

Mandatory Policies of Health and Environmental Sciences Institute

Adopted by the HESI Executive Committee on behalf of the HESI Board of Trustees

November 23, 2015

1 Introduction and Scope

1.1 **Binding Effect of these Policies.** The Board of Trustees of the Health and Environmental Sciences Institute (“HESI”) has adopted the following policies as mandatory.

1.2 **Nature of HESI.** HESI is organized and operated as a nonprofit, charitable and scientific organization. It is required by law always to act in the service of the public good rather than in the service of corporate or other private interests. HESI’s activities include the participation of and contributions from scientists working in industry, academia, government, civil society, and other sectors. Many projects in the HESI portfolio receive substantial funding from industry collaborators, and many HESI programs also receive critically important financial support from international organizations, government agencies, and private foundations. The contributions of time, money, and expertise that HESI receives from multiple sources are provided upon the shared understanding that HESI’s work is scientifically rigorous, scrupulously neutral, and free from improper influence by the sources of its funding. For all of these reasons, each HESI project and program must first and foremost conduct itself and its activities with a view to serving the public interest.

2 Board Governance of HESI

2.1 **Role of HESI Board.** The fundamental requirements of the HESI board is to ensure that:

- (a) Be created, composed, and operated in a manner consistent with the applicable laws, rules, and regulations of the country(ies) where it is incorporated.
- (b) Acts in accordance with the ethical and organizational standards set forth in the organization’s charter agreement with ILSI, its governing instruments, and these policies.
- (c) The board exercises effective oversight over the management and finances of HESI, and provides strategic direction to HESI management. Such oversight requires board approval of budgets and supervision of programs and activities to ensure their sustainability, scientific merit, and adherence to these policies.

2.2 **Tripartite Participation on the HESI Board.** At least half of the trustees of the HESI board must be considered “public sector” trustees as defined in these policies. To be considered a public sector trustee, the individual must be able to demonstrate that he or she is substantially and actively engaged in teaching, research, and/or administrative programs of a public institution (university, nonprofit research institute, foundation, governmental, intergovernmental or quasi-

government bodies).

2.3 Duty of Loyalty. HESI will communicate to all of its trustees that, whether they are employed in the public or private sector, each of them serves in an individual capacity, and all actions taken in one's capacity as a trustee must be in the best interest of the HESI rather than the interest of the trustee's employer.

2.4 No Compensation for Board Service. Trustees shall not be compensated by HESI for serving on the board or any committee. However, to the extent permitted by applicable law, HESI may reimburse the reasonable and necessary costs of attending official functions. HESI shall not make loans of its funds to trustees, staff, or any other person.

2.5 Internal Controls and Financial Records and Policies. HESI will ensure that it has in place effective internal controls, systems of checks and balances, and formalized record keeping, which with the aims of safeguarding the assets of HESI; assuring compliance by HESI with applicable laws, rules, regulations, and these policies; and adhering to the public interest mission of ILSI and HESI. At a minimum, such internal controls shall include the following:*

- (a) keeping detailed books, records, and accounts which accurately and fairly reflect the transactions and dispositions of assets;
- (b) a system of internal controls which provides reasonable assurances that grants, transactions and other expenditures are properly authorized and appropriately recorded;
- (c) policies for incurring and reimbursement of reasonable travel and other expenses;
- (d) educating staff regarding who can authorize particular transactions;
- (e) ensuring that multiple staff members and/or trustees in the organization understand the flow of monies through HESI; and
- (f) providing sufficient information to the board to give assurance that HESI's investment portfolio is being responsibly managed, consistent with applicable investment guidelines.

2.6 Governance Records and Policies. The HESI Board must ensure that HESI maintains the following written records and policies:

* HESI's legal counsel and chief financial officer are available to assist HESI in complying with these requirements.

- (a) copies of current organizational documents such as articles of incorporation (or articles of association) and bylaws;
- (b) official minutes of meetings and actions of HESI's board of trustees, recorded reasonably promptly after the meeting or action in question;
- (c) a policy requiring trustees to declare actual and potential conflicts of interests no less frequently than annually;
- (d) a whistleblower policy that protects employees and other HESI personnel against retaliation for reporting suspected financial irregularities; and
- (e) a document retention policy that provides for the safekeeping of key HESI documents and the prevention of their destruction upon receiving notice of a legal inquiry into the HESI's operations.

3 Management and Operation of the HESI

3.1 Executive Director Position. The day-to-day operations of HESI should be managed and directed by an Executive Director who shall be responsible to the HESI board. HESI will establish a clear job description or terms of reference for the Executive Director position, which should be periodically reviewed by the board. The Executive Director should not be a voting member of the HESI board.

3.2 Executive Director Evaluation and Compensation - The board of HESI will evaluate the Executive Director's performance no less than annually. Compensation of the Executive Director should be overseen by the full board, or by the executive, finance or compensation committee. If these functions are carried out by a board committee, the responsible committee should report fully to the entire board. Compensation levels should be fair, reasonable, and not excessive, and should take into account the nature and amount of work required by the Executive Director, as well as benchmarks from comparable institutions.

3.3 No Credit or Loans of Funds to Staff. HESI shall not extend credit, including personal loans, to its Executive Director or other staff member, to or any family member of any such persons.

3.4 Communications Management. In its external communications, HESI must strive to ensure that it exemplifies HESI's values of scientific excellence, rigor, and integrity; financial and legal probity; and paramount dedication to the public interest. HESI staff, volunteers, and committees shall avoid making public statements that are inconsistent with these policies, such as statements that amount to lobbying, advocacy of policy positions, or endorsement of commercial interests.

3.5 Financial Sponsorship of HESI Activities.

- (a) All significant scientific and programmatic activities of the HESI shall be adopted in accordance with a process approved by the HESI board.
- (b) In deciding whether to undertake any activity, and in executing such activities after such a decision has been taken, HESI should ensure that the activities:

- (i) fit with the broad mission of HESI and the specific objectives, strategic plan, and staffing capabilities of HESI;
 - (ii) are carried out in a scientifically legitimate and accurate manner;
 - (iii) include the substantial participation of public sector scientists;
 - (iv) conform to HESI's policies;
 - (v) do not involve the endorsement or advertising of any particular brand or company product, or display of sponsor or other company logos;
 - (vi) include disclosure of relevant facts and important information where their omission would present an unbalanced view of an issue in which the sponsor(s) have a perceived or actual conflict of interest.
- (c) HESI shall not undertake any scientific or programmatic activity that is funded solely by industry sponsors unless it has at least three financially distinct funding sponsors as well as strong technical support from public sector scientific partners and has been approved by the HESI board. The purpose of this rule is to avoid undue domination of the activity by the sponsoring company(ies), and to ensure that the activity is directed to issues of broad, public interest, rather than merely the commercial interests of the sponsor(s).

3.6 Avoidance of Conflicts of Interest. In its relations with corporate organizations, HESI must avoid a perception of or actual conflict of interest and act at all times in ways that will only enhance the credibility and professional recognition of HESI and the global ILSI network. HESI shall not authorize any use of the HESI name and logo: (a) in connection with activities in which HESI has no substantive involvement; or (b) that could impact negatively upon HESI's credibility or reputation, such as by allowing corporate donors or member companies to display the HESI name or logo in connection with commercial advertisements or promotional literature.

3.7 Commissioned Research and Research Grants Awarded by HESI. When HESI commissions one or more scientists to conduct research, and when a HESI committee awards a research grant to a third party, HESI shall ensure that the following principles are respected:

- (a) The research shall be conducted in an objective manner so that its structure is presented factually and without bias or predetermined outcomes and be such that it is verifiable and reproducible.
- (b) The research shall be designed so that it is a reasonably powerful and unbiased test of the hypothesis or question being evaluated. Investigators should maintain their intellectual honesty in proposing and performing all aspects of research so that it is uninfluenced by competing interests, including financial interests.
- (c) The scientific independence, autonomy, and integrity of the investigators involved must be respected. Without limitation, this means that once a design, protocol, or implementation plan has been established for a project investigators shall not be required to accept suggestions or changes to the design, protocol, or implementation, or to resulting manuscripts, which are proposed by the HESI, by corporate sponsors, or by other entities involved in funding the work in question.
- (d) Remuneration for work and tokens of appreciation for investigators shall not depend on the outcome or interpretation of the research. This principle does not preclude stopping studies using pre-specified adaptive designs to permit a change in course when the original purpose of the study appears to be futile or dangerous. It also does not preclude deciding which, if any, new work is to be undertaken on the basis of results of a prior study. The research should be based on observable phenomena.
- (e) HESI shall provide a copy of these principles regarding commissioned research and research grants to all investigators engaged in such research.
- (f) Results of the funded research will be made publicly accessible via peer-reviewed publication, distribution on an accessible website, presentation in a public forum or conference, or other such means.

3.8 Publications. Publications of HESI's scientific efforts shall reflect the high standards of the organization. To that end:

- (a) Authors should make a full disclosure of financial interests that would reasonably appear to affect the contents of the article or work's communication. This includes disclosure of industry relationships, advisory relationships, financial and other conflicts of interest.
- (b) Relevant interests (financial and otherwise) and/or advisory relationships of the authors shall be cited in publications. It is recognized that guarding against conflicts of interest is important in all research, not simply industry-sponsored publications, but it is especially important in these.
- (c) Authors shall adhere to accepted guidelines for authorship and publications.
- (d) External funders of the research and/or other sponsors shall be mentioned by name in publications and other forms of disclosure, if applicable.
- (e) Ghost authorship (when an individual makes a substantial contribution to the research or the writing of the manuscript, but is not listed as an author) is not allowed in HESI sponsored studies or publications.

3.9 **Committee Leadership and Guidance.** HESI’s scientific committees, chartered by the HESI Emerging Issues Committee and/or HESI Program Strategy and Stewardship Committee, shall be led by chair persons that are drawn from both the public and private sector. These volunteer leaders will work in collaboration with the assigned HESI staff person to ensure that the strategic focus of the committee is consistent with the chartered scientific objectives for that project, that a diversity of technical and sector perspectives are integrated into the program design and implementation, and that the outputs of the committee are aligned with HESI’s mission to produce science with a public benefit.

4 Representation of HESI in Meetings of Government Agencies, International Organizations, and Other Authoritative Bodies.

4.1 **Commentary on Pending Regulations / Legislation.** HESI will not comment upon or propose public policy solutions in relation to proposed, pending, or existing legislation (i.e., statutory law established by a parliament or other legislative arm of government). With regard to proposed, pending, or existing regulations (i.e., rules established by administrative bodies to implement legislation), HESI may provide regulators information relating to HESI’s scientific expertise, but they may not propose public policy solutions or advocate the commercial interests of their member companies or other parties. All commentary on pending regulation and legislation by HESI in any part of the world must be reviewed and approved by ILSI’s legal counsel in advance of its submission to any public authority.

5 Additional Policies

5.1 **Anti-Corruption Policy.** HESI is bound by the ILSI Anti-Corruption Policy, which should be distributed to trustees and staff of HESI as well as any person, company, or organization that acts or purports to act on behalf of HESI.

5.2 **Antitrust Policy.** HESI is bound by the ILSI Antitrust Statement, which is distributed to participants in meetings of HESI.

5.3 **Code of Ethics and Standards of Conduct.** HESI—together with its employees, trustees, agents, and other representatives—is bound by the ILSI Code of Ethics and Standards of Conduct. In addition, each HESI has specific policies that promote honest and ethical conduct, including the handling of conflict-of-interest issues at both the board and staff levels; accurate and clear disclosure of financial matters; legal compliance; confidential use of proprietary information; and prompt internal reporting of violations of the code or of applicable law, with appropriate protection against retaliation because of any good-faith report. The policies should be readily available to the public, for example, by posting on the HESI's website, or by reference in its annual report.

5.4 **Diversity Policy.** HESI is bound to and complies with the ILSI Diversity Policy.

6 Implementation, Compliance Monitoring, and Enforcement

- 6.1 **Implementation.** These policies are effective for HESI and its staff, programs, and official activities as of the date of their adoption by the HESI board. Accordingly, upon the adoption of these policies, HESI will:
- (a) Confirm that its governance, operations, and activities are in compliance with these policies; and
 - (b) Communicate these policies to each member of its board, each of its employees, and each of its volunteer collaborators, and ensure that these policies are at all times readily accessible to such persons.
- 6.2 **Compliance Monitoring.** Because the failure to adhere to these policies could detrimentally affect some or all other members of the HESI organization or the broader ILSI network, HESI shall take measures to ensure that all HESI activities and initiatives implement and comply with these policies, and to correct violations of these policies.
- 6.3 **Enforcement.** HESI's legal counsel shall have primary responsibility and authority to monitor, investigate, and verify compliance with these policies. HESI's legal counsel shall report to the HESI board of trustees on an annual basis regarding compliance with these policies.
- 6.4 **Review and Revision of Policies.** HESI shall review and revise these policies on a periodic basis.

These policies were adopted by the HESI Executive Committee on behalf of the HESI Board of Trustees on November 23, 2015.