

# Formation Bio

# Code of Conduct

As of January 2023

## **Our Mission**

Formation Bio's mission is to bring new treatments to patients faster and more efficiently. We work to reimagine clinical development by eliminating traditional inefficiencies which cause the high cost of clinical trials. While innovating, we take great care to follow this Code of Conduct to protect patients, doctors, employees and business partners.

## **Our Code of Conduct**

Our Code of Conduct defines our standards of work and outlines our commitment to compliance with applicable regulations. It is available online and in print, and we share it with employees, business partners, and vendors.



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## Company Values

The company values outlined below drive our actions with both our internal Formation Bio colleagues and external partners and vendors. The values are the foundation for our Code of Conduct.

### **Think in First Principles**

When we hear, “It’s always been done this way,” we ask “why,” and strive to understand whether it can be done better or more efficiently than it has in the past. We aren’t afraid to zig when others zag. Our team applies first-principles thinking to our industry expertise, breaking problems down into their fundamental building blocks and reconstructing upwards. We approach work with curiosity and purpose, seeking to understand desired outcomes before choosing a plan of action or following a formula or approach that others have taken previously.

### **Deliver Care**

Our success hinges upon a culture that can sustain innovation and productive collaboration over the long haul. We must care for ourselves, our customers and one another by building an environment of trust, transparency, and continuous growth. This includes creating a diverse, equitable, inclusive work environment where all are valued, celebrated, and feel they belong. We serve as allies to our colleagues, stand up for each other, and make the space to ensure that everyone’s voice is heard.

### **Be a Scientist**

In our industry, time is of the essence – every missed learning opportunity can make a real difference in whether patients see new treatments come to market. Maximizing our learning rate requires scientific discipline: stating hypotheses, testing, measuring and tracking results. We take the scientific methodology seriously and apply it to everything we do, and when faced with ambiguity, we meet it with rigor and curiosity.

### **Champion the Mission**

Our mission is to bring treatments to patients faster and more efficiently. The mission defines the work we do and don’t do, the way we prioritize projects, and who we choose to partner with. We work tirelessly to bring new treatments to patients faster, without ever compromising safety and quality.

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## Company Hotline

Formation Bio employees are expected to uphold the standards outlined in this Code of Conduct and our Employee Handbook. We all play a part in ensuring that Formation Bio is a great place to work where all employees feel included and that they belong. Part of building an inclusive environment is ensuring that your colleagues are following the standards that we uphold. If you see anything that concerns you, we ask that you report it immediately to a member of the Leadership Team or the People Team. You may have a concern related to one or all of the following:

- A violation of the Code of Conduct or failure to adhere to a Formation Bio policy or procedure
- Any form of harassment, discrimination, or retaliation
- A workplace safety concern or violation

If you wish to report something, please call our employee hotline 646-355-8823 to leave a message or speak with a member of the People Team. When you call the hotline, you will hear the following options:

- If you are calling to raise a complaint about harassment, discrimination, or retaliation that you have experienced or observed in any form at work, please press 1.
- If you are calling to report a workplace or trial site safety concern or violation, please press 2.
- If you are calling to report a violation of our clinical code of conduct, please press 3.

Please be assured that your reported issue will be reviewed, investigated and addressed in full, while ensuring that we maintain confidentiality to the best of our ability. Formation Bio does not tolerate any form of retaliation and will protect individuals who report issues.



## Sexual Harassment

We adhere to the The New York City Human Rights Law which prohibits any form of discrimination in employment, including sexual harassment. ***You are required to take annual sexual harassment prevention training in accordance with the Law.***

You can find the New York City sexual harassment training page at <https://www.nyc.gov/site/cchr/law/sexual-harassment-training.page>. A direct link to the training video (in English) can be found at <https://www.nyc.gov/assets/cchr/training/english/index.html>.

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## Clinical trials (GxP)

Bringing new treatment to patients is a complex process involving a wide array of work, including but not limited to pre-clinical testing, clinical trials, safety monitoring, and manufacturing of investigational products. Many regulations govern each of these categories. The purpose of regulations is to make sure drugs are safe and effective, and patients' and trial participants' wellbeing is protected.

Navigating the regulatory landscape can be challenging, and often requires access to a specific expertise in specialized areas of regulations. At Formation Bio, we are committed to identifying and understanding all regulatory requirements relevant to our areas of work and we regularly seek guidance from experts to help us interpret and apply those requirements in our areas of business.

When we plan and conduct clinical trials, the interests and concerns of trial participants and their caregivers are top of mind. We adhere to high ethical, medical, and scientific standards and requirements established by regulatory agencies, ethics committees, and IRBs.

But our job is not done by simply complying with requirements. We care more. We relentlessly ask ourselves: How can we do better for patients and trial participants? At all times, we consider the interests and concerns of patients and their caregivers, clinical research staff, study sponsors and ethics committees/institutional review boards and regulatory agencies.

Throughout our work, we follow the below guidelines:

We only engage in trials designed to test legitimate scientific hypotheses.

We work diligently to ensure the safety of our clinical trial participants, from their physical safety to the protection of their confidentiality and data rights according to applicable regulations.

We strive to increase diversity in clinical trials through in-house recruitment strategies (digital recruitment, hub and spoke model) that unlock access to trials for underrepresented populations. Lack of diversity in clinical trials is a complex problem, partly caused by the lack of access to clinical trials for community physicians and their patients. This results in underrepresentation of certain populations in clinical trials, even though those populations may be disproportionately affected by the condition studied. We are working to solve that problem.

Inefficiencies in clinical trial processes lead to a high cost of trials and translate into a high cost of treatment for the patient. At Formation Bio, we

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examine all clinical trial processes in first principles in order to distinguish what really matters and what can be innovated or eliminated. This allows us to run trials cheaper and faster, while still complying with all regulatory requirements.

We utilize state-of-the-art processes and technology to assure the integrity of the data generated from our trials.

We comply with all requirements for the reporting of adverse events as well as any issues with product quality.

We adhere with all requirements for the listing of our trials at [clinicaltrials.gov](http://clinicaltrials.gov) as well as timely and transparent reporting of study results.

We will train sites not to bill federal insurance programs or any insurance programs for trial-specific activities, and will not engage in trials which induce utilization of healthcare resources outside of protocol-specified procedures.



## Interactions with healthcare professionals

### *Clinical site compensation*

The industry faces a number of challenges in ensuring research objectivity in its healthcare professionals, particularly as it relates to compensation. Our mission prioritizes making new treatments available to the population, and our company value “Be a Scientist” underscores our belief in impartial research consistent with the scientific method.

Formation Bio takes a critical eye to financial and other incentives that could jeopardize the scientific method. Formation Bio compensates investigators or their institutions for providing protocol-required services in clinical trials managed by Formation Bio or on behalf of Sponsors. At Formation Bio, we make sure that the way we engage with physicians does not create a possibility of undue influence over trial-related decisions, or conflict of interest. This is especially important in order to protect trial participants’ rights and wellbeing, and ensure that investigators’ decisions are driven by the trial protocol, and not by monetary gains.

Payment to clinical investigators or their institutions should be reasonable and based on work performed by the investigator and the investigator’s staff, not on any other considerations. Such compensation must be fair, reasonable, and at fair market value.

In order to accomplish this, Formation Bio:

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Requires a written contract or budgetary agreement specifying the nature of the research services to be provided and the basis for payment for those services.

Does not compensate clinical investigators or institutions in company stock or stock options for work performed on individual clinical trials.

Does not tie payments or compensation of any sort to the outcome of clinical trials.

Does not permit clinical investigators or their immediate family to have a direct ownership interest in the specific pharmaceutical product being studied.

Provides for or reimburses clinical investigators and their staff for reasonable travel, lodging, and meals during company-sponsored meetings with investigators.

Collects and reports to the government all payments and transfers of value to U.S.-licensed physicians and teaching hospitals in accordance with the Sunshine Act.

## ***Clinical trial participants***

The patient experience in clinical trials is not always paid appropriate attention. Beyond the regulatory protections we satisfy, we push beyond this status quo with respect for patients as both the participants in clinical trials and as the future beneficiaries of their treatments. We view an augmented trial participant experience as a necessary element of the future of clinical development - only if patients are willing to participate in trials will we advance the clinical trial process to develop new treatments faster and more efficiently.

As trial participants, patients volunteer their time and donate their information, so new treatments can be developed. It is our obligation to treat patients' information with respect, and use it only for the purpose they donated it for. We work hard to make trial participants' experience less burdensome, by reducing time needed for trial visits and making data collection more efficient.

We believe that knowledge is key when making important decisions, such as participation in a clinical trial. We work to provide prospective patients with clear and helpful information they can base their decision on. We do not unduly influence patients in any way, such as coercion, and will seek to be transparent wherever possible in as simple and clear a manner as we can.

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## ***Data protection***

Formation Bio is committed to informed, sustainable, ethical, and compliant data collection and processing. We identify, protect, and appropriately manage sensitive information. Data privacy is a key element in the design and deployment of our systems, products, and services.

We believe in the importance of privacy, and protect personal information from misuse. We challenge ourselves to reassess our rigor, such as in utilizing the minimum information necessary for the work at hand, as our processes and technologies evolve. This rigor ensures we are able to empower our work involving data responsibly.

Our stance on privacy means little if we can't protect it from malicious attacks. We implement advanced protections to maintain security administratively, technically, physically, and psychologically.



## **Our partners and vendors**

We partner with organizations whose standards and ethos are aligned with ours.