

# Heron Therapeutics, Inc. Comprehensive Compliance Program

Heron Therapeutics, Inc. ("Heron") is committed to establishing and maintaining a comprehensive and effective compliance program in accordance with the "Compliance Program Guidance for Pharmaceutical Manufacturers" issued by the Office of Inspector General, U.S. Department of Health and Human Services on May 5, 2003 (the "OIG Guidance"), "Code of Interactions with Health Care Professionals" by the Pharmaceutical Research and Manufacturers of America effective January 2009 (the "PhRMA Code"), and California SB 1765 (California Health and Safety Code 119400, 119402).

Our Heron Compliance Program reflects our unwavering commitment to the highest standards of corporate conduct and integrity. Our Compliance Program contains policies, procedures, and processes to address risk areas identified in the OIG Guidance and PhRMA Code, with the fundamental elements of our Compliance Program described below. As recommended by the OIG Guidance, our Compliance Program has been established consistent with the unique environment that exists at Heron, including our organization's size, organizational structure, and operations. Further, our Compliance Program is regularly reviewed and evaluated to help ensure it continues to meet our evolving compliance needs.

### **COMPLIANCE PROGRAM OVERVIEW**

### 1) Leadership and Structure

**Compliance Officer.** Heron has appointed a Compliance Officer, who is charged with establishing, operating and monitoring the Compliance Program, including oversight of healthcare compliance. The Compliance Officer has direct access to the Heron Board of Directors and senior management, and provides regular reports on the status of the Compliance Program. The Compliance Officer has authority to seek advice from independent legal counsel or other outside experts when appropriate, and is responsible to exercise independent judgment in assessing and implementing compliance-related matters or changes.

**Compliance Committee.** Heron has established a Compliance Committee to advise, counsel, and support the Compliance Officer in the effective implementation of the Compliance Program. The Compliance Committee is comprised of senior management from functional units across the company. It meets on a regular basis, at least quarterly, to assess the operational risks and potential compliance concerns facing the company and identify areas of the Compliance Program for enhancement and further development.



## 2) Written Standards

Heron has established written compliance-related policies and procedures that are consistent with the evolving business and strict regulatory environment. The written policies and procedures, including our Code of Ethics and Business Conduct, outline Heron's commitment to compliance and corporate accountability and are designed to follow the framework laid out by the OIG Guidance and PhrMA Code. Any employee that violates these standards is subject to appropriate disciplinary action, up to and including termination.

Heron does not permit gifts, promotional materials, items, or activities prohibited by the PhRMA Code, OIG Guidance, or FDA regulations. For items and activities that are not prohibited, Heron has set a cumulative annual spending limit of \$2,500 per healthcare professional, outside of the context of legitimate investigative and consultative arrangements. The is an upper limit and addresses spending on healthcare professionals for occasional meals and snacks, meals provided in connection with a Heron speaker program, and any permitted gifts, such as medical related textbooks. We track and monitor compliance with this promotional spending limit to the best of our ability and will modify our internal processes as necessary.

## 3) Education and Training

All employees are required to receive compliance training applicable to their job functions and responsibilities, which includes training on this Compliance Program and applicable Compliance policies. In addition, further specialized training may be provided where a need for additional training has been identified. Annual healthcare Compliance training is required of all employees, contractors and agents who engage in, or support, commercial activities. Heron regularly reviews, evaluates, and updates its training programs to strengthen the programs' overall effectiveness and help ensure they continue to meet the educational needs of our employees.

### 4) Internal Lines of Communication

Heron is committed to fostering an environment where open communication is encouraged. This includes, in particular, asking questions or reporting potential instances of inappropriate activity without fear of retribution. Heron employees are encouraged to reach out to their Supervisor, Human Resources, the Compliance Officer, or the General Counsel to report suspected violations of our Code, policies, or the law. Further, employees may report anonymously to Heron's third party Ethics and Compliance "Hotline" accessible 24 hours a day, seven days a week.

Heron employees are obligated to report actual or suspected violations of the Code, our policies, or the law. Heron has a strict non-retaliation policy – there will be no reprisals for good faith reporting and employees will be protected from any form of retaliation.



## 5) Auditing and Monitoring

Heron recognizes that a comprehensive auditing and monitoring plan is critical to maintaining the effectiveness of a Compliance Program. Heron engages in auditing and monitoring of various business practices to ensure compliance with our written standards. The subject of our auditing and monitoring efforts, as well as the extent and frequency of our reviews, may vary according to a variety of factors, including changing regulatory requirements, changes in business practices and other considerations. The auditing and monitoring program is reviewed periodically to ensure that it is focused on the right business activities and risks. As appropriate, auditing and monitoring results will be reported to the Legal department and senior management in order to help guide Heron's risk-assessment process.

## 6) Responding to Potential Violations

The purpose of our Compliance Program is to prevent and detect violations of law or company policy. As the OIG Guidance recognizes, however, the implementation of this Compliance Program cannot guarantee that improper employee conduct will be entirely eliminated. Nonetheless, it is Heron's expectation that employees will comply with the Compliance Program and all associated policies and procedures. In the event that Heron becomes aware of violations of law or company policy, we will promptly investigate the matter and, where appropriate, take disciplinary action up to and including termination. Where appropriate, Heron will also implement corrective measures to address potential policy gaps and prevent future violations.

### 7) Corrective Action

Heron will provide clear disciplinary policies that set out the consequences of violating the law or company policy. After investigation of a reported or detected issue, Heron will assess whether disciplinary action is appropriate, and whether a violation is in part due to gaps in our policies, practices, training or internal controls, and take action to prevent future violations.

For a copy of this Compliance Program, please email ComplianceHTX@herontx.com