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Scientific Integrity Review

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ACRONYMS AND ABBREVIATIONS

COI	Conflict of Interest
CRO	Contract Research Organization
CV	Curriculum Vitae
EAG	Expert Advisory Group
ILSI	International Life Sciences Institute
PI	Principal Investigator
PPP	Public-Private Partnerships
RFP	Request for Proposals
The Academy	National Academy of Public Administration
TOP	Transparency and Openness Promotion

SECTION 1: BACKGROUND

International Life Sciences Institute (ILSI) was incorporated in 1978 and is a nonprofit, worldwide organization whose mission is to provide science that improves human and environmental health. For 40 years, ILSI has addressed problems in food, nutrition, and environmental sciences by engaging experts in academia, government and industry.[1] ILSI is divided into one global entity and various geographic entities, in addition to the ILSI Research Foundation.

Established in 1991, ILSI North America is the largest entity and the only US-Canadian organization that brings together scientists from government, academia, and industry to advance nutrition and food safety research. According to the By-Laws, ILSI North America's members can come from the food, beverage, pharmaceutical, and chemical industries; all members are companies, as individuals, consultants, and trade associations are ineligible for membership. Companies which are involved in the manufacture and/or sale of tobacco products and alcohol are also ineligible for membership.

According to the ILSI North America By-Laws, academics who participate in ILSI North America's scientific committees and governance bodies are not officially "members" of ILSI North America in that they do not provide financial contributions. ILSI North America officials noted that, in practice, academic representatives are fully integrated into the governance structures of the organization, comprising 50 percent of the Board of Trustees and its subcommittees, and they participate in the committees which develop the research. Government scientists who participate in the scientific committees and governance bodies of ILSI North America are called "liaisons," because they have no fiduciary responsibility and do not speak on behalf of their government agencies.

ILSI North America's research programs are primarily funded by its industry membership. There is widespread skepticism about the credibility and transparency of industry-funded research. In recent years, a growing body of literature has examined the impacts of funding sources on research outcomes and raised concerns about skewing research findings in favor of industry funders.[2] As an industry-funded sponsor of scientific research, ILSI North America has worked extensively with federal agencies and scientific professional societies to develop a framework—*the Guiding Principles for Private Funding of Food Science and Nutrition Research* (the Guiding Principles)—to ensure scientific integrity within multi-sector food and nutrition research partnerships. In 2009, these principles were published in six high-impact peer-reviewed journals with the expectation that all of ILSI North America's research activities were to be conducted in this manner.

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[1] "Frequently Asked Questions," International Life Sciences Institute, accessed November 29, 2018, http://ilsi.org/about/frequently-asked-questions/.

[2] Mozaffarian D. Conflict of Interest and the Role of the Food Industry in Nutrition Research. *JAMA.*2017;317(17):1755–1756. doi:10.1001/jama.2017.3456 https://jamanetwork-com.mutex.gmu.edu/journals/jama/fullarticle/2623631.

1.1 Project Objective and Scope

ILSI North America engaged the National Academy of Public Administration (the Academy) to conduct an in-depth analysis of its projects from 2013 to 2017 in comparison to the Guiding Principles. The purpose of the review was to provide objective, external verification that all research activities conducted at ILSI North America adhered to the Guiding Principles. This review is expected to drive improvement within ILSI North America, and enhance the transparency with which ILSI North America adheres to its Guiding Principles.

1.2 Methodology

In order to conduct this study, the Academy formed an Expert Advisory Group (EAG) consisting of three distinguished Academy Fellows with a broad range of relevant skills to guide this study. The EAG provided guidance to a four-member professional Academy study team. The brief biographical sketches of EAG members and study team can be found in Appendix B.

The study team performed both primary and secondary research to develop findings and recommendations. The study team conducted a thorough and rigorous review of ILSI North America's contracts/grant agreements and policy manual to determine their adherence to ILSI North America's Guiding Principles. Language from 44 contracts/grant agreements and 24 publications from 2013 to 2017 were analyzed throughout the course of this project. Additionally, the study team interviewed several principal investigators and ILSI North America officials, including the Executive Director, Committee Managers, Communications Manager, and General Counsel, to gain their insights into the thoroughness with which ILSI North America upholds its Guiding Principles. The combined perspectives allowed the study team an opportunity to develop a well-rounded understanding of the practical implementation of ILSI North America's Guiding Principles. The study team collected information about ILSI North America's committee structure and processes as background information, but did not perform an evaluation of the effectiveness of the structure and processes. All interviews were conducted on a not-for-attribution basis. Appendix C provides a list of the individuals who were interviewed. Moreover, the study team also researched best practices in the areas of scientific integrity, ethics, and transparency to glean lessons learned and practices that might be instructive to ILSI North America.

1.3 ILSI North America Governance Structure

ILSI North America is guided by a Board of Trustees (the Board), which is responsible for establishing organization-wide programmatic and fiscal policies.[3] The Board is composed of at least 50 percent academic and public sector representatives, with the remainder composed of

[3] ILSI North America Internal Policies and Procedures

individuals representing ILSI North America industry members.[4] The current board has 26 members, comprised of 14 academic members and 12 industry representatives.[5] Most of the Board's work is performed by five board committees, each of which is also comprised of 50:50 public vs. private sector representatives. The committee pertinent to this study is the Program Assessment and Strategic Collaborations Committee (the Board Program Committee), which is tasked with reviewing new committees or new research activities. The review of the Board Program Committee serves as an important check point to ensure that any new project is within the scope of ILSI North America's mission and delivers research which serves the interest of public health. ILSI North America's Executive Director is charged with managing and directing activities of ILSI North America, as prescribed by the Board (Appendix D provides ILSI North America's Organizational Chart).[6]

ILSI North America's research activities are carried out through committees. As of November 2018, ILSI North America has 13 active committees. Every committee has various representatives from member companies and must have at least one government scientist and one academic representative (see Table 1). Each committee is supported by a program manager and support staff.[7]

Table 1 – ILSI North America Committees and Membership Representation[8]

	Committees	# of Projects	# of Industry Members	# of Gov't Liaison	# of Scientific Advisors	Total Members
Nutrition	Carbohydrate Committee	4	14	1	2	17
	Protein Committee	1	9	2	1	12
	Sodium Committee	2	8	pending	1	9
	Bioactive Committee	5	9	1	2	12
	Dietary Lipids Committee	2	6	1	1	8
	Balancing Food and Activity for Health Committee**	1	3		1	4

[4] "Organizational Structure," International Life Sciences Institute, accessed November 29, 2018, http://ilsi.org/wp-content/uploads/2016/05/Organizational-Structure-2008.pdf.
[5] "ILSI North America 2017 Annual Report," International Life Sciences Institute North America, accessed November 29, 2018 http://ilsina.org/wp-content/uploads/sites/6/2018/01/AR2017/#12
[6] "ILSI North America Bylaws," International Life Sciences Institute North America, accessed November 29, 2018, http://ilsi.org/northamerica/wp-content/uploads/sites/6/2016/03/NA-Bylaws_2015.pdf.
[7] Program Managers and support staff are ILSI North America employees.
[8] Table 1 is not an exhaustive list of all ILSI North America committees. The committees in this table sponsored projects that were included in this review.

	Committees	# of Projects	# of Industry Members	# of Gov't Liaison	# of Scientific Advisors	Total Members
	Fortification Committee**	2	4	pending	2	6
	Food Value Decisions*	1				
	Gut Microbiome Committee	1	13	4	4	21
	Low-Calorie Sweeteners	2	8	1	1	10
Food Safety	Food Microbiology Committee	4	10	4	2	16
	Food and Chemical Safety Committee[9]	5	15	3	1	19
	Caffeine Committee	1	7	1	1	9
	PHO Task Force*	2		2		

Data Source: ILSI North America Website

*Committees are currently inactive

**These committees are in the process of sun-setting.

The number of member companies varies by committee, but each committee must have no less than four industry members to ensure that no single company has sole influence over the research questions. Committee membership may fluctuate year-to-year, but each industry member commits to serving at least a one-year term. Academic representatives serve for a two-year term with the option to renew for two more consecutive terms (total of 6 years). The choice and term length of government representatives is made by the government agency in which they serve.

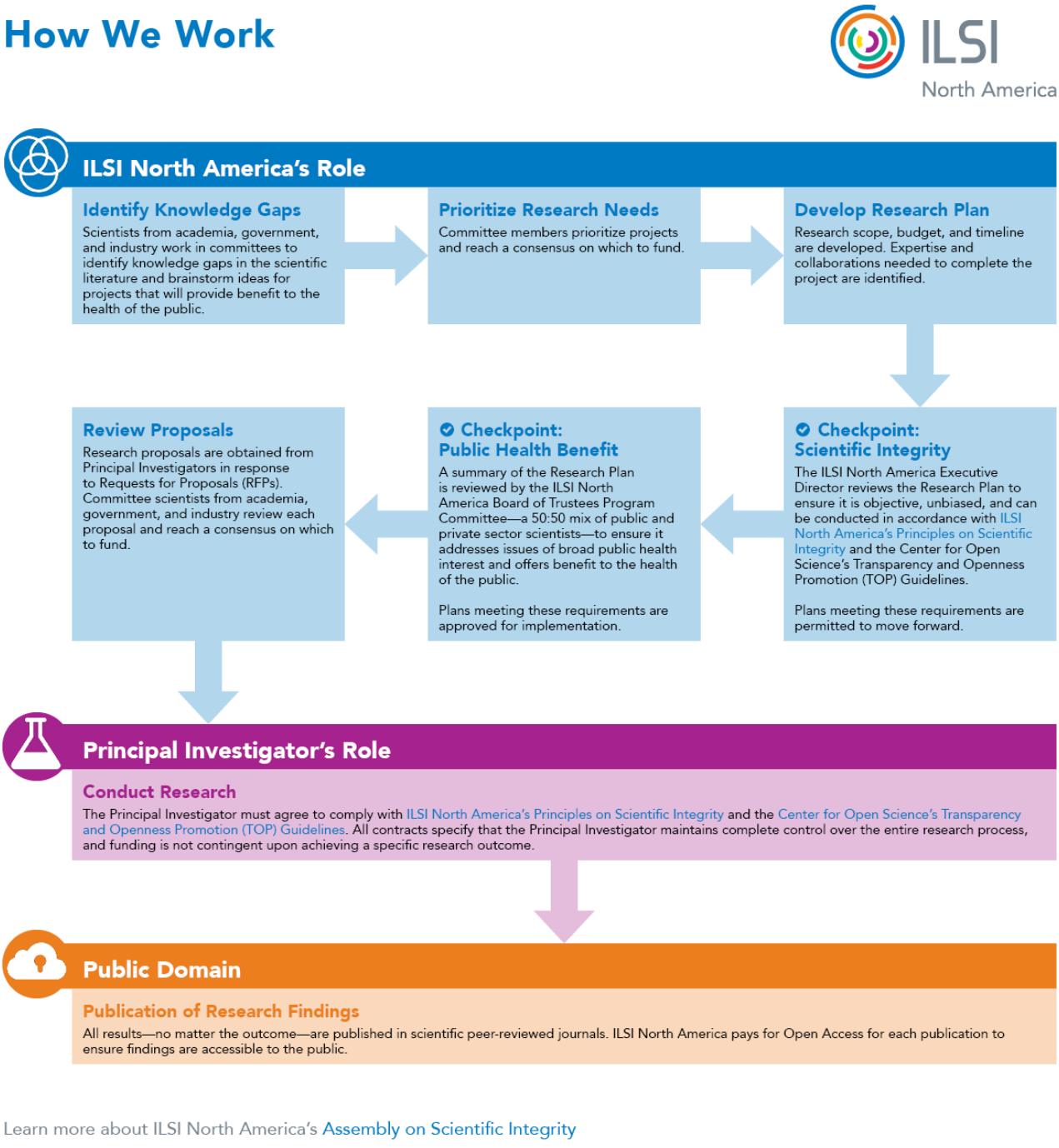
Government and academic representatives serve as technical experts on committees. Although they are non-voting members[10], they provide feedback on research methods, and industry members often solicit their input and advice before voting. Government and academic representatives are expected to attend all meetings, and ILSI North America provides travel and accommodation funding (when allowed by their agency or institution) to help accommodate their attendance. In-person committee meetings occur at least once a year, with additional teleconference meetings when necessary.

Committee budgets are funded through assessments paid by the industry members. Each company contributes the same amount of money to fund the work of the committee; therefore, the total

[9] While the Food and Chemical Safety Committee has one science advisor as of August 2018, it has had 2 for at least the last eight years and is currently in the process of getting a second scientific advisor.

[10] Many government liaisons choose not to vote because of the restrictions of their specific agencies. ILSI North America does not stop them from voting if they are allowed to.

budget for the committee's work is a function of the number of industry members on the committee. However, the amount allocated to each project is determined by the committee as a whole, based on the nature of the research, and within the framework of a two- to three-year research plan. Figure 1[11] below depicts ILSI's work process:



[11] "How We Work," International Life Sciences Institute North America, accessed November 29, 2018, http://ilsina.org/our-work/how-we-work/.

1.4 Actions to Enhance Research Transparency and Integrity

ILSI North America has developed a wide range of programs to promote scientific integrity.[12] In 2007, ILSI North America established the Conflict of Interest and Scientific Integrity Working Group which published *Funding Food Science and Nutrition Research: Financial Conflicts and Scientific Integrity* in 2009.[13] In this paper, ILSI North America proposed eight Guiding Principles to specify ground rules to reduce bias and conflict-of-interest in industry-sponsored research. These eight principles will be further discussed in Section 1.5.

Engagement in public-private partnerships (PPP) creates additional transparency and integrity-related challenges which ILSI North America sought to address in its 2013 publication "Principles for building public-private partnerships to benefit food safety, nutrition, and health research." Identifying the 12 general principles for PPPs (see Appendix E), ILSI North America's Conflict of Interest and Scientific Integrity Group explicated the necessary guidelines that PPPs should follow to support the effective carrying out of unbiased research.

In 2015, ILSI North America established the Scientific Integrity Working Group, followed by the 2017 creation of the Assembly on Scientific Integrity, an assembly centered on the idea of scientific integrity as a core ILSI North America principle, which includes members of the ILSI North America Board, all member companies of ILSI North America,[14] and the ILSI North America Canadian Advisory Committee.[15] In 2016, ILSI North America developed a Scientific Integrity Resource Guide that outlines scientific integrity activities by federal agencies, foundations, nonprofit organizations, professional societies, and academia in the United States.[16]

ILSI Global Coordination developed a set of Mandatory Policies[17] in 2016 for all ILSI affiliates, including ILSI North America, which outlined its scientific integrity guidance. These Mandatory Policies were updated in August 2018. Additionally, as of July 2018, all new ILSI North America projects must work to adhere to the Center for Open Science's Transparency and Openness

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[12] "Scientific Integrity," International Life Sciences Institute North America, accessed November 29, 2018, http://ilsina.org/our-work/scientific-integrity/.

[13] Sylvia Rowe et. al., "Funding food science and nutrition research: financial conflicts and scientific integrity" *Nutrition Reviews* 67, no. 5 (1 May 2009): 264–272, https://doi.org/10.1111/j.1753-4887.2009.00188.x.

[14] ILSI North America is in the process of redefining the Assembly to include people from both public and private sectors.

[15] Rickey Yada, "ILSI North America: Update on ILSI North America Assembly on Scientific Integrity" YouTube video, 7:40, posted by ILSI Global, September 6, 2017, https://www.youtube.com/watch?v=O05PPbDOqow.

[16] Alison Kretser, Delia Murphy, and Johanna Dwyer, "Scientific integrity resource guide: Efforts by federal agencies, foundations, nonprofit organizations, professional societies, and academia in the United States," *Critical Reviews in Food Science and Nutrition* 57, no. 1 (2017): 163-180, http://doi.org/10.1080/10408398.2016.1221794.

[17] In January 2016, the Board of Trustees of ILSI adopted a set of policies as mandatory for all ILSI entities throughout the world. The Mandatory Policies cover a wide range of areas, including: scientific integrity, board governance, management and operation, legislative and regulatory matters, ILSI attendance before authoritative bodies, anti-corruption, antitrust statement, and diversity.

Promotion (TOP) Guidelines which provides eight standards for promoting and practicing transparent, reproducible, and rigorous research.

1.5 8 Guiding Principles

In 2009, ILSI North America developed *8 Guiding Principles for Private Funding of Food Science and Nutrition Research* (the 8 Guiding Principles) to provide an overarching framework to preserve the integrity and credibility of food and nutrition scientific research. The 8 Guiding Principles include:

1. Conduct or sponsor research that is factual, transparent, and designed objectively, and, according to accepted research will answer the appropriate questions, rather than favor a particular outcome;
2. Require control of both study design and research itself to remain with scientific investigators;
3. Not offer or accept remuneration geared to the outcome of a research project;
4. Ensure, before the commencement of studies, that there is a written agreement that the investigative team has the freedom and obligation to attempt to publish the findings within some specified time frame;
5. Require, in publications and conference presentations, full signed disclosure of all financial interests;
6. Not participate in undisclosed paid authorship arrangements in industry-sponsored publications or presentations;
7. Guarantee accessibility to all data and control of statistical analysis by investigators and appropriate auditors/reviewers; and
8. Require that academic researchers, when they work in contract research organizations (CRO) or act as contract researchers, make clear statements of their affiliation; and require that such researchers publish only under the auspices of the CRO.

There is a wide range of sources of bias (e.g. cognitive bias, statistical bias, technical bias, etc.) in scientific research, and the 8 Guiding Principles focus on managing potential conflict and bias related to research funding sources (i.e., industry funding). Funding sources do not automatically lead to biased research outcomes, and this set of principles is intended to serve as "a checklist to help ensure insulation of any research project from the provision of the resources enabling the project."[18] In other words, the purpose is to protect research integrity by separating scientific activities (research design, execution, publishing, etc.) from financial sources.[19]

Principles 1 and 2 provide high-level directions, while Principles 3-8 identify more specific requirements. Establishing legal requirements and policy guidance is a critical step to implementing these principles. This report primarily focuses on comparing ILSI North America's research contracts, publications, and policies and procedures against the requirements of the 8

[18] Rowe et al., "Funding," 262-274.
[19] Ibid

Guiding Principles. Although beyond the scope of this study, it is important to recognize that these policy or contractual requirements are not sufficient to guarantee a successful implementation of the 8 Guiding Principles. It requires an effective governance structure and operational processes to support the implementation and protect research objectivity.

The authors of the 8 Guiding Principles stated that it is the responsibility of all parties—both funders and recipients—to implement the requirements of the Guiding Principles.[20] This study assesses the practices and procedures of ILSI North America as a funding organization.

[20] Ibid.

SECTION 2: DISCUSSION AND ANALYSIS

2.1 Review of ILSI North America's Contracts, Publications, and Policy Guidance

ILSI North America has undertaken various actions to improve its contract management and ensure the requirements of scientific integrity are integrated into project contracts and grant agreements. In 2016, ILSI North America updated its contract and grant agreement templates to reflect the scientific integrity requirements set forth by ILSI's Mandatory Policies. ILSI North America added standard provisions into its contract and agreement templates to enforce consistency and improve the clarity of contractual requirements and obligations.

Additionally, ILSI North America revised its *Policy and Procedures* in March 2018. This policy manual describes ILSI North America's mission, core values, membership, and governance structure, and delineates the organization's policy on the operation of committees and the management of research activities. The following presents detailed analysis of ILSI North America's contracts, publications, and policy guidance.

Principle 1 *Conduct or sponsor research that is factual, transparent, and designed objectively, and, according to accepted research will answer the appropriate questions, rather than favor a particular outcome*

Discussion: From 2013 to 2017, 81 percent of ILSI North America's contracts included some provisions/requirements on scientific integrity and independence. In 2016, ILSI North America updated its contract template and added standard language that lays out more detailed expectations for research independence, autonomy, and integrity:

> *The research shall be conducted in an objective manner so that its results are presented factually and without bias or predetermined outcomes and be such that it is verifiable and repeatable.*
>
> *The research shall be designed so that it is an adequate and unbiased test of the hypothesis or question being evaluated. 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.*

ILSI North America's *Policy and Procedures* has clear requirements on the objectivity of research design. ILSI North America researchers are required to:

> *Conduct the research objectively so that the structure of the research is presented factually and without* bias *and be such that it is verifiable and reproducible and is not geared solely toward producing the desired outcome for the sponsor." "The research will 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.[21]

Analysis: Contractual terms and policy guidance are not sufficient to provide reasonable assurance that ILSI North America's research activities adhere to Principle 1. ILSI North America officials stated that the organization's governance structure and processes were designed to ensure the objectivity and transparency of research activities. For example, the participation of representatives from academia and government is an important mechanism to minimize bias and ensure the objectivity of the decision-making processes of ILSI North America committees. As discussed in Section 1.3, every committee is required to have at least one academic and one government advisor, and research projects cannot go forward without the input of academic/government advisors. All committees make their decisions (e.g., selection of proposals, budget, work plans, etc.) based on consensus. The committees' decisions reflect the thoughts of all committee members and involve collective responsibility and accountability. In addition, all research projects are reviewed and approved by the Executive Director and Board Program Committee, which has a 50:50 mix of public and private sector scientists, to ensure those projects address issues of broad public health interests.

Each committee is funded by the membership fee paid by its industry members, and according to ILSI North America's policy manual, pooling financial resources as a group enables committees to avoid supporting projects that will benefit individual member companies while ensuring that research activities serve the public interest.[22] However, this funding structure does not fully address the concerns about industry funded research, as ILSI North America is largely industry funded, and the majority of committee members are from industry/corporations. As one interviewee suggested, a more balanced representation of academic/government members on committees may help alleviate the perceived bias against industry funded research projects. Another important check on research design is the peer review publishing process, which will be discussed in greater detail under Principle 4.

ILSI North America has an established structure and processes in place to protect research objectivity and transparency. However, determining whether the processes and structure are effective and sufficient is out of the scope of this project. It requires a more comprehensive, detailed organizational assessment (i.e., How do the committees work in practice? How do committee members work with each other? How much influence do government or academic representatives have? etc.) to make any structural/procedural conclusions or recommendations.

Principle 2 *Require control of both study design and research itself to remain with scientific investigators*

[21] Ibid.
[22] Ibid.

Discussion: Seventy-six percent of ILSI North America's contracts (2013-2017) contain provisions on the control of research design. Starting in 2016, ILSI North America adopted standard contractual language so that it is clear that the Principal Investigator (PI) maintains complete control over the entire research process:

> *The scientific independence, autonomy, and integrity of the investigators involved must be respected by ILSI NA and all entities that contribute to the funding of the research. 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 ILSI N.A., by corporate sponsors, or by other entities involved in funding the work in question.*

Additionally, the PI's full research proposal, which outlines project scope, research design, and methodology, is attached to and made a part of the contract/agreement; and the PI is contractually required to "perform completely the project described in the proposal." Over the past five years, approximately 75 percent of ILSI North America publications included a declaration of research independence from the author(s) (e.g., "ILSI had no role in the study design, data collection and analysis, interpretation of the data, or preparation of the manuscript").

The requirements in ILSI North America's Policy and Procedures—*the research and its design will be formulated with significant input from the principal investigator*[23]—may lead to some confusion over who has the ultimate control of research design, as research design formulated with "significant input" from the PI does not necessarily suggest that research design is controlled by the PI.

Analysis: While ILSI North America has very clear contractual requirements on the control of research design, in practice, it is difficult to assess whether research design is actually controlled by PIs. Committee members offer comments on research proposals, interim reports, final reports, or other research products. Although the PIs are not required to accept the comments, soliciting committees' feedback could be perceived as a source of undue influence from industry funders. In many cases, bias associated with industry-funded research is a matter of perception.

PI interviewees generally believe that they have the control of study design and research. One PI noted that ILSI North America committees offered very detailed comments on the research proposal, and they revised the research proposal accordingly. However, this is a typical practice for industry funded research projects, and the interviewee did not think the committee's comments affected the objectivity and independence of the research. For some projects, PIs are invited to attend a kickoff meeting with all committee members and throughout the project, PIs are invited to provide regular project updates to the committee. Multi-year contracts are required to "include a provision for monitoring and communicating the research results to the committee,

[23] Ibid.

including submission of progress reports from the investigator."[24] There are different views among PI interviewees on these procedural practices of ILSI North America. Some PIs noted that these reporting/meeting requirements are reasonable and allow for open scientific discussions, while one PI did not want to participate in the meetings with all committee members to avoid influence from industry members. The committee manager worked with this individual to tailor the process, thereby addressing the PI's concerns. ILSI North America has been responsive to the specific concerns of PIs and strives to enhance research integrity and transparency.

Principle 3 *Not offer or accept remuneration geared to the outcome of a research project*

Discussion: The purpose of Principle 3 is straightforward, and ILSI North America has developed clear contractual and policy requirements on project payments. Over the past five years (2013-2017), 81 percent of ILSI North America's contracts included some type of payment provisions/payment schedules. For most projects, ILSI North America made a series of installment payments in accordance with agreed-upon schedules and upon the fulfillment of the conditions set forth in contracts. After ILSI North America revised its contract template in 2016, in addition to the payment schedules, it is clearly stated that:

> *Compensation for work performed pursuant to this Agreement shall not depend on the outcome or interpretation of the research.*

ILSI North America's *Policy and Procedures* also contains similar requirements that project payments do not depend on research outcomes. Interviewees from ILSI North America reported that PIs must complete the projects and submit all deliverables specified in the contracts in order to get paid. Payments do not depend on the quality or the outcomes of the PI's research. ILSI North America has never experienced any payment-related issues.

Principle 4 *Ensure, before the commencement of studies, that there is a written agreement that the investigative team has the freedom and obligation to attempt to publish the findings within some specified time frame*

Discussion: The peer review system serves as a major mechanism to guarantee a certain level of research quality[25] and scrutinizes potential conflicts of interest (COI), biases, and scientific misconduct. From 2013 to 2015, 16 out of 19 completed projects published their research findings and outcomes in peer reviewed journals.[26]

[24] Ibid.
[25] There has been public debate about the value and credibility of the peer review process—whether peer review actually provide assurance of research quality. This is out of the scope of this project.
[26] The number of publications does not include the Future Leader Award projects. The study team focused on the publications from 2013 to 2015, as manuscripts resulting from projects conducted in 2016 and 2017 may still be in preparation and/or the peer review process.

Principle 4 requires PIs to have a plan to publish their findings within some specified timeframe before the project starts. To achieve the requirement of Principle 4, ILSI North America has clear policy guidance on publishing research findings and outcomes. In its policy manual, it is stated:

> *The Principal Investigator is free to publish the results of the study irrespective of the findings. Publication of the results of the scientific research is encouraged irrespective of the findings. This should be specified in the written contract and protocol. The scientist shall always be free to publish the findings of the research within a period of time specified in advance in the written contract or protocol.*
>
> *The method of publication should be stipulated in the contract.*

ILSI North America's standard contract provision on publication is:

> *ILSI NA encourages the presentation and publication of work undertaken under its auspices. To the extent reasonably feasible, the Institution shall afford ILSI NA an opportunity to comment on any prepublication draft manuscripts related to the work supported by the grant Agreement…the Institution is under no obligation to accept such comments; they are to be viewed as helpful and advisory in nature.*

Although the standard contract provision does not reflect the specific requirements of Principle 4, from 2013 to 2017, about 90 percent of ILSI North America's contracts at least partially met the requirements of Principle 4. Some projects included their publishing plan in research proposals, while others connected their publishing plans with payment schedules. Half of ILSI North America's contracts/research proposals identified a time frame for publishing research outcomes, and 40 percent of the contracts included requirements on publishing, but did not specify the time frame.

Analysis: ILSI North America does not have explicit contractual requirements on specifying a publishing timeframe. One PI interviewee explained that it is a normal practice not to identify a timeframe for publication in the contract because it is difficult to anticipate the timeframe before the project starts. According to ILSI North America officials, the contract provides a start and end date of the project, and PIs are generally expected to submit their manuscripts to ILSI North America and peer-reviewed journals by the project end date. In practice, researchers do not receive the final payment from ILSI North America without submitting a draft manuscript (eight out of the seventeen projects in 2016 and 2017 included an explicit requirement that the final payment was to be made "upon submission of the manuscript to a peer-review journal for publication"). ILSI North America interviewees also noted that all PIs are required to publish research results in peer reviewed journals, as well as present their findings at conferences.

Principle 5 *Require, in publications and conference presentations, full signed disclosure of all financial interests*

Principle 6 *Not participate in undisclosed paid authorship arrangements in industry-sponsored publications or presentations*

Discussion: Disclosure is widely endorsed as an essential tool to manage COI or the appearance of COI.[27] Principles 5 and 6 focus on ILSI North America's disclosure requirements—all PIs are expected to provide a full-signed disclosure of all financial interests in publications and conference presentations. In addition, PIs are required to disclose their paid authorship arrangements in industry-sponsored publications or presentations.

ILSI North America's *Policy and Procedures* details the organization's conflict of interest disclosure requirements. ILSI North America requires:

> *Full and regular internal reporting and external disclosure of financial interests that would reasonably appear to affect the welfare of subjects or the conduct or communication of research.*
>
> *Disclosure of industry relationships, financial and other conflicts of interest when communicating to the public, other investigators, their institutions, and journals. Relevant interests and/or advisory relationships of the researchers shall be cited in publications and other forms of disclosure. It is recognized that guarding against conflicts of interest is important in all research, not simply industry-sponsored research.*
>
> *Relevant interests (financial and otherwise) and/or advisory relationships of the authors shall be cited in the 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.*

From 2013 to 2017, most of ILSI North America's contracts did not have clear disclosure requirements. In 2016, ILSI North America added some standard language related to COI into its contract/agreement templates. However, it still does not fully reflect the disclosure requirements of Principle 5 and 6.

> *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.*

Analysis: While there are no specific contractual requirements, about 63 percent of publications included a disclosure of financial interests or a statement of "no conflicts of interest." Some PIs

[27] Institute of Medicine, "5 Managing Conflicts of Interest: General Models and Approaches," in *Patient Outcomes Research Teams (PORTS): Managing Conflict of Interest*, eds. Molla S. Donaldson and Alexander M. Capron, (Washington, DC: The National Academies Press, 1991), doi: 10.17226/1821.

attached their detailed Curriculum Vitae (CV) that clearly described their employers, professional affiliations, and publications related to the research proposals. Although CVs provide another way to disclose potential COI, they do not meet the very specific requirements of Principle 5.

ILSI North America's contracts did not have specific language on paid authorship in industry-sponsored publications/presentations (Principle 6). According to ILSI North America officials, Principles 5 and 6 are closely related. Paid authorship in industry-sponsored publications is viewed as a special type of COI, so in most cases, if a PI declares that he/she has "no conflict of interest", it suggests that he/she does not have paid authorship arrangements.

The 8 Guiding Principles are interconnected. The successful implementation of Principle 4 (publishing) also offers some assurance that the disclosure requirements of Principles 5 and 6 are addressed. Peer reviewed journals often have their own disclosure policies and procedures to manage COI issues and provide another layer of protection against potential COI.

Principle 7 *Guarantee accessibility to all data and control of statistical analysis by investigators and appropriate auditors/reviewers*

Discussion: Openness is a critical principle for scientific research. It has become a widely recognized and accepted practice to share research data, methods used in the analysis, and key research materials.[28] Replication of research findings across studies serves as an important mechanism to control research bias, increase the reliability of research findings, and maintain the integrity of the research process. Providing access to research data and methodology is essential to the replication of research findings and outcomes.

Principle 7 requires that both raw research data and statistical analysis methods are available to investigators, auditors, and reviewers. Technological advancements have significantly enhanced the capability to make the research data and methodology openly available to any researchers for the purpose of reproducing the results. Starting in 2016, ILSI North America's contract template contains standard language on data sharing:

> *All data created in the course of the funded project shall be made available for download from a digital repository under terms and conditions no more restrictive than the Science Commons Protocol for Implementing Open Access Data…*

ILSI North America's contracts did not contain language that specified the requirement to publish the methods used in research analysis. Over the past five years (2013-2017), only one project explicitly laid out its plan to publish analysis methodology as one of the project deliverables in the contract.

[28] National Research Council, "3 Guiding Principles for Scientific Inquiry," in *Scientific Research in Education*. (Washington, DC: The National Academies Press, 2002), doi: 10.17226/10236.

Similarly, ILSI North America's policy manual has requirements on open data, but no explicit requirements on the accessibility of research methods. ILSI North America's *Policy and Procedures* requires that:

> *All research and other data resulting from projects funded by committees will be published in peer reviewed publications, made public by the investigator or his/her institution, or by the committee in the event the former fails or declines to do so.*

Analysis: There is no explicit contractual requirement on methodology transparency; however, interviewees from ILSI North America noted that, in practice, PIs are expected to publish both research data and methodology; and this is also a requirement of peer reviewed journals. In addition, as discussed in Section 1.4, ILSI North America recently became a signatory of the TOP Guidelines, which identify very detailed requirements on data transparency and analytic methods transparency. To implement the TOP Guidelines, ILSI North America and its funded researchers are committed to making data, descriptions of data processing procedures, and analytical methods (e.g., program code, scripts for statistical packages, etc.) publicly available for purposes of reproducing published research results. [29]

Principle 8 *Require that academic researchers, when they work in contract research organizations (CRO) or act as contract researchers, make clear statements of their affiliation; and require that such researchers publish only under the auspices of the CRO*

Discussion: Over the past five years, ILSI North America sponsored ten projects with CROs. Although there is no specific contractual requirement related to the requirements of Principle 8, all PIs of these CRO projects listed the CROs as their affiliations and also published under the auspices of the CROs.

Recommendation 1

The study team's analysis in Section 2.1 suggests a number of areas where ILSI North America's contractual requirements or policy requirements are not clear and may cause misunderstanding. Interviewees from ILSI North America noted that, although the 8 Guiding Principles are not formally identified in the contracts, the substance of these principles is reflected in the contractual requirements. However, since some of the Guiding Principles provide very specific direction, the study team suggests that **ILSI North America consider further revising its contract/grant agreement provisions and policy guidance to more explicitly reflect the requirements of the 8 Guiding Principles and avoid confusion**:

- ILSI North America should revise its contract/grant agreement provisions to explicitly identify the requirements on specifying the timeframe for publishing research outcomes

[29] "ILSI North America Implementation of the TOP Guidelines," International Life Sciences Institute NA, accessed November 29, 2018, http://ilsina.org/wp-content/uploads/sites/6/2018/07/ILSI-North-America-TOP-Guidelines-Implementation-final.pdf.

(Principle 4), COI disclosures (Principle 5 and 6), and research methodology transparency (Principle 7).

- ILSI North America should revise its policy guidance to clarify requirements on research design (Principle 2) and the accessibility of research methodology (Principle 7).

2.2 Issues related to ILSI North America's Internal Control System

Compliance and Enforcement

Developing clear, complete policy and legal requirements sets the foundation for sound internal control practices. An essential element of an effective internal control system is strong compliance and enforcement mechanisms. Without robust enforcement and oversight, it is difficult to assess whether policies and rules are implemented and working as intended. In *Funding Food Science and Nutrition Research: Financial Conflicts and Scientific Integrity*, the authors of the 8 Guiding Principles emphasized that "each organization wishing to adopt these guidelines needs to develop its own quality-control mechanism to ensure good compliance."[30]

While ILSI North America has set various legal/contractual requirements and policies to implement the 8 Guiding Principles, it is not clear whether there are effective enforcement processes in place to monitor compliance with these contractual and policy requirements. For example, as discussed in Section 2.1, ILSI North America has developed COI disclosure requirements (Principle 5) in its *Policy and Procedure*—"relevant interests (financial and otherwise) and/or advisory relationships of the authors shall be cited in the publications." However, ILSI North America's policy guidance does not specify how this requirement should be implemented. There does not appear to be a standard compliance review process to enforce the implementation of this disclosure requirement. For the past five years, about 63 percent of publications included a COI statement (i.e., a disclosure of financial interests or a statement of "no conflicts of interest"). Additionally, the study team's interviews suggest that ILSI North America does not have formal procedures in place to consistently vet the COI disclosures from researchers to ensure the disclosures are up-to-date and complete.[31] [32]

Principle 7, ILSI North America's requirement on open data, provides an additional example. ILSI North America recently added a contractual language on making research data available for download from a digital repository. However, there does not appear to be a process in place to follow up and monitor whether scientific investigators fulfill this requirement after the contract ends.

[30] Rowe et al., "Funding," 262-274.
[31] OECD, "*Managing Conflict of Interest in the Public Sector: A Toolkit*," (Paris: OECD Publishing, 2005), https://doi.org/10.1787/9789264018242-en.
[32] ILSI North America officials noted that they reviewed the COI disclosures for some projects.

To supplement the 8 Guiding Principles, ILSI North America recently adopted the Center for Open Science's TOP guidelines, which provided more specific requirements and more actionable steps for the organization to protect research transparency, objectivity, and credibility. The principles and requirements of the TOP guidelines are clearly stated; however, it is not clear that ILSI North America has developed or put in place a plan to develop management check and control processes to ensure research projects meet the requirements of the TOP guidelines.

Rigorous compliance and enforcement should be at the forefront of every organization. Policy guidance and rules are not sufficient. Once they are in place, it is important to establish a formal compliance review process to determine whether all research activities actually follow the requirements and whether the rules and requirements are working as intended.

Recommendation 2:

To bolster internal controls for contract management and strengthen the implementation of its policy guidance, **ILSI North America should build effective monitoring and enforcement mechanisms**:

- ILSI North America's policy guidance should clearly identify the roles and responsibilities for monitoring compliance.
- ILSI North America should establish standard compliance review processes and procedures to ensure all parties perform their contractual obligations.
- The outcomes of compliance reviews should be clearly documented.

Process Documentation

Another internal control issue that emerged from the study team's research is the lack of process documentation at ILSI North America. Process documentation is a critical component of an effective internal control system.[33] ILSI North America manages its research activities through a decentralized process. There is organization-wide policy guidance in place; however, committees have the authority to tailor the processes as needed. As a result, processes and procedures vary by committees, and at the organization level, there does not appear to be a clear picture of how committees operate. Given their diverse project portfolios, flexibility is essential for committees to manage their projects effectively. However, it is important for ILSI North America to have some level of documentation of its operational processes at both the organization level and the committee level, while the extent of documentation depends on the size and complexity of processes.

At the organization level, the *Policies and Procedures* document is ILSI North America's only operational guidelines document. ILSI North America interviewees noted that they have processes

[33] U.S. Government Accountability Office, *Standards for Internal Control in the Federal Government*. GAO-14-704G (Washington, DC, 2014), accessed November 29, 2018, https://www.gao.gov/assets/670/665712.pdf.

and procedures in place (e.g., process for managing publications, contract management process, etc.), but do not have written documentation of these processes. Process documentation will help an organization clearly define and formalize roles and responsibilities for performing process steps, institutionalize the processes, ensure performance and accountability, support institutional knowledge transfer, facilitate new employee training, and improve processes as needed. The lack of process documentation can lead to significant internal control deficiencies.

Recommendations 3:

To further streamline its work processes and strengthen its internal control system, **ILSI North America should document its operational processes at both the organization level and the committee level:**

- Process documentation should be developed by appropriate officials and formally approved by the ILSI North America's Board of Trustees. Stakeholder input should be solicited, as appropriate, prior to finalizing the documents.
- ILSI North America should ensure all essential operating procedures and processes are appropriately documented and maintained. Process documents should identify the roles and responsibilities of key participants, important procedure/process steps, and key stakeholders who should be involved in the processes.
- ILSI North America should keep process documentation as a living part of its operation and conduct annual reviews of its essential processes to identify what works and what needs attention.
- Process documents should be shared with ILSI North America staff and other relevant stakeholders.

SECTION 3: STRENTHENING ILSI NORTH AMERICA'S REPUTATION FOR RESEARCH INTEGRITY

Based on the study team's research, it is clear that ILSI North America is committed to achieving and maintaining high standards of scientific integrity in their research activities. Industry funding plays a vital role in supporting food science and nutrition research, due to limited research funding from other sources.[34] However, there has been a long-standing debate on the credibility and objectivity of industry funded research. ILSI North America has made significant efforts to reduce funding-based bias or perceived bias in research activities, and as one interviewee said, it requires more vigilance and caution than usual to manage potential conflicts and real/ perceived bias in industry-supported science.

ILSI North America is following, or has recently adopted, promising practices in many areas related to scientific integrity. There are additional internal management practices that would benefit ILSI North America. In this report, the study team identified specific internal control weaknesses and developed recommendations to improve contract management oversight procedures, including:

- Consider further revising its contract/grant agreement provisions and policy guidance to more explicitly reflect the requirements of the 8 Guiding Principles and avoid confusion;
- Establish effective monitoring and enforcement mechanisms to ensure compliance with contractual and policy requirements; and
- Document operational processes at both the organization level and the committee level.

The scope of this project is limited. The findings and recommendations presented in this report are mainly based on our review of ILSI North America's contracts, publications, and policy manual and interviews with several PIs and ILSI North America officials. A comprehensive organizational review is required to develop a full understanding and assessment of the effectiveness of ILSI North America's policies, procedures, and structures to protect scientific integrity and objectivity of its research activities. Over the course of this project, the study team identified a number of additional structural and process issues worth further exploration. Although there is not sufficient information to support formal recommendations in this report, these issues have the potential to significantly affect ILSI North America's ability to protect the credibility and transparency of its research activities:

- Committee composition—Should ILSI North America require a more balanced representation of academic and government members on their committees? As some interviewees suggested, increasing the number of academic or government representatives may help address the concerns about undue influence from industry members.
- 8 Guiding Principles—Should ILSI North America consider revising the 8 Guiding Principles to reflect the current operating environment? As the authors of the Guiding Principles stated, the paper is "intended to be a dynamic document, prompting ongoing discussion

[34] Dariush Mozaffarian, "Conflict of Interest and the Role of Food Industry in Nutrition Research," *JAMA* 317, no. 17 (2017), 1755–1756. doi:10.1001/jama.2017.3456.

and refinement of the guidelines it presents."[35] The 8 Guiding Principles were developed 10 years ago, and it is important to regularly review these principles to determine whether they are still appropriate in a rapidly evolving environment or whether any refinements or updates are required.

- Models for enhancing research integrity—There is a variety of tools and practices available to strengthen the objectivity and transparency of research activities. For example, to increase transparency, ILSI North America could establish a permanent public inventory of summaries of funded research. Upon completion of the research, the summary should be updated to include information on how to access archived data. Subsequently, citations to published work stemming from the research should be listed with the summary. This inventory would increase the transparency of ILSI North America funded research, both to enhance external credibility and to facilitate the assessment of the adequacy of the ongoing monitoring of contract compliance. Another example is addressing research misconduct (e.g., fabrication, falsification, plagiarism, etc.) and other ethical violation. To protect research integrity, it is critical to establish clear policies and procedures for responding to misconduct/ethical violation allegations concerning research supported by ILSI North America. The roles and responsibilities of ILSI North America and other parties should be clearly defined in the policy guidance. These leading practices provide useful models for ILSI North America to consider as it continues to develop its policy and process to protect the integrity of its research activities.

[35] Sylvia Rowe et. al., "Funding food science and nutrition research: financial conflicts and scientific integrity" *Nutrition Reviews* 67, no. 5 (1 May 2009): 264–272, https://doi.org/10.1111/j.1753-4887.2009.00188.x.

APPENDIX A: SUMMARY OF RECOMMENDATIONS

Recommendation 1

ILSI North America should consider further revising its contract/grant agreement provisions and policy guidance to more explicitly reflect the requirements of the 8 Guiding Principles and avoid confusion:

- ILSI North America should revise its contract/grant agreement provisions to explicitly identify the requirements on specifying the timeframe for publishing research outcomes (Principle 4), COI disclosures (Principle 5 and 6), and research methodology transparency (Principle 7).
- ILSI North America should revise its policy guidance to clarify requirements on research design (Principle 2) and the accessibility of research methodology (Principle 7).

Recommendation 2:

To bolster internal controls for contract management and strengthen the implementation of its policy guidance, ILSI North America should build effective monitoring and enforcement mechanisms:

- ILSI North America's policy guidance should clearly identify the roles and responsibilities for monitoring compliance.
- ILSI North America should establish standard compliance review processes and procedures to ensure all parties perform their contractual obligations.
- The outcomes of compliance reviews should be clearly documented.

Recommendations 3:

To further streamline its work processes and strengthen its internal control system, ILSI North America should document its operational processes at both the organization level and the committee level:

- Process documentation should be developed by appropriate officials and formally approved by the ILSI North America's Board of Trustees. Stakeholder input should be solicited, as appropriate, prior to finalizing the documents.
- ILSI North America should ensure all essential operating procedures and processes are appropriately documented and maintained. Process documents should identify the roles and responsibilities of key participants, important procedure/process steps, and key stakeholders who should be involved in the processes.
- ILSI North America should keep process documentation as a living part of its operation and conduct annual reviews of its essential processes to identify what works and what needs attention.
- Process documents should be shared with ILSI North America staff and other relevant stakeholders.

APPENDIX B: EAG AND STUDY TEAM BIOGRAPHIES

EXPERT ADVISORY GROUP

Mridul Gautam - President, Nevada Research and Innovation Corporation; Vice President for Research and Innovation, Research & Innovation, University of Nevada, Reno; Professor, Mechanical Engineering, University of Nevada, Reno; Associate Vice President for Research, Office of Research and Economic Development, West Virginia University; Vice President WVU Research Corporation, West Virginia University; Professor, Mechanical Engineering, West Virginia University; Associate Professor Mechanical Engineering, West Virginia University; Assistant Professor, Mechanical Engineering, West Virginia University

Sarah F. Jaggar - Project Director, National Academy of Public Administration, Strategic Advisor and Project Lead, Zelos, LLC. Former Senior Advisor, National Academy of Public Administration; Project Lead, KAA Federal Solutions, Inc.; Senior Strategic Advisor, Partnership for Public Service; Former Managing Director, U.S. Government Accountability Office; Principal, Birch & Davis Associates, Inc; Principal, Arthur Young & Company. Instructor, School of Policy, Government, and International Affairs, George Mason University; Instructor, Institute of China Affairs, University of Maryland; Adjunct Faculty, Department of Health Policy and Administration, School of Public Health, University of North Carolina at Chapel Hill; Guest Lecturer, Duke University.

David Weimer - Edwin E. Witte Professor of Political Economy, Robert M. La Follette School of Public Affairs, University of Wisconsin- Madison. Former positions with University of Wisconsin: Field Chair, Political Methodology; Glenn B. and Cleone Orr Hawkins Professorship; Field Chair, American Politics; and Distinguished Visiting Professor. Former positions with the University of Rochester: Acting Director, Public Policy Analysis Program; Director of Graduate Studies, Department of Political Science; Research Fellow, Rochester Center for Economic Research; Professor of Political Science and Public Policy; Associate Professor of Political Science; Deputy Director, Public Policy Analysis Program; Assistant Professor of Political Science; and Instructor in Political Science. Former positions with Lingnan College, Hong Kong: Visiting Professor, Faculty of Social Sciences, and Director, Center for Public Policy Studies. Former Economist, Office of Policy, Planning and Analysis, U.S. Department of Energy. Former positions at University of California-Berkeley: Teaching Fellow and Teaching Assistant, Graduate School of Public Policy.

STUDY TEAM

Brenna Isman, *Director of Academy Studies* – Ms. Isman has provided project oversight and direction at the Academy focusing on federal agencies and the regulatory community. She is an experienced facilitator and her expertise focuses on development of communication and business strategy frameworks, analysis of ongoing transformation initiatives, and strengthening stakeholder engagement. Prior to joining the Academy, Ms. Isman was a Senior Consultant for the Ambit Group and a Consultant with Mercer Human Resource Consulting, facilitating effective organizational change and process improvement. As the Assistant Director for Executive Education for the Kogod School of Business at American University, Ms. Isman developed curriculum for business certificate

programs and managed program delivery. She holds an M.B.A. from American University and a B.S. in Human Resource Management from the University of Delaware.

Chloe Yang, *Project Director* – Since joining the Academy in 2009, Ms. Yang has worked on projects with a range of agencies and organizations. These include the National Academies of Sciences, Engineering, and Medicine Study and Administrative Processes Review, the National Science Foundation—Review of the Use of Cooperative Agreements, the USDA Agricultural Research Service Administrative and Financial Management Services Review, and the NASA Advisory Council Process Assessment. Before joining the Academy, Ms. Yang was the research intern at the Foundation of Environmental Security and Sustainability. She has also worked as an intern at the Woodrow Wilson Center for Scholars and a research assistant at George Mason University (GMU). She graduated from GMU with a Masters in Public Administration. She also holds a bachelor's degree in Financial Management from the Renmin University of China.

Kate Connor, *Research Analyst* – Ms. Connor joined the Academy in 2018 and is currently serving on several Academy studies, including work for the Agricultural Research Service and the Defense Nuclear Facilities Safety Board. Prior to joining the Academy, she also served as a Public Policy and Government Relations Intern with the American Association of University Women and as an intern on the U.S. Senate Committee on the Budget. Ms. Connor taught high school for several years in Guilford County, North Carolina and she recently graduated from Georgetown University with a Master's in Public Policy. Ms. Connor also holds a Bachelor of Arts in History and Political Science and a Master's in Teaching from the University of North Carolina at Chapel Hill.

Amanda Zink, *Research Associate* - Ms. Zink joined the Academy in 2018 and is currently serving on several Academy studies, including work for the National Security Nuclear Administration and the U.S. Agency for International Development. Prior to joining the Academy, she worked as a Program Intern with the Institute for Defense and Business, and as a Research Intern with the Vice Chair of the Wake County Board of Commissioners. Ms. Zink also worked as a Policy Analyst with the Institute for Emerging Issues to develop a policy framework centered on rural-urban economic development. Ms. Zink holds a Bachelor of Arts in Public Policy and Global Studies, with a minor in Politics, Philosophy and Economics from the University of North Carolina at Chapel Hill.

APPENDIX C: LIST OF INTERVIEWEES

Principal Investigators

Chung, Mei – Tufts University

Farber, Jeffrey – University of Guelph

Haber, Lynne – University of Cincinnati College of Medicine

Moshfegh, Alanna – U.S. Department of Agriculture, Agricultural Research Service

Weaver, Connie – Purdue University

ILSI North America

Kretser, Alison – Director, Science Programs

Larrick, Brienna – Manager, Scientific Program Communications

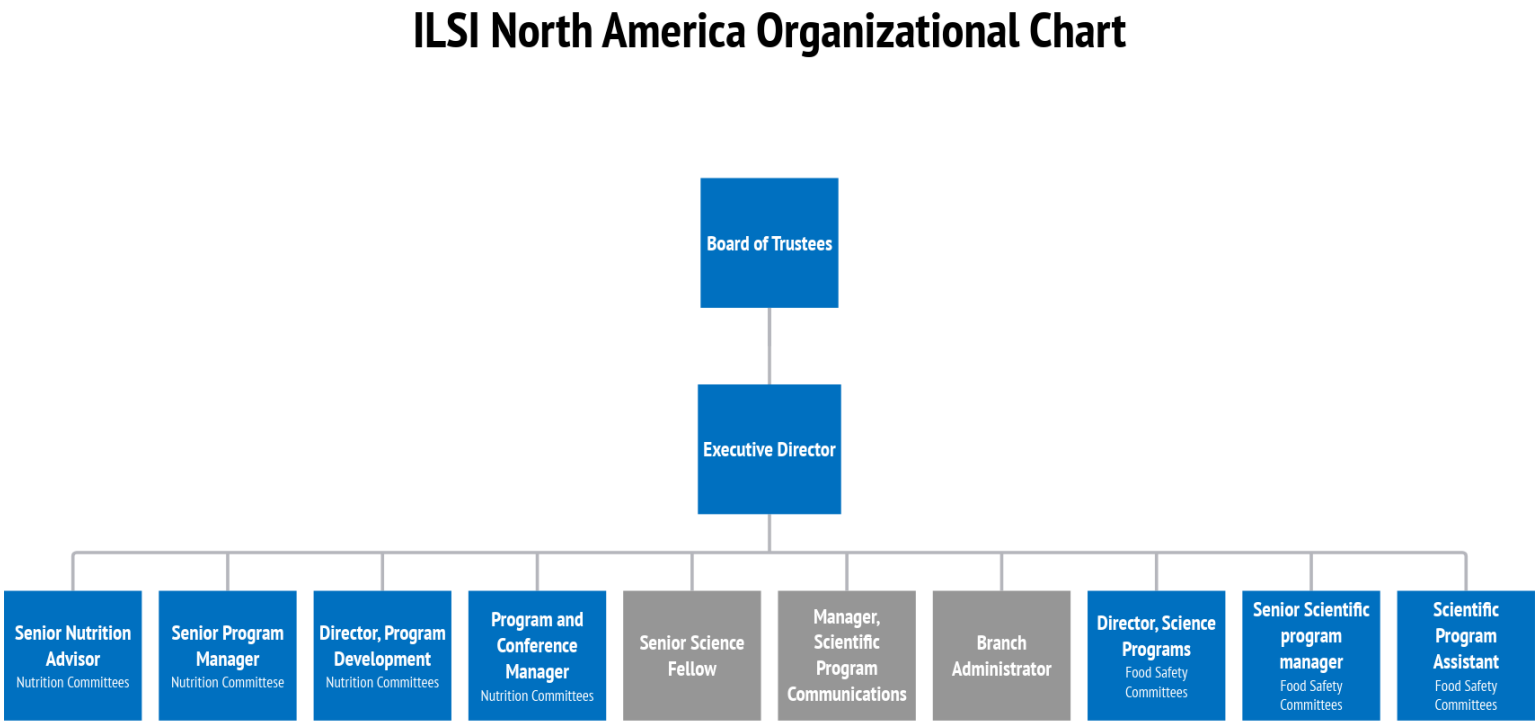
Latulippe, Marie – Senior Program Manager

Lyle, Barbara – Senior Nutrition Advisor

Thorp Clare – Executive Director

Sullivan, Shawn – ILSI General Counsel

APPENDIX D: ILSI NORTH AMERICA ORGANIZATIONAL CHART[36]



[36] This chart reflects the current titles of ILSI North America staff.

APPENDIX E: PRINCIPLES FOR BUILDING PUBLIC-PRIVATE PARTNERSHIPS

Prerequisite principle

1. Have a clearly defined and achievable goal to benefit the public.

Governance principles

2. Articulate a governance structure including a clear statement of work, rules, and partner roles, responsibilities, and accountability, to build in trust, transparency, and mutual respect as core operating principles—acknowledging there may be "deal breakers" precluding the formation of an effective partnership in the first place.
3. Ensure that objectives will meet stakeholder partners' public and private needs, with a clearly defined baseline to monitor progress and measure success.

Operational principles

4. Considering the importance of balance, ensure that all members possess appropriate levels of bargaining power.
5. Minimize conflict of interest by recruiting a sufficient number of partners to mitigate influence by any single member and to broaden private-sector perspectives and expertise.
6. Engage partners who agree on specific and fundable (or supportable through obtainable resources) research questions to be addressed by the partnership.
7. Enlist partners who are committed to the long term as well as to the sharing of funding and research data.
8. Along with government and the private sector, include academics and other members of civil society (e.g., foundations, NGOs, consumers) as partners.
9. Select objective measurements capable of providing common ground for both public and private-sector research goals.
10. Adopt research questions and methodologies established by partners with transparency on all competitive interests, ideally in the precompetitive space.
11. Be flexible in implementing the PPP process.
12. Ensure ongoing transparent communications both among partners and between the PPP and the public.

APPENDIX F: BIBLIOGRAPHY

Institute of Medicine. "5 Managing Conflicts of Interest: General Models and Approaches." In *Patient Outcomes Research Teams (PORTS): Managing Conflict of Interest*, edited by Molla S. Donaldson and Alexander M. Capron. Washington, D.C.: The National Academies Press, 1991. doi: 10.17226/1821.

International Life Sciences Institute NA. "ILSI North America Implementation of the TOP Guidelines." Accessed November 29, 2018. http://ilsina.org/wp-content/uploads/sites/6/2018/07/ILSI-North-America-TOP-Guidelines-Implementation-final.pdf.

International Life Sciences Institute North America. "How We Work." Accessed November 29, 2018. http://ilsina.org/our-work/how-we-work/.

International Life Sciences Institute North America. "ILSI North America Bylaws." Accessed November 29, 2018. http://ilsi.org/northamerica/wp-content/uploads/sites/6/2016/03/NA-Bylaws_2015.pdf.

International Life Sciences Institute North America. "Our Team." Accessed November 29, 2018. http://ilsina.org/about-us/our-team/.

International Life Sciences Institute North America. "Scientific Integrity." Accessed November 29, 2018. http://ilsina.org/our-work/scientific-integrity/.

International Life Sciences Institute. "Frequently Asked Questions." Accessed November 29, 2018. http://ilsi.org/about/frequently-asked-questions/.

International Life Sciences Institute. "Organizational Structure." Accessed November 29, 2018. http://ilsi.org/wp-content/uploads/2016/05/Organizational-Structure-2008.pdf.

Kretser Alison, Delia Murphy, and Johanna Dwyer. "Scientific integrity resource guide: Efforts by federal agencies, foundations, nonprofit organizations, professional societies, and academia in the United States." *Critical Reviews in Food Science and Nutrition* 57, no. 1 (2017): 163-180. http://doi.org/10.1080/10408398.2016.1221794.

Mozaffarian, Dariush. "Conflict of Interest and the Role of Food Industry in Nutrition Research." *JAMA* 317, no. 17 (2017): 1755–1756. doi:10.1001/jama.2017.3456.

National Research Council. "3 Guiding Principles for Scientific Inquiry." In *Scientific Research in Education*. Washington, D.C.: The National Academies Press, 2002. doi: 10.17226/10236.

OECD. "*Managing Conflict of Interest in the Public Sector: A Toolkit.*" Paris: OECD Publishing, 2005. https://doi.org/10.1787/9789264018242-en.

Rowe, Sylvia, Nick Alexander, Fergus Clydesdale, Rhona Applebaum, Stephanie Atkinson, Richard Black, Johanna Dwyer, et. al. "Funding food science and nutrition research: financial conflicts and scientific integrity," *Nutrition Reviews* 67, no. 5 (1 May 2009): 264–272. https://doi.org/10.1111/j.1753-4887.2009.00188.x

U.S. Government Accountability Office, *Standards for Internal Control in the Federal Government*. GAO-14-704G. Washington, DC, 2014. Accessed November 29, 2018. https://www.gao.gov/assets/670/665712.pdf.

Yada, Rickey. "ILSI North America: Update on ILSI North America Assembly on Scientific Integrity." YouTube video. 7:40. Posted by ILSI Global, September 6, 2017. https://www.youtube.com/watch?v=O05PPbDOqow.