

## Ionic Pharmaceuticals Financial Conflicts of Interest (FCOI) Policy

*Version 1; Effective July 1st, 2021*

*In accordance with the Code of Federal Regulation (42 CFR Part 50, Subpart F, Responsibility of Applicants for Promoting Objectivity in Research for Which Public Health Service (PHS) Funding Is Sought; and 45 CFR Part 94, Responsible Prospective Contractors) and the Federal Acquisition Regulation (FAR Part 9.5, Organization and Consultant Conflicts of Interest)*

### 1. Policy Statement

As a professional research corporation, Ionic Pharmaceuticals, LLC (hereinafter “**Ionic**”) is committed to protecting the integrity and objectivity of its research activities by ensuring that the design, conduct, and reporting of research will not be biased or appear to be biased by a personal financial conflict of interest. Ionic has implemented this policy to identify, manage, reduce, or eliminate financial conflicts of interest.

The procedures described in this policy were created and designed to comply with i) specific regulatory requirements for U.S. Public Health Service (PHS)-sponsored research (42 CFR Part 50 Subpart F and 45 CFR Part 94) and ii) specific regulatory requirements for U.S. Army Medical Research Acquisition Activity (USAMRAA)-sponsored research (FAR Part 9.5), and are also intended to provide a basic framework and standards for identifying, evaluating, and managing potential financial conflicts of interest relating to Ionic's other research activities. For non-PHS and non-USAMRAA research, the specific steps, timing, determinations, documentation, and notifications may be tailored as appropriate but will remain focused on maintaining Ionic's high standards for research integrity and effectively eliminating or managing actual or potential financial conflicts of interest, including the appearance of the same.

### 2. Reason for Policy

This policy and related procedures have been developed to identify, manage, mitigate, neutralize, or eliminate actual, apparent, and potential financial conflicts of interest. The policy was written to be in conformance with the Code of Federal Regulations (CFR) 42, Part 50, Subpart F, Responsibility of Applicants for Promoting Objectivity in Research for Which Public Health Service (PHS) Funding Is Sought\*; 45 CFR Part 94, Responsible Prospective Contractors; and FAR Part 9.5, Organization and Consultant Conflicts of Interest.

\* These regulations do not cover Small Business Innovation Research (SBIR)/Small Business Technology Transfer (STTR) Program Phase 1 applications or awards but do apply to applicants and recipients under the SBIR/STTR Program Phase II. SBIR is the extramural research program for small business that was established by the Awarding Components of PHS and certain other Federal agencies under Pub. L. 97-219, the Small Business Innovation Development Act, as amended. The term SBIR Program includes the STTR Program, which was established by Pub. L. 102-564.

Ionic will maintain an up-to-date written, enforced policy on financial conflicts of interest that complies with applicable regulations, including any federal financial conflict of interest regulations. The policy will be posted and available via the Company's publicly accessible website. The Company will inform covered individuals of the policy and of their responsibilities regarding disclosure. The Company will inform covered individuals in the event the policy is revised and updated.

### 3. Definitions

For purposes of this policy, the following definitions shall apply:

**Designated Official** is the individual designated by Ionic to oversee the financial conflicts of interest process, including solicitation and review of disclosures of significant financial interests.

**Equity interest** includes any stock, stock option, or other ownership interest, and its value may be determined through reference to public prices or other reasonable measures of fair market value.

**Financial conflict of interest (FCOI)** means a significant financial interest that could directly and significantly affect the design, conduct, or reporting of research as determined by Ionic through the Designated Official.

**Financial interest** means anything of monetary value, whether or not the value is readily ascertainable.

**Immediate family** refers to an Investigator's spouse and dependent children.

**Investigator** means the project director/principal investigator and any other person who is responsible for the design, conduct, or reporting of the research or proposed research.

**PHS** means the U.S. Public Health Service, an operating division of the U.S. Department of Health and Human Services (HHS), and any components of the PHS to which the authority involved may be delegated, including the National Institutes of Health.

**PHS Awarding Component** means the organizational unit of the PHS that funds the research that is subject to 42 CFR Part 50, Subpart F, and 45 CFR Part 94.

**PHS-funded or PHS-sponsored Research** means research funded under PHS grants, cooperative agreements, or contracts, authorized under the PHS Act or other statutory authority.

**Public Health Service Act, or PHS Act** means the statute codified at 42 U.S.C. 201 et seq.

**Remuneration** includes, for example, salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship).

**Research** means a systematic investigation, study, or experiment designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social sciences research. The term encompasses basic and applied research (e.g., a published article, book, or book chapter) and product development (e.g., a diagnostic test or drug).

**Significant financial interest (SFI)** means a financial interest consisting of one or more of the following interests of the Investigator and his/her immediate family that reasonably appear to be related to the Investigator's Ionic project responsibilities, including:

1. With regard to interests in any publicly traded entity, a financial interest consisting of any remuneration received from the entity in the 12 months preceding the disclosure and any equity interest (e.g., stock, stock option, or other ownership interest) in the entity as of the date of disclosure, in which the value when aggregated exceeds \$5,000;
2. With regard to interests in any non-publicly traded entity, a financial interest consisting of any remuneration received from the entity in the 12 months preceding the disclosure, in which the value when aggregated exceeds \$5,000, or when the Investigator or his/her immediate family holds any equity interest (e.g., stock, stock option, or other ownership interest);
3. Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests, in which the value when aggregated exceeds \$5,000;

Significant financial interests also include any reimbursed or sponsored travel (i.e., that which is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available) related to the Investigator's Ionic project responsibilities, provided, however, that this disclosure requirement does not apply to travel that is reimbursed or sponsored by a Federal, state, or local government agency; an institution of higher education as defined at 20 U.S.C. 1001(a); an academic teaching hospital; a medical center; or a research institute that is affiliated with an institution of higher education. Disclosure of such travel is to include the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration.

SFI also includes all financial interests received from a foreign institution of higher education or the government of another country (see FAQs E.21 and E.24 and NIH Guide Notice NOT-OD-18-160).

Significant financial interest does not include the following:

- Salary, royalties, or other remuneration paid by Ionic (or a subrecipient as applicable) to the Investigator if the Investigator is currently employed or otherwise appointed by Ionic, including that paid for intellectual property rights assigned or licensed to Ionic and agreements to share in royalties related to such rights;
- Any ownership interest in Ionic (or a subrecipient as applicable) held by the Investigator (e.g., Employee Stock Ownership Plan);
- Income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles;
- Income from seminars, lectures, or teaching engagements sponsored by a Federal, state, or local government agency; an institution of higher education as defined at 20 U.S.C. 1001(a); an academic

teaching hospital; a medical center; or a research institute that is affiliated with an institution of higher education; or

- Income from service on advisory committees or review panels for a Federal, state, or local government agency; an institution of higher education as defined at 20 U.S.C. 1001(a); an academic teaching hospital; a medical center; or a research institute that is affiliated with an institution of higher education.

**USAMRAA** means the U.S. Army Medical Research Acquisition Activity.

**USAMRAA-sponsored Research** means research funded under USAMRAA grants, cooperative agreements, or contracts.

## 4. Procedures

### 4.1. Responsibilities of Ionic's Designated Official

The Designated Official (or his/her designee, used throughout) shall be responsible for the following:

- Informing Ionic Investigators of their obligations under this policy and any related regulations;
- Providing and maintaining a form for disclosing FCOIs (the Ionic FCOI Disclosure Form)
- Reviewing disclosures of significant financial interest (SFI) with Ionic's Administrator to determine whether they are related to the PHS- or USAMRAA-sponsored research and, if so, whether they constitute financial conflicts of interest (prior to expending PHS/USAMRAA funds, and ongoing) (i.e., an SFI that could directly and significantly affect the design, conduct, or reporting of the PHS/USAMRAA-sponsored research);
- Providing adequate guidelines to Investigators consistent with the regulation for the above determination;
- Screening and managing potential financial conflicts of interest (prior to expending PHS/USAMRAA funds, and ongoing);
- Providing to Investigators examples of conditions or restrictions that might be imposed to manage conflicts of interest (e.g., full public disclosure, appointment of an independent monitor, modification of the research plan, etc.);
- Maintaining all records relating to disclosures of financial interests, Ionic's review of and response to such disclosures, and any related actions under this policy;
- Ensuring inclusion of any required certifications in applications for funding or contract proposals; and
- Reporting and disclosure as required under this policy and applicable regulations.

The Designated Official shall also have the following responsibility regarding PHS/USAMRAA-sponsored **subrecipients**:

- Taking reasonable steps to ensure that Investigators for **subrecipients** (e.g., subgrantees, subcontractors, or collaborators) fully comply with this policy or provide Ionic with sufficient assurances to enable Ionic's compliance with all applicable laws or regulations. To this end, the written agreement between Ionic and the subrecipient will specify whether Ionic's or the subrecipient's financial conflicts of interest policy will apply to the subrecipient's Investigators and, if the subrecipient's policy will apply, the Designated Official will:
  - Obtain certification from the subrecipient that its policy complies with Ionic's policy and the applicable regulations (absent such certification, Ionic's policy will apply to the subrecipient's Investigators), and
  - Establish time periods for subrecipient reporting of financial conflicts of interest to Ionic that enable Ionic to report such conflicts in a timely manner, as required under its policy and the applicable regulations.

If Ionic's policy will apply to the subrecipient Investigators, Ionic will be responsible for meeting the requirements of this policy and the reporting obligations reflected in the applicable regulations.

### 4.2. Responsibilities of Ionic's PHS- and USAMRAA-sponsored Investigators

- Completing FCOI training as described elsewhere in this Policy
- Submitting to the Designated Official a FCOI Disclosure Form, if such a SFI exists, prior to working on PHS/USAMRAA-sponsored projects, or as soon as possible when a new SFI comes into existence
- Updating any submitted Financial Interest Disclosure Form annually or within 30 days of a change in financial status (acquisition of new financial interest), whichever occurs first.
- Following management plan as prescribed by the Designated Official for FCOIs.

### 4.3. Internal Reporting Requirements

For PHS- and USAMRAA-sponsored research in particular, as part of the funding application or proposal and prior to performing any work on the research, each Investigator who is planning to participate in the research is required

by regulation to complete a **FCOI Disclosure Form** and submit the FCOI Disclosure Form to Ionic's Administrator. This requirement also applies to Investigators who are or who work for subgrantees, subcontractors, or collaborators on PHS/USAMRAA-sponsored research. FCOI Disclosure Forms will be provided to Investigators in conjunction with the annual training and will be otherwise made available. Ionic's Administrator will review FCOI Disclosure Form submissions with the Designated Official. The information reported on the Disclosure Form includes a listing of the Investigator's known significant financial interests and those of his/her immediate family (spouse and dependent children) that reasonably appear to be related to the research or that are in entities whose financial interests could be affected by the research.

Ionic Investigators in non-PHS-funded and non-USAMRAA-sponsored research who have any significant financial interest that may reasonably appear to be affected by the research are also expected to complete the Disclosure Form and submit it to Ionic's Administrator.

Investigators are expected to submit an updated Disclosure Form during the period of the award as necessary (at least annually for PHS/USAMRAA-sponsored research). The annual update will typically be done in conjunction with completion of the annual training. Such disclosures shall include any information that was not previously disclosed; any change in information regarding any previously disclosed significant financial interest; no later than at the time of application for PHS- and USAMRAA-sponsored research; or, within 30 days of discovery or acquisition, any new significant financial interest (e.g., an interest acquired through purchase, marriage, or inheritance).

#### 4.4. Determination and Management of Financial Conflicts of Interest

Upon receipt of a completed FCOI Disclosure Form, the Designated Official shall determine whether an Investigator's significant financial interest is related to the subject research and, if so, whether the interest constitutes a financial conflict of interest under this policy and any applicable regulations (performed prior to expending PHS/USAMRAA funds, and ongoing). The Investigator may be required to submit additional information as part of the process. A disclosed interest may be related to the subject research either because the interest could be affected by the research or because it is in an entity whose financial interest could be affected by the research. A financial conflict of interest exists if the significant financial interest could directly and significantly affect the design, conduct, or reporting of the research.

If Ionic determines that a financial conflict of interest exists, a **financial conflicts of interest management plan** will be implemented prior to expending PHS/USAMRAA funds, will be monitored on an ongoing basis, and will remain in effect at least until completion of the project. The management plan will include appropriate steps to manage, reduce, neutralize, or eliminate the conflict. The following are examples of conditions or restrictions that might be imposed:

- Disclosure to research participants or the public of significant financial interests (e.g., when presenting or publishing the research);
- Monitoring of research by independent reviewers;
- Modification of the research plan;
- Disqualification of staff from participation in all or a portion of the research;
- Reduction or divestiture of a financial interest; or
- Severance of relationships that create actual or potential conflicts.

In addition to the conditions or restrictions described above, Ionic may require the management of conflicting financial interests in other ways as it deems appropriate.

When i) an Investigator who is new to participating in the research project, or when ii) an existing Investigator discloses a new SFI, or when iii) Ionic identifies an SFI that was not disclosed timely by an Investigator or, for whatever reason, was not previously reviewed by the Institution during an ongoing PHS/USAMRAA-sponsored research project (e.g., was not timely reviewed or reported by a subrecipient), the institution's Designated Official(s) shall within sixty (60) days review disclosures of SFIs, determine whether the SFI is related to PHS/USAMRAA-sponsored research; determine whether an FCOI exists; and, if so, implement, on at least an interim basis, a management plan that shall specify the actions that have been, and will be, taken to manage such FCOI.

#### 4.5. External Reporting Requirements

Ionic will disclose financial conflicts of interest as required by applicable laws or regulations. Before expending any funds under a PHS or USAMRAA award (and ongoing), Ionic will ensure **public accessibility** by posting financial conflicts of interest information, including revisions to such FCOI information, as well as this FCOI Policy, on a publicly available web site and by responding in a timely manner to written requests as required under the regulations. Such publicly accessible information will include the minimum elements as provided in the regulation,

will be updated at least annually and within 60 days of a newly identified FCOI, and will remain available for 3 years from the date the information was most recently updated.

The Designated Official will report to the PHS Awarding Component, as detailed in the regulations, the existence of any financial conflict of interest that has not been eliminated and will ensure that Ionic has implemented a plan to manage the conflict.

- Ionic will send initial, annual (i.e., ongoing) and revised FCOI reports, including all required information defined in the regulation and/or NIH's FAQ H.5, to the NIH via the eRA Commons FCOI Module for Ionic and its subrecipients, if applicable, as required by the regulation: prior to ending PHS funds; within 60 days of identifying a FCOI for new Investigators or newly identified FCOIs for existing investigators; at least annually (coinciding with submission of the project's annual progress report, which will provide the status of the FCOI and any changes to the management plan, if applicable, at least until the completion of the project); and after a retrospective review to update a previously submitted report, if new information is discovered following completion of the review.

If a financial conflict of interest is identified after its initial reporting and during ongoing research (e.g., through participation of a new Investigator) and has not been eliminated, Ionic will provide the PHS Awarding Component with an update within 60 days and ensure that it has implemented a plan to manage the conflict. If the financial conflicts of interest report involves a significant financial interest that was not disclosed by an Investigator or not previously reviewed or managed by Ionic (e.g., not reviewed or reported by a subrecipient in a timely manner) or a FCOI management plan with which an Investigator failed to comply, Ionic will undertake a retrospective review. Such retrospective review will determine whether there was bias in the design, conduct, or reporting of the PHS-funded research, or portion thereof, conducted prior to the identification and management of the conflict. If bias is found, Ionic will promptly notify the PHS Awarding Component and submit a mitigation report to explain what action(s) have been or will be taken to mitigate the effects of the bias in accordance with the regulation. Such notification will include all reporting elements (e.g., entity name, name of the investigator with the FCOI, nature of SFI(s), value of the SFI(s), etc.) as required by the regulation. See Section 4.7, Noncompliance, for further details on retrospective review.

Upon request, Ionic will provide HHS or USAMRAA with information relating to any Investigator disclosure of significant financial interests; Ionic's review of, and response to, such disclosure; and whether the disclosure resulted in Ionic's determination of a financial conflict of interest.

#### 4.6. Confidentiality

Ionic will, to the extent possible, protect the confidentiality of disclosures. In every instance, Ionic will endeavor to balance the privacy interests of individuals with its responsibility and obligation to identify and manage conflicts of interest. Disclosures will be available to Ionic staff only on a need-to-know basis and will not be disclosed outside of Ionic unless necessary to comply with contractual, legal, or regulatory requirements.

#### 4.7. Noncompliance

If an Investigator knowingly fails to comply with this policy (e.g., fails to identify an actual or potential financial conflict of interest), Ionic may take appropriate disciplinary action (i.e. sanctions), which may include, without limitation, termination of the Investigator's participation in the research. In addition, for PHS- and USAMRAA-sponsored research, failure to comply with this policy or the applicable regulations shall result in the following:

- If the Investigator's failure to comply with this policy or a financial conflicts of interest management plan has biased the design, conduct, or reporting of the sponsored research, Ionic shall promptly notify the PHS Awarding Component or the USAMRAA grants officer of the corrective action taken or to be taken;
- Ionic will make available to HHS or USAMRAA all records pertinent to financial conflicts of interest and the management of those conflicts; and
- If HHS or USAMRAA determines that a clinical PHS/USAMRAA-sponsored research project whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment has been designed, conducted, or reported by an Investigator with a financial conflict of interest that was neither disclosed nor managed, Ionic shall require disclosure of the conflicting interest in each public presentation of the results of the research and shall request an addendum to previously published presentations, if necessary.

Ionic shall Complete a **retrospective review** within 120 days of the Institution's determination of noncompliance when an SFI is not disclosed timely or previously reviewed or whenever an FCOI is not identified or managed in a timely manner, including:

- Failure by the Investigator to disclose a significant financial interest that is determined by the Institution to constitute a financial conflict of interest;
- Failure by the Institution to review or manage such a financial conflict of interest;
- Failure by the Investigator to comply with the financial conflict of interest management plan

The documentation for the retrospective review shall include at least the following key elements: Project number and title, PD/PIs, name of the Investigator having the FCOI and the entity with which the FCOI exists, reasons for the retrospective review, the detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documentation reviewed), and the findings and conclusions of the review.

#### 4.8. Training and Education

Investigators receive training to promote objectivity in research and to ensure Investigator compliance with regard to the applicable regulations and significant financial interest disclosure obligations. The training module and other resources developed by NIH will be updated as appropriate and can be accessed through the [NIH Web site](#). Investigators are to be made aware of: i) this FCOI Policy, ii) the Investigator's corresponding disclosure responsibilities, and iii) the applicable Federal Regulations (42 CFR 50F; 45 CFR 94; FAR 9.5).

Ionic requires Investigators to complete such training annually, and when any of the following occurs:

- Ionic revises its financial conflicts of interest policy or procedures in any manner that affects the Investigator's obligations;
- An Investigator is new to Ionic;
- Prior to engaging in research related to any PHS/USAMRAA-sponsored research project; or
- Ionic finds that an Investigator is not in compliance with this policy or a financial conflicts of interest management plan.

#### 4.9. Retention of Records

The Designated Official will retain financial conflicts of interest disclosure forms, records of Ionic's review of and response to such disclosures (whether or not a disclosure resulted in the Institution's determination of a financial conflict of interest), all actions under the Institution's policy or retrospective review, and other supporting information consistent with Ionic's Record Retention policy. For PHS/USAMRAA-sponsored research, records of all financial disclosures, whether or not they result in a reporting obligation, and all actions taken by Ionic with respect to each financial conflict of interest will be retained for at least 3 years from the date of submission of the final expenditures report or final payment on the contract or, where applicable, from other dates specified in 45 CFR 74.53(b), 45 CFR 75.361, or 48 CFR Part 4, Subpart 4.7.

### 5. Point of Contact

If you have a conflict of interest or if you have a question to discuss, contact the Ionic Administrator at [info@ionicpharma.com](mailto:info@ionicpharma.com).