

## **L2 Diagnostics, LLC**

### **Conflict of Interest Policy**

Employees, consultants, and others involved with L<sup>2</sup> Diagnostics, LLC, including for grant-supported activities, must refrain from using their positions for purposes that are, or give the appearance of being, motivated by a desire for private financial gain for themselves or others, such as those with whom they have family, business, or other ties. This includes: receipt from outside parties of financial interests, gifts, gratuities, and favors; nepotism; and, such other areas as political participation and bribery.

If an employee, consultant, and others involved with L<sup>2</sup> Diagnostics, LLC has a question as to what outside activities, relationships, or financial interests are proper or improper, he should address that question to the Company's Managing Director. An employee, consultant, or others involved with L<sup>2</sup> Diagnostics, LLC should provide for advance notification to his supervisor of outside activities, relationships, or financial interests that in any way may be related to the business of the Company.

Improper conflict of interest activities and/or failure to notify the Company of situations that could lead to a conflict of interest can result in an immediate termination of employment of an employee or consultant, and cessation of work with others.

### **Financial Conflict of Interest Policy**

All employees and others involved in projects with L2 Diagnostics, LLC involving NIH funding will comply with the financial conflict of interest (FCOI) requirements applicable to all Institutions that apply for NIH research funding. Proper stewardship of Federal funds includes ensuring objectivity of results by protecting Federally-funded research from compromise by FCOI. All Company Investigators are required to make themselves aware of their obligations under the FCOI regulation (42 CFR Part 50, Subpart F). All Investigators must review and complete the general conflict of interest information and related tutorials provided by NIH for individuals who are responsible for the design, conduct or reporting of NIH-supported research: <http://grants.nih.gov/grants/policy/loi/index.htm>.

The Company's enforcement and administrative process to identify and handle conflicting interests as required under the FCOI regulation (42 CFR Part 50, Subpart F) include the following steps: (1) All employees or others involved in projects involving NIH funding must report to the Company's Managing Director all financial and other interests (and those of any related person) that (a) would appear or could be interpreted to appear affected by the NIH funded research or (b) are in entities whose financial or other interest would appear to be affected by the NIH funded research; and, (2) the Company's Managing Director will then work to ensure that the Company follows all relevant requirements of the FCOI regulation (42 CFR Part 50, Subpart F) including determination of whether a FCOI exists, reporting to the NIH, and instituting a plan to manage, reduce or eliminate conflicting interests. "Interests" include, but are not limited to, salary, consulting fees, honoraria, payments for any services, equity interests (e.g., stocks, stock options, or other ownership interests), and intellectual property rights (e.g., patents, copyrights, and royalties from such rights). With regards to NIH-funded research through subgrantees/contractors/subcontractors/collaborators, all employees and the Company's Managing Director must take reasonable steps to ensure that Investigators working for these entities comply with the regulation; identification of any actual or potential conflicting interests should be reported to the Company's Managing Director immediately.

Compliance is mandatory with regards to the financial conflict of interest regulatory requirements of Title 42, Code of Federal Regulations (CFR), Part 50, Subpart F, "Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought," referred to as the "2011 revised FCOI regulation."

The 2011 revised FCOI regulation establishes standards to ensure that the design, conduct, or reporting of research funded under Public Health Service (PHS) grants is not biased by any conflicting financial interest of an Investigator (42 C.F.R. 50.601 et seq.). In accordance with 42 CFR 50.604(a), as an NIH funding applicant and recipient we are

required to maintain an up-to-date, written, enforced policy on financial conflicts of interest that complies with this subpart.

This Financial Conflict of Interest policy will be made available to any requesting party outside of the Company within 5 days of request.

ALL EMPLOYEES and OTHERS involved in L2 Diagnostics, LLC projects involving NIH funding will comply with the financial conflict of interest (FCOI) requirements applicable to all Institutions that apply for NIH research funding. Proper stewardship of Federal funds includes ensuring objectivity of results by protecting Federally-funded research from compromise by FCOI.

ALL INVESTIGATORS are required to make it their individual responsibility to be aware of their obligations under the FCOI regulation (42 CFR 50.602). All Investigators involved with company NIH funded grants must review and complete the general conflict of interest information and related tutorials provided by NIH for individuals who are responsible for the design, conduct or reporting of NIH-supported research:  
<http://grants.nih.gov/grants/policy/coi/index.htm>.

Each Investigator who is planning to participate in the PHS-funded research must disclose to the Company's designated official (Managing Director) the Investigator's significant financial interests (and those of the Investigator's spouse and dependent children) no later than the time of application for PHS-funded research. (42 CFR 50.604(e))

Each Investigator who is participating in the PHS-funded research must submit an updated disclosure of significant financial interests at least annually, at the end of the calendar year, during the period of the award. Such disclosure shall include any information that was not disclosed initially to the Company pursuant to paragraph (e)(1) of this section, or in a subsequent disclosure of significant financial interests (e.g., any financial conflict of interest identified on a PHS-funded project that was transferred from another Institution), and shall include updated information regarding any previously disclosed significant financial interest (e.g., the updated value of a previously disclosed equity interest). (42 CFR 50.604(e))

Each Investigator who is participating in the PHS-funded research must submit an updated disclosure of significant financial interests within thirty days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new significant financial interest. (42 CFR 50.604(e))

The Company's enforcement and administrative process to identify and handle conflicting interests as required under the FCOI regulation (42 CFR Part 50, Subpart F) include the following steps: (1) ALL EMPLOYEES including ALL INVESTIGATORS involved in projects involving NIH funding must disclose to the Company's Managing Director all financial and other interests (and those of any related person) that (a) would appear or could be interpreted to appear affected by the NIH funded research or (b) are in entities whose financial or other interest would appear to be affected by the NIH funded research; and, (2) the Company's Managing Director will then work to ensure that the Company follows all relevant requirements of the FCOI regulation (42 CFR Part 50, Subpart F) including determination of whether a FCOI exists, reporting to the NIH, and instituting a plan to manage, reduce or eliminate conflicting interests.

"Interests" include, but are not limited to, salary, consulting fees, honoraria, payments for any services, equity interests (e.g., stocks, stock options, or other ownership interests), and intellectual property rights (e.g., patents, copyrights, and royalties from such rights).

Initial "disclosure" must include reimbursed or sponsored travel that is received in the preceding 12 months (NIH Guide Notice [NOT-OD-13-004](#)).

If our company implements a management plan with regards to a FCOI, the Company will monitor Investigator compliance with the management plan on an ongoing basis, no less than on a quarterly basis, until the completion of the PHS-funded research project 42 CFR 50.605(a)(4).

With regards to NIH-funded research through subgrantees/contractors/subcontractors/collaborators, all employees and the Company's Managing Director will take reasonable steps to ensure that Investigators working for these entities comply with the regulation; identification of any actual or potential conflicting interests should be reported to the Company's Managing Director immediately.

Prior to the Company's expenditure of any funds under a PHS-funded research project, the Company shall provide to the PHS Awarding Component an FCOI report regarding any Investigator's significant financial interest found by the Company to be conflicting and ensure that the Company has implemented a management plan in accordance with this subpart. In cases in which the Company identifies a financial conflict of interest and eliminates it prior to the expenditure of PHS-awarded funds, the Company shall not submit an FCOI report to the PHS Awarding Component. (42 CFR 50.605(b)(1))

For any financial conflict of interest previously reported by the Company with regard to an ongoing PHS-funded research project, the Company shall provide to the PHS Awarding Component an annual FCOI report that addresses the status of the financial conflict of interest and any changes to the management plan for the duration of the PHS-funded research project. The annual FCOI report shall specify whether the financial conflict is still being managed or explain why the financial conflict of interest no longer exists. The Company shall provide annual FCOI reports to the PHS Awarding Component for the duration of the project period (including extensions with or without funds) in the time and manner specified by the PHS Awarding Component. (42 CFR 50.605(b)(4))

All Investigators are required to undergo the following training requirements (as established in 42 CFR 50.604(b)): Each Investigator will be informed of the Company's policy on financial conflicts of interest, the Investigator's responsibilities regarding disclosure of significant financial interests, and of the relevant regulations. Each Investigator will be required to complete training regarding the same prior to engaging in research related to any PHS-funded grant and at least every four years, and immediately when any of the following circumstances apply: (1) The Company revises its financial conflict of interest policies or procedures in any manner that affects the requirements of Investigators; (2) An Investigator is new to the Company; or (3) The Company finds that an Investigator is not in compliance with the Company's financial conflict of interest policy or management plan.

The Company will maintain records relating to all Investigator disclosures of financial interests and the Company's review of, and response to, such disclosures (whether or not a disclosure resulted in the Company's determination of a financial conflict of interest) and all actions under the Company's policy or retrospective review, if applicable, for at least three years from the date the final expenditures report is submitted to the PHS or, where applicable, from other dates specified in 45 CFR 74.53(b) and 92.42(b) for different situations.

Whenever, in the course of an ongoing PHS-funded research project, an Investigator who is new to participating in the research project discloses a significant financial interest or an existing Investigator discloses a new significant financial interest to the Company, the designated official(s) of the Company (the Managing Director) shall, within sixty days: review the disclosure of the significant financial interest; determine whether it is related to PHS-funded research; determine whether a financial conflict of interest exists; and, if so, implement, on at least an interim basis, a management plan that shall specify the actions that have been, and will be, taken to manage such financial conflict of interest. Depending on the nature of the significant financial interest, the Company may determine that additional interim measures are necessary with regard to the Investigator's participation in the PHS-funded research project between the date of disclosure and the completion of the Company's review. (42 CFR 50.605(a)(2))

The Company will maintain enforcement mechanisms, including during periodic project reviews, and establish new mechanisms as deemed necessary, and provide for employee sanctions or other administrative actions, to ensure Investigator compliance as appropriate (as required under 42 CFR 50.604(j)). Improper Financial Conflict of Interest activities and/or failure to notify the Company of situations that could lead to a conflict of interest can result in an immediate termination of employment.

Whenever an Company identifies a significant financial interest that was not disclosed timely by an Investigator or, for whatever reason, was not previously reviewed by the Company during an ongoing PHS-funded research project (e.g., was not timely reviewed or reported by a subrecipient), the designated official(s) shall, within sixty days: review the significant financial interest; determine whether it is related to PHS-funded research; determine whether a

financial conflict of interest exists, and, if so, implement, on at least an interim basis, a management plan that shall specify the actions that have been, and will be, taken to manage such financial conflict of interest going forward. In addition: (A) Whenever a financial conflict of interest is not identified or managed in a timely manner including failure by the Investigator to disclose a significant financial interest that is determined by the Company to constitute a financial conflict of interest; failure by the Company 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 Company shall, within 120 days of the Company's determination of noncompliance, complete a retrospective review of the Investigator's activities and the PHS-funded research project to determine whether any PHS-funded research, or portion thereof, conducted during the time period of the noncompliance, was biased in the design, conduct, or reporting of such research. (B) The Company will document the retrospective review; such documentation shall 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 FCOI; (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. (42 CFR 50.605(a)(3))

Based on the results of the retrospective review, if appropriate, the Company shall update the previously submitted FCOI report, specifying the actions that will be taken to manage the financial conflict of interest going forward. If bias is found, the Company will notify the PHS Awarding Component promptly and submit a mitigation report to the PHS Awarding Component. The mitigation report will include, at a minimum, the key elements documented in the retrospective review above and a description of the impact of the bias on the research project and the Company'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; analysis of whether the research project is salvageable). Thereafter, the Company will submit FCOI reports annually, as specified elsewhere in this subpart. Depending on the nature of the financial conflict of interest, the Company may determine that additional interim measures are necessary with regard to the Investigator's participation in the PHS-funded research project between the date that the financial conflict of interest or the Investigator's noncompliance is determined and the completion of the Company's retrospective review. (42 CFR 50.605(a)(3) (iii))

If the failure of an Investigator to comply with an Company's financial conflicts of interest policy or a financial conflict of interest management plan appears to have biased the design, conduct, or reporting of the PHS-funded research, the Company shall promptly notify the PHS Awarding Component of the corrective action taken or to be taken. The PHS Awarding Component will consider the situation and, as necessary, take appropriate action, or refer the matter to the Company for further action, which may include directions to the Company on how to maintain appropriate objectivity in the PHS-funded research project. PHS may, for example, require Institutions employing such an Investigator to enforce any applicable corrective actions prior to a PHS award or when the transfer of a PHS grant(s) involves such an Investigator. (42 CFR 50.605(a))

In any case in which the HHS determines that a PHS-funded research project of clinical research whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment has been designed, conducted, or reported by an Investigator with a financial conflict of interest that was not managed or reported by the Company as required by this regulation, the Company requires the Investigator involved to disclose the financial conflict of interest in each public presentation of the results of the research and to request an addendum to previously published presentations (42 CFR 50.606(c)).

Because our Company may carry out the PHS-funded research through a subrecipient (e.g., subcontractors or consortium members), the Company will take reasonable steps to ensure that any subrecipient Investigator complies with subpart 42 CFR 50.604(c) including by: (1) Incorporating as part of a written agreement with the subrecipient terms that establish whether the financial conflicts of interest policy of the awardee Company or that of the subrecipient will apply to the subrecipient's Investigators. (2) If the subrecipient's Investigators must comply with the subrecipient's financial conflicts of interest policy, the subrecipient shall certify as part of the agreement referenced above that its policy complies with this subpart. If the subrecipient cannot provide such certification, the agreement shall state that subrecipient Investigators are subject to the financial conflicts of interest policy of the awardee Company for disclosing significant financial interests that are directly related to the subrecipient's work for

the awardee Company; (3) Additionally, if the subrecipient's Investigators must comply with the subrecipient's financial conflicts of interest policy, the agreement referenced above shall specify time period(s) for the subrecipient to report all identified financial conflicts of interest to the awardee Company. Such time period(s) shall be sufficient to enable the awardee Company to provide timely FCOI reports, as necessary, to the PHS as required by this subpart; (4) Alternatively, if the subrecipient's Investigators must comply with the awardee Company's financial conflicts of interest policy, the agreement referenced above shall specify time period(s) for the subrecipient to submit all Investigator disclosures of significant financial interests to the awardee Company. Such time period(s) shall be sufficient to enable the awardee Company to comply timely with its review, management, and reporting obligations under this subpart. (5) Providing FCOI reports to the PHS Awarding Component regarding all financial conflicts of interest of all subrecipient Investigators consistent with this subpart, *i.e.*, prior to the expenditure of funds and within 60 days of any subsequently identified FCOI.

This Financial Conflict of Interest policy will be made available to any requesting party outside of the Company within 5 days of request.

Additionally, the Company will provide the required provision of public accessibility of identified financial conflicts of interests as required by 42 CFR 50.605(a)(5) which requires:

(i) Prior to the Company's expenditure of any funds under a PHS-funded research project, the Company shall ensure public accessibility, via a publicly accessible Web site or written response to any requestor within five business days of a request, of information concerning any significant financial interest disclosed to the Company that meets the following three criteria: (A) The significant financial interest was disclosed and is still held by the senior/key personnel as defined by this subpart; (B) The Company determines that the significant financial interest is related to the PHS-funded research; and (C) The Company determines that the significant financial interest is a financial conflict of interest.

(ii) The information that the Company makes available via a publicly accessible Web site or written response to any requestor within five business days of a request, shall include, at a minimum, the following: the Investigator's name; the Investigator's title and role with respect to the research project; the name of the entity in which the significant financial interest is held; the nature of the significant financial interest; and the approximate dollar value of the significant financial interest (dollar ranges are permissible: \$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.

(iii) If the Company uses a publicly accessible Web site for the purposes of this subsection, the information that the Company posts shall be updated at least annually. In addition, the Company shall update the Web site within sixty days of the Company's receipt or identification of information concerning any additional significant financial interest of the senior/key personnel for the PHS-funded research project that was not previously disclosed, or upon the disclosure of a significant financial interest of senior/key personnel new to the PHS-funded research project, if the Company determines that the significant financial interest is related to the PHS-funded research and is a financial conflict of interest. The Web site shall note that the information provided is current as of the date listed and is subject to updates, on at least an annual basis and within 60 days of the Company's identification of a new financial conflict of interest. If the Company responds to written requests for the purposes of this subsection, the Company will note in its written response that the information provided is current as of the date of the correspondence and is subject to updates, on at least an annual basis and within 60 days of the Company's identification of a new financial conflict of interest, which should be requested subsequently by the requestor.

(iv) Information concerning the significant financial interests of an individual subject to paragraph (a)(5) of this section shall remain available, for responses to written requests or for posting via the Company's publicly accessible Web site for at least three years from the date that the information was most recently updated.

End.

Effective 4/28/21