Modulight.bio
Precision neural therapies

Policy on Conflict of Intrest in Research and Sponsored Programs

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I. Summary

Modulight.bio is committed to operating ethically and in compliance with applicable legal and regulatory requirements. Even the appearance of a significant conflict of interest in research at Modulight.bio can be damaging to the reputation of Modulight.bio.

Modulight.bio's *Policies on Conflicts of Interest, Commitment and Consulting* provides a comprehensive approach for the identification, disclosure and oversight of all conflicts arising from the external interests and activities of Modulight.bio. The Policies require employees, officers, and trustees to disclose financial relationships for review on an annual basis. This Policy is a part of the *Policies* and requires disclosure of financial interests on a per-project basis by individuals participating in research and sponsored programs at Modulight.bio.

Under this Policy, individuals participating in research and other sponsored programs must disclose all financial interests that reasonably appear to be related to the individual's responsibilities at Modulight.bio and to the specific project. Modulight.bio, through its Conflicts of Interest Management Procsess (CIMP), a process that will be led by an officer of the company, will then review and evaluate such disclosures, determine if a conflict of interest exists, and determine whether such conflict can be managed or must be eliminated in order to permit the researcher to engage in the project.

II. Applicability

This Policy applies to all Investigators participating in a study or Sponsored Project conducted at or under the auspices of Modulight.bio. All capitalized terms shall have the meaning set forth in Section X below.

III. General Policy

A. Investigators participating in a Sponsored Project conducted at or under the auspices of Modulight.bio have a primary obligation to serve the purposes to which Modulight.bio is dedicated. As part of this obligation, Investigators have a duty to conduct research free of any appearance of impropriety or conflict of interest.

B. A "**Conflict of Interest**" exists in a Sponsored Project when Modulight.bio's designated officials reasonably determine that an Investigator's Financial Interest could affect or be affected, or appear to affect or be affected, by the design, conduct or reporting of the Sponsored Project.

C. To assure that all potential Conflicts of Interest are identified, all Investigators participating in a Sponsored Project must submit disclosures of personal financial interests, of any value, of the Investigator and his or her Immediate Family that reasonably appear related to the Investigator's Institutional Responsibilities with Modulight.bio before and during the life of the Sponsored Project.

D. All potential Conflicts of Interest require disclosure, evaluation and either management or elimination under this Policy.

E. Certain Conflicts of Interest are too significant to manage and must be eliminated. When an Investigator has a Significant Financial Interest, the Investigator may not participate in a Sponsored Project. An exception to this policy may be made only when the Chief Executive Officer (CEO) of Modulight.bio or an officer appointed by him to lead the CIMP determine that Compelling Circumstances exist to merit an exception and a conflict management plan is adopted to maintain research integrity and serve the best interests of subjects enrolled in the research.

IV. Disclosure

Investigators must submit annual and project specific disclosures as described below. Disclosures must be completed and submitted even if no Financial Interests are disclosed. Disclosures of Financial Interests must be made in specific amounts. For PHS Sponsored Projects, disclosures of Paid/Reimbursed Travel must specify each instance of paid or reimbursed travel at a minimum, as well as the purpose of each trip, the identity of each sponsor/organizer, its destination and its duration.

A. Annual Disclosures. All Investigators who are part of Modulight.bio are required under Modulight.bio's *Policy on Conflicts of Interest in Business Affairs* to complete and submit an annual disclosure, which is reviewed in accordance with that Policy.

B. Project Disclosure – Upon Submission. Each Investigator planning to participate in a proposed Sponsored Project must complete and submit a research financial interest disclosure when prompted to following submission of the Sponsored Project to Modulight.bio CEO. In the disclosure, Investigators must disclose all Financial Interests that reasonably relate to the Investigator's Institutional Responsibilities with Modulight.bio and to the specific Sponsored Project. The CIMP review and evaluation as described below.

C. Project Disclosure – Upon Annual Continuations. Each Investigator participating in a Sponsored Project must also complete and submit an investigator financial interest disclosure at each annual continuation of the Sponsored Project to the CEO. Disclosures with Financial Interests will be subject to the review and evaluation process outlined in Section V.A below.

D. Project Disclosure – New Financial Interests. While a Sponsored Project is on-going, an Investigator must complete and submit an investigator financial interest disclosure to the CEO for any new Financial Interest prior to acquiring such Financial Interest. The Investigator must not acquire the new Financial Interest unless and until the acquisition has been disclosed, reviewed, evaluated and permitted as contemplated by this Policy.

E. Confidentiality. All disclosures will be kept confidential and disclosed only on a need-to-know basis as required to perform the review and evaluation required by this Policy and to meet Modulight.bio's disclosure and/or reporting requirements under applicable laws, regulations, grants and/or contracts.

V. Review and Evaluation of Project Disclosures

A. Conflict of Interest Management Procsess (CIMP) Review. The CIMP, led by an officer of the company that was apooined to lead this process by the CEO, is responsible for the review of each disclosure of a Financial Interest to determine if it could give rise to a Conflict of Interest in the Sponsored Project, as described below.

(i) **No Potential Conflict of Interest.** For disclosures of Financial Interests that the CIMP finds do not reasonably appear to give rise to a Conflict of Interest, the CIMP will advise the CEO that there is no Conflict of Interest and no conflict management plan is required.

(ii) **Potential Conflict of Interest without Significant Financial Interest.** For initial disclosures of a Financial Interest that is not a Significant Financial Interest, the CIMP will determine if a Conflict of Interest exists. If so, the Investigator's participation will generally be permitted, subject to an appropriate conflict management plan issued by the CIMP. Conflict management plans issued by the CIMP may be appealed to Modulight.bio's CEO. No expenditures may occur on the Sponsored Project until the CIMP's review and evaluation is complete and a conflict management plan is agreed to by both the principal investigator on the Sponsored Project and the Investigator with the disclosed Financial Interest, if a different individual.

(iii) **Potential Conflict of Interest with Significant Financial Interest.** For initial disclosures of a Significant Financial Interest that could give rise to a Conflict of Interest, the CIMP will make a determination whether or not Compelling Circumstances exist to justify the Investigator's participation in the Sponsored Project notwithstanding the disclosed Significant Financial Interest.

For matters giving rise to a significant potential Conflict of Interest, the CIMP, in consultation with the Legal Counsel, will first use diligent efforts to eliminate or manage the conflict. If the CIMP is unable to eliminate or manage the conflict, the CIMP may refer the matter to the CEO.

If Compelling Circumstances are found, the CIMP will approve a conflict management plan as contemplated below. If Compelling Circumstances are not found or a conflict management plan is not approved or agreed to as provided in Section V.B below, the Conflict of Interest must be eliminated in order for the Investigator to be permitted to carry out the Sponsored Project. No expenditures may occur on the Sponsored Project until the CIMP's review and evaluation is complete and a conflict management plan is agreed to by both the principal investigator on the Sponsored Project and the Investigator with the disclosed Significant Financial Interest, if a different individual; or until the Conflict of Interest has been eliminated.

(iv) **Previously Reviewed Disclosures.** For disclosures of a Financial Interest that has previously been reviewed and evaluated and is subject to a conflict management plan issued under this Policy, the CIMP may, in its discretion, approve the continuation of the conflict management plan. If the nature of the previously reviewed Financial Interest has changed or the amount materially increased, however, the disclosed Financial Interest will be reviewed and evaluated by the CIMP under this Policy as an initial disclosure for the Sponsored Project of a Financial Interest as provided in (ii) and
(iii) above, a new conflict management plan may be adopted, and the Investigator's failure to disclose the change in the nature or amount of the previously reviewed Financial Interest will be treated as a violation of this Policy.

B. Conflict Management Plan. If an Investigator's participation in a Sponsored Project is permitted notwithstanding a Conflict of Interest, the Investigator's participation must be subject to a conflict management plan issued by the CIMP. The purpose of the conflict management plan will be to foster transparency in related interests and relationships, maintain the objectivity of research design, conduct, and reporting, and best serve the rights and welfare of subjects enrolled in the research. The conflict management plan must be agreed to by both the principal investigator on the Sponsored Project and the Investigator with the disclosed Financial Interest, if a different individual. In its review of Human Subjects Research projects, the IRB will consider the conflict management plans. The Sponsored Project cannot commence until IRB approval is released following receipt of the final determination and/or conflict management plan under this Policy. The principal investigator on the Sponsored Project and the Investigator with the managed Conflict of Interest must comply with all terms in the conflict management plan for the duration of the Sponsored Project. The CIMP is responsible for monitoring the compliance with the conflict management plan on an ongoing basis until the completion of the Sponsored Project.

C. Appeals to Modulight.bio's CEO. Determinations of the CIMP may be appealed to Modulight.bio's CEO. Appeals must be in writing and submitted to the CIMP. The CIMP will provide copies of the appeal to the CEO. Decisions of the CEO are final.

D. Timing. The review and evaluation of an Investigator's disclosure and the issuance and implementation of any conflict management plan under this Policy must be completed prior to the expenditure of any awarded funds for the Sponsored Project or the commencement of the Investigator's involvement in the Sponsored Project (including any enrollment of research subjects).

VI. Disclosure of Interests in Publications and Presentations

All Investigators must disclose their financial interests in publications and presentations whenever the Investigator has financial relationships with entities that could be perceived to influence, or that give the appearance of potentially influencing, what was included in the publication or presentation. Investigators with financial interests must adhere to any disclosure requirements in their conflict management plan and must comply with any disclosure requirements of the applicable journal or conference. If a disclosure requirement is not clear, Investigators should broadly disclose all applicable financial interests. Failure to make required disclosures or to comply with management plans is a violation of this Policy and will be cause for disciplinary action.

VII. Special PHS and Other Sponsor Requirements

A. Research Sponsors often impose additional rules about conflicts of interest as a condition of providing funding. It is the policy of Modulight.bio to comply with all such requirements, including the PHS Regulations which apply to all research funded by a PHS agency (i.e., NIH, AHRQ, CDC, FDA, HRSA, SAMHSA, OG, OASH, ASPR, ATSDR, and IHS). This Policy is believed to be in compliance with the applicable federal sponsoring agency requirements, including the PHS Regulations. To the extent there is any issue about whether or not this Policy wholly complies with a Sponsor requirement, it is to be interpreted to assure compliance. Each Investigator is responsible for assuring his or her compliance with the requirements applicable to the Investigator's specific Sponsored Project.

B. For Sponsored Projects subject to the PHS Regulations ("PHS Sponsored Projects"), in addition to the review and evaluation in Section V, the additional requirements outlined in Modulight.bio's Procedures on Conflicts of Interest in Research and Sponsored Programs covered by the PHS Regulations apply. The additional requirements include the following:

(i) A "PHS Conflict of Interest" exists when Modulight.bio's designated official(s) reasonably determines that a PHS Significant Financial Interest could *directly and significantly* affect the design, conduct, or reporting of a PHS Sponsored Project (see *Procedures on Conflicts of Interest in Research and Sponsored Programs covered by the PHS Regulations* of this

document).

(ii) PHS Conflict of Interest Findings. The CIMP is responsible for determining if a disclosure of a PHS Significant Financial Interest in a PHS Sponsored Project has resulted in a PHS Conflict of Interest. If a PHS Conflict of Interest is determined to exist, it shall be managed and/or eliminated as a Conflict of Interest in accordance with Section V.

(iii) Retrospective Reviews/ Mitigation Reports. If an initial or ongoing disclosure of a PHS Significant Financial Interest that could give rise to a PHS Conflict of Interest for the PHS Sponsored Project is not disclosed or reviewed in a timely manner, the CIMP will review and evaluate the disclosure. If the CIMP makes a PHS Conflict of Interest determination for a late disclosure or review, it will issue a conflict management plan within 60 days of the disclosure or review, as applicable. When non- compliance is found, the CIMP will conduct and document within 120 days of a determination of such non-compliance, a retrospective review of the Investigator's activities and the PHS Conflict of Interest. Examples of non-compliance include failure of an Investigator to disclose a PHS Significant Financial Interest that could give rise to a PHS Conflict of Interest in a timely manner; failure of Modulight.bio to review and manage a PHS Significant Financial Interest determined to constitute a PHS Conflict of Interest in a timely manner; or failure of an Investigator to comply with the terms of a COI management plan relative to a PHS Conflict of Interest. This retrospective review will determine whether the PHS Sponsored Project, or any portion thereof conducted during the period of non-compliance, was biased in the design, conduct, or reporting of such PHS Sponsored Project. If a retrospective review results in a finding of bias, the CIMP must file a mitigation report with the PHS sponsor. Retrospective reviews and mitigation reports, if required, must be completed by the CIMP in a timely manner. In any case in which the HHS determines that a PHS-funded 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 an Investigator with a PHS Conflict of Interest that was not managed or reported as required by the regulation; Modulight.bio must require the Investigator(s) involved to disclose the PHS Conflict of Interest in each public presentation of the results of the research and to request an addendum to previously published presentations.

(iv) Public Access and Conflicts Reporting. The PHS Regulations impose public access and reporting requirements with respect to a PHS Conflict of Interest. Public access requirements include posting certain information about a PHS Conflict of Interest that Modulight.bio's placement on a publicly accessible Web site or provision of a written response to any requestor within five (5) business days. Conflicts reporting includes reporting obligations related to a PHS Conflict of Interest prior to Modulight.bio's expenditure of any funds for the project, reporting obligations related to PHS Conflict of Interest subsequent to the initial reporting (including annual FCOI reports) or for PHS Conflict of Interest later disclosed or identified during a project, and reporting obligations related to a conflict mitigation plan or retrospective review. The CIMP, in collaboration with SPA and the principal investigator/project director of the applicable PHS Sponsored Project, is responsible for complying with any public access, reporting and/or other requirements required by the PHS Regulations arising from a finding of a PHS Conflict of Interest.

VIII. Sub-recipients

Investigators outside of Modulight.bio (e.g., sub-grantees, sub-contractors, collaborators or consultants) may also have Conflicts of Interest in a Sponsored Project. Modulight.bio may subject any Investigators outside of Modulight.bio to the pertinent portions of this Policy and will subject such Investigator to this Policy when required by the Research Sponsor. In such cases, the outside Investigator's institution must represent in writing that it has a written conflicts policy in effect that applies to its investigators, that the policy complies with all applicable Research Sponsor requirements, and that it will report applicable conflicts of interest to Modulight.bio in the time period and including the disclosure requirements required by the Research Sponsor. If the institution cannot make this representation, the outside

Investigator must agree to comply with this Policy, in which case Modulight.bio's CEO shall have discretion to determine how this Policy should be implemented and/or adjusted for the specific Sponsored Project.

IX. Training

Investigators involved in a Sponsored Project may be required by the CIMP and/or a Research Sponsor to periodically complete an appropriate conflict of interest training program prior to engaging in a Sponsored Project. For example, each Investigator participating in a PHS Sponsored Project must complete training regarding this Policy and the PHS Regulations prior to engaging in a PHS Sponsored Project, at least every four years thereafter, and as otherwise may be required by the CIMP.

X. Definitions

A. "**Compelling Circumstances**" means those facts that convince the CEO and/or the CIMP that an Investigator may participate in a Sponsored Project despite the existence of a Significant Financial Interest. Factors that may be evaluated by the CIMP in determining whether Compelling Circumstances are present are listed in Modulight.bio's Procedures on Research Conflict of Interest and Sponsored Programs.

B. A "**Conflict of Interest"** exists in a Sponsored Project when Modulight.bio's designated officials reasonably determine that an Investigator's Financial Interest could affect or be affected, or appear to affect or be affected, by the design, conduct or reporting of the Sponsored Project.

C. A "**Financial Interest**" is held when an Investigator or a member of his or her Immediate Family has a personal financial interest that reasonably appears to be related to the Investigator's Institutional Responsibilities with Modulight.bio and includes all personal financial interests in the Research Sponsor or in any other Financially-Interested Company or (ii) has Intellectual Property Rights covering products or processes being used in the Sponsored Project. Examples of Financial Interests are Management, Board, or Employment Position, Ownership Interests, Consulting Compensation, Paid/Reimbursed Travel, Royalty Income, and Intellectual Property Rights, where:

(i) A "**Management, Board, or Employment Position**" means a position or appointment to serve, in either a personal or representative capacity, as a director, trustee, partner, executive, manager, officer, employee, or equivalent, whether paid or unpaid, at any outside entity.

(ii) "**Ownership Interests**" are equity interests held, either directly or indirectly, including stock and stock options (or entitlement to the same); of any amount in either a publicly-traded or non-publicly- traded entity. (*Exception: Mutual Funds*– Interests of any amount in diversified investment vehicles, such as broad-based publicly-traded, diversified mutual funds and exchange traded funds, as long as the Investigator, or his or her Immediate Family members, collectively, do not have a 15% or greater direct or indirect interest in the vehicle and do not have a Management, Board, or Employment Position in the vehicle, are <u>not</u> Ownership Interests.)

(iii) "**Consulting Compensation**" means salary, consulting fees, honoraria, paid authorship, lecture fees, other emoluments, stock, stock options, royalties or "in kind" compensation directly or indirectly received from an entity (or entitlement to the same), whether in connection with a Management, Board, or Employment Position or for consulting, lecturing, or service on a scientific advisory board, data safety monitoring board, steering committee for a clinical trial, executive committee for a clinical trial, or other committee for an outside entity, or for any other purpose, that have been received in the past calendar year or are expected to be received in the current or next calendar year.

(iv) "**Paid/Reimbursed Travel**" means the occurrence and value of any paid/sponsored (i.e.,

sponsored travel is 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), and/or reimbursed travel, whether in connection with a Management, Board, or Employment Position or for consulting, lecturing, or service on a scientific advisory board, data safety monitoring board, steering committee for a clinical trial, executive committee for a clinical trial, or other committee for an outside entity, or for any other purpose, that have been received in the past calendar year (i.e., no less than the past 12 months) or are expected to be received in the current or next calendar year.

(v) "**Royalty Income**" means payments linked to product sales, or the written contractual right to receive future royalties, directly or indirectly, under an issued or pending patent, license or copyright, that has been received in the past calendar year or is expected to be received in the current or next calendar year. For the purpose of this Policy, Royalty Income includes all income received by an Investigator from Modulight.bio in accordance with the Modulight.bio intellectual property policies.

(vi) An "**Intellectual Property Right"** is an issued or pending patent, license or copyright covering products or processes being used in the Sponsored Project and includes, for the purpose of this Policy, the right to income from Modulight.bio in connection with a patent, license or copyright held by or to be held by Modulight.bio (for further information, see the Modulight.bio intellectual property policies).

The following are **not** Financial Interests under this Policy:

(a) Salary from Modulight.bio and cost-related payments for services or reimbursements from Modulight.bio.

(b) Payments to Modulight.bio, or via Modulight.bio to the Investigator, which are directly related to the reasonable costs incurred in the conduct of a Sponsored Project or to the payment of indirect costs and are specified in a grant, agreement or contract between Modulight.bio and the Research Sponsor.

(c) Income or Paid/Reimbursed Travel from seminars, lectures, or teaching engagements sponsored by, and 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.

D. "**Financially-Interested Company**" means an outside entity which would reasonably appear to affect or be affected by the conduct or outcome of a Sponsored Project at Modulight.bio. This term includes: (1) the manufacturer or distributor (including business partners and affiliates) of any drug or device or other product or process being used in the Sponsored Project and (2) any entity acting as the agent of the Research Sponsor or another Financially-Interested Company (e.g., a contract research organization). The term also *may* include a company that provides *direct* and *primary* competition for the investigational product if the Investigator actually knows that the financial interests of the company would reasonably appear to affect or be affected by the Sponsored Project.

E. "**Human Subjects Research**" means research involving an Investigator's intervention or interaction with a living human individual or with an individual's identifiable information at or under the auspices of Modulight.bio as defined by the IRB under its policies.

F. "**Immediate Family**" means the person's spouse, domestic partner, person in a civil union or similar relationship, dependent children, or other family members residing in the person's household.

G. **"Institutional Responsibilities**" means an Investigator's professional responsibilities on behalf of Modulight.bio, including research, or any other professional responsibility incurred by the investigators possession in Modulight.bio.

H. "**IRB**" refers to Modulight.bio's Institutional Review Board and any other authorized Institutional Review Board for Human Subjects Research conducted at or under the auspices of Modulight.bio.

I. An **"Investigator**" is any person in Modulight.bio, regardless of title or position, who is any of the following in connection with a Sponsored Project at or under the auspices of Modulight.bio:

1. Responsible for the designing, conducting or reporting of the Sponsored Project;
2. Proposing to be the principal investigator/program director, or key personnel in a grant application for the Sponsored Project submitted by Modulight.bio;
3. Serving as the principal investigator/program director, co-investigator, sub-investigator, or key personnel on the Sponsored Project; or
4. Listed as an investigator or coordinator on an IRB application for the Sponsored Project.

Investigator also includes outside persons (e.g., sub-grantees, contractors, collaborators or consultants of Modulight.bio) who are determined by Modulight.bio, in consultation with the principal investigator/program director of the Sponsored Project, to be responsible for the design, conduct, or reporting of the Sponsored Project conducted at or under the auspices of Modulight.bio. Section VIII of this Policy outlines the circumstances under which such outside Investigators will be required to comply with the pertinent portions of this Policy.

J. "**Non-Human Subjects Research**" means any basic research, animal research, and other research conducted at or under the auspices of Modulight.bio that is not Human Subjects Research, regardless of the source of funding.

K. "**PHS**" means the 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 the National Institutes of Health (NIH). See Section VII.A for a list of other PHS agencies.

L. "**PHS Regulations**" means the regulations issued by the U.S. Department of Health and Human Services (HHS) entitled "Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought and Responsible Prospective Contractors," (see: http://grants.nih.gov/grants/policy/coi/), as the same may be amended from time to time.

M. "**PHS Sponsored Projects**" means Sponsored Projects subject to the PHS Regulations.

N. "**Pre-Clinical Research**" means any Non-Human Subjects Research which is reasonably anticipated (1) to be a component of a submission to the FDA related to a product or process to be tested on human subjects (including an IND or IDE submission) or (2) to develop into research involving human subjects within the coming twelve (12) months.

O. A "**Research Sponsor"** is any government agency (federal, state, or municipal), foundation, not-for-profit or for-profit entity providing either monetary or material support for a Sponsored Project.

P. "**Significant Financial Interest**" is defined as follows:

(i) For a Human Subjects Research project, a Financial Interest is a "**Significant Financial Interest"** if it is (a) any Management, Board, or Employment Position (including as a director, trustee, partner, senior executive, officer or employee); (b) Ownership Interests (including stocks, options and warrants) of greater than $10,000 in a publicly-held company; (c) Ownership Interests of any amount in a privately-held company; (d) Consulting Compensation (including salary, consulting income and honoraria), Paid/Reimbursed Travel for personal benefit as determined by the CIMP (e.g., a gift or a trip whose primary purpose is pleasure or celebration), and Royalty Income, when aggregated, of greater than $25,000 in any relevant year; or (e) any Intellectual Property Right being tested, developed, or validated in the Human Subjects Research.

(ii) For a Pre-Clinical Research project, a Financial Interest is a "**Significant Financial Interest"** if it

is any Management, Board, or Employment; (b) Ownership Interests of greater than $10,000 in a publicly-held company; (c) Ownership Interest of any amount in a privately-held company; or (d) Consulting Compensation, Paid/Reimbursed Travel for personal benefit as determined by the CIMP, and Royalty Income, when aggregated, of greater than $25,000 in any relevant year.

(iii) For all Non-Human Subjects Research (other than Pre-Clinical Research) or Sponsored Programs, a Financial Interest is a "**Significant Financial Interest"** if it is (a) any Outside Position; (b) Ownership Interests of greater than $25,000 in a publicly-held company; (c) Ownership Interests of any amount in a privately-held company, or (d) Consulting Compensation, Paid/Reimbursed Travel for personal benefit as determined by the CIMP, and Royalty Income, when aggregated, of greater than $40,000 in any relevant year.

(iv) "PHS Significant Financial Interest" means:

(a) A financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator's spouse and dependent children) that reasonably appears to be related to the Investigator's Institutional Responsibilities:

(1) With regard to any publicly traded entity, a PHS Significant Financial Interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds $5,000. For purposes of this definition, remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship); equity interest includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value;

(2) With regard to any non-publicly traded entity, a PHS Significant Financial Interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds $5,000, or when the Investigator (or the Investigator's spouse or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest); or

(3) Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.

(b) The occurrence in the twelve (12) months preceding the disclosure 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 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.

(v) The following are not PHS Significant Financial Interests under this Policy:

(a) salary, royalties, or other remuneration paid by Modulight.bio to the Investigator if the Investigator is currently employed or otherwise appointed by Modulight.bio, including intellectual property rights assigned to Modulight.bio and agreements to share in royalties related to such rights;

(b) 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;

Regulations of this document.

Q. "**Sponsored Program**" means any activity conducted at or under the auspices of Modulight.bio that receives funding from outside Modulight.bio other than a Human Subjects Research project and a Non-Human Subjects Research project.

R. "**Sponsored Project**" means any Human Subjects Research project, any Non-Human Subjects Research project, or any Sponsored Program.

XI. Enforcement

A. Violations of this Policy are subject to disciplinary action, up to and including termination of employment or association with Modulight.bio, in accordance with Modulight.bio disciplinary policies and procedures applicable to the respective Investigator.

B. A new proposal or continuation submission for a Sponsored Project will not be considered complete, and Modulight.bio will not proceed with a Sponsored Project or submit a proposal to a Research Sponsor, unless all Investigators participating in the Sponsored Project have both (i) completed and submitted an annual disclosure as provided in the *Policy on Conflicts of Interest in Research and Sponsored Programs* within the previous twelve (12) months and (ii) completed and submitted an investigator financial interest disclosure for the Sponsored Project as required by this Policy. Failure to make timely submissions will result in delays.

C. If there is a determination by the CEO that the failure of an Investigator to comply with this Policy has biased the design, conduct, or reporting of a Sponsored Project, Modulight.bio will promptly notify the Research Sponsor and any other potentially affected party, require other notifications (e.g., to journals and sponsors of public presentations) as appropriate, and take appropriate other actions to maintain appropriate objectivity in the Sponsored Project.

D. In addition, in any case where the Sponsored Project's purpose is to evaluate the safety or effectiveness of a drug, medical device or treatment and the Sponsored Project has been designed, conducted or reported by an Investigator with a Conflict of Interest that was not managed or reported to Modulight.bio as required, the CIMP will notify the CEO. Additionally, the CIMP may require the Investigator involved to disclose the Conflict of Interest in each public presentation of the results of the research and to request an addendum to previously published presentations.

XII. Administration

A. Questions. Any questions relating to this Policy should be directed to the CEO, or the Legal Counsel, or the officer leading the CIMP.

B. Reporting. The CIMP must provide reports of its activities under this Policy to Modulight.bio's CEO on an annual basis.

C. Records Retention. Records related to this Policy will be maintained in accordance with Modulight.bio's Policy on Record Retention as in effect from time to time. In addition, the CIMP will maintain records of all disclosures it receives, all determinations made, all conflict management plans, all final decisions, and all other actions under this Policy for the longest of (i) three (3) years from the date of submission of final expenditure reports for the Sponsored Project, (ii) any other period required by the research agreement with the Research Sponsor, or (iii) until the resolution of any action involving those records. Additional procedures governing Modulight.bio's records retention responsibilities for projects covered by the PHS Regulations are outlined in Modulight.bio's *Procedures on Conflicts of Interest in Research and Sponsored Programs covered by the PHS Regulations*.

APPEND
IX

Procedures on Conflicts of Interest in Research and Sponsored Programs Covered by the PHS Regulations

I. Summary

Modulight.bio's *Policy on Conflicts of Interest in Research and Sponsored Programs* (the Policy) sets forth Modulight.bio's policies on the disclosure, review, evaluation and determinations related to potential conflicts of interests arising out of Modulight.bio's research and other sponsored programs. Under Section VI.A of the Policy, it is the policy of Modulight.bio to comply with all rules about conflicts of interest imposed by Research Sponsors as a condition of providing funding to Modulight.bio. These Procedures are intended to ensure compliance with the regulations adopted by the Public Health Service of the U.S. Department of Health and Human Services (the PHS Regulations). These Procedures supplement the Policy and apply to all Sponsored Projects subject to the PHS Regulations.

II. Definitions

Capitalized terms not defined in these Procedures are defined in Modulight.bio's *Policy on Conflicts of Interest in Research and Sponsored Programs*.

A. As provided in Section IX.M of the Policy, "**PHS**" means the 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.

The following offices/agencies are part of PHS:

- Administration for Children and Families (ACF)
- Administration for Community Living (ACL)
- Agency for Healthcare Research and Quality (AHRQ)
- Agency for Toxic Substances and Disease Registry (ATSDR)
- Centers for Disease Control and Prevention (CDC)
- Food and Drug Administration (FDA)
- Health Resources and Services Administration (HRSA)
- Indian Health Service (IHS)
- National Institutes of Health (NIH)
- Office of Global Affairs (OGA)
- Office of the Assistant Secretary for Health (OASH)
- Office of the Assistant Secretary for Preparedness and Response (ASPR)
- Substance Abuse and Mental Health Services Administration (SAMHSA)

B. As provided in Sections VI.B(i) and IX.N of the Policy, a "**PHS Conflict of Interest**" exists when Modulight.bio's designated official(s) reasonably determines that a Financial Interest that rises to a PHS Significant Financial Interest could *directly and significantly* affect the design, conduct, or reporting of a Sponsored Project subject to the PHS Regulations.

C. As provided in Section IX.O of the Policy, "**PHS Regulations**" means the regulations issued by the U.S. Department of Health and Human Services (HHS) entitled "Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought and Responsible Prospective Contractors," (see: http://grants.nih.gov/grants/policy/coi/), as the same may be amended from time to time.

D. "**PHS Significant Financial Interest**" means:

(i) A financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator's spouse and dependent children) that reasonably appears to be related to the Investigator's Institutional Responsibilities:

(a) With regard to any publicly traded entity, a PHS Significant Financial Interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds $5,000. For purposes of this definition, remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship); equity interest includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value;

(b) With regard to any non-publicly traded entity, a PHS Significant Financial Interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds $5,000, or when the Investigator (or the Investigator's spouse or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest); or

(c) Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests; or

(ii) The occurrence in the twelve (12) months preceding the disclosure 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 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.

The following are **not** PHS Significant Financial Interests under this Policy:

(a) salary, royalties, or other remuneration paid by Modulight.bio to the Investigator if the Investigator is currently employed or otherwise appointed Modulight.bio, including intellectual property rights assigned to Modulight.bio and agreements to share in royalties related to such rights;

(b) 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; and

(c) 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.

E. "**PHS Sponsored Project**" means any Sponsored Project subject to the PHS Regulations, including any Sponsored Project funded by PHS (e.g., the NIH) that is covered by the requirements of the PHS regulations, and any Sponsored Project funded by a non-PHS Research Sponsor that has incorporated the requirements of the PHS Regulations.

III. Disclosure

Section IV of the Policy outlines the disclosure requirements for Investigators participating in Sponsored Projects conducted at or under the auspices of Modulight.bio. These disclosure requirements apply to Investigators participating in PHS Sponsored Projects.

In addition to the requirements in Section III of the Policy, for disclosures of Financial Interests in the form of Paid/Reimbursed Travel by Investigator in PHS Sponsored Projects, such disclosures must specify for each disclosed travel reimbursement and travel paid at a minimum, the purpose of each trip, the identity of each sponsor/organizer, its destination and its duration.

IV. Review and Evaluation of Disclosures

Section V of the Policy outlines the procedures under which Modulight.bio reviews and evaluates each disclosure made by an Investigator participating in a Sponsored Project to determine if a disclosed Financial Interest could give rise to a Conflict of Interest in the Sponsored Project and to review and evaluate the disclosure to determine if the Investigator may participate in the Sponsored Project and, if participation is permitted, to implement a conflict management plan. These review and evaluation requirements apply to disclosures by Investigators participating in PHS Sponsored Projects.

In addition to the requirements outlined in Section V of the Policy, the following additional procedures apply for disclosures by Investigators participating in PHS Sponsored Projects:

A. CIMP's Initial Review. Pursuant to Sections V.A of the Policy, the officer leading the Conflict of Interest Management Procsess (CIMP) has responsibility for the review and evaluation of each disclosure of Financial Interest to determine if a potential Conflict of Interest exists. In addition to the requirements outlined in Section V.A of the Policy, the CIMP is responsible for Investigators in PHS Sponsored Projects for determining (i) whether any disclosed Financial Interest is a PHS Significant Financial Interest, and (ii) whether any PHS Significant Financial Interest is "related" to a PHS Sponsored Project and could give rise to a PHS Conflict of Interest in a PHS Sponsored Project.

(i) **No PHS Significant Financial Interest.** When CIMP determines that all disclosures of Financial Interests for a Sponsored Project are not PHS Significant Financial Interests, the CIMP will advise the Office of Sponsored Programs Administration that there is no PHS Conflict of Interest present.

(ii) "Relatedness" and PHS Conflict of Interest.

a. When CIMP determines that certain disclosures are PHS Significant Financial Interests, the CIMP will determine if the Investigator's PHS Significant Financial Interests are "related" to the PHS Sponsored Project.

b. An Investigator's PHS Significant Financial Interest is "related" to PHS Sponsored Project when the CIMP reasonably determines that the PHS Significant Financial Interest could affect or be affected, or appear to affect or be affected, by the PHS Sponsored Project or is in an entity whose financial interest could affect or be affected, or appear to affect or be affected, by the research.

c. For disclosures of PHS Significant Financial Interest that the CIMP determines

are "related" to a specific PHS Sponsored Project, the CIMP will review and evaluate the matter as a potential PHS Conflict of Interest under Section IV.B. below.

d. For disclosures of PHS Significant Financial Interest that the CIMP determines are not "related" to the PHS Sponsored Project, the CIMP will advise the Office leading the Sponsored Programs and the Investigator, as appropriate, that there is no "related" PHS Significant Financial Interest present and no PHS Conflict of Interest.

The CIMP may involve the Investigator, the Investigator's department, the CEO and the Legal Counsel in its evaluations under this Section IV.A.

B. CIMP's PHS Conflict of Interest Findings. For disclosures of PHS Significant Financial Interest that the CIMP determines are "related" to a specific PHS Sponsored Project in Section IV.A. above, the CIMP must determine if the disclosure could give rise to a PHS Conflict of Interest in the PHS Sponsored Project. A PHS Conflict of Interest exists when the CIMP reasonably determines that the PHS Significant Financial Interest could *directly and significantly* affect the design, conduct, or reporting of the PHS Sponsored Project.

In determining whether an Investigator's PHS Significant Financial Interest could create a PHS Conflict of Interest, the CIMP will consider the role of the Investigator and the opportunity (if any) to bias the results, the nature of the research being proposed, and the value of the PHS Significant Financial Interest in relation to the size and value of the entity. In addition, the CIMP may also consider the following factors:

1. The magnitude of the PHS Significant Financial Interests (e.g., the amount of consulting, or the percentage or value of equity); or

2. The number and nature of relationships an Investigator has with an entity. Multiple entanglements can create a relationship with an outside entity that is stronger than the sum of the parts; or

3. Whether the research is of a basic or fundamental nature directed at understanding basic scientific processes; or

4. Whether the goal of the research is to validate or invalidate a particular approach or methodology that could affect the value of the PHS Significant Financial Interest; or Whether the degree of replication and verification of research results is such that immediate commercialization or clinical application is not likely; or

5. Whether the goal of the project is a comparative evaluation of a technology in which an Investigator has a PHS Significant Financial Interest; or

6. Where the PHS Significant Financial Interest is in the sponsor of the research, and the sponsor is a licensee of the Investigator's technology, the amount of commercialization payments received by the faculty member from that technology, both currently or in the future; or

7. Whether the goal of the research is to evaluate an invention linked to the PHS Significant Financial Interest (such as where the PHS Significant Financial Interest is a patent, or an interest in a company that has licensed the invention); or

8. Whether the research involves human subjects; or

9. Where the research involves human subjects, whether there are double blind conditions or the involvement of a data and safety monitoring board; or

10. Where the PHS Significant Financial Interest is in a privately held company, whether the research could have a significant impact on the company's business or financial outlook or whether the Investigator's PHS Significant Financial Interest could result in the Investigator having influence over company decisions; or

11. Whether other scientific groups are independently pursuing similar questions; or

12. Whether sufficient external review of the research conducted and the reporting of research results exist to mitigate undue bias; or

13. Whether the project involves a subaward to an entity in which the Investigator has a PHS Significant Financial Interest.

For all reviews of potential PHS Conflict of Interest, the CIMP's finding will be documented and will be included in any conflict management plan approved by the CIMP under Section IV.C. below.

The CIMP may involve the Investigator, the Investigator's department, the CEO and the Legal Counsel in its evaluations under this Section IV.B.

C. PHS Conflict Management Plan. Section V.B. of the Policy outlines the procedures related to conflict management plans issued by the CIMP in the event an Investigator's participation in a PHS Sponsored Project is permitted notwithstanding a PHS Conflict of Interest. There are no additional requirements for PHS Sponsored Projects other than that the CIMP's finding of a PHS Conflict of Interest will be included in the conflict management plan approved by the CIMP. The CIMP is responsible for monitoring the compliance with all PHS conflict management plans on an ongoing basis until the completion of the PHS Sponsored Project. For PHS Sponsored Projects requiring IRB review, these conflict management plans are to be considered as part of the IRB's review.

D. Appeals to the CEO. In accordance with Section V.D. of the Policy, determinations by the CIMP related to a finding of PHS Conflict of Interest may be appealed to Modulight.bio's CEO. Appeals must be in accordance with the requirements of Section V.D. of the Policy. Decisions of the CEO are final.

E. Timing. The disclosure, review and evaluation of an Investigator's disclosure of a Financial Interest related to a PHS Sponsored Project and the issuance and implementation of any conflict management plan as outlined above must be completed prior to any expenditure on the PHS Sponsored Project or the commencement of the Investigator's involvement in the PHS Sponsored Project. For disclosures prior to the commencement of the PHS Sponsored Project, no expenditures on PHS Sponsored Project will be permitted until the Investigator has complied with the disclosure requirements of the Policy and has agreed, in writing, to comply with any plans determined by the CIMP necessary to manage the PHS Conflict of Interest. Whenever, in the course of an ongoing PHS Sponsored Project, an Investigator who is new to participating in the project discloses a PHS Significant Financial Interest or an existing Investigator discloses a new PHS Significant Financial Interest to Modulight.bio, the CIMP will, within sixty (60) days: review the disclosure of the PHS Significant Financial Interest; determine whether it is "related" to PHS Sponsored Project; determine whether a PHS Conflict of Interest exists; and, if so, implement a conflict management plan that will specify the actions taken to manage such PHS Conflict of Interest.

F. Reporting. The CIMP will communicate with the PHS Awarding Component to notify it of the existence and the nature of a PHS Conflict of Interest and whether the PHS Conflict of Interest has been managed, reduced, or eliminated. See Section VI below.

G. Record-Keeping. The CIMP will keep a record of Investigator disclosures of financial interests and any review of, and response to, such disclosure and all actions under this Procedure. Such records will be maintained and kept for three years from the date the final expenditures report is

submitted for grants, for three years from the date of final payment for contracts, or, where applicable, for time periods as otherwise specified in relevant PHS Regulations.

V. Public Accessibility to Information Related to PHS Conflicts of Interest

CIMP, on behalf of Modulight.bio, will ensure public accessibility, by written response to any requestor within five (5) business days of a request, of information concerning any PHS Significant Financial Interest disclosed that meets the following three criteria:

(i) The PHS Significant Financial Interest was disclosed and is still held by the senior/key personnel. Senior/key personnel are the PD/PI and any other person identified as senior key personnel by Modulight.bio in the grant application, progress report or any other report submitted to the PHS by Modulight.bio;

(ii) The CIMP has determined that the PHS Significant Financial Interest is "related" to the PHS Sponsored Project (see Section IV.A(ii) above); and

(iii) The CIMP has determined that the PHS Significant Financial Interest is a PHS Conflict of Interest.

The information that the CIMP, on behalf of Modulight.bio, will make available in a written response to any requestor within five (5) business days of request will include, at a minimum, the following:

(i) The Investigator's name;
(ii) The Investigator's title and role with respect to the research project;
(iii) The name of the entity in which the PHS Significant Financial Interest is held;
(iv) The nature of the PHS Significant Financial Interest;
(v) The approximate dollar value of the PHS Significant Financial Interest in the following ranges: $0-$4,999; $5,000-9,999; $10,000 - $19,999; amounts between $20,000-$100,000 by increments of $20,000; amounts above $100,000 by increments of $50,000), or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value; and
(vi) A description of how the financial interest relates to NIH-funded research and the basis for Modulight.bio's determination that the PHS Significant Financial Interest conflicts with such research.

When Modulight.bio responds to written requests for the purposes of public accessibility, it will ascertain from the Investigator that the information provided is current as of the date of the correspondence, and will note in its written response that the information is subject to updates, on at least an annual basis and within sixty (60) days of Modulight.bio's identification of a new PHS Conflict of Interest, which should be requested subsequently by the requestor.

Information concerning a PHS Conflict of Interest will remain available, for responses to written requests for at least three (3) years from the date that the information was most recently updated.

VI. Reporting of PHS Conflicts of Interest

Prior to the expenditure of any funds under a PHS Sponsored Project, the CIMP, will provide to the PHS Awarding Component a PHS Conflict of Interest report (i.e., a new FCOI report) compliant with PHS Regulations regarding any Investigator's PHS Significant Financial Interest found to give rise to a PHS Conflict of Interest and will ensure that the Investigator has agreed to and implemented the corresponding management plan. While the award is ongoing (including any extensions with or without funds), the CIMP, in collaboration with the Office of Sponsored Programs Administration, will provide to the PHS Awarding Component an annual PHS Conflict of Interest report that addresses the status of the PHS Conflict of Interest (i.e. whether conflict is still being managed or why it no longer exists) and any changes in the management plan.

For any PHS Significant Financial Interest that is identified as conflicting subsequent to an initial PHS Conflict of Interest report during an ongoing PHS Sponsored Project (e.g., upon the participation of an Investigator who is new to the research project or a new PHS Significant Financial Interest), Modulight.bio will provide to the PHS Awarding Component, within sixty days, a new PHS Conflict of Interest report regarding the PHS Conflict of Interest and ensure that Modulight.bio has implemented a management plan and the Investigator has agreed to the relevant management plan.

VII. Subrecipient Requirements

Modulight.bio will, as part of a written subaward with a subrecipient, contractor or collaborator under a PHS prime award, establish whether the Policy applies or whether the financial conflict of interest policy of the subrecipient will apply to the subrecipient, contractor or collaborator's Investigator(s). If the subrecipient, contractor or collaborator relies on its conflicts of interest policy, the subrecipient, contractor or collaborator will certify as part of the subrecipient agreement, that its policy complies with 42 CFR Part 50 and 45 CFR Part 94, as appropriate. In either case, the subaward will include time periods to meet the disclosure and/or financial conflict of interest reporting requirements of Modulight.bio under the PHS Regulations. The subrecipient, contractor or collaborator's institution shall be responsible for having its relevant Investigators provide to Modulight.bio the appropriate disclosures at the time of application or as required.

Pursuant to Section VII of the Policy, if the subrecipient cannot make this representation, the outside Investigator must agree to comply with this Policy, in which case Modulight.bio's CEO will have discretion to determine how this Policy should be implemented and/or adjusted for the specific PHS Sponsored Project.

Consistent with the PHS Regulations, Modulight.bio will make publicly accessible any PHS Conflicts of Interest involving a subrecipient, contractor or collaborator investigator as outlined in Section V above and will report each PHS Conflict of Interest involving subrecipient, contractor or collaborator investigator as outlined in Section VI above.

VIII. Training Requirements

Each Investigator must complete training on Modulight.bio's *Policy on Conflict of Interest in Research and Sponsored Programs* prior to engaging in a PHS Sponsored Project and when any of the following circumstances apply:

1) Modulight.bio revises the Policy or these Procedures in any manner that affects the requirements of Investigators (training will be completed in the manner and within the time frame specified in communications by CIMP announcing such changes);

2) An Investigator is new to Modulight.bio (training must be completed within 30 days of joining Modulight.bio); or

3) Modulight.bio finds that an Investigator is not in compliance with this Procedure to Modulight.bio's Conflict of Interest Policy or a management plan issued under this Procedure (training must be completed within 30 days in the manner specified by the CIMP).

In addition, each Investigator must complete the training at least every four years and as otherwise may be required by the CIMP.

IX. Failure to Comply

Section VI(B)(iv) of the Policy outlines the consequences for failures to comply with the requirements of this policy; non-compliance includes failure of an Investigator to disclose a PHS Significant Financial Interest that could give rise to a PHS Conflict of Interest in a timely manner, failure of

Modulight.bio to review and manage a PHS Significant Financial Interest determined to constitute a PHS Conflict of Interest in a timely manner, or failure of an Investigator to comply with the terms of a COI management plan relative to a PHS Conflict of Interest.

1. Review. If an initial or ongoing disclosure for the PHS Sponsored Project of a PHS Significant Financial Interest that could give rise to a PHS Conflict of Interest is not disclosed in a timely manner, the CIMP will, within sixty (60) days: review the disclosure of the PHS Significant Financial Interest; determine whether it is "related" to a PHS Sponsored Project; determine whether a PHS Conflict of Interest exists; and, if so, implement a conflict management plan that will specify the actions taken to manage such PHS Conflict of Interest. Depending on the nature of the PHS Significant Financial Interest, the CIMP may determine that additional interim measures are necessary with regard to Modulight.bio's participation in the PHS Sponsored Project between the date of disclosure and the completion of Modulight.bio's review and determination.

2. Retrospective Reviews/Mitigation Reports. For non-compliance, such as failure by the Investigator to disclose a PHS Significant Financial Interest that is determined by Modulight.bio to constitute a PHS Conflict of Interest; failure by Modulight.bio to review or manage such a financial conflict of interest; or failure by the Investigator to comply with a financial conflict of interest management plan, the CIMP will, within 120 days of Modulight.bio's determination of noncompliance, complete a retrospective review of the Investigator's activities and the PHS Sponsored Project(s) to determine whether any PHS Sponsored Project, or portion thereof, conducted during the time period of the noncompliance, was biased in the design, conduct, or reporting of such research.

The CIMP must document the retrospective review. Such documentation will include, but not necessarily be limited to, all of the following key elements: (1) Project number; (2) Project title; (3) PD/PI or contact PD/PI if a multiple PD/PI model is used; (4) Name of the Investigator with the PHS Conflict of Interest; (5) Name of the entity with which the Investigator has a financial conflict of interest; (6) Reason(s) for the retrospective review; (7) Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed); (8) Findings of the review; and (9) Conclusions of the review.

Based on the results of the retrospective review, if appropriate, the CIMP will update the previously submitted PHS Conflict of Interest report, specifying the actions that will be taken to manage the PHS Conflict of Interest going forward. If bias is found, the CIMP will notify the PHS Awarding Component promptly and submit a mitigation report to the PHS Awarding Component. The mitigation report must include, at a minimum, the key elements documented in the retrospective review above and a description of the impact of the bias on the Sponsored Project and Modulight.bio's plan of action or actions taken to eliminate or mitigate the effect of the bias (e.g., impact on the research project; extent of harm done, including any qualitative and quantitative data to support any actual or future harm; and/or analysis of whether the research project is salvageable). Thereafter, the CIMP will submit PHS Conflict of Interest reports annually, as specified elsewhere in this Procedure.

In any case in which the PHS determines that an NIH-funded 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 an Investigator with a PHS Conflict of Interest that was not managed or reported as required by the regulation, Modulight.bio must require the Investigator(s) involved to disclose the PHS Conflict of Interest in each public presentation of the results of the research and to request an addendum to previously published presentations.

Depending on the nature of the PHS Conflict of Interest, the CIMP may determine that additional interim measures are necessary with regard to the Investigator's participation in the PHS Sponsored Project between the date that the PHS Conflict of Interest or the Investigator's noncompliance is determined and the completion of the retrospective review.

X. Questions

Any questions relating to this Policy should be directed to the CEO, the Legal Counsel, or the CIMP.