

OPERATING POLICIES OF HEALTH AND ENVIRONMENTAL SCIENCES INSTITUTE

1. **Nature of HESI.** The Health and Environmental Sciences Institute (“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. **Binding Effect of these Policies.** To enable HESI better to fulfill its mission, the HESI Board of Trustees has adopted as mandatory the policies, principles, and statements contained in the following appendices:

Appendix A. Board Governance of HESI

Appendix B. Management and Operation of HESI

Appendix C. Scientific Integrity and Transparency

Appendix D. Anti-Corruption Policy

Appendix E. Antitrust Statement

Appendix F. Code of Ethics

Appendix G. Statement of Ethical Research Practices

Appendix H. Data Sharing Principles

Appendix I. Authorship Policy

Appendix J. Policy on Contractual Arrangements

Appendix K. Contract Review and Approval Policy

3. **Implementation.** These policies apply to HESI, its staff, its programs, and its official activities as of the date of their adoption by the HESI Board. Accordingly, HESI will:

- (a) Confirm that its governance, operations, and activities comply with these policies; and
- (b) Communicate these policies to each member of its Board, each of its employees, its Emerging Issues Committee, and each of its volunteer collaborators, and ensure that these policies are readily accessible to such persons.

4. **Compliance Monitoring.** 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.

5. **Enforcement.** HESI’s legal counsel shall 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. **Review and Revision of Policies.** HESI shall review and revise these policies on a periodic basis.

Updated and approved by the HESI Board of Trustees on January 23, 2024.

APPENDIX A
BOARD GOVERNANCE

1. **Role of HESI Board.** The fundamental requirements of the HESI Board are to ensure that:
 - (a) HESI is established, composed, and operated in a manner consistent with all applicable laws, rules, and regulations.
 - (b) HESI acts in accordance with the ethical and organizational standards set forth in the organization’s governing instruments, Code of Ethics, Anti-Corruption Policy, Antitrust Statement, and these policies.
 - (c) HESI’s Board exercises effective oversight over the scientific portfolio, strategic direction, management and finances of HESI. Such oversight requires Board approval of budgets and strategic review of programs and activities to ensure their sustainability, scientific merit, and adherence to these policies.

2. **Multi-sector 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/she/they are substantially and actively engaged in teaching, research, and/or administrative programs of a public institution (university, nonprofit research institute, foundation, clinical center, governmental, intergovernmental or quasi-government body).

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

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.

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 are consistent 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 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.

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

- (a) copies of current organizational documents such as articles of incorporation and bylaws;
- (b) official minutes of meetings and actions of HESI's Board of Trustees, recorded reasonably
- (c) promptly after the meeting or action in question;
- (d) a policy requiring Trustees to declare actual and potential conflicts of interests no less frequently than annually;
 - 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.

APPENDIX B
MANAGEMENT AND OPERATION OF HESI

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.
2. **Executive Director Evaluation and Compensation.** The performance and compensation of the Executive Director shall be evaluated on an annual basis in the manner described in the HESI bylaws.
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.
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. Whenever they are acting as representatives of HESI, HESI staff, members, 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.
5. **Financial Sponsorship of HESI Activities.**
 - (a) All significant scientific and programmatic activities of 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;
do not involve the endorsement or advertising of any particular brand or company product.
 - (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).

6. **Committee Leadership and Guidance.** HESI's scientific committees, chartered by the HESI Emerging Issues Committee and/or HESI Board of Trustees, shall be led by chairpersons who are drawn from both the public and private sector. These volunteer leaders will work in collaboration with the assigned HESI staff person(s) 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 is 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.

APPENDIX C
SCIENTIFIC INTEGRITY AND TRANSPARENCY

1. **Avoidance of Conflicts of Interest.** In its relations with collaborating organizations, HESI must always avoid any perception of or actual conflict of interest and must act in ways that will only enhance the credibility and professional recognition of HESI. 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.

2. **Contracted Research and Research Grants Awarded by HESI.** When HESI enters into a contract with, or awards a grant to, a scientist or organization for the conduct of research, 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. Study design, results, and analysis shall be transparent such that the study could be reproduced.
 - (b) The research shall adhere to contemporary standards for scientific and statistical rigor to evaluate the hypothesis. Investigators must 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 project investigators, they shall not be required to accept suggestions or changes to the design, protocol, or implementation, or to resulting manuscripts, which are proposed by 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.
 - (e) HESI shall communicate 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. **Publications.** Publications of HESI's scientific efforts shall reflect the high standards of the organization. To that end:
 - (a) Authors must make a full disclosure of financial and other 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) Authors shall adhere to the guidelines for authorship as designated by the publishing journal and to the HESI authorship guidelines.

(c) External funders of the research and/or other sponsors shall be mentioned by name in publications and other forms of disclosure, if applicable.

4. **Prohibition on Legislative Advocacy**. HESI will not propose legislative solutions to legislators (members of a parliament or other legislative arm of government) in any country. Before initiating contact on behalf of HESI with any legislative officer for any reason, the responsible HESI staff person or HESI member must notify the HESI Executive Director.

APPENDIX D ANTI-CORRUPTION POLICY

Maintaining a Corruption-Free Culture. HESI is committed to sustaining a culture free from corruption in transactions between government officials and employees and other representatives of HESI. Bribes, loans, and other illicit compensation offered or paid to government officials can subject the individuals and organizations who provide them to very serious civil and criminal penalties, including fines, debarment from government contracting, court supervision, and—for individuals—imprisonment. Moreover, engaging in corrupt practices could severely damage the public trust that organizations such as HESI seek to cultivate through their work in support of global public health.

Statement of HESI Policy.

1. *Compliance with Applicable Law.* It is the policy of HESI that each of our trustees, employees, staff, agents, representatives, and other third parties that interact with government officials on behalf of HESI shall comply with the anti-bribery laws of the countries where HESI engages in activities.
2. *General Prohibition on Bribery.* Bribery of any kind, in any country, regardless of local custom or practice, is strictly prohibited. For this purpose, “bribery” means the act of offering, giving, promising, asking, agreeing, receiving, accepting, or soliciting something of value or of an advantage so to induce or influence an action or decision. Bribery includes any inducement, reward, or object/item of value offered to another individual in order to gain commercial, contractual, regulatory, or personal advantage.
3. *Prohibition on Bribery of Officials.* No HESI trustee, employee, staff, agent, representative, vendor or any other third party with which HESI works shall make any payment or provide anything of value, directly or indirectly, to any official or employee of any government, state-owned enterprise, or international organization (an “Official”), in order to induce such Official to do or omit to do any act in violation of the lawful duty of such official; or to influence that Official to secure any improper advantage for HESI or for HESI’s member companies. This policy includes, but is not limited to, a prohibition on obtaining or retaining business, or directing business to any person or entity.
4. *Prohibition on Facilitation Payments.* All HESI trustees, employees, staff, agents, representatives, and other third parties acting on HESI’s behalf are prohibited from making any form of facilitation payments, which are a form of bribery that involves expediting or facilitating the performance of an Official for a routine governmental action.
5. *Prohibition on Use of HESI Assets for Political Purposes.* No HESI funds or in-kind contributions shall be used to make contributions to political parties or candidates for elected office in any country.

6. *Record-Keeping.* It is also the policy of HESI that each of its employees, staff, agents, representatives, vendors and all third parties that work with HESI make and keep books, records, and accounts, which, in reasonable detail, accurately reflect any transactions and dispositions of HESI.
7. *Incidental Expenses and Reimbursements.* To the extent permitted by applicable national and local law, HESI may reimburse travel expenses and provide meals and entertainment to Officials as part of a legitimate HESI business activity, so long as the benefit to the Official remains reasonable. In all such cases, the benefit should be merely incidental to the business purpose and should not be intended or likely to be perceived as an attempt improperly to influence the Official's decision in any matter.

Scope of Policy. Representatives of HESI who are covered by this policy include employees, officers, and agents of companies that are members of HESI when those persons are acting for HESI in a representative capacity. In addition to the civil and criminal fines and penalties imposed by applicable anti-corruption laws, violators of this HESI policy may be subject to disciplinary measures imposed by HESI. Penalties for violations will vary with the circumstances but may include termination of the offender's relationship with HESI.

Compliance. HESI shall develop training and other educational materials for the individuals covered by this policy to ensure that the policy is fully understood and implemented. HESI's staff in its Washington, DC headquarters shall serve as a clearinghouse for requests for information and clarification by such individuals.

APPENDIX E ANTITRUST STATEMENT

This policy has been adopted by the Board of Trustees of the Health and Environmental Sciences Institute (HESI). It applies to all staff, trustees, advisors, and members of HESI.

HESI is a scientific and charitable organization whose mission is to collaboratively identify and help to resolve global health and environment challenges through the engagement of scientists from academia, government, industry, NGOs, and other strategic partners.

All activities and discussions connected with HESI should be directed to promoting understanding and resolution of significant scientific challenges in human and environmental health and safety.

No activity or discussion at any meeting of HESI or other function may be engaged in for the purpose of bringing about any understanding or agreement among members to (a) raise, lower, or stabilize prices; (b) regulate production; (c) allocate markets; (d) encourage boycotts; (e) foster unfair trade practices; (f) assist monopolization, or (g) in any way violate applicable antitrust, anti-monopoly, or competition laws.

HESI meetings shall not be occasions where participants:

1. Discuss prices or pricing policies, or any marketing policy with a direct or indirect effect on pricing or any other terms of sale;
2. Confer about division or allocation of sales territories or customers;
3. Establish blacklists or boycotts of suppliers, purchasers, or competitors;
4. Coerce members to implement particular programs or policies;
5. Resolve problems unique to a single member or a small, select group of members;
6. Exchange or disseminate information relating to costs of production, distribution, or marketing or
7. Conduct or plan any lobbying activities.

Any questions regarding the meaning or applicability of this policy, as well as any concerns regarding activities or discussions at HESI meetings, should be promptly brought to the attention of the Chair of the HESI Board of Trustees or HESI's legal counsel.

APPENDIX F CODE OF ETHICS

The Health and Environmental Sciences Institute (“HESI”) is committed to generating science for a safer and more sustainable world. We believe that achieving this goal requires open, active, and ethical collaborations involving scientists with diverse technical and professional expertise. Our collaborators share a commitment to producing science for public benefit and a mutual respect for human, animal, and environmental health and safety.

We understand that HESI’s scientific credibility and impact is the product of the high ethical standards of our members and our staff. As such, we commit ourselves to pursuit of the following HESI values:

- **Collaboration**: Respectful interactions that recognize differences and leverage synergies in perspective, approach, and interpretation of scientific issues are core to HESI’s mission. By supporting this diversity and interaction, we enrich HESI’s ability to generate relevant and rigorous science.
- **Respect**: HESI is committed to a safe and collegial work environment, so that all HESI activities take place in a climate of understanding and mutual respect for the dignity and worth of each individual.
- **Diversity**: HESI is committed to promoting access, equity, and inclusiveness; and to discouraging discrimination based on race, color, disability, national origin, religion, ethnicity, gender, sexual orientation, age, socio-economic status, and other forms of discrimination that violate applicable laws or otherwise deny the essential humanity of all people. In both the hiring of staff and the appointment of members of the Board and other HESI governance bodies, HESI will seek to establish a genuinely diverse workplace and governing body.
- **Transparency**: Access to quality information and contemporary methods is essential to public and environmental health decision-making. All of HESI’s scientific programs are committed to the generation of robust and publicly accessible resources and activities.
- **Independence**: In the context of HESI’s programs and efforts, all HESI members must act in the interest of HESI’s mission to generate science with a public benefit for improved human and environmental health. We understand that HESI does not promote legislative policy changes or advocate for individual stakeholders or products.
- **Integrity**: HESI’s scientific programs and organizational activities will be conducted to the highest standards of ethical conduct and scientific rigor. As HESI members and staff, we will exhibit a respect for laws, regulations, ethical standards for human and animal research, and for our colleagues around the world. We will adhere to HESI’s operating policies with regard to disclosing conflicts and solely to produce science for public benefit.
- **Opportunity**: HESI provides equal opportunity and equal consideration to all members and staff without regard to sex, gender identity or expression, race, color, national or ethnic origin, religion or religious belief, age, marital status, sexual orientation, disabilities, or veteran status. As these principles are fundamental to HESI’s mission, we request that any concerns regarding potential non-compliance be forwarded to HESI’s legal counsel (ssullivan@hesiglobal.org).

APPENDIX G

STATEMENT OF ETHICAL RESEARCH PRACTICES

The Health and Environmental Sciences (“HESI”) is a nonprofit organization that is organized and operated under United States law for scientific, educational, and charitable purposes. HESI complies with all laws, rules, and regulations that apply to its activities. HESI also is committed to observance of the principles described in the HESI Code of Ethics.

HESI is not subject to legal requirements to obtain approval by Institutional Review Boards (“IRBs”) or Institutional Animal Care and Use Committees (“IACUCs”). However, although HESI employees do not directly conduct experimental research, such studies are often conducted as part of collaboratively designed studies developed as part of HESI’s scientific consortia. To the extent that our collaborators are subject to IRB approval requirements, HESI expects those collaborators to comply fully with those requirements. In addition, HESI strongly endorses the observance of humane animal practices in the laboratories of its collaborators as reflected in authoritative sources such as the U.S. National Research Council’s *Guide for the Care and Use of Laboratory Animals*, *Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes*, and the *Australian Code of Practice for the Care and Use of Animals for Scientific Purposes*.

APPENDIX H DATA SHARING PRINCIPLES

The following principles are:

- Offered as ethical guidance and best practice for HESI's scientific projects and programs;
- Not legally binding;
- Subject to variation in implementation to be managed on a project-by-project basis; and
- Provided with recognition that HESI has no general nondisclosure agreements with its Sponsors or participants, so participants must take care not to share proprietary company information.

Guiding Principles

- HESI, as a nonprofit foundation, is committed to producing science with benefit to public and scientific community at large.
- HESI initiatives typically do not seek to generate or hold intellectual property rights for purposes of commercialization.
- HESI's scientific programs operate on the principal that the sharing of information about best practices in risk and safety assessment, analytical methodologies, non-proprietary mechanisms and biological/ecological systems, R&D challenges, etc. offers an opportunity for development of the scientific community at large and can operate effectively in an open, peer-to-peer discussion forum.
- Unless otherwise specified, data generated as a result of the financial, intellectual and/or in-kind contributions of multiple committee members is considered a 'committee product' and is thus subject to committee input with regard to timing, nature, and focus of its external communication and publication.
- All external communication efforts on behalf of the committee or that cite unpublished committee work or objectives, should be shared in advance with the committee leadership and manager to provide an opportunity for input.
- Data generated independently of a HESI committee (e.g., with no input from the committee re: funding, study design, study execution, or study interpretation), may sometimes be shared with a committee on an informational basis. These data/efforts are either wholly owned by the provider (or shared with the committee by permission of the co-owners) and may subsequently be published/communicated externally by the owners in other forums with no consultation from the committee.

APPENDIX I AUTHORSHIP POLICY

Authorship on scientific, peer-review manuscripts is an important matter to HESI. HESI is committed to transparency, accountability and scientific integrity and uphold these standards in a number of ways including in all published works. HESI practices the following guidelines when it comes to naming authors on our manuscripts:

In general, authors of HESI publications have the following responsibilities:

- All authors are accountable for the parts of the work they have completed and are accountable for the main conclusions of the paper.
- All authors are responsible for the contents of the paper and the scientific integrity.

In order to achieve authorship, the following criteria must be met:

- Substantial contribution to the conception, design, research, or implementation of the work or written manuscript. Authors must identify and define their specific contributions prior to being a named author.
- If contributions were not towards writing, authors must at a minimum review and provide comments and their approval to the final manuscript.
- Agreement to be accountable for the final work per the above.

Any individuals or organizations who contribute but do not meet the above criteria may be mentioned in the acknowledgements section of the manuscript. Additionally, at the discretion of the named authors (and per journal guidelines) – a HESI Committee may be named as an author.

HESI Committees are encouraged to establish any additional guidelines specific to their manuscripts at the beginning of each project. These should be in writing (either through minutes or documented elsewhere.)

Resources:

<http://www.icmje.org/recommendations/browse/roles-and-responsibilities/defining-the-role-of-authors-and-contributors.html>

<https://www.councilscienceeditors.org/resource-library/editorial-policies/white-paper-on-publication-ethics/2-2-authorship-and-authorship-responsibilities/>

<https://www.pnas.org/content/115/11/2557>

<https://www.aje.com/en/arc/ethics-manuscript-authorship/>

APPENDIX J POLICY ON CONTRACTUAL ARRANGEMENTS

HESI occasionally requires the services of a third party to perform specific tasks in order to accomplish the objectives of its committees or of the organization as a whole (the latter are referred to herein as “Organization-Wide” activities). The expenditure and the selection of a specific vendor for such purposes must be approved by the relevant Committee in the case of committee-sponsored activities, or by the HESI Board of Trustees Finance Committee in the case of Organization-Wide activities. Sponsors of HESI are not disqualified from serving as paid contractors to HESI. However, no organization may receive any such compensation unless and until the following procedure has been followed:

1. The HESI Committee or other body desiring to contract for the services in question must prepare a written request for proposals (“RFPs”) setting forth the details of the work to be performed and any relevant terms of the work. No representative of any HESI sponsor company that expects to submit a proposal may participate in any manner in the drafting of the RFP.
2. The RFP must be sent to at least three and preferably at least five organizations believed by the requesting HESI Committee or other body to be capable of performing the work. No representative of any HESI sponsor company that expects to submit a proposal may participate in any manner in deciding which organizations will receive an RFP.
3. The RFP must be posted prominently on the HESI website from the time it is sent to potential bidders until bidding is closed. Unsolicited proposals from organizations that reasonably appear capable of performing the work must be included among the proposals to be evaluated.
4. A proposal evaluation group composed of at least three members of the relevant Committee (or, in the case of Organization-Wide activities, of the Finance Committee) shall evaluate the proposals. No person may be a member of the proposal evaluation group if s/he or an immediate family member currently or within the immediately preceding 12 months is employed by, receives compensation from, or otherwise has a financial interest in, any organization which has submitted a proposal.
5. The proposal evaluation group shall choose for the work the proposal that the group considers to provide the best value for the money, which may not necessarily be the least expensive proposal. No preference may be given to any proposal submitted by any HESI sponsor company.
6. The proposal evaluation group shall document in writing the basis for its decision within 60 days after making its selection. The written documentation of the decision, which may take the form of written minutes, shall state, at a minimum, the identities of all organizations from which proposals were received, the prices quoted in each proposal, the extent to which any proposals deviated from the statement of work set forth in the RFP, the extent to which and reasons why any proposal was deemed to provide greater value than other proposals, and, if the lowest cost proposal is not selected, the reasons why the proposal selected was deemed to provide greater value than the lowest cost proposal(s).

The requirements of this policy do not apply where one or more of the following circumstances exist:

- A. The aggregate amount of anticipated payments under the anticipated contract will not exceed US \$10, 000.
- B. The anticipated contract is for an extension, modification, continuation, or further phase of work for HESI that has already been commenced or completed by an existing contractor, and the relevant HESI staff member and/or committee chairperson proposes that the new contract be awarded to that existing contractor.
- C. The anticipated contract is for work that will be done by the contractor at a price substantially below the contractor's combined direct and indirect costs, and the Executive Director approves the award of the contract to that contractor. Examples of such circumstances include: (a) when the contractor will provide all labor services for free, and the funds provided pursuant to the contract will be used only to purchase supplies; and (b) when the contractor will be paid only its direct costs, and it is demonstrated that the contractor will incur indirect costs in excess of 10%. These examples are illustrative only and are not an exclusive list of circumstances in which this exception would be applicable.
- D. The relevant committee or working group has concluded that there is only one suitable candidate to perform the work, and the Executive Director concurs in this assessment. In the event that the entity deemed to be the only suitable candidate is a sponsor company of HESI, this exception does not apply unless the chairperson of HESI's Board of Trustees also concurs in the assessment. Concurrences of the Executive Director and the board chairperson should be recorded in writing.

APPENDIX K
CONTRACT REVIEW AND APPROVAL POLICY

This Contract Review and Approval Policy (this “**Policy**”) is mandatory for all Health and Environmental Sciences Institute (“**HESI**”) employees. It applies to all contracts made on behalf of or in the name of HESI.

1. Covered Contracts. Contracts covered by this Policy include, without limitation, all agreements, licenses, leases, promissory notes, instruments, assignments, powers of attorney, terms and conditions, memoranda of understanding, letters of intent, settlements, releases, waivers, renewals, amendments, or modifications to existing contracts, and other similar documents. Oral agreements are not authorized regardless of whether there is a monetary exchange.

2. Authorized Signatories. No person may sign any contract on behalf of HESI unless the individual is properly authorized to sign the contract (the “**Authorized Signatory**”). The following individuals are Authorized Signatories for HESI:

- The Executive Director.
- The Deputy Director.
- The Legal Counsel (for contracts having a value up to \$10,000 USD).

3. Legal Review or Preparation of Contracts. The Legal Counsel will conduct the legal review or preparation of all contracts except those in which no party has a total commitment value of more than \$ 5,000 USD, whether such commitment is financial or for an in-kind provision of HESI staff time.

4. Prior to Execution. The relevant HESI Employee and the Legal Counsel have primary responsibility for review of contracts. They must identify the terms and conditions of the contract that are acceptable or unacceptable to HESI. In addition, the HESI Employee is responsible for confirming that:

- The program or activity to which the contract relates has been approved by the relevant HESI committee or other HESI body.
- The program or activity has the necessary funds and resources to enter into and meet HESI’s obligations under the contract.
- The contract correctly describes any services to be provided, goods to be purchased or sold, fees or other amounts to be paid, payment terms, and deliverables.
- The contract terms and conditions include the entire understanding between the parties, without additional oral explanations or promises that are not included in the contract.

5. Contract Execution and Deposit. The Legal Counsel will submit the contract to the Authorized Signatory for signature, preferably by electronic means. The Legal Counsel will make a copy of the executed contract available to the HESI Employee and the Branch Administrator, who will ensure that the fully executed contract is properly deposited in HESI’s SharePoint database.