

Achieving a transparent, actionable framework for public-private partnerships for food and nutrition research^{1–4}

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ABSTRACT

Officers and other representatives of more than a dozen food-, nutrition-, and health-related scientific societies and organizations, food industry scientists, and staff of the USDA, the CDC, the Food and Drug Administration, and the NIH convened on 8 December 2014 in Washington, DC, to reach a consensus among individuals participating on guiding principles for the development of research-oriented, food- and nutrition-related public-private partnerships. During the daylong working meeting, participants discussed and revised 12 previously published guidelines to ensure integrity in the conduct of food and nutrition research collaborations among public, nonprofit, and private sectors. They agreed to reconvene periodically to reassess the public-private partnership principles. This article presents the guiding principles and potential benefits, outlines key discussion points, and articulates points of agreement and reservation. *Am J Clin Nutr* 2015;101:1359–63.

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INTRODUCTION

Although a number of groups have addressed criteria for conduct of public-private partnerships (PPPs),¹² most reports were not readily accessible in the public domain until, in 2013, a group organized by the North American branch of the International Life Sciences Institute (ILSI North America), a nonprofit scientific organization funded primarily from its industry membership, published proposed criteria (1). In 2014, the Interagency Committee for Human Nutrition Research of the federal government undertook to convene a working meeting to reach consensus on guiding principles for the development of food- and nutrition research-related PPPs. Taking the ILSI North America published principles as a starting point, a number of nutrition, food safety, and health nonprofit organizations and government agencies belonging to the Interagency Committee for Human Nutrition Research, including the USDA, the CDC, the Food and Drug Administration, and the NIH, participated.

Work on rules and a framework for PPPs has gone on for several decades: conferences and workshops have been con-

ducted, internationally and domestically, both by government agencies and by private-sector organizations. However, until the

¹ This publication is a summary of a working meeting held on 8 December 2014 to discuss and reach a consensus on guiding principles for public-private partnerships related to food and nutrition research. The activity was undertaken by the American Society for Nutrition (ASN) through a cooperative agreement with the USDA. As a meeting summary, the article was reviewed for accuracy by participants at the meeting (see **Supplemental Information** for the attendee list). The article did not undergo a separate editorial peer review by the editors of *The American Journal of Clinical Nutrition*. ASN's journals feature a section called "From the American Society for Nutrition," which is devoted to content that originates from the Society rather than the journals. This article is being published in the Society section because of its applicability to the broad food and nutrition community and the need to widely disseminate the consensus principles described in the article for widespread adoption. Any opinions expressed in this article are not necessarily those of the authors' affiliations and have not been formally endorsed by government agencies.

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⁴ Supplemental Information is available from the "Supplemental data" link in the online posting of the article and from the same link in the online table of contents at <http://ajcn.nutrition.org>.

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¹² Abbreviations used: ILSI North America, North American branch of the International Life Sciences Institute; NGO, nongovernmental organization; PPP, public-private partnership.

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recent work cited above, specific guidance on managing and making operational food- and health-related research PPPs has been lacking in the public domain. Given the urgent need for an expanded, rigorous, and focused research agenda in food and nutrition; shrinking availability of public funding for research; and the growing need for pooling research expertise and resources to address complex issues, it has become even more critical to call for the formation of PPPs to help maximize research opportunities addressed collaboratively. Participants believed that a convergence around principles would create a new impetus for and guide the formation of research-focused PPPs.

The discussion shed light on the challenges that await future collaborations between public and private agencies interested in food and health. One striking feature of the meeting was the virtual unanimity expressed by participants from public and private organizations in support of the concept of PPPs and the principles previously published. The present article offers a summary of the discussion and presents the emerging principles.

CONTEXT AND PRECONDITIONS

After the introduction of the food-, nutrition-, and health-related organizations represented at the conference, the USDA's Under Secretary for Research, Education, and Economics and Chief Scientist Catherine Woteki offered a broad overview of the relation between food and health research, pointing out some of the special attributes of food that make it a sensitive research area, such as its intimate nature, its cultural/religious significance to various groups, and other societal values that affect food systems. Several major points were emphasized:

- The public has traditionally looked to the food industry to ensure food safety and to provide nutrient information.
- PPPs around food research have been put forth for a quarter century or more.
- A number of potential models have been put forth over the years.

Dr. Woteki emphasized the need to move forward on a set of guiding principles on the formation and operation of food—including its safety—and nutrition research PPPs. Such a move would be an important and useful step, both in maintaining public trust in PPPs and in pooling public and private resources available to advance publicly sponsored research to enhance public understanding.

ANALYSIS OF THE PROPOSED PRINCIPLES

With that orientation, attendees reviewed the meeting's purpose and preconditions for successful PPPs. Participants agreed that they were in attendance to develop a transparent and actionable framework for the establishment and operation of PPPs to achieve the best food- and nutrition-related research outcomes. The Statement of Task offered at the meeting's outset served as the consensus rationale for the work at hand. That statement began, "There is an urgent need for an expanded, rigorous, and focused research agenda in food and nutrition that is driven by increased awareness that food, nutrition, and human health are closely linked through complex interactions, and

a recognition that associated costs contribute substantially to rising national health care expenditures."

The meeting participants also agreed that the framework of principles to be developed would be made publicly available for use as a model by interested public and private organizations. Attendees would encourage their organizations to promote the principles by, for example, supporting publication of the framework in the relevant publications of partner organizations. It was made clear in discussion that PPPs were reserved for specific applications of the private sector working with government agencies, generally with multiple partners. Most research is conducted under one of many existing mechanisms, such as specific cooperative agreements, that dictate the rules of engagement when a federal agency works with a single private partner.

Early on, the question was raised about the advantage of creating a PPP as a research tool. Once the public health goal has been identified, it was argued that a major prerequisite to establishing a PPP is the prospective partners' willingness to perform a Justification and Feasibility exercise, where they establish whether the PPP is truly necessary and ascertain whether the contemplated partnership is workable. One participant argued that "if you cannot explain in writing why and how the PPP would work, perhaps you should not be attempting to create the partnership. But even if you can justify forming the PPP, it may not be feasible for any number of reasons." Financial or human resources may not be sufficient, there may be organizational mission conflicts, etc. Once the Justification/Feasibility phase has been completed, the PPP must proceed to a Development/Governance phase and an Implementation/Evaluation phase, guided by the principles.

Participants heard that another essential prerequisite for beginning the partnership is mutuality of interest: that is, each partner must have a specific stake and have an interest served by the partnership to be fully committed to the PPP. The prospective partners must see their separate self-interests served by the collaboration or there would be no incentive to join. Therefore, in a viable PPP, each partner would have a vested interest in both the common, public-benefit goal and its own interest.

PROPOSED PRINCIPLES

With the context established, participants moved to a general discussion of the 12 principles published in 2013 (1) that the participants used as a starting point. The first principle is a prerequisite, the second and third offer governance guidance, and the remainder focus on operational issues. The draft principles are included below as part of the discussion of each principle. The agreed-on principles are listed in **Text Box 1**.

Draft principle 1 on goals

The first draft principle is "Have a clearly defined and achievable goal to improve the health of the public." Suggested at the outset was the substitution of "public good" for "public health" in this first principle about goals. For some organizations, public benefit might not always refer to a public health benefit. It was agreed that this principle is one that needs to run through all phases of PPP development and implementation, and that the partners need to be

Text Box 1 Final consensus principles**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.

continually mindful of the public benefit goal of the partnership and communicate that fact to the public.

One participant inquired as to an ethical overview of the PPP—whether the principles required that there be an ethical review at any point. The USDA Under Secretary for Research, Education, and Economics and Chief Scientist pointed out that all public agencies already are set up to make certain that any PPP furthers the mission of the agency. For example, existing USDA processes for cooperative agreements include certification that a project is in the interest of the department with no financial conflict of interest for federal scientists involved or for their immediate families. It was suggested that if an ethical review were part of the public entity’s PPP rules, that would suffice.

Draft principles 2 and 3 on governance

The relevant draft principles are as follows: “Articulate 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” (principle 2) and “Ensure that objectives will meet stakeholder partners’ needs, with a clearly defined baseline to monitor progress and measure success” (principle 3).

As to these governance principles, there was considerable discussion about the need for transparency both with regard to the public and the various partners. Participants were in agreement that transparency and open communications were crucial to building the mutual trust, external and internal, that would be necessary for the collaboration to succeed long term; furthermore, they agreed that monitoring progress and success over time

was important. One attendee raised the issue of an exit strategy in the event that a partner opted to leave the PPP at any point in its development and operation, so as not to cause undue disruption. Such an option would need to be spelled out in the partnership governance documents.

Draft principles 4 and 5 on balance

The relevant draft principles are as follows: “Considering the importance of balance, ensure that all members possess appropriate levels of bargaining power” (principle 4) and “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” (principle 5).

With regard to the fourth principle about balance, it was pointed out that it would be inherently difficult for the nonpublic partners in a PPP to share decision making and bargaining authority with other partners because of the competitive nature of private entities. On the fifth principle, it was suggested that the reference to conflict of interest should include the understanding that the many forms of possible bias are included. Alternative wording was suggested to make clear that vested interests would not be precluded among the partners: participants recognized that, in some cases, real or apparent conflict of interest (or vested interests) is possible, so full disclosure, transparency, and potential recusal on specific issues are recommended. Interestingly, there was relatively little controversy in the discussion of the fifth principle. Conflict of interest has been a prominent topic in scientific circles over the past decade, and there is substantial agreement that such conflicts must be managed in research, in private partnerships, and in PPPs. There seems to be little controversy among scientists in appreciating that.



Draft principle 6 on research questions

The sixth draft principle is “Engage partners who agree upon specific and fundable research question(s) to be addressed by the partnership.” Agreement on fundable research projects was taken to mean projects where funding is feasible for the PPP partners, who agree on specific research questions to be supported by the PPP. As to the concept of shared goals by the partners of a PPP, some conferees pointed out that although the main public benefit goal needs to be shared by partners, not all secondary goals must be shared, but that it would be sufficient for a PPP to have “mutually agreed-on goals.” In other words, a PPP could have several goals, some of which benefit one partner and some another, but no goal would be perceived as negative for any partner.

Draft principle 7 on commitment and sharing

The seventh draft principle is “Enlist partners who are committed to the long-term goals as well as to the sharing of funding and research data.” With regard to this principle about commitment and sharing of funding and research data, one participant noted that the “long-term” commitment referenced would have been agreed on earlier as a precondition to crafting a PPP. But other participants pointed out that a PPP need not be only strategic but also tactical, implying a shorter term. Participants also noted that “funding” might refer to in-kind contributions in addition to financial resources. Other questions raised in the discussion of this principle were as follows:

- To whom does the shared funding apply—with whom?
- Does the long-term commitment apply to a long-term public benefit?
- Should the funding agency or funders be explicitly prohibited from unfairly influencing the research direction or communication?

Draft principle 8 on partners

The eighth draft principle is “Along with government and the private sector, include academics and other members of civil society as partners.” On this principle, questions were raised as to the definition of civil society and whether every research PPP would find such an inclusion appropriate. There was a discussion of what kind of prospective partners would qualify as “civil society”: members of nongovernmental organizations (NGOs), for example, or representatives of foundations might be “civil society.” PPPs, it was agreed, should be open to them, but there should not be a requirement that they be part of the partnership. Some workshop participants argued that the PPP should be open to members of the general public or general public groups; they pointed out that government agencies, to some people, are not necessarily representative of the public. Other attendees made the point that it is necessary to distinguish partners from stakeholders, who should not have the ability to modify the PPP but who should definitely be included in the communications for the sake of transparency and to make the PPP as inclusive as possible.

Draft principle 9 on measurement

The ninth draft principle is “Select objective scientific measurements capable of providing common ground for both public- and

private-sector research goals.” The issue of measurements stimulated significant discussion, with some in the group arguing that subjective measures are used in research along with objective measurements. It was agreed that there should be some goals capable of being measured objectively so that the PPP would have a way of gauging success or failure in a manner that would be transparent, but it was assumed that additional measures, including subjective measures, could always be added to the PPP’s list of secondary goals.

Draft principle 10 on vested interests

The 10th draft principle is “Adopt research questions and methodologies established by partners with no vested financial interest in them, ideally in the precompetitive space.” There was some alternate wording suggested for this principle about questions and methodologies, so that the principle would not preclude vested interests on the part of one or another partner. Rather, it would demand disclosure and transparency and move the PPP’s work into precompetitive space rather than in areas in which the partners might come into conflict with one another or with the broader public. Some participants pointed out that there would have to be vested interests involved in the PPP’s work or the partners would not have sufficient incentive to be part of the collaboration.

Draft principle 11 on flexibility and communications

The 11th draft principle is “Be flexible and ensure ongoing transparent communications.” This principle about flexibility in implementation provoked some discussion as to what exactly constitutes “flexibility.” It was agreed that partners would need to be flexible as far as the PPP process went and that robust, ongoing communication among partners could aid in that objective. Communication had also been singled out earlier as a key to achieving mutual trust among partners and between partners and the public. Several participants advised creating 2 separate principles out of number 11—one urging process flexibility and one dealing with communication.

Draft principle 12 on a third-party convener

The 12th draft principle is “Consider a third-party convener to ensure equality at the table, clarify rules, establish operational guidelines, and specify funding arrangements.” There were also concerns expressed with regard to consideration of a third-party convener. Some suggested retaining the recommendation as part of the PPP conversation (including this article) but not as a principle. There was general agreement that a neutral third party might facilitate the PPP-formation process, to aid in the event of a problem with the operational guidelines, and to ensure greater awareness of the guiding principles among the partners. Although the attendees eventually deleted the third-party convener principle, that suggestion remains as a key PPP consideration depending on the type and size of the partnership, stage of its implementation, and the appropriateness of using a convener for specific purposes. After discussion, the group agreed that communication was, in fact, a critical focus and, as suggested in the previous discussion, the 11th principle was accordingly edited into 2 principles, with the 12th designed to reflect the importance of ongoing transparent communication.

SUMMARY: KEY THEMES OF THE DISCUSSION

A number of refinements and clarifications to the proposed principles were agreed to during the meeting (see Text Box 1). The group also agreed that the framework carried with it an assumption of appropriateness to specific circumstances. Furthermore, there was consensus that references to governance in PPP documents should be understood to include the concept of good stewardship. One suggestion resonated with all present: a glossary would be helpful as a resource, so that there would be a common understanding of the terms. Some suggested that terms needing clarification in a glossary are “fundable,” “public benefit,” “objective,” “civil society,” “conflict-of-interest disclosure,” “data sharing,” and “precompetitive space.” A glossary is planned and will be available on the ASN website (www.nutrition.org/).

Overall, several participants stressed that more precision and clarity were needed in some of the guidelines, although this goal could perhaps best be achieved as the principles are used for specific purposes by specific organizations. One can envision many different research collaborations, operating under varied structures; the guidance offered here might not apply to every PPP as it is being pursued, but following the best practices guidance offered by the revised principles can serve not only to enhance food- and nutrition-research PPP transparency but also to ensure public confidence in the research outcomes.

PROPOSED REVISIONS AND GOING FORWARD

The consensus principles together constitute the framework for creating and operating PPPs. The major conclusions of the meeting were as follows:

- A unanimous acceptance by participants of 12 consensus principles, as modified, to serve as a framework, as guidance, in creating and operating PPPs.
- PPP governance is a key issue in applying the principles, from selecting public and private goals and objectives to evaluating and communicating progress.
- Publication of the guidelines in multiple journals and other outlets would significantly broaden their reach and their influence on research endeavors.
- The framework developed at the workshop should be an ongoing process that participants have committed to revisit on a regular basis.

Participants agreed to promote and/or publish these principles entirely or in summary and to revisit the PPP guideline discussion at regular intervals in coming years. They also discussed publicizing the working meeting itself at other meetings and conferences in the coming weeks and months and, of course, in this

article. They agreed that a working glossary would be a useful tool in understanding the principles, especially for organizations not present at the workshop that might benefit from PPPs. They listed potential additional benefits of the principles and the discussion:

- In view of the ongoing diminution of available research funding, both public and private, a boost to the movement toward PPPs is timely and important to grow resources for nutrition, food, and health research.
- The consensus on principles to serve as a framework for creating and operating PPPs will open future opportunities for research collaborations.
- The clarity of the enunciated PPP framework and process will establish their value to the private sector and aid in enhancing public confidence in PPP research.
- The agreed-on principles can be expected to stimulate a robust discussion of PPPs in the academic community, which should be involved in the move to more effective research models.
- The PPP framework provided by consensus principles, although initially directed at the organizational level, will be disseminated over time to a number of additional audiences, from research leadership to project leaders, to principal investigators.
- Mutual trust will likely be enhanced between the public and private sectors, including industry, NGOs, foundations, and other such entities.

All agreed that with the momentous research questions awaiting serious work and requiring major funding, the present effort at creating an effective framework for public-private collaborations could yield extraordinarily important and fruitful results. The principles, by establishing a framework built of transparency, good governance, and robust communications, may significantly enhance public confidence in the PPP structure and the resulting health-related science.

We thank the December 8th meeting participants for thoughtful and constructive comments during the meeting and in follow-up review.

The authors' responsibilities were as follows—NA: developed the first draft in consultation with SR; and all of the members of the Working Group on Public-Private Partnerships (the authors): contributed to subsequent reviews and revisions and approved the manuscript.

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