Auro Vaccines LLC Conduct of Scientific Research Policy

I. POLICY

Integrity in research and scholarly activities is the responsibility of the entire academic and commercial community. Scientists work in an environment in which there is an important sense of trust. Published material is assumed to have been obtained during the author's investigations. Falsification or fabrication of such data is intolerable. Auro Vaccines LLC (Auro Vaccines) is responsible for promoting academic and commercial practices that discourage scientific misconduct. Auro Vaccines is responsible for developing policies and procedures to address scientific misconduct and for providing the necessary education, training and resources to all employees and consultants for dealing with allegations or other evidence of scientific misconduct.

All employees and consultants of Auro Vaccines share responsibility for developing and maintaining standards to assure the highest ethical conduct of research and detection of abuse of these standards. Fraud or misconduct in carrying out research activities undermines the integrity of the scientific enterprise, and erodes the public trust in the scientific community to conduct research and communicate results using the highest standards and ethical practices. This responsibility to prevent and detect misconduct, however, must be assumed without creating an atmosphere that discourages the openness and creativity which are vital to scientific research.

Misconduct in research work by any Auro Vaccines employee is a breach of contract. Furthermore, misconduct in scientific research work by others associated with Auro Vaccines (e.g., consultants, advisors, directors) will not be tolerated. Auro Vaccines considers such a breach adequate cause for termination of employment.

As discussed further in Part IV, these policies and procedures are also intended to bring Auro Vaccines into compliance with federal regulations applicable to allegations of misconduct related to research funded by the Public Health Service (PHS). In the event of any conflict between any provision of this policy and the federal regulations applicable to a specific case, the federal regulations shall be followed.

The policies and procedures outlined here apply to all employees, consultants and directors, paid or unpaid, engaged in research and scholarly writing. A copy of this policy shall be provided to all of those individuals. This policy is not intended to address administrative issues of an ethical nature which are covered by other policies; for example, discrimination, affirmative action, and conflicts of interests which are covered by other Auro Vaccines policies.

The scope of this scientific misconduct policy and procedures is not limited to matters related to externally sponsored research but covers all research, regardless of source of support.

II. DEFINITION OF SCIENTIFIC MISCONDUCT

Scientific misconduct involves any form of behavior which entails an act of deception whereby one's work or the work of others is misrepresented, and includes fabrication, falsification, plagiarism, or other practices that seriously deviate from those that are commonly accepted within the scientific community for proposing, conducting or reporting research. Other terms such as research fraud, scholarly misconduct or research misconduct, are subsumed within the term scientific misconduct as defined below. Scientific misconduct is distinguished from honest error and from honest differences in interpretations or judgments of data that are inherent in the scientific process. Further, misconduct involves significant breaches of integrity which may take numerous forms such as, but not limited to, those outlined below:

A. Falsification of Data: Ranging from fabrication to deceptive selective reporting of findings and omission of conflicting data, or willful suppression and/or distortion of data.

B. Plagiarism: The appropriation of the language, ideas, or thoughts of another and representation of them as one's own original work.

C. Improprieties of Authorship: Improper assignment of credit, such as excluding others; misrepresentation of the same material as original in more than one publication; inclusion of individuals as authors who have not made a definite contribution to the work published; or submission of multi-authored publications without the concurrence of all authors.

D. Misappropriation of the Ideas of Others: An important aspect of scholarly activity is the exchange of ideas among colleagues. New ideas gleaned from such exchanges can lead to important discoveries. Scholars also acquire novel ideas during the process of reviewing grant applications and manuscripts. However, improper use of such information could constitute fraud. Wholesale appropriation of such material constitutes scientific misconduct.

E. Violation of Generally Accepted Research Practices: Serious deviation from accepted practices in proposing or carrying out research, improper manipulation of experiments to obtain biased results, deceptive statistical or analytical manipulations, or improper reporting of results.

F. Material Failure to Comply with Federal Requirements Affecting Research: including but not limited to serious or substantial, repeated, willful violations involving the use of funds, care of animals, human subjects, investigational drugs, recombinant products, new devices, or radioactive, biologic or chemical materials.

G.

Inappropriate Behavior in Relation to Misconduct: Including inappropriate accusation of misconduct; failure to report known or suspected misconduct; withholding or destruction of information relevant to a claim of misconduct and retaliation against persons involved in the allegation or investigation.

H.

Deliberate misrepresentation of qualifications, experience, or research accomplishments to advance the research program, to obtain external funding, or for other professional advancement.

I.

Misappropriation of funds or resources. For example, misuse of funds for personal gain.

III. PROCEDURES FOR HANDLING ALLEGATIONS OF FRAUD/MISCONDUCT

Auro Vaccines must undertake the examination (as described below) of any allegation of scientific misconduct. In the Investigation which may follow, Auro Vaccines will focus on the substance of the issues and be guided by the following imperatives:

A.

The process pursued to resolve allegations of misconduct must not damage science itself, or the academic process.

B.

Auro Vaccines will provide vigorous leadership in the pursuit and resolution of all charges.

C.

All participants in the Investigation will be treated with justice and fairness and with sensitivity to their reputations.

D.

Procedures must preserve the highest attainable degree of confidentiality compatible with an effective and efficient response.

E.

The integrity of the process must be maintained by painstaking avoidance of real or apparent conflict of interest.

F.

The procedures should be as expeditious as practical.

G.

Pertinent facts at each stage of the response should be documented.

H.

Auro Vaccines will pursue allegations within the scope of this policy without regard to whether related civil or criminal proceedings have been initiated or are underway. In the event of such proceedings, Auro Vaccines, may, at its option, suspend Investigation temporarily but is not under an obligation to do so, as the standards of Auro Vaccines may differ from those of the courts.

I.

Auro Vaccines shall recognize and discharge its responsibility after resolving allegations of misconduct to communicate the results of the investigating process internally, to all involved individuals; and externally, to the public, the sponsors of research, the scientific literature, and the scientific community as appropriate.

1. Initiation of an Investigation Regarding an Allegation of Misconduct

A person who believes that scientific misconduct has occurred should discuss the matter with the President to determine whether or not the conduct falls under the purview of this document or under other applicable Auro Vaccines procedures. If it is determined that the alleged conduct is within the scope of this document, the allegation shall be reported, in writing, to the employee and/or director and/or consultant. All written allegations must be reported to the President, with a copy to the Senior Patent Counsel, as well as to Vice President & General Counsel of Auro Vaccines' parent company, Aurobindo Pharma USA, Inc. (Aurobindo). These three individuals shall comprise a Committee of Investigation ("the Committee")

If the President has a possible conflict of interest or is unavailable to begin an Investigation immediately, the allegations should be referred to the Committee, who shall designate a substitute administrator to oversee examination of the allegation and carry out responsibilities assigned to the President under this policy with respect to the specific allegation in question.

The President shall informally review any allegation of scientific misconduct, confer with legal counsel, and determine whether the allegation warrants initiation of the Investigation process according to the policies and procedures for scientific misconduct, or whether other policies and procedures, such as those relevant to employment grievances, should be invoked. The President will counsel the individual (s) bringing the allegation as to the policies and procedures to be used. If the reporting individual chooses not to make a formal allegation but the President believes an Investigation is warranted, the Investigation process will be initiated.

Even if the individual against whom an allegation is made (hereafter referred to as the respondent) leaves or has left Auro Vaccines before the case is resolved, Auro Vaccines will pursue an allegation of misconduct to its conclusion.

2. Investigation

a.
The Committee shall first undertake fact finding in an expeditious manner to determine if an allegation is deserving of further formal Investigation, and if formal Investigation is not warranted, to make recommendations concerning the disposition of the case. Records of the Investigation are confidential.
b.
The President is responsible for notifying all parties in writing of the charges and

of the procedures that will be used to examine the charges.

c.

Where the complainant seeks anonymity, the Committee shall operate in such a way as to maintain that anonymity to the degree compatible with accomplishing the fact-finding purpose of the Investigation. Such anonymity cannot, however, be assured. Further, anonymity of the complainant is neither desirable nor appropriate where the testimony of the complainant is important to the substantiation of the allegations. The Committee shall convene a hearing and shall have the responsibility for ensuring that all of these procedures are followed and shall have the authority to conduct all Committee hearings and proceedings.

d.

Information, expert opinions, records and other pertinent data may be requested by the Committee. All involved individuals are obliged to cooperate fully with the Committee by supplying such requested documents and information. Uncooperative behavior is unacceptable and may result in immediate implementation of a formal Investigation or shall be grounds for termination of employment.

e.

All parties to the case, including the Committee and the respondent, may request documents, present evidence, and call witnesses. The Committee and the respondent may examine or cross-examine any witnesses.

f.

Timely access to copies of all documents reviewed by the Committee will be assured to all parties. All material will be considered confidential and shared only with those with a need to know. The President and the members of the Committee are responsible for the security of relevant documents. Copies of all documents and related communications are to be securely maintained in the Office of the President.

g.

Additional hearings may be held and the Committee may request the involvement of outside experts. The Investigation must be sufficiently thorough to permit the Committee to reach a firm decision about the validity of the allegation(s) and the scope of the wrongdoing or to be sure that further Investigation could not alter an inconclusive result. Whenever possible, interviews should be conducted of all individuals involved either in making the allegation or against whom the allegation is made, as well as other individuals who might have information regarding key aspects of the allegations; complete summaries of these interviews should be prepared, provided to the interviewed party for comment or revision, and included as part of the investigatory file.

h.

In the course of an Investigation, additional information may emerge that may justify broadening the scope of the Investigation beyond the initial allegations. Should this occur the respondent is to be informed in writing of significant new directions in the Investigation. The Committee shall make a judgment on the veracity of the allegations.

i.

As Auro Vaccines is responsible for protecting the health and safety of research subjects, patients, employees, interim administrative action prior to conclusion of the Investigation may be indicated. Such action ranging from slight restrictions to complete suspension of the respondent and notification of external sponsors, if indicated, is initiated by the President but may be taken only after consultation with the Committee and legal counsel.

j.

All parties in the Investigation are obliged to cooperate in a timely fashion by producing any additional data or information requested for the Investigation by the Committee or by the respondent, if approved by the Committee. Copies of all materials secured by the Committee shall be provided to the respondent and other concerned parties as judged appropriate by the Committee.

k.

The respondent shall have an opportunity to address the charges and evidence in detail. The respondent may be accompanied by and confer with legal counsel at hearings but is expected to speak for him/herself.

l.

All affected individual(s) will be afforded maximum confidentiality, to the extent possible, throughout the Investigation. All hearings are deemed confidential and may be declared closed by request of any of the principals. Written notification of hearing dates and copies of all relevant documents will be provided by the President in advance of scheduled meetings. Proceedings will be tape-recorded by the Committee and copies of the tapes will be made available to involved parties upon request. The Committee will have full authority over the conduct of the hearing(s) and may consult outside counsel, if necessary, to resolve legal issues.

m.

After all evidence has been received and hearings completed, the Investigating Committee shall meet in closed sessions to deliberate and prepare its findings and recommendations. Written findings shall be dated and signed by all Committee members.

n.

All significant developments during the Investigation as well as the findings and recommendations of the Committee will be reported by the President to the research sponsor.

o.

The Committee shall issue a report and communicate the same to the respondent. This report shall include evidence reviewed, interview summaries, and conclusions of the Investigation. The respondent shall be given the opportunity to comment in writing upon the findings and recommendations of the Committee.

p.

Every effort should be made to complete the Investigation within 120 days; this includes conducting the Investigation, preparing the report of findings, making that report available for comment by the subjects of the Investigation, and issuing the report. If they can be identified, the persons who raised the allegations will be provided with those portions of the report that address their role and opinions in the Investigation.

q.

It is acknowledged that some cases cannot be fully investigated in 120 days. In

such cases, the Committee should compile a progress report, identify reasons for the delay, estimate time required to complete the Investigation, and rcommend an extension of time. The President shall convey to the funding agency such information as may be required by it, and at intervals as required by the agency.

r.

The respondent shall be notified of the Committee's findings, and the President's decision regarding application of sanctions. If the sanctions involve a recommendation for termination of employment, applicable disciplinary or termination procedures shall be followed.

s.

Detailed documentation of an Investigation, even where it has been determined that an Investigation is not warranted, will be maintained securely by Auro Vaccines for at least three years, and provided to the sponsoring agency upon request.

t.

Under certain circumstances, Auro Vaccines may be expected to notify the sponsoring agency or funding source at a point prior to the initiation of an Investigation, and the policies of that agency, including applicable federal regulations, will be followed. Where notification is not required by regulation or the timing of notice is at the discretion of Auro Vaccines, factors used in determining the timing of such notification will include the seriousness of the possible misconduct, reasonable indication of possible criminal violations, the presence of an immediate health hazard, consideration of the interests or specific requirements of the funding agency and of the interests of the scientific community, the public, and the individual who is the subject of the Investigation and his/her associates.

u.

The Committee may determine (i) that a correction of the literature is required and/or (ii) that the culpable party be reprimanded for lax supervision, faulty techniques, or inattention to detail.

v.

If the Committee finds the allegations were not made in good faith, it should refer the matter to the President, since it is a violation of Auro Vaccines policy when an allegation of misconduct is not made in good faith.

w.

If the Committee plans to terminate the Investigation for any reason prior to completion of the Investigation process, a report of the termination, including a description of the reasons for such termination shall be made.

3. Resolution

a.

Finding of absence of scientific misconduct

All research sponsors and others initially informed of the Investigation should be informed in writing that allegations of misconduct were not supported. If the allegations are deemed not to have been made in good faith, appropriate actions

should be taken against the complainant in accordance with this policy. If the allegations, however incorrect, are deemed to have been made in good faith, no disciplinary measures are indicated and efforts should be made to prevent retaliatory actions and to protect, to the maximum extent possible, the positions and reputations of the persons who made the allegations as well as those against whom allegations of misconduct were not confirmed. In publicizing the finding of no misconduct, Auro Vaccines will be guided by whether public announcements will be harmful or beneficial in restoring any reputation(s) that may have been lost.
Usually, such decision will rest with the person who was innocently accused.

b.
Presence of scientific misconduct

When an Investigation confirms misconduct, the Committee shall be responsible for determining and implementing sanctions as appropriate. The President is responsible for notification to all federal agencies, sponsors or other entities initially informed of the Investigation of the outcome. Auro Vaccines must take action appropriate for the seriousness of the misconduct, including but not limited to the following:

1) Institutional Disciplinary Action including:

a) Removal from particular project

b) Special monitoring of future work

c) Letter of reprimand

d) Probation for a specified period with conditions specified

e) Suspension of rights and responsibilities for a specified period

f) Financial restitution

g) Termination of employment

2) Notification: consideration should be given to formal notification of involved parties such as:

a) Sponsoring agencies, funding sources

b) Co-authors, co-investigators, collaborators

c) Editors of journals in which fraudulent research was published

d) State professional licensing boards

e) Editors of journals or other publications, other institutions, sponsoring agencies, and funding sources with which the individual has been affiliated

f) Notification of professional societies

3) The President also shall take action to protect, to the maximum extent possible, the positions and reputations of those persons who made the confirmed allegations.

IV. SPECIAL PROVISIONS FOR EXAMINING ALLEGATIONS SUBJECT TO PHS MISCONDUCT REGULATIONS

This policy is intended to meet the requirements of Title 42, Subchapter H, Code of Federal Regulation, Subparts A-E, sections 93.25 through 93.523 (the "PHS Misconduct Regulations"). The PHS Misconduct Regulations apply to Auro Vaccines because it applies for research, research-training, or research-related grants or cooperative agreements under the Public Health Service ("PHS") Act. These regulations require Auro Vaccines to investigate and report instances of alleged or apparent misconduct involving research or research training, applications for support of research or research training, or related research activities that are supported with funds made available under the PHS Act. It is anticipated that this Auro Vaccines Policy will be changed, from time to time, to comply with any changes required by amendment of these regulations.

The scope of this policy is not limited to matters related to research supported by the PHS Act. All research and scholarly activity, regardless of source of support, is subject to the same standard of integrity. Misconduct in scholarly work will be censured by Auro Vaccines in all cases. Misconduct associated with research funded under the PHS Act can result in additional federal sanctions against investigators, as well as sanctions against Auro Vaccines, and must be reported to federal authorities as specified below.

In this part of this Policy, the following definitions apply:

"ORI" means the Office of Research Integrity, a component of the Office of the Director of the National Institutes for Health (NIH), which oversees the implementation of all PHS policies and procedures related to scientific misconduct; monitors the individual

investigations into alleged or suspected scientific misconduct conducted by institutions that receive PHS funds for biomedical research projects or programs; and conducts investigations as necessary.

A.

Compliance with Regulations

It is Auro Vaccines' policy to comply with all requirements of the PHS Misconduct Regulations applicable to Misconduct. Auro Vaccines will file institutional assurances as required by section 93.301 of the PHS Misconduct Regulations.

In order to remain in compliance with the assurance Auro Vaccines will:

1. Keep current and upon request provide to ORI, and other PHS officials this policy and other policies Auro Vaccines may develop to encourage scientific integrity.
2. Inform its employees of this Policy and the importance of compliance with this policy.
3. Take immediate and appropriate action as soon as misconduct on the part of employees or persons within Auro Vaccines' control is suspected or alleged. Actions shall include interim measures to protect Federal funds and ensure that the purposes of Federal financial assistance are being carried out.
4. In accordance with the PHS Misconduct Regulation, inform and cooperate with ORI with regard to each investigation of possible misconduct.

B.

Reports to ORI

The President must make all reports to ORI which are required by 93.302, or other parts of the PHS Misconduct Regulations, in connection with allegations of misconduct subject to those regulations. More specifically, the President will report:

1. Auro Vaccines' decision to initiate any Investigation. This report will be made in writing to the Director, ORI, on or before the date the Investigation begins, and will include, at a minimum, the name of the person(s) against whom the allegations have been made, the general nature of the allegation, and the PHS application or grant number(s) involved. In general, it will be Auro Vaccines' policy to disclose in this notice no more than the minimum information required under the PHS Misconduct Regulations.
2. During the Investigation of the allegations, any developments which disclose facts that may affect current or potential Department of Health and Human Services funding for the respondent or that the PHS needs to know to ensure appropriate use of Federal funds and otherwise protect the public interest.
3. If Auro Vaccines as a result of the Investigation process, plans to terminate an Investigation for any reason without completing all relevant requirements under 93.301, a copy of this report of such planned

termination, including a description of the reasons for such termination, shall be submitted to ORI in accordance with federal regulations.

4. The result of the Investigation, which shall be filed with ORI within 120 days of the institution of the Investigation unless an extension is granted by ORI. The final report will describe the policies and procedures under which the Investigation was conducted, how and from whom information was obtained relevant to the Investigation, the findings, and the basis for the findings, and include the actual text or an accurate summary of the views of any individual(s) found to have engaged in Misconduct, as well as a description of any sanctions under consideration, pending, or taken by Auro Vaccines.
5. If the Investigation cannot be completed within 120 days, the Committee shall forward an extension request to the Executive Committee, who will then forward the request to the Office of Research Integrity (ORI). Such a request shall include an explanation for the delay, an interim report on the progress to date, an outline of what remains to be done and an estimated date of completion.
6. Immediately, at any stage of the Investigation, any determination by Auro Vaccines that any of the following conditions exists:

   a. Immediate health hazard;

   b. Need to protect Federal funds or equipment;

   c. Immediate need to protect the interests of the persons making the allegations or the individuals who are the subjects of the allegations as well as their co-investigators and associates, if any;

   d. Probability that the alleged incident is going to be reported publicly;

   e. Reasonable indication of possible criminal violation (a report for this reason must be made within 24 hours of obtaining the information leading to this conclusion).

C.

Recordkeeping

Detailed documentation of the Investigation shall be maintained. A copy of all documentation prepared and maintained during the Investigation shall be made available to the Director, ORI.

Conduct of Scientific Research Policy – Auro Vaccines LLC

I_____acknowledge that I have received the Conduct of Scientific Research Policy provided by Auro Vaccines LLC.

_____ I acknowledge that I have read this policy.

_____ I understand his policy.

_____

Signature Date