

## **Mustang Bio, Inc. Financial Conflict of Interest Policy**

### **I. INTRODUCTION**

#### **A. Purpose**

This policy implements U.S. federal requirements pertaining to “Objectivity in Research” promulgated by the Public Health System (“PHS”) of the U.S. Department of Health and Human Services (“HHS”), which includes the U.S. National Institutes of Health (“NIH”), the Biomedical Advanced Research and Development Authority (“BARDA”), the Center for Disease Control and Prevention, and the Agency for Healthcare Research and Quality (“FCOI Policy”). Financial Conflict of Interest (“FCOI”) requirements, related to PHS Organization-funded research, are published in U.S. regulations 42 CFR Part 50, Subpart F and 45 CFR Part 94.

The intent of this FCOI Policy is to promote objectivity in research by establishing standards to ensure there is no reasonable expectation that the design, conduct or reporting of research performed under grants or contracts with PHS Organizations will be biased by any conflicting financial interest. To apply for funding with PHS Organizations, Mustang must be able to certify, in each application for funding, that Mustang:

- Has in effect, an up-to-date, written and enforced administrative process to identify and manage FCOI;
- Will promote and enforce Covered Individual compliance with the regulation;
- Will manage FCOI and provide initial and ongoing FCOI reports;
- Will make FCOI and significant financial interest information available to the PHS Organization, promptly, upon request; and
- Will fully comply with the regulation’s requirements.

Mustang’s FCOI process addresses training requirements; disclosure, review, and monitoring requirements; reporting requirements; maintenance of records; enforcement mechanisms and remedies for noncompliance; sub-recipient requirements; and public accessibility requirements.

#### **B. Scope**

A Mustang employee or contractor who submits a grant or contract proposal or conducts research under a PHS Organization’s funding grants or contracts must adhere to the applicable requirements of the PHS Organization, including those involving the disclosure and regulation of outside activities and financial interests. Specific FCOI laws and regulations are applicable to all project directors and principal investigators, whether employees or contractors, who are responsible for the design, conduct and reporting of research work under grants and contracts with PHS Organizations.

A number of non-PHS organizations have adopted the PHS regulations. These include, but are not limited to, the American Cancer Society, the American Heart Association, and the Juvenile Diabetes Research Foundation. FCOI disclosure process may be implemented on a case-by-case basis for non-PHS, non-profit organizational funded grants requiring similar disclosure, but this policy does not require it.

## II. DEFINITIONS

- A. Covered Individual ("CI"):** Any Mustang employee or contractor who is responsible for the design, conduct or reporting of a PHS-Funded Research project or proposed for such project, including any project director, principal investigator and any other key personnel designated as such in a PHS-Funded grant application or contract.
- B. Covered Individual Responsibilities:** A Covered Individual's professional responsibilities performed on behalf of an entity that proposes to undertake or undertakes PHS-Funded Research.
- C. Equity Interest:** Any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value.
- D. Financial Conflict of Interest ("FCOI"):** A Financial Interest that could directly and significantly affect the design, conduct or reporting of PHS-Funded Research.
- E. Financial Interest:** Any interest of monetary value, regardless of whether the value is readily ascertainable.
- F. Immediate Family:** A Covered Individual's spouse or domestic partner and dependent children.
- G. Mustang:** Mustang Bio, Inc. or any company that is majority-owned by Mustang Bio, Inc.
- H. Non-Significant Financial Interests ("Non-SFI"):** include the following types of Financial Interests:
  - a. Remuneration paid by an entity to which a CI owes Covered Individual Responsibilities, if the CI is currently employed or otherwise appointed by such entity, including intellectual property rights assigned to such entity and any agreement to share in royalties related to such rights; or
  - b. Any ownership interest in an entity held by the CI or income from investment vehicles, such as mutual funds and retirement accounts, so long as the CI does not directly control the investment decisions made in these vehicles; or
  - c. Income from seminars, lectures, or teaching engagements sponsored by a US 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
  - d. Income from service on advisory committees or review panels for a US 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.
- I. PHS:** Public Health Service of the U.S. Department of Health and Human Services, and any components of the PHS to which the authority involved may be delegated, including, among others, the NIH. A listing of the PHS agencies and their offices may be located on the U.S. Department of Health and Human Services Organizational Chart.

- J. PHS-Funded Research:** any Research funded by way of a grant from, or a contract with, a PHS Organization.
- K. PHS Organization:** (i) an agency that is part of the PHS or (ii) an organization that has adopted the PHS Regulations, but not a non-governmental non-profit organization.
- L. PHS Regulations:** U.S. 42 CFR Part 50, Subpart F and 45 CFR Part 94.
- M. Remuneration:** (i) salary and any payment for services including consulting fees and honoraria; (ii) any Equity Interest; and (iii) travel reimbursement related to the Covered Individual Responsibilities.
- N. Research:** 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, including basic and applied research (e.g., a published article, book, or book chapter) and product development (e.g., a diagnostic test or drug).
- O. Significant Financial Interest (“SFI”):** A Financial Interest consisting of one or more of the following interests of a Covered Individual (and those of the Covered Individual’s Immediate Family) that reasonably appear to be related to Covered Individual Responsibilities, but specifically excludes any Non- SFI:
  - a.** Any Remuneration received from any publicly traded entity in the twelve months preceding the disclosure and the value of any Equity Interest in such entity as of the date of disclosure, when aggregated, exceeds \$5,000; or
  - b.** Any Remuneration received from any non-publicly traded entity in the twelve months preceding the disclosure and the value of any Equity Interest in such entity as of the date of disclosure, when aggregated, exceeds \$5,000; or
  - c.** Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.

### III. TRAINING REQUIREMENTS

Mustang will inform each Covered Individual of Mustang’s FCOI Policy, the Covered Individual Responsibilities, and the PHS Regulations. In addition, Each Covered Individual is required to complete FCOI training prior to engaging in PHS-Funded Research, at least every four years, and immediately, if Mustang revises the FCOI Policy that affects requirements of Covered Individuals, a Covered Individual is new to Mustang or a Covered Individual is not in compliance with the FCOI Policy or of a management plan.<sup>1</sup>

### IV. DISCLOSURE, REVIEW AND MONITORING REQUIREMENTS

Mustang requires each Covered Individual to disclose SFIs (and those of the Covered Individual’s Immediate Family) related to the Covered Individual Responsibilities that meet or exceed the definition of SFI. This disclosure must occur no later than at the time of application for PHS-Funded Research, at least annually during the period of the award, and within 30 days of discovering or acquiring a new SFI.<sup>2,3</sup>

Investigators also must disclose the occurrence of 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 their Institutional 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. Such disclosure will include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. Institutional official(s) will determine if further information is needed, including a determination or disclosure of monetary value, to determine whether the travel constitutes an FCOI with the PHS-funded research.

Those individuals designated by Mustang to administer the FCOI will solicit and review disclosures of SFIs of the Covered Individual (and those of the Covered Individual's Immediate Family) related to a Covered Individual Responsibilities.<sup>4</sup> These designated individuals shall determine, pursuant to compliance guidelines approved by Mustang, whether a Covered Individual's SFI is related to PHS-Funded Research and, if so related, whether the SFI is an FCOI.<sup>5</sup>

These designated individuals shall, prior to Mustang expenditure of award funds, review all Covered Individual SFI disclosures, determine if any SFIs relate to PHS-Funded Research, determine if an FCOI exists (i.e., SFI that could directly and significantly affect the design, conduct, or reporting of the PHS-Funded Research), and develop and implement management action plans, as needed, to manage FCOIs.<sup>6</sup>

Disclosure of SFIs will be reviewed for purposes of making an FCOI determination and implementing a management plan, as needed:

- When required for a Covered Individual who is new to participating in a PHS-Funded Research project or for an existing Covered Individual, who discloses a new SFI<sup>7</sup>;
- Within 60 days whenever Mustang identifies an SFI that was not disclosed by a Covered Individual or not previously reviewed by Mustang.<sup>8</sup>

Mustang will take such actions necessary to manage FCOIs, including any financial conflicts of a Subcontractor, if applicable, and monitor Covered Individual compliance with management plans until completion of the PHS-Funded Research project.<sup>9</sup>

## **V. REPORTING REQUIREMENTS**

Initial, annual (i.e., ongoing) and revised FCOI reports will be sent to the PHS Organization including all reporting elements required by the regulation<sup>10</sup> for Mustang and its sub-recipients, if applicable, as required by PHS Regulations:

- Prior to expenditure of funds;
- Within 60 days of identification of an FCOI for a Covered Individual who is newly participating in the project;
- Within 30 days for new, or newly identified, FCOIs, for existing Covered Individuals;
- At least annually (at the same time as when Mustang is required to submit the annual progress report, multi-year progress report, if applicable, or at the time of extension) to

- provide the status of the FCOI and any changes to the management plan, if applicable, until the completion of the project;
- Following a retrospective review to update a previously submitted report, if appropriate.

In the event Mustang identifies an SFI that was not disclosed, identified, reviewed, or managed in a timely manner (as required by the PHS Regulations and described above), then within 60 days, a review and determination of whether an FCOI exists will be made; and if it exists, such FCOI will be reported to the PHS Organization. Additionally, if an FCOI exists, within 120 days of Mustang's determination of noncompliance, a retrospective review of the Covered Individual's activities and PHS-Funded Research shall be completed to determine whether any of the funded research, or a portion thereof, conducted during the time period of the noncompliance was biased in the design, conduct or reporting of such research. During the time the retrospective review is being conducted, a management plan will be implemented, on at least an interim basis. The management plan will specify the actions that have been, and will be, taken to manage the FCOI going forward. Subsequent to the retrospective review, if applicable, the existing FCOI report will be updated; and if bias is found, the PHS Organization will be notified promptly and receive a mitigation report.

The PHS Organization will be notified promptly if a Covered Individual's failure to comply with the FCOI Policy or if an FCOI management plan appears to have biased the design, conduct or reporting of the PHS-Funded Research, and, in such an instance, inform the PHS Organization of the corrective action taken or to be taken.<sup>11</sup>

## **VI. MAINTENANCE OF RECORDS**

FCOI-related records will be maintained:<sup>12</sup>

- For at least three years from the date the final expenditure report is submitted to the PHS Organization;
- From other dates specified in 45 CFR 74.53(b) and 92.42(b) where applicable.

## **VII. ENFORCEMENT MECHANISM AND REMEDIES FOR NONCOMPLIANCE**

Mustang may adopt one or more enforcement mechanisms, up to and including but not limited to termination of employment or contractual engagement, as applicable, to ensure Covered Individual compliance and corrective actions are taken in the event of a deviation from this FCOI Policy and applicable requirements.<sup>13</sup>

In any case in which HHS determines that a PHS-Funded Research project of clinical research, whose purpose is to evaluate the safety or effectiveness of a drug, medical device or treatment, has been designed, conducted or reported by a Covered Individual with an FCOI that was not managed or reported by Mustang as required, the Covered Individual will be required to disclose the FCOI in each public presentation of the results of the research, and request an addendum to previously published presentations and publications.<sup>14</sup>

## **VIII. THIRD PARTY REQUIREMENTS**

Any contractor or collaborator who carries out PHS-Funded Research with Mustang (“Subcontractor”) must certify, via written agreement, that it will follow this FCOI Policy or the Subcontractor’s own FCOI Policy.<sup>15</sup>

If the Subcontractor certifies that it will comply with this FCOI Policy, the agreement applicable to its engagement regarding PHS-Funded Research with Mustang must specify the time periods for the Subcontractor to report all SFI to Mustang in order to provide sufficient time to comply with timely review, management and reporting obligations required by this FCOI Policy.

If the Subcontractor certifies that it will comply with its own FCOI Policy, the written agreement with the Subcontractor shall include:

- A copy of the Subcontractor FCOI Policy;
- A certification by the Subcontractor that its policy complies with all applicable laws, regulations, and rules (including, but not limited to the PHS Regulations; and
- Time periods for the Subcontractor to report any identified FCOI to Mustang defined to permit sufficient time to enable Mustang to provide timely FCOI reports under this FCOI Policy, as necessary, to the PHS Organization.

## **VIII. ACCESSIBILITY OF DISCLOSURE DOCUMENTATION**

The most recent version of this FCOI Policy will be published on the Mustang website.<sup>16</sup>

Information concerning identified FCOIs will be made available to a requesting PHS organization within five business days of receipt of a written request from such PHS organization. Cis must update the information at least annually, and within 60 days of a newly identified FCOI. All records regarding identified FCOIs will remain available for three years from the date of the last payment by PHS Organization.<sup>17</sup>

Mustang Bio, Inc. FCOI Policy\Updated: October 2021

---

<sup>1</sup> 42 CFR 50.604(b)

<sup>2</sup> 42 CFR 50.603

<sup>3</sup> 42 CFR 50.604(e)(1)-(3)

<sup>4</sup> 42 CFR 50.604(d)

<sup>5</sup> 42 CFR 50.604(f)

<sup>6</sup> 42 CFR 50.605(a)(1)

<sup>7</sup> 42 CFR 50.605(a)(2)

<sup>8</sup> 42 CFR 50.605(a)(3)(i)-(iii)

<sup>9</sup> 42 CFR 50.604 (g) and 42 CFR 50.605 (a)(4)

<sup>10</sup> 42 CFR 50.604(h) and 42 CFR 50.605(b)

<sup>11</sup> 42 CFR 50.606(a)

<sup>12</sup> 42 CFR 50.604(i)

<sup>13</sup> 42 CFR 50.604(j)

<sup>14</sup> 42 CFR 50.606(c)

<sup>15</sup> 42 CFR 50.604(c)(1)(i)-(iii)

<sup>16</sup> 42 CFR 50.604(a)

---

<sup>17</sup> 42 CFR 50.605(a)(5)(i)-(iv)