NIH Policy Manual

1167 - Public–Private Partnerships

Issuing Office: OD/OSP **Phone:** (301) 594-6058

Release Date: 9/25/2007 ? **Technical Revision Date:** 1/30/2023 ?

Transmittal Notice

1. **Explanation of Material Transmitted:** This new chapter serves as a reference guide to many of the relevant legal authorities, policies, ethics issues, and other considerations in identifying and using the various available mechanisms to implement Public–Private Partnerships.
2. **Filing Instructions:**

   Remove: None.
   Insert: NIH Manual 1167, dated 9/25/2007.

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- Content of this chapter, contact the issuing office listed above.
- NIH Manual System, contact the Office of Management Assessment, on 301-496-4606.
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A. Purpose

NIH encourages the pursuit of its mission through Public Private Partnerships (PPPs), when appropriate. NIH PPPs are intended to accelerate progress in research, synergize strengths to overcome gaps, improve understanding of challenges in health and biomedical research, and foster alliances to advance the nation's biomedical research. PPPs can thereby provide a means to leverage NIH resources to accomplish agency goals in biomedical research that would be otherwise impossible, less efficient, or incomplete if conducted through NIH programs alone. Just as with other NIH activities, in the setting of PPPs, the NIH promotes rigorous science in the interest of improving the public health; favors a fair, transparent, and inclusive process without discrimination or prejudice; and promotes the generation of knowledge for public use.

B. Background

Public-Private Partnerships involve the NIH/IC (either the NIH as a whole or with single or multi-IC involvement) in collaboration with any of a wide range of other organizations, including patient advocacy groups, foundations, pharmaceutical or biotechnology industry members, and academic institutions. Partnerships may take many forms and range widely in

size and scope. Partnership activities center on the shared goals and mandates of the partners, leveraging knowledge, skills, resources, and services to achieve synergy. All NIH/IC partnerships are science-driven, aim to improve the public health, and are structured to uphold the principles of transparency, fairness, inclusiveness, scientific rigor, and compliance with Federal statutes and regulations, and HHS, and NIH policies.

This manual chapter serves as a reference guide to many of the relevant legal authorities, policies, ethics issues, and other considerations in identifying and using the various available mechanisms to implement PPPs.

C. Definitions and Acronyms

1. **Definitions**

   A Public-Private Partnership (PPP) is an agreement to work in concert with a nonfederal party or parties to advance mutual interests to improve health. Although gifts, contracts, and technology transfer agreements (such as Cooperative Research and Development Agreements (CRADAs), Material Transfer Agreements (MTAs), Clinical Trial Agreements (CTAs)) involve relationships with a nonfederal party or parties, these are not considered to be PPPs at NIH and are and will continue to be governed by applicable statutes, regulations, and policies.

2. **Acronyms**

   CRADA = Cooperative Research and Development Agreement
   DEC = Deputy Ethics Counselor
   HHS = Department of Health and Human Services
   FNIH = Foundation for the National Institutes of Health
   FDA = Food and Drug Administration
   FOIA = Freedom of Information Act
   IC = Institute or Center
   NIH MC = NIH Manual Chapter
   MOU = Memorandum of Understanding
   LOI = Letter of Intent
   NIH = National Institutes of Health
   OER = Office of Extramural Research
   OFACP = Office of Federal Advisory Committee Policy
   OFM = Office of Financial Management
   OGC = Office of the General Counsel
   OHSR = Office of Human Subjects Research
   OIR = Office of Intramural Research
   OLAW = Office of Laboratory Animal Welfare
   OPERA = Office of Policy for Extramural Research Administration
   OSP = Office of Science Policy
   OTT = Office of Technology Transfer, Office of Intramural Research
   PPP = Public-Private Partnership

D. Policy

1. **Principles Relevant to a Decision to Enter Into a PPP**

   Each IC is responsible for evaluating potential partnerships in the specific context of the IC mission. Consideration should be given to scientific priorities, availability of resources needed to pursue the PPP, roles and contribution of each of the participating partners, and potential public perception of the PPP. The cornerstone of the evaluation framework is an analysis of organizational benefits, risks, and competing interests in achieving the applicable IC's mission. NIH ICs may decide at any time not to proceed with a partnership opportunity as a result of this evaluative process or other exigencies. Provided below are some guiding principles in the form of questions that may be useful in assessing whether or not to enter into a particular PPP.

   - Can the goals of the partnership opportunity be clearly articulated? Are they consistent with the IC's mission? Are they reflected in an MOU?
   - Do the proposed activities represent a sufficiently high priority for the participating IC(s) that they might have been implemented entirely with appropriated funds, if such funds had been available?
   - Does the partnership provide synergy with NIH resources and expertise, such that more can be accomplished or progress will be more rapid because of the PPP, than if the NIH were to implement the project alone?
   - Has there been an assessment of other business practices or organizational activities of the potential partner that may represent or suggest a direct or indirect conflict with NIH's mission and/or NIH or HHS policies?
   - Would any terms of the proposed partnership require deviation from current administrative practices and procedures (e.g., funding priorities, scientific review, grants or contracts administration practices)?
   - Are there proposed oversight mechanisms and milestones that could be used to gauge progress and identify potential or emerging conflicts during the partnership?

2. **Partners to a PPP**

   PPPs allow the NIH to engage with any of a wide variety of other organizations whose mission or goals overlap with NIH's to achieve shared aims. Included among potential partners are non-commercial entities, such as patient advocacy organizations, foundations, research institutions, and academic scientists, as well as for-profit partners such as pharmaceutical, biotechnology or device/diagnostic manufacturing companies, private research institutions, and others.

3. **Initiation of a PPP**

   PPPs can be initiated in several ways. NIH staff within one or more ICs may conceive of a project or area of science amenable to implementation through a PPP. Potential

partners may already be known or may need to be sought for the implementation of the scientific agenda. Alternatively, outside entities may directly contact PPP program staff, IC staff and/or FNIH staff seeking partnerships with the NIH. PPP program staff can also assist in identifying partners. In all cases, the goals and contributions of the partnership need to be clearly defined. IC PPP Coordinators and the PPP program staff can assist ICs in defining the goals, structure, governance, and oversight of the partnership and can also assist in identifying additional partners. (For further information regarding PPPs, contact the Office of Science Policy at SciencePolicy@od.nih.gov; for further information about FNIH see http://www.fnih.org).

Each IC is responsible for the establishment and oversight of its own PPP activities and for seeking input and advice from OSP, OGC, OER, OIR, OTT and other program offices, as appropriate. For PPPs that are determined by the IC to be large, novel, or complex, or sensitive politically or programmatically, the IC should decide if it must be approved and executed by the IC Director or his or her designee.

4. **Format of a PPP**

Generally, an agreement to enter into a PPP should be memorialized in a Memorandum of Understanding (MOU) (reference NIH Manual 1168, pending release), which sets forth the overarching relationship among the partners, including the purpose of the PPP, the activities, responsibilities, and roles of the parties, and the relevant legal authorities. For guidance in drafting MOUs prior to the publication of NIH Manual 1168, please contact OGC (301 496 6043) and/or PPP program staff (301 594 6058). The activities of the PPP may be implemented through other mechanisms, such as clinical trial agreements, grants, contracts, co-sponsorships and gifts, which continue to be governed by the applicable statutes, regulations, and policies for that mechanism/relationship under the auspices of the applicable IC office.

5. **Structure and Governance of a PPP**

Partnerships can take a variety of forms, and the structure and the governance of the partnership is dictated by the nature of the activities involved and the permissible role of the participants. PPPs can also vary tremendously in scope, ranging, for example, from a simple joint conference to a complex, multi-party agreement to fund a major, multi-site study.

In the simplest terms, the roles of the partners are largely constrained by what entity is conducting the partnership activity. When the NIH conducts an activity, whether supported with appropriated funds or funds that come into the NIH by gift or transfer, the NIH activity is governed by federal law and policy and authority over that activity cannot be delegated or diluted. In contrast, when a PPP activity is conducted by non-governmental entities, a wider variety of decision-making and governance arrangements can be considered. The diagram below will help to graphically render the alternatives and will help delineate the alternatives:

	Resources coming into NIH	No resources coming into NIH
Government activity	A	B
Partner-centered activity	D	C

The two parameters particularly relevant in evaluating PPP structure and governance design are locus of the activity and what is the flow of resources and monies into and through the PPP. Cases A and B describe government activities undertaken in the setting where government and partner missions align and that a PPP is desired. Cases C and D describe situations where shared design and decision-making occur, though in case D some discrete aspect(s) of the PPP is conducted as a government activity.

Cases A and B:

A. Government Activities

The goals and interests of all partners are sometimes best served by extending the ability of the NIH to conduct its usual activities undertaken through existing NIH authorities, including, among other things, the conduct of intramural research, and the solicitation and award of grants and contracts. In such cases, resources are typically conveyed to the NIH and the eventual expenditure of funds or use of resources is by standard Federal governmental mechanisms. The NIH Manual discussing Extramural Funding Initiatives (pending release) discusses the limited participation outside partners can have in such circumstances.

B. Government and Partner Activities in Parallel

Some partnerships involve the NIH working in tandem with nonfederal parties to accomplish specified goals. These partnerships may or may not involve the direct expenditure of funds, but do not involve the exchange of any funds between the parties. For example, an NIH program might agree to notify its applicants of the availability of further funding from an outside organization through a private grant award program. See Extramural Funding Initiative NIH Manual (pending release). Another example might involve the NIH entering into a co-sponsorship agreement with one or more partners for the planning and implementation of a meeting. In this case, monies may be spent independently by the partners to defray the costs of the event. The joint planning and conduct of the meeting would be as an official duty government activity for the NIH participants. Any government monies used to support the activity would, as in case A, be via the standard Federal governmental mechanisms.

Cases C and D:

In cases where the goals and objectives of all of the partners can only be accomplished by joint design, decision-making and oversight, it may be necessary to locate the partnership outside the NIH. This can be done by working closely, for example, with a charitable foundation, such as the Foundation for NIH or another non-profit entity. In

such cases, the convening and managing body for the partnership is the non-federal entity, which is not subject to the limitations applicable to federal agencies. Thus, a nonfederal entity may be able to solicit funds; award grants and contracts under its own policies; convene scientific meetings and obtain advice from experts; and oversee certain partnership activities. In terms of the federal involvement in such partnerships, all laws and policies continue to apply to the conduct of federal employees and federal activities. For example, a federal employee serving on an executive committee of the partnership serves in that capacity as a federal employee engaged in an official duty activity. The federal contribution to the partnership, such as the award of grants, must be consistent with federal requirements.

C. Partner-Centered Activity

Some partners seek to conduct what are largely their own activities, but desire NIH's involvement in the form of expertise and technical assistance. In such cases, NIH may provide advisory scientific, grant, contract or other technical expertise or other contributions, but the activity remains entirely outside the government with respect to decision-making, use of resources, and implementation. An example of such a partnership is Grand Challenges for Global Health. See http://www.grandchallenges.org/Pages/default.aspx.

D. Partner-Centered Activity with Government Activity occurring within the PPP

When the governance of a PPP is centered outside the government, particular aspects of the PPP may, nonetheless, be best accomplished as government activities. For example, a component of the partnership may entail expanding the capacity of an ongoing grant program or using existing government infrastructure to support a database. Examples of this model include a PPP known as the Genetic Information Association Network (GAIN), to which one of the government's contributions is housing and managing the database containing the GAIN data and overseeing access and use of that data (http://www.fnih.org/work/past-programs/genetic-association-information-network-gain). Another example is The Biomarkers Consortium in which some individual biomarker projects within the consortium may be conducted as government activities (http://www.fnih.org/Biomarkers%20Consortium/Biomarkers_home.shtml).

Regardless of which structure is employed in a particular partnership, the contributions and roles of the parties need to be clearly defined. IC PPP Coordinators, PPP program staff and OGC are available to assist ICs in defining the goals, structure, policies, governance, and oversight of the partnership and can also assist in identifying additional partners.

6. **Funding Issues in PPPs**

Some, but not all, PPPs involve the receipt and expenditure of funds by NIH. When engaging in a PPP, NIH must continue to use its standard mechanisms for receiving, holding, and obligating funds, as authorized by law.

A. *Receiving Funds*

A federal agency may not augment its appropriation from outside sources absent specific statutory authority. The only mechanisms available to NIH to accept outside funding are gifts, through the FNIH, CRADAs, royalties, and interagency transfers. Those pertinent to PPPs are listed below, along with references to the relevant statutory authorities and NIH Manual Chapters on each topic.

- Gifts. Pursuant to Section 231 of the Public Health Service (PHS) Act [42 U.S.C. 238], the Secretary and Secretary's delegates are authorized to accept gifts (monetary and otherwise) that are conditional or unconditional. NIH policies on gifts are set forth in full in NIH Manual 1135. Limitations on the acceptance of certain gifts are set forth in full at Paragraph H of Chapter 1135. Limitations that may be especially pertinent in a PPP include the limitation that gifts may not be accepted if conditions imposed by the donor are illegal, contrary to public policy, burdensome, unreasonable to administer, are contrary to generally accepted public standards, or would create a conflict of interest or the appearance of a conflict of interest to a reasonable person, which cannot be resolved satisfactorily by an ethics official. In addition, gifts may not be accepted if they are tendered for the purpose of securing an endorsement or with the expectation of receiving a future benefit, such as a contract award, from NIH. Gifts may also not be used for supporting or supplementing a federal employee's salary. Gifts cannot be solicited. Gift funds are available for expenditure for the same purposes and in the same manner as regularly appropriated funds and are subject to the same controls and audit as other funds.
- FNIH. The sole purpose of the FNIH is "to support the National Institutes of Health in its mission, and to advance collaborations with biomedical researchers from universities, industries, and nonprofit organizations." See Section 499 of the Public Health Service Act [42 U.S.C. 290b et. seq.] Among its broad authorities, the FNIH is authorized to transfer funds to NIH, such funds being then subject to all Federal limitations relating to Federally-funded research. FNIH can also "solicit and accept gifts, grants, and other donations, establish accounts, and invest and expend funds..." When contemplating a partnership with the FNIH, it should be remembered that, notwithstanding its mission, the FNIH is an independent organization. It is not obliged to enter into specific partnerships or projects with or on behalf of NIH; NIH personnel cannot control funds, personnel or activities of the FNIH; FNIH would generally not be considered to be within the ambit of NIH's attorney-client privilege; and FNIH charges administrative fees for its services. Additional information on FNIH can be found at http://www.fnih.org/.

B. *Spending Funds*

Any requirement or obligation by NIH to obligate funds or conduct an activity in a PPP must be one that is statutorily authorized and is carried out in accordance with standard

procedures and policies applicable to the mechanism being used. Any commitment by NIH to undertake an activity pursuant to a PPP must be one that is in accord with NIH's or the relevant IC's mission. Further guidance regarding the use of gift funds in the setting of partnerships for extramural grant initiatives may be found in the Non-federal Support of Extramural Funding Initiatives NIH Manual, pending release, or call OGC (301 496 6043) or PPP Program staff (301 594 6058) for further advice.

In addition, the IC must ensure that any activities undertaken or funded through a PPP would constitute a sufficiently high priority for the participating IC that it might have been implemented entirely with appropriated funds, if such funds had been available. A PPP should represent synergy between the public and the private activities in furthering the NIH mission. It is critical that the public be able to look at the IC activities under a PPP and conclude that IC decision-making was science-based, priority-driven, and in the public interest.

7. **Clearance of PPPs**

Due to the complexity of the policy and legal issues likely to arise in the development of PPPs, early consultation with OGC and PPP Program staff is strongly recommended.

In light of the wide variation in form and scope of PPPs, ICs should decide about the need for PPP approval by the NIH Director or IC Director(s), as appropriate, or his/her designee, particularly if the PPP is determined to be of sufficient magnitude, complexity, or sensitivity. Each IC is responsible for determining what approval criteria to apply.

Under current HHS policy all MOUs (reference HHS memo of Nov. 14, 2002, on file at OFM) with outside organizations must go through Departmental review before execution. Since PPPs are memorialized as MOUs, PPPs are, therefore, subject to this policy. At NIH, MOUs should be sent to the Deputy Chief Financial Officer, OFM, OD for coordination of HHS clearance.

In addition, MOUs, LOIs, and all other binding and non-binding agreements with foreign entities (not including contracts or federal assistance actions as well as all International Agreements, must be cleared through the HHS Office of Global Health Affairs. The Fogarty International Center at NIH is also available for consultation on international issues.

It is expected that NIH ICs developing or implementing PPPs will notify the PPP Program in the Office of Science Policy (OSP), and keep OSP staff apprised of PPP activities generally. OSP serves as the formal NIH liaison to the FNIH and therefore should be notified of all PPPs with FNIH.

8. **Frequent Legal Issues in PPPs**

There is no independent PPP authority; PPPs are implemented through existing legal authorities and mechanisms. In addition, the activities undertaken as part of a PPP are

subject to Federal statutes, regulations, and policies. Issues that frequently arise include, among others, data collection, data storage, data access, data sharing, proprietary and/or confidential business information, information collection, human subjects research protections, including privacy, and intellectual property.

Application of specific statutes that may be implicated in a PPP must be evaluated for each PPP independently. ICs are strongly encouraged to consult with OGC and other resources when developing and implementing a PPP. The following list is by no means exhaustive, but identifies some of the statutes and regulations that are commonly implicated in PPPs.

a. *Freedom of Information Act*

The Freedom of Information Act (FOIA), 5 U.S.C. § 552, provides individuals with a right to access records in the possession of the Federal Government. All agencies of the executive branch are required to disclose records upon receiving any written request for the records, although the Government may withhold information pursuant to nine exemptions and three exclusions contained in the Act. FOIA may be important to consider in PPPs where (confidential or proprietary) information will be shared among PPP Participants. For more information on FOIA, see http://www.nih.gov/icd/od/foia/#policies or contact the NIH Freedom of Information Act Office.

b. *Privacy Act*

The Privacy Act, 5 U.S.C. § 552a, can generally be characterized as an omnibus "code of fair information practices" that attempts to regulate the collection, maintenance, use, and dissemination of personal information by federal executive branch agencies. For more information on the Privacy Act, see http://oma.od.nih.gov/ms/privacy/ or contact your respective IC Privacy Act Coordinator. http://oma.od.nih.gov/about/contact/browse.asp?fa id=3.

c. *Paperwork Reduction Act*

The Paperwork Reduction Act, 44 U.S.C. § 3501 et seq., governs the collection of information by Government agencies from members of the public. Under the Act, agencies planning to conduct or sponsor a collection must obtain Office of Management and Budget approval prior to undertaking the collection. The statute defines “collection of information” to include any identical or standardized questions posed to more than 9 members of the public, whether the questions are in written, electronic, or oral form. For more information on the PRA, see http://www.whitehouse.gov/omb/inforeg/infocoll.html

d. *Federal Advisory Committee Act*

The Federal Advisory Committee Act, P.L. 92-463, 5 U.S.C. App., requires agencies to follow specific procedures when creating, operating, overseeing, and

terminating advisory committees. An advisory committee subject to FACA is any committee, board, commission, council, conference, panel, task force or other similar group, or any subcommittee or other subgroup thereof, which is established or used by one or more agencies. A committee is not an advisory committee under FACA if it is composed wholly of full-time officers or employees of the Federal Government. For more information on FACA, contact the NIH Office of Federal Advisory Committee Policy http://www3.od.nih.gov/cmo/ .

e. *Human Subjects Protections*

All research involving human participants conducted by NIH or funded in whole or in part by NIH must comply with 45 C.F.R. Part 46, Protection of Human Subjects. This includes research conducted in collaboration with outside parties. The Office for Human Research Protections within the DHHS Office of the Secretary interprets and oversees implementation of 45 C.F.R. Part 46. See http://www.hhs.gov/ohrp/ In addition, clinical investigations of FDA-regulated products are governed by similar regulations at 21 C.F.R Parts 50 and 56; seehttp://www.fda.gov/oc/gcp/. The Office of Human Subjects Research (OHSR) within the NIH helps NIH investigators understand and comply with ethical principles and regulatory requirements involved in human subjects research within the Intramural Research Program. Information about OHSR is available at http://www.nihtraining.com/ohsrsite/index.html

f. *Intellectual Property*

There is a significant volume of federal law, regulation, and NIH policy governing the handling of intellectual property. For additional information, see the resources and contact your IC technology transfer office, the OGC, OTT (http://www.ott.nih.gov/), or the OPERA Division of Extramural Inventions and Technology Resources (DEITR) (http://grants1.nih.gov/grants/intell-property.htm).

g. *Vertebrate Animal Use*

All research involving the use of live vertebrate animals in any activity supported or conducted by the NIH must comply with the Public Health Service Policy on Humane Care and Use of Laboratory Animals (PHS Policy) as required by the Health Research Extension Act of 1985 (Public Law 99-158). This includes research conducted in collaboration with outside parties. The Office of Laboratory Animal Welfare (OLAW) within the Office of Extramural Research interprets and oversees implementation of the PHS Policy. For more information about the requirements of the PHS Policy contact OLAW (http://olaw.nih.gov).

9. **Frequent NIH Policy Issues in PPPs**

Depending on the activity planned via the PPP, a variety of issues unique to that PPP must be resolved through negotiation by all participating partners. Among the issues that might require articulated policies are:

- data sharing within the partnership
- how PPP results and data can be become a public resource and how that resource can be made available and to whom
- how PPP confidentiality and conflict of interest will be assessed and handled
- anti-trust policies to protect industry partners in a PPP
- how grants and contracts will be handled and managed
- other

NIH is bound by existing law and policy with regard to NIH activities under the partnership. To ensure compliance with federal law and NIH policy, consultation with PPP Program staff and OGC is highly recommended as policies are drafted and negotiated.

A significant body of NIH policy is also relevant to the design, initiation, establishment, operation and clearance of PPPs. Among the relevant policy guidance documents are listed below. For additional information, seek advice and assistance from the IC PPP Coordinator, the PPP Program staff, or other resources.

- Principles and Guidelines for Recipients of NIH Research Grants and Contracts on Obtaining and Disseminating Biomedical Research Resources guidance –http://www.ott.nih.gov/pdfs/64FR72090.pdf
- Report of the National Institutes of Health (NIH)Working Group on Research Tools – http://www.nih.gov/news/researchtools/index.htm
- NIH Data Sharing Policy – http://grants2.nih.gov/grants/policy/data_sharing
- NIH Model Organism Sharing Policy –http://grants2.nih.gov/grants/policy/model_organism/
- OER Peer Review Policy – http://grants2.nih.gov/grants/peer/peer.htm
- Intellectual Property policies, including Best Practices for Licensing Genomic Inventions and NIH Principles and Guidelines for Sharing of Biomedical Resources:http://www.ott.nih.gov/policy/policies_and_guidelines.html and http://grants1.nih.gov/grants/intell-property.htm
- Ethics topics, including guidelines for official duty activities, conflicts of interest, intramural/extramural collaborations: – http://ethics.od.nih.gov/topics.htm

E. Ethics and Oversight

PPPs are official duty activities for NIH staff and NIH policies regarding guidance for official duty activities will govern NIH staff participation in PPPs. (reference Official Duty Activity Policy). Financial and other conflict of interest requirements and rules are also applicable.

In carrying out their official duties, federal employees must adhere to government-wide ethics requirements, set forth in Title 18 of the U.S. Code, the Standards of Ethical Conduct for Employees of the Executive Branch, 5 C.F.R. Part 2635 and the Supplemental Standard of Ethical Conduct for HHS Employees, 5 C.F.R. Parts 5501 and 5502. PPPs are official duty activities in which the NIH as an agency interacts with other entities in order to accomplish shared aims. Among other things, these laws prohibit conflicts of interest and the solicitation of gifts, govern gift acceptance by individual employees, and restrict the use of titles and authorities for the gain of other persons and entities. Ethics rules also govern acceptance of funds from prohibited sources. Seehttp://ethics.od.nih.gov/.

Participation of an NIH employee in a PPP may elicit conflicts of interest in the setting of official duties as a result of an employee's personal financial interests or relationships. In addition, concerns of bias can arise between various official duties. In this case, an employee may, for example, be restricted from certain official duties due to partnership interactions with a current or future applicant for extramural grant funding, or conversely in developing a PPP with an established grantee. Further guidance regarding the evaluation and management of Conflict of Interest and Official Duty Activities can be referenced at (for principles and examples please see ODA chart and guidance URL – http://ethics.od.nih.gov/topics/ODA/2-ODA-chart-6-9-06.pdf). Consultation regarding specific employee conflicts or potential conflicts should be sought with the employee's supervisor, the IC DEC, with the OD Ethics Office, and/or with the OGC, Ethics Division, per ODA policy.

It is equally critical that actual or apparent conflicts of interest are identified at the agency and IC level and considered before entering into a PPP. Each IC is responsible for ensuring that conflicts are managed or eliminated before finalizing a PPP. The PPP Review Checklist, attached as Appendix 1, must be maintained by the IC in accordance with records retention and disposal requirements in NIH Manual 1743 as specified in Section H.

F. Resources

Expertise on the suitability of an activity for a PPP, the appropriate structure for a PPP, and the ethics and legal considerations entailed in entering into a PPP reside in various offices. Resources to reference when considering a PPP include:

- for general and specific information relating to PPPs, examples of past PPPs, and for guidance and advice, contact the IC PPP Coordinator and/or the Program on PPPs in the Office of Science Policy (pppartnerships@od.nih.gov and http://ppp.od.nih.gov/);
- for information on legal authorities, acceptance and expenditure of funds, mechanisms, and drafting of MOUs, contact OGC, NIH Branch and refer to NIH Manual 1168 on MOUs (pending). For guidance in drafting MOUs prior to the publication of NIH Manual 1168, please contact OGC (301 496 6043) and/or PPP program staff (301 594 6058);
- for ethics issues, contact the relevant IC's Deputy Ethics Counselor, the NIH Ethics Office, or the OGC, Ethics Division.

- for intellectual property issues, contact your IC technology transfer office, OTT, OGC, NIH Branch, or OPERA Division of Extramural Inventions and Technology Resources (DEITR);
- for intramural and extramural technology transfer policies, contact your IC technology transfer office, OTT or OPERA Division of Extramural Inventions and Technology Resources (DEITR) (for extramural);
- for technology transfer matters handled by your IC (CRADAs, MTAs, CTAs, etc.) under a PPP, contact your IC technology transfer office (Technology Development Coordinator);
- for grants issues, contact the relevant IC's Grants Officer or OER;
- for contracts issues, contact the relevant IC's contract officer or the NIH Office of Acquisition Management and Policy;
- for information on delegations of authority, contact the NIH Delegations Officer;
- for information on FOIA, contact your IC FOIA Officer;
- for information on Privacy, contact your IC Privacy Act Coordinator;
- for information on the Paperwork Reduction Act, contact OPERA;
- for information on the Federal Advisory Committee Act, contact OFACP;
- for information on human subjects issues, contact OHSR;
- for information on vertebrate animal use, contact OLAW.

G. Examples

PPPs can vary markedly in scope, scale, and organization. Examples of PPPs can be found at: http://ppp.od.nih.gov. Further details are available from the Program on PPPs, Office of Science Policy Analysis, Office of Science Policy.

H. Records Retention and Disposal

All records (e-mail and non-e-mail) pertaining to this chapter must be retained and disposed of under the authority of NIH Manual 1743, "Keeping and Destroying Records, Appendix 1, "NIH Records Control Schedule," Item 2300-730-7, Financial Disclosure Reports" and Item 2300-730-8, "Standards of Conduct Files."

NIH e-mail messages. NIH e-mail messages (messages, including attachments, that are created on NIH computer systems or transmitted over NIH networks) that are evidence of the activities of the agency or have informational value are considered Federal records. These records must be maintained in accordance with current NIH Records Management guidelines. Contact your IC Records Officer for additional information.

All e-mail messages are considered Government property and, if requested for a legitimate Government purpose, must be provided to the requestor. Employees' supervisors, NIH staff conducting official interviews or investigations, and the Office of Inspector General may request access to or copies of e-mail messages. E-mail messages must also be provided to Congressional oversight committees if requested and are subject to Freedom of Information

Act request. Since most e-mail systems have back-up files that are retained for significant periods of time, e-mail messages and attachments are likely to be retrievable from a back-up file after they have been deleted from an individual's computer. The back-up files are subject to the same request as the original messages.

I. Internal Controls

The purpose of this manual issuance is to describe some of the legal, ethical, and policy issues to be considered in the development of public-private partnerships.

1. **Office Responsible for Reviewing Internal Controls Relative to the Chapter:** The Program on Public-Private Partnerships in the Office of Science Policy has the lead responsibility for updating the information outlined in the chapter.
2. **Frequency of Review:** Periodic reviews, at least annually.
3. **Method of Review:** IC staff should periodically review whether the NIH intramural, extramural, and administrative communities are adhering to the policies on PPPs and be able to make the reviews available if necessary.
4. **Review reports are sent to:** The Deputy Director for Management (DDM). Reports should indicate that controls are in place and working well or indicate internal management control issues that should be brought to the attention of the DDM.

Appendix 1 - PPP Review Checklist

The purpose of this assessment checklist is to ensure that a proposed Public-Private Partnership (PPP) furthers the mission of the agency and maintains the integrity of the science and the scientific process. The checklist should be filled out by the program official with primary responsibility for the PPP and should be reviewed and executed by the IC Director or designee.

1. Are the goals of the partnership opportunity explicit and consistent with the IC's mission and reflected in an appropriately cleared MOU?
   No Yes
2. Are the activities undertaken or funded a sufficiently high priority for the participating IC that they might have been implemented entirely with appropriated funds, if such funds had been available?
   No Yes
3. Has there been an assessment of other business practices or organizational activities of the potential partner that may represent or suggest a direct or indirect conflict to NIH's mission and policies?
   No Yes
4. Is the partnership consistent with current administrative practices and procedures (e.g., funding priorities, scientific review, grants administration practices)?
   No Yes
5. Are there defined oversight mechanisms in the IC that can be used to gauge progress and identify potential or emerging conflicts during the partnership?
   No Yes

6. Are funds or other resources being provided to NIH in support of this PPP?
   No Yes
7. Are funds or other resources being provided to third parties by any of the non-federal partners in support of this PPP?
   No Yes

PLEASE PROVIDE A FULL DESCRIPTION OF THE FACTS AND THIS CHECKLIST TO THE APPROPRIATE IC POINT OF CONTACT AND, IF APPLICABLE, A PROGRAMMATIC JUSTIFICATION AND/OR STEPS TAKEN TO MANAGE ANY POTENTIAL CONFLICTS IF NEEDED.

Note: A copy of the MOU is attached.

Reviewed and Approved on _____:(date)

_____ (IC signatory)

Each IC should reassess this PPP at appropriate intervals