REGENERON PHARMACEUTICALS, INC.
FINANCIAL CONFLICTS OF INTEREST POLICY FOR PHS-FUNDED RESEARCH

I. INTRODUCTION

This Financial Conflicts of Interest Policy for PHS-Funded Research ("FCOI 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") and the Biomedical Advanced Research and Development Authority ("BARDA"). Financial Conflict of Interest ("FCOI") requirements related to PHS-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 help ensure that the design, conduct or reporting of research performed with funds received from PHS Organizations will not be biased by any conflicting financial interest. To apply for funding with PHS Organizations, Regeneron Pharmaceuticals Inc. ("Regeneron") must be able to certify, in each application for funding, that Regeneron:

- has in effect, an up-to-date, written and enforced process to identify and manage FCOI;
- will promote and enforce 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 regulatory requirements.

II. DEFINITIONS

A. **Covered Individual:** Any person regardless of title or position (including collaborators, contractors, fee-for-services providers and/or consultants) who is responsible for the design, conduct or reporting of Research funded by the PHS, or proposed for such funding.

B. **Covered Individual Responsibilities**: A Covered Individual's responsibilities performed on behalf of Regeneron.

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 Significant Financial Interest that could directly and significantly affect the design, conduct or reporting of PHS-Funded Research.

E. **Financial Interest:** Anything 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. **Non-Significant Financial Interests ("Non-SFI")**: include the following:

i. Any income from investment vehicles, such as mutual funds and retirement accounts, as long as the Covered Individual (or Covered Individual's Immediate Family) does not directly control the investment decisions made in these vehicles; or

ii. 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

iii. 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; or

iv. Salary, royalties or other Remuneration paid by Regeneron to the Covered Individual if the Covered Individual is currently employed or otherwise appointed by Regeneron; or

v. Travel reimbursement or sponsorship 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.

H. **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 and BARDA. A listing of the PHS agencies and their offices may be located on the U.S. Department of Health and Human Services Organizational Chart.

I. **PHS-Funded Research**: Any Research funded by way of a grant from, or a contract or cooperative agreement with, a PHS Organization. PHS-Funded Research does not include work performed under a cooperative research and development agreement or an "other transaction authority" agreement.

J. **PHS Organization**: An agency that is part of the PHS and funds particular Research under a grant, contract, or cooperative agreement.

K. **PHS Regulations**: U.S. 42 CFR Part 50 Subpart F and 45 CFR Part 94.

L. **Remuneration**: Any payment for services including consulting fees and honoraria.

M. **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, basic and applied research (e.g., a published article, book or book chapter) and product development (e.g., a diagnostic test or drug).

N. **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 the Covered Individual's Responsibilities, but specifically excluding any Non-SFI:

i. any Remuneration received from any publicly traded entity in the 12 months preceding the disclosure, and the value of any Equity Interest in such entity as of the date of disclosure, that exceeds $5,000 when aggregated; or
ii. any Remuneration received from any non-publicly traded entity in the 12 months preceding the disclosure that exceeds $5,000 when aggregated or any Equity Interest in such entity of any value as of the date of disclosure; or
iii. income related to intellectual property rights and interests (e.g. patents, copyrights) that exceed $5,000 in the aggregate, upon receipt of such income; or
iv. any travel reimbursement or sponsorship.

III. TRAINING REQUIREMENTS

Unless covered by a third-party FCOI policy as agreed with Regeneron, each Covered Individual is required to complete training on Regeneron's FCOI Policy prior to engaging in PHS-Funded Research, at least every 4 years, and immediately, if (a) Regeneron revises the FCOI Policy that

affects requirements of Covered Individuals or (b) a Covered Individual is not in compliance with the FCOI Policy or a management plan.

IV. SUBRECIPIENT REQUIREMENTS

Regeneron will by agreement require any subrecipient or subcontractor performing PHS-Funded Research to either (a) mandate that its Covered Individuals comply with this FCOI Policy or (b) comply with the subrecipient's or subcontractor's FCOI policy if the subrecipient or subcontractor certifies that its policy complies with PHS Regulations. Regeneron will require all disclosures and reports by a subrecipient's or subcontractor's Covered Individual under either policy to be made to Regeneron at least 15 days before any corresponding disclosure or report is due to the U.S. Government.

V. DISCLOSURE, REVIEW AND MONITORING REQUIREMENTS

Each Covered Individual is required to disclose SFIs (and those of the Covered Individual's Immediate Family) that meet or exceed the definition of SFI. This disclosure must occur before any payment by Regeneron is made to a Covered Individual, at least annually during the period of the PHS-Funded Research, and within 30 days of discovering or acquiring a new SFI. For any Covered Individual anticipated to perform work on a particular project involving PHS-Funded Research, Regeneron will also require each such Covered Individual to disclose SFIs before the date of submission for Regeneron's proposal for the project if the Covered Individual's anticipated role in the project is known before proposal submission.

Regeneron will designate individual/s to review disclosures of SFIs of the Covered Individual (and those of the Covered Individual's Immediate Family). The designated individual/s will review all Covered Individual SFI disclosures, determine if any SFIs relate to PHS-Funded Research, determine if an FCOI exists and develop and implement management action plans, as needed, to manage FCOIs:

- before work on a particular PHS-Funded Research project begins for any Covered Individual that is known to Regeneron prior to such time; and
- within 60 days whenever Regeneron identifies an SFI that was not disclosed by an Covered Individual or not previously reviewed by the Regeneron.

The designated individual/s must establish a process to monitor a Covered Individual's compliance with management action plans until completion of the PHS-Funded Research project. For any report of an SFI involving travel reimbursement or sponsorship, the designated individual/s must be provided information relating to the purpose, destination, and duration of each trip and the identity of the relevant sponsor or organizer. If requested by the designated individual/s, additional information, including the monetary value of the trip, must be disclosed to determine whether the reimbursement or sponsorship constitutes an FCOI.

VI. REPORTING REQUIREMENTS

Regeneron will send initial, annual and revised reports listing FCOI of Covered Individuals ("FCOI Reports") to the relevant PHS Organization:

- prior to expenditure of funds for PHS-Funded Research; and
- within 60 days of identification of a FCOI for a Covered Individual who is newly participating in an on-going project; and
- at least annually to provide the status of the FCOI and any changes to the management plan, if applicable, until the completion of the project; and
- following a retrospective review to update a previously submitted report, if appropriate.

Whenever Regeneron identifies an SFI that was not disclosed, identified, reviewed or managed in a timely manner, Regeneron's designated individual/s will, within 60 days, review and make the determination of whether an FCOI exists, and report the FCOI if it exists to the relevant PHS Organization:

- If an FCOI exists, Regeneron will within 120 days of the Regeneron's determination of noncompliance/nondisclosure complete a retrospective review of the Covered Individual's activities and PHS-Funded Research to determine whether any of the PHS-Funded Research conducted during the time period of the noncompliance/nondisclosure biased the design, conduct or reporting of such Research.
- Regeneron will document the retrospective review as required by PHS Regulations.
- Subsequent to the retrospective review, if applicable, Regeneron will update the existing FCOI report and, if bias is found, Regeneron will notify the relevant PHS Organization promptly and submit a mitigation action plan with details required by PHS Regulations.

Regeneron will notify the relevant PHS Organization promptly if a Covered Individual fails to comply with the FCOI Policy or an FCOI management plan and inform the relevant PHS Organization of the corrective action taken or to be taken.

VII. PUBLIC ACCESS

Before expending funds on a particular PHS-Funded Research project, Regeneron will establish procedures for public access to information concerning any SFI that is disclosed to Regeneron and (a) continues to be held by key personnel for a particular project, (b) is determined by Regeneron to be related to the project, and (c) is determined by Regeneron to constitute an FCOI. Regeneron will make this information available within 5 business days of receiving a written request for at least 3 years after the information was most recently updated. Regeneron will

include details specified in PHS Regulations when responding to any such request. Regeneron will also make this FCOI Policy available on a publicly accessible website.

VIII. MAINTENANCE OF RECORDS

Regeneron will maintain all FCOI-related records:

- for at least 3 years from the date on which, for grants and cooperative agreements, the final expenditure report is submitted to the relevant PHS Organization or, for contracts, final payment is made; or
- for the time periods specified in 45 CFR 75.361 or 48 CFR Part 4, Subpart 4.7, as applicable.

During the applicable period identified above, Regeneron will also make all FCOI-related records available to each relevant PHS Organization upon request.

IX. ENFORCEMENT MECHANISM AND REMEDIES FOR NONCOMPLIANCE

Regeneron will maintain adequate enforcement mechanisms and provide for corrective action to promote Covered Individual compliance.

In any case in which the U.S. Department of Health and Human Services determines that a PHS-Funded Research project of clinical research, with a purpose of evaluating 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 Regeneron as required, Regeneron will require the Covered Individual to disclose the FCOI in each public presentation of the results of the PHS-Funded Research, and request a similar addendum to previously published presentations and publications.