional Travel and Expense Policy* is [here](#)
- Always use good judgment and make decisions that are consistent with our values. If the right course of action is ever unclear, [ask for guidance](#).

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ACCURATE RECORDKEEPING

SAFEGUARDING OUR REPUTATION AND ASSETS

Data integrity is crucial to the successful operation of our business, so we follow all applicable laws and internal standards in our everyday transactions.

WHAT THIS MEANS FOR YOU

Be Accurate, Complete, and Honest

Information recorded in Otsuka's books and records is used every day to make important business decisions. Some information we maintain is also submitted to government and regulatory agencies. Make sure that anything you record or produce is complete and accurate and fully discloses the true nature of the business transaction.

If you are responsible for creating or maintaining business records, remember that all transactions must be authorized and recorded in compliance with our standards, applicable laws and regulations, and generally accepted accounting standards.

Falsifying records and accounts or misrepresenting or omitting facts or information could constitute fraud and result in severe penalties. It can also lead to disciplinary action, up to and including termination of employment.

Data accuracy is more than a legal responsibility; it is about operating our business ethically and with integrity. If you become aware of any omission, inaccuracy, or false entry, report it promptly.

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BUSINESS RECORDS INCLUDE, BUT ARE NOT LIMITED TO, THE PAPER OR ELECTRONIC VERSIONS OF THE MATERIALS LISTED BELOW

- Strategic and business plans.
- Timesheets.
- Contracts.
- Bills.
- Invoices.
- Ledgers.
- Vouchers.
- Clinical data.
- E-mails.
- Regulatory filings.
- Voicemail.
- Sales call records.
- Sample disbursements.
- Expense reports and required receipts.
- Production and quality data.
- Compensation records.
- Performance evaluations.
- Research results.
- Training records.
- Clinical safety/pharmacovigilance records.
- Text messages.

Find Out More

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- Always use good judgment and make decisions that are consistent with our values. If the right course of action is ever unclear, [ask for guidance](#).

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RECORDS MANAGEMENT

SAFEGUARDING OUR REPUTATION AND ASSETS

We have adopted good records management practices that allow us to meet our legal, tax, and regulatory requirements, protect our intellectual property, and safely dispose of information that is no longer needed.

WHAT THIS MEANS FOR YOU

Follow our Records and Retention Standards

In today's business environment, we create, send, receive, and store records—including e-mail, text, Microsoft Teams, and voice mail messages. Each of us has a responsibility to retain these records in accordance with applicable legal, financial, and regulatory retention requirements and to store them in locations approved for that purpose.

We are also responsible for disposing of company records that have satisfied their retention requirements, as directed by our standards.

Requirements for creation, maintenance, access rights, storage, retention, and disposal can vary depending on your business unit and location. Make sure you are familiar with the specific standards that apply to you and the work you do by periodically reviewing the [**Corporate Records Retention Schedule**](#).

WE EXPECT THIRD-PARTIES TO FOLLOW OUR STANDARDS

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Otsuka suppliers are also required to abide by our records management standards. Do your part to ensure that they understand and comply with this obligation.

CHECK FOR “LEGAL HOLD” RESTRICTIONS BEFORE DISPOSING

Some records may have a legal hold placed on them which means they may be relevant to a subpoena, litigation, investigation, or audit and should not be modified or disposed of until LRBO releases them.

- A legal hold notice is a communication issued by LRBO suspending the ordinary records management, retention and disposal system. A legal hold may be issued when a litigation, government investigation, audit or other inquiry is pending or is reasonably anticipated to occur.

When a legal hold is issued, all records that are relevant to the subject matter described in the legal hold must be retained and preserved, without alteration, even if the *Corporate Records Retention Schedule* would otherwise allow for their disposal.

A legal hold may require the retention of documents and other information that go beyond the definition of a record. For instance, you might not need to retain drafts under the *Corporate Records Retention Schedule*, but you might need to retain them subject to a legal hold.

Comply with requests to hold documents until you are notified that they can be released. Be aware that destroying, discarding, withholding, or altering records that are pertinent to an audit, litigation, or governmental investigation is a crime.

If you have questions about whether records, documents, or other information that might not meet the definition of “record,” are subject to a legal hold notice, contact LRBO.

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DID YOU KNOW

As we operate in a highly regulated industry, certain records and documentation must be stored for specified periods of time and access to certain records may be limited.

To find out more about retention and disposal requirements for your business group, contact Otsuka Document Management Services at

DMSDocumentManagementServices@otsuka-us.com.

Find Out More

- The *Corporate Records Management and Retention Policy* is [here](#).
- The *Supplier Code of Ethics and Professional Conduct* is [here](#).
- Always use good judgment and make decisions that are consistent with our values. If the right course of action is ever unclear, [ask for guidance](#).

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AVOIDING CONFLICTS OF INTEREST

SAFEGUARDING OUR REPUTATION AND ASSETS

We avoid situations that could create—or appear to create—a conflict between our personal interests and the interests of Otsuka.

WHAT THIS MEANS FOR YOU

Put Otsuka's Interests First

A conflict of interest occurs (or could occur) when you let a direct or personal gain affect business decisions you make on Otsuka's behalf. Always make business decisions based on good judgment and objectivity, not personal interests or benefit.

AVOID ACTIVITIES THAT MIGHT AFFECT YOUR OBJECTIVITY

While it is not possible to list every situation that may be an issue, recognizing a potential conflict can help you avoid one:

- **Personal relationships.** Potential conflicts can arise if you hire, manage, or conduct business with close personal friends or relatives, or if you have a romantic relationship with a supervisor, subordinate, co-worker, customer or vendor.
- **Investments.** A conflict can also arise if you or a family member holds a financial interest in—or exercises control over—one of our suppliers, customers, or competitors.
- **Outside activities.** Board directorships or advisory roles with companies, universities, or other organizations may pose a conflict if they interfere with your job at Otsuka.

- **A second job.** Work outside of Otsuka can pose a potential conflict if it competes with the work you do for us or interferes with the time, talent, and energy you bring to your job.
- **Personal benefits.** You should not use your position or company resources at Otsuka to gain a personal benefit or provide any type of compensation for yourself or your friends or relatives.
- **Gifts.** Gift giving and receiving may also pose a conflict when doing so influences—or appears to influence—your decision making. Make sure you know, understand, and comply with our standards regarding conflicts of interest, anti-bribery, and corruption.

TRANSPARENCY IS THE KEY

Not all instances are problematic. When addressed promptly, many conflicts can be resolved in a way that is acceptable to both you and Otsuka.

Disclose any actual or potential conflicts of interest to U.S. E&C at conflictsofinterest@otsuka-us.com. You are required to let us know about situations that may cause a conflict of interest so we can take action to reduce risk (reputational, financial, or ethical) for you, colleagues, and the company.

AVOID CONFLICTS BETWEEN PERSONAL INTERESTS AND OTUKA'S INTERESTS

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Find Out More

- The *Avoiding Conflicts of Interest Policy* is [here](#).
- Always use good judgment and make decisions that are consistent with our values. If the right course of action is ever unclear, [ask for guidance](#).

GIFTS AND ENTERTAINMENT

SAFEGUARDING OUR REPUTATION AND ASSETS

Under the right circumstances, gifts and entertainment can create goodwill and build relationships. They can also create a potential conflict of interest. Never engage in an activity that could raise concerns about your or the company's integrity.

WHAT THIS MEANS FOR YOU

Understand the Rules

When it comes to gifts and entertainment to and from vendors, remember the \$100 rule:

- If the value is less than or equal to \$100 and the items are not given on a regular basis, you may give or accept the gift.
- For guidance on handling gifts to HCPs, government officials, or gifts that exceed \$100, reach out to conflictofinterest@otsuka-us.com.

There are significant legal restrictions that apply to offers of gifts or entertainment to HCPs and to government officials.

Never offer anything of value to individuals (or their related institutions) in these roles without obtaining approval in advance from U.S. E&C.

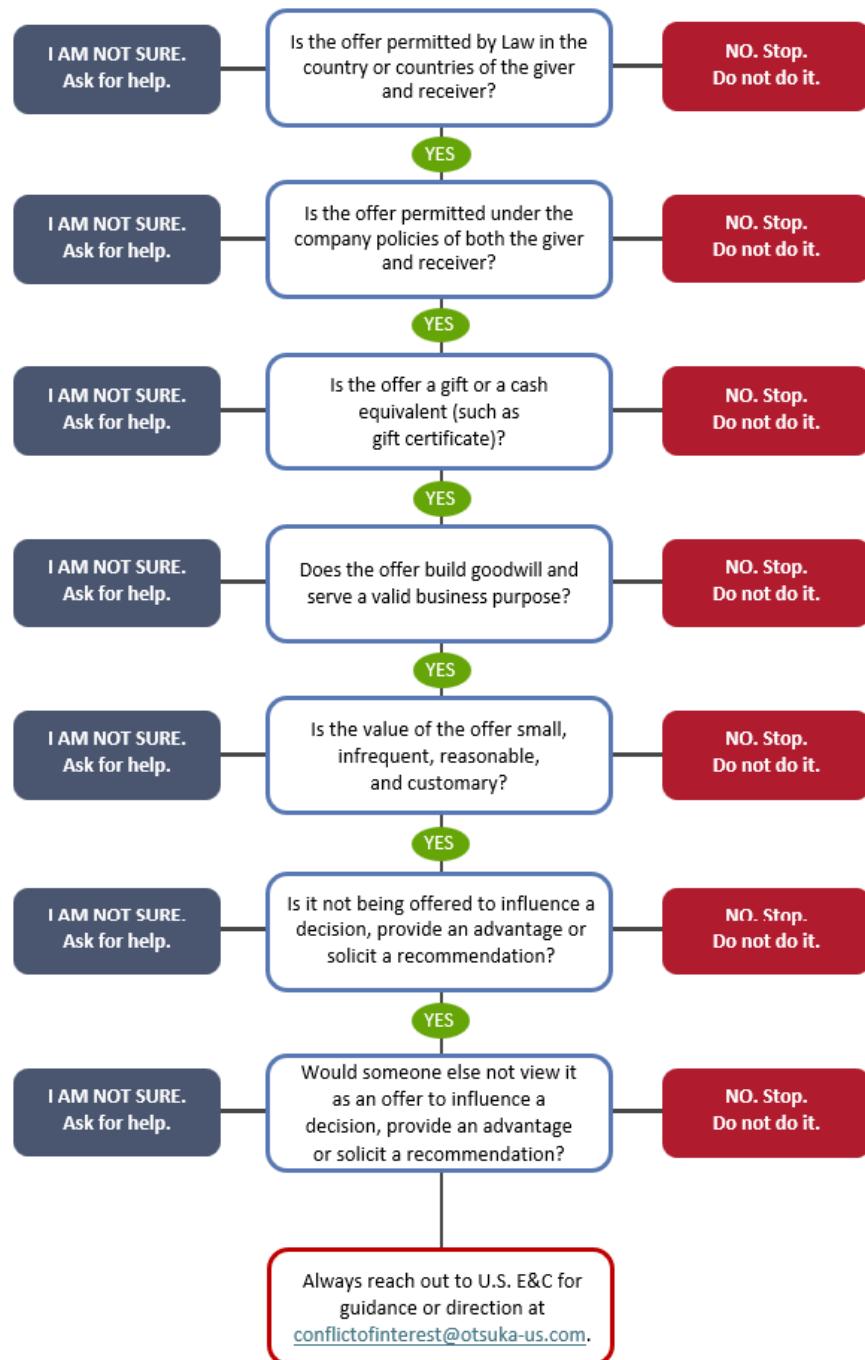
It is never appropriate, under any circumstances, to solicit a gift or entertainment. For offers of gifts and entertainment contemplated for non-HCPs and non-government officials, consider the following ethical decision making tree.

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BEFORE PROCEEDING, ASK YOURSELF



Gifts and entertainment guidelines help us maintain Otsuka's culture of integrity by setting appropriate parameters for vendor-provided gifts.

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INTERNAL EMPLOYEE GIFT GIVING AND RECOGNITION

Gifts for employees for life events are subject to approval.

The company SOAR program is the approved internal program to provide employee recognition in a compliant manner, including proper reporting for payroll tax purposes under IRS guidelines.

No gift or recognition expense is reimbursable for non-full-time employees (e.g., contract workers).

Find Out More

- The *Avoiding Conflicts of Interest Policy* is [here](#).
- The *Gifts and Entertainment eBook* is [here](#).
- *The North American Regional Travel and Expense Policy* is [here](#).
- *The Purchase Card and Meeting Card Policy* is [here](#).
- Always use good judgment and make decisions that are consistent with our values. If the right course of action is ever unclear, [ask for guidance](#).

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COMMUNICATING ABOUT OTSUKA

SAFEGUARDING OUR REPUTATION AND ASSETS

Communications about Otsuka must be accurate, complete, timely, and protect confidential information from unauthorized disclosure.

WHAT THIS MEANS FOR YOU

Direct Questions to the Proper Resource

To help ensure that accurate information is conveyed to the public, regulatory authorities, and others, we have designated individuals to serve as our official spokespersons.

If you are approached for information and you are not a designated spokesperson for Otsuka, do not make any statements or answer questions on our behalf.

Advise that you are not authorized to answer questions for Otsuka, then obtain the name of the person making the request and notify the appropriate internal contact.

FOR

CONTACT

Questions from the media

Corporate
Communications

Questions from regulatory agencies

Regulatory Affairs

Questions regarding financial performance

Corporate
Communications

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Questions regarding legal issues	LRBO
Questions from government representatives e.g., Congress, agency officials, White House officials, state and local (Governors, lawmakers, Medicaid directors).	Government Affairs
Inspections	QM or CQM

YOU ARE A REPRESENTATIVE OF OUR COMPANY

Remember, what you say in your interactions not only reflects on you but may impact how others view Otsuka.

When you are speaking on Otsuka's behalf (e.g., representing Otsuka through a speaking engagement or releasing a publication that relates to our company), pre-clearance is required.

- If you are speaking at a conference in an individual capacity, you must obtain pre-clearance approval from your manager, Corporate Communications, and U.S. E&C. Never use or share confidential information.
- Any materials you plan to use must also be approved in advance by Corporate Communications and U.S. E&C.
- When attending trade conferences, medical conferences, or other business venues, honor your obligation to protect our confidential information and the confidential information of the companies with which we do business.

DID YOU KNOW

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Communications about our company must be approved in advance before they can be circulated externally. To find out more about communicating on behalf of Otsuka, contact Alicea Shaak, Senior Manager, Media Relations & External Communications at Alicea.Shaak@otsuka-us.com

Find Out More

- Speaker engagement and presentation guidance is in Appendix A of the *Avoiding Conflicts of Interest Policy*, [here](#).
- Always use good judgment and make decisions that are consistent with our values. If the right course of action is ever unclear, [ask for guidance](#).

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SOCIAL MEDIA

SAFEGUARDING OUR REPUTATION AND ASSETS

We work in a highly regulated industry. Always use social media compliantly, appropriately, and abide by Otsuka's policies and procedures.

WHAT THIS MEANS FOR YOU

Review The Social Media Policy

The [Social Media Policy](#) defines social media and the various types of social media and covers acceptable use and behavior for both Otsuka-sponsored and personal social media activities.

As an Otsuka employee, it is your responsibility to understand and comply with our company *Social Media Policy*. If the right course of action is ever unclear, reach out to LRBO for help.

Use Good Judgment

Social media offers a great forum for the exchange of ideas, but it also introduces risks and carries with it certain responsibilities. We rely on you to use good judgment in your social networking activities on both your company-issued and personal devices.

Remember, anything that you post online is available to the public. The internet archives almost everything and deleted postings can be searched.

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Never post content about Otsuka's trade secrets, private, proprietary, or confidential information.

ALWAYS BE FAIR AND RESPECTFUL

Any knowingly false postings regarding our company or its products, or postings that violate Otsuka's policies and this Code of Conduct could result in disciplinary action. Never post content that:

- Is discriminatory, harassing, intimidating, or offensive.
- Violates copyright or trademark rights.
- Violates another individual's right to personal privacy.
- Discloses confidential information about our company or third-parties who conduct business with—or on behalf of—our company.

EXPRESS ONLY YOUR PERSONAL OPINIONS

If you write anything related to the work you do or subjects associated with Otsuka, make it clear that you are not speaking on behalf of Otsuka.

Only authorized colleagues can use social media to speak on behalf of our company in an official capacity.

Find Out More

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- The *Social Media Policy* is [here](#).
- Always use good judgment and make decisions that are consistent with our values. If the right course of action is ever unclear, [ask for guidance](#).

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FOCUSING ON OUR COMMUNITIES

We are good corporate citizens and value our place in the global community, working inside and outside of our corporate walls to make a difference.

6.1 Protecting the Environment

6.2 Promoting Human Rights

6.3 Political Involvement

6.4 Social Impact

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PROTECTING THE ENVIRONMENT

FOCUSING ON OUR COMMUNITIES

We respect the environment and are committed to minimizing the negative impact of our operations and promoting the sustainable use of natural resources.

WHAT THIS MEANS FOR YOU

Help Us Build on Our Commitment

Our responsibility to protect the environment is among our top priorities. Comply with company programs, policies, and procedures designed to meet applicable environmental health and safety standards and take an active role in identifying ways to help reduce our overall footprint.

A few simple acts can have a significant environmental impact:

- Recycle whenever possible
- Reduce your personal consumption of water and energy
- Conserve paper by limiting printing
- Report any actual or potential environmental hazard to your site facilities team or OtsukaHealthandSafety@otsuka-us.com.

Find Out More

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- Always use good judgment and make decisions that are consistent with our values. If the right course of action is ever unclear, [ask for guidance](#).

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PROMOTING HUMAN RIGHTS

FOCUSING ON OUR COMMUNITIES

All human beings, everywhere in the world, have the right to be treated with dignity and respect.

WHAT THIS MEANS FOR YOU

Honor Our Commitment

We show respect for human dignity and the rights of the individual by supporting the principles set forth in the United Nations Declaration of Human Rights and complying with employment laws in the markets where we operate.

We prohibit the employment of underage children or forced labor, as well as any form of physical punishment or abuse.

Find Out More

- Always use good judgment and make decisions that are consistent with our values. If the right course of action is ever unclear, [ask for guidance](#).

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POLITICAL INVOLVEMENT

FOCUSING ON OUR COMMUNITIES

We encourage free expression and participation in civic and political activities.

WHAT THIS MEANS FOR YOU

Participate Responsibly as an Individual

We support your participation as a private citizen in the political process and respect your desire to address the needs of the communities where you live and work. Make sure that if you engage in political activities, they are lawful, appropriate, and do not create a conflict between your personal interests and those of Otsuka.

Always make it clear that your views and actions are your own and do not represent those of our company.

Activities should be conducted on your own time and at your own expense—never use Otsuka funds, facilities, or the company name in connection with your activities unless authorized to do so.

KNOW THE RULES REGARDING POLITICAL CONTRIBUTIONS

You have the right to make personal contributions to a political party, campaign, or candidate from your own funds, subject to applicable legal limits, but do not make any contributions, or otherwise obligate contributions, on behalf of Otsuka or have any expectation of being reimbursed for the contributions you make.

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GOVERNMENT AFFAIRS IS OUR COMPANY LIAISON

Government Affairs has the primary responsibility for coordinating our activities with government officials and policy makers. Do not communicate with public officials about Otsuka-related issues or speak on our behalf, and never offer or give anything of value to members of Congress, the Executive Branch, or their staff.

DID YOU KNOW

There are complex federal and state restrictions that regulate the kinds of political contributions we can offer as a company. For more information about Otsuka's political initiatives or about legislation affecting our industry, contact Government Affairs.

Find Out More

- Always use good judgment and make decisions that are consistent with our values. If the right course of action is ever unclear, [ask for guidance](#).

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SOCIAL IMPACT

FOCUSING ON OUR COMMUNITIES

We consider it a privilege to break down barriers, remove inequities, and walk alongside the communities we serve as allies and advocates. This privilege fuels us, every day, to make a positive impact on those communities in the work we do, and through our charitable activities and donations.

EMPLOYEE COMMUNITY ENGAGEMENT

Employee community engagement is a core component of Otsuka's culture and we encourage all employees to get involved. There are multiple programs offered that amplify community engagement, such as paid time off for volunteering (VTO), an hourly rate earned for the time you spend volunteering that can be donated to a non-profit of your choice (Dollars for Doers) and, Otsuka will match dollar-for-dollar your donation to a non-profit up to a maximum amount (Company Match). Please reach out to OtsukaCares@otsuka-us.com for policies and details on each of these programs.

Company-sponsored activities are strictly voluntary and have no bearing on your performance evaluation or your employment with Otsuka.

PHILANTHROPY

In addition to supporting the community engagement work of our employees, Otsuka also funds two independent legal entities – The Sozosei Foundation, a philanthropic organization and the Otsuka Patient Assistance Foundation, Inc. (OPAF), a free medication,

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health and wellness organization. Otsuka America Pharmaceutical, Inc. does not control or influence how these independent entities distribute funds.

The Sozosei Foundation

The Sozosei Foundation was established as a separate legal entity in 2019 as a philanthropic arm of Otsuka. The Foundation is governed by an independent Board of Directors who oversee the strategic direction of the Foundation. The Foundation is guided by a spirit of "Jissho," or "proof through execution," as it employs its unique assets and skills to contribute to the well-being of people, families, and communities. Thanks to Otsuka, the Foundation is able to fuse a profound understanding of the healthcare landscape with an equally profound sense of corporate social responsibility to advance our goal of building healthier communities.

The Foundation's primary focus is to eliminate the use of jail and prisons for the diagnosis and treatment of mental illness. To learn more about the Foundation, visit www.SozoseiFoundtion.org.

The Otsuka Patient Assistance Foundation, Inc. (OPAF)

The Otsuka Patient Assistance Foundation, Inc. (OPAF) was created in 2017 as an independent, non-profit health and wellness organization, focused on reducing barriers that patients face who have been prescribed an Otsuka medication.

Eligible patients have access to free Otsuka medications as well as external resource connectivity, free Nature Made vitamins, and select patients have access to free generic medications. To learn more about OPAF, please visit the OPAF website www.otsukapatientassistance.com.

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We comply with all rules and regulations regarding drug donation and only donate our products to reputable organizations or well-defined government programs, where we can be confident that our products are directed to—and benefit—the intended recipients.

Find Out More

- Always use good judgment and make decisions that are consistent with our values. If the right course of action is ever unclear, [ask for guidance](#).

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OUR BIG VENTURE COMPANY – CLOSING THOUGHTS

Our reputation is a priceless asset, one that has been built over many years. The responsibility to uphold it rests with each one of us. You are key to the success of our company. Each one of us, every day, in every decision has the opportunity to build on our culture of integrity.

With your help and your commitment, we will continue to innovate, to shape change in the industry, and to enhance the health and wellbeing of patients around the world.

Use this Code to guide your daily behavior. It should be viewed as a company policy, and as with other company policies, compliance with it is considered a condition of employment. This Code, however:

- Is not a contract, nor does it in any way alter the at-will employment status of employees in the United States.
- May be amended from time to time. The version in Inkling will always reflect the latest revisions and updates.

"One's personal worth is determined by how many people he or she has made happy"

-Masahito Otsuka