POLICY AND PROCEDURES

OFFICE OF TRANSLATIONAL SCIENCES

CDER Staff Participation in Public Private Partnerships and Consortia

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PURPOSE

The purpose of this MAPP is to facilitate consistency and continuity throughout CDER as the Center engages in Public Private Partnerships (PPPs) and consortia. This MAPP establishes responsibilities for those engaged in collaborative activities with a PPP or consortium convened by an external organization. This MAPP also establishes a process for CDER staff to obtain clearance for participation in these activities, and to obtain appropriate assurances regarding CDER's terms and conditions for engagement from external organizations with which we engage.

BACKGROUND

This MAPP applies to PPPs and consortia convened by external organizations in which CDER and multiple stakeholder organizations, including non-profit and for-profit

organizations, are working together to achieve a shared goal by building knowledge or developing a common understanding of issues and potential solutions. These collaborations may include other governmental entities and must be coordinated by non-profit organizations (if CDER participates in the collaboration). A third party non-profit coordinating organization is in a unique position to bring together other non-profit and for-profit organizations.

Under the auspices of FDA's Critical Path Initiative, Advancing Regulatory Science Initiative, and similar programs, FDA is engaged in a number of PPPs and consortia with other government, academic, scientific, patient, and industry organizations to foster scientific collaborations. These efforts are often utilized to encourage the development of new tools to facilitate innovation in medical product development.

CDER staff is often asked to participate in PPPs and consortia to facilitate, inform, and provide a regulatory perspective as well as to help external groups to understand CDER's current thinking. It is essential that CDER staff is aware of potential conflicts of interest and avoid any appearance of undue influence. A CDER employee who participates in a PPP or consortium as part of his or her official duties may be designated as a CDER PPP Liaison to the collaborative activity. CDER PPP Liaisons are appointed to collaborations where CDER views the project objectives as a valuable effort consistent with the FDA mission, and where the CDER employee has the potential to aid the PPP or consortium in achieving those objectives. An employee serving as a CDER PPP Liaison is appointed after the Center Director has approved the activity per the procedures outlined in this MAPP.

FDA has established that an employee may serve as an Officer, Director, or on a Board of an outside organization in an official capacity, as long as official duty activities criteria, as defined by the FDA Division of Ethics and Integrity, are met. According to the FDA Division of Ethics and Integrity's internal communication, an employee must: 1) obtain a determination from the Office Director and Center Director that their service in this capacity is in the interest of the Agency; and 2) contact the FDA's Office of Chief Counsel for a determination of whether it is within FDA's legal programmatic authority to assign the employee to this position. While not specifically bound by the description of the activities of the CDER PPP Liaison, it is the expectation that anyone who serves as an Officer, Director, or on a Board of an outside organization in an official capacity should also be mindful of the principles of this MAPP and adhere to the principles of transparency described in this document.

Through these partnerships, CDER and stakeholders leverage expertise and resources for the conduct of mutually beneficial scientific activities in the precompetitive domain. Such activities are aimed at bridging scientific gaps in drug discovery and development. For example, CDER is involved in several PPPs to promote development of research tools, platforms, clinical databases, and predictive models to advance knowledge of diseases and safety profiles of drugs. Project results generated by these PPPs are made broadly available to the public to benefit public health.

For purposes of determining whether a collaborative activity is covered by this MAPP, it is important to assess whether there is a collaborative activity separate from any excluded arrangement. For example, CDER may complete a contract that requires the contractor to create and manage a PPP. While this MAPP would not cover the contract, it would cover the PPP that is created pursuant to the contract. Similarly, a PPP may give rise to technology transfer (e.g., Cooperative Research and Development Agreements (CRADAs) and data transfer agreements) or to a co-sponsorship agreement between FDA and one or more of the participants in the PPP. While the technology transfer agreement or co-sponsorship agreement would not be covered by this MAPP, the PPP would remain subject to it. For more information, see the References section.

POLICY

1. CDER PPP Liaisons are not self-appointed to a PPP or consortium activity.
2. CDER must receive a formal request for participation in a PPP or consortium activity.
3. The CDER management will ensure that the convener of each proposed PPP or consortium activity (PPP Convener) submits a formal request for a CDER PPP Liaison by completing the *Request for CDER Participation in a PPP or Consortium Activity Form* which includes the following assurances (See Attachment):

    - Any membership or registration fees required for participation will be directly related to the costs of the PPP or consortium activity.
    - The PPP or consortium activities and scientific publications will be based on sound scientific evidence and will promote the development of new tools to foster innovation, improve medical product development, and advance public health.
    - The PPP Convener agrees not to mislead interested parties by suggesting in written or oral promotion that:
        1) Industry funds or fees will pay for access to, or influence on, FDA. (FDA's participation in the collaboration may be disclosed as a factual matter.)
        2) FDA endorses the organizer, its activities, or its products.
    - The PPP Convener understands the conditions imposed by federal ethics rules on FDA participants, including conditions on the acceptance of gifts, honoraria, travel reimbursement, and prospective employment.
    - The PPP Convener will publicly disseminate the outcomes of PPP or consortium activities.

- The PPP Convener will post regular updates on the PPP or consortium website, including new projects, outcomes, and work products associated with the PPP or consortium activity.

4. When a CDER Office Director (or designee) confirms that his or her Office will participate in the PPP or consortium activity, he or she assigns one or more CDER PPP Liaison(s) to that activity.
5. The Center Director (or designee) approves all CDER involvement in PPP and consortium activities, before any CDER staff resources are committed to the activity.
6. If the PPP Convener does not uphold the assurances listed in the *Request for CDER Participation in a PPP or Consortium Activity Form*, CDER's participation in the activity may be terminated by the Center Director.
7. CDER Offices are required to submit an annual update of the PPP or consortium activity to the CDER PPP Coordinator, using the *CDER PPP Liaison Annual Update Form*.
8. CDER staff participation in PPP or consortium activities are limited to providing a general perspective on regulatory standards, scientific issues, and scientific gaps related to precompetitive drug development. CDER staff participation will not be related to any specific regulatory application, product, or other non-public information.
9. CDER staff may not participate in any of the financial or legal functions or decisions of the PPP or consortium.
10. If a CDER employee involved in a PPP or consortium activity has a significant role involving a regulatory submission directly related to the PPP or consortium efforts, recusal from participating in the regulatory review activities, the PPP or consortium activities, or both, may be required.

RESPONSIBILITIES

CDER Center Director (or designee) will:

- Review the *Request for CDER Participation in a PPP or Consortium Activity Form*, submitted by the PPP Convener.
- Conduct an evaluation of the appropriateness of the PPP Convener's request for CDER's participation.
- Discuss, with the appropriate CDER Office Directors, which CDER Offices and disciplines best address the needs of the PPP or consortium activity.
- Communicate comments and concerns about potential conflicts of interest to the CDER Office Director, CDER Office of Regulatory Policy (ORP), Office of

Chief Council (OCC), Office of General Council (OGC), or FDA Division of Ethics and Integrity, as appropriate.

- Approve or disapprove all requests for CDER staff to participate in PPP or consortium activities convened by external organizations.
- Make the final determination to terminate CDER's involvement in a PPP or consortium activity, if warranted.

CDER Office Director (or designee) will:

- Review the *Request for CDER Participation in a PPP or Consortium Activity Form*, submitted by the PPP Convener.
- Conduct an evaluation of the appropriateness of the PPP Convener's request for CDER's participation.
- Confirm that the PPP or consortium activity will be of value to his or her Office. If confirmed, commit appropriate staff resources.
- Select one or more CDER employees to serve as CDER PPP Liaison(s) to support the activity.
- Evaluate the need for the CDER PPP Liaison to be recused from participating in the PPP or consortium activity, or future regulatory decisions, should circumstances arise that could require recusal (e.g., the PPP or consortium activity results in an official regulatory submission to the agency).
- Annually evaluate the value of each PPP or consortium activity.

Director, Office of Translational Sciences (OTS) will:

- Appoint the CDER PPP Coordinator.

CDER PPP Coordinator will:

- Submit requests for CDER participation in PPP or consortium to the Center Director and Office Director for evaluation and approval.
- Receive final decision regarding CDER's participation in PPP or consortium from Center Director.
- Provide final official correspondence to the PPP Convener confirming or denying CDER's engagement in the requested PPP or consortium.
- Update the Center Director on the ongoing value of the PPP or consortium activities on an annual basis.
- Update the Center Director on any concerns regarding CDER's continued engagement with a PPP or consortium.
- Receive documentation and maintain a database of the following:
    - All requests for CDER's participation in PPP and consortium activities and the outcome of each request (granted, denied, etc.).
    - All PPP and consortium activities approved by the Center Director.
    - All PPP Conveners with whom CDER engages in activities.

  - All CDER PPP Liaisons.
  - Annual updates on PPP and consortium activities, including the ongoing value of activities to CDER.
  - Documentation of the CDER PPP Liaison's acknowledgement and understanding of the policies pertaining to this MAPP.
- Maintain a public website with a listing of active approved PPP and consortium activities and links to the external website of the PPP or consortium.

CDER Office of Regulatory Policy (ORP) will:

- At the discretion of the Center Director, conduct a secondary evaluation of the appropriateness of the request from the PPP Convener.
- If requested, advise the Center Director and Office Director on options for continuing or terminating CDER's participation in the collaborative activity, in the event that CDER becomes aware of any potential violation by the PPP Convener.
- Consult with the FDA Division of Ethics and Integrity or OCC as needed.

FDA Division of Ethics and Integrity will:

- At the discretion of the Center Director, conduct a secondary evaluation of the appropriateness of the request from the PPP Convener.
- Evaluate the need for the CDER PPP Liaison to be recused from participating in the PPP or consortium activity or future regulatory decisions should circumstances arise that could require recusal (e.g., the PPP or consortium activity results in an official regulatory submission to the agency).

CDER Employee(s) will:

- If approached by an external organization to participate in a PPP or consortium, consult with his or her supervisor regarding the request.
- If the Office Director determines that the activity may be of value to CDER, request that the PPP Convener complete and submit the appropriate documentation for evaluation.

CDER PPP Liaison(s) will:

- Become familiar with this MAPP and its attachments.
- Complete the *CDER PPP Liaison Initiation Form* and submit the form to the CDER PPP Coordinator.
- Before participating in a PPP or consortium activity, discuss with his or her immediate supervisor the applicable restrictions on sharing non-public information, and what the employee can and cannot share or discuss while participating in the PPP or consortium activity.
- Complete and submit the *CDER PPP Liaison Initiation Form* to the CDER PPP Coordinator.

- Annually complete and submit the *CDER PPP Liaison Annual Update Form* to the CDER PPP Coordinator.
- Follow the clearance procedure for FDA publications set forth in MAPP 4510.2, *CDER Clearance of FDA-Related Articles, Speeches, and other Publications*.
- Consult with relevant CDER staff and other Centers, when appropriate, to understand CDER's thinking on specific precompetitive scientific issues in order to adequately advise the PPP or consortium participants; arrange to bring other FDA staff into the discussions, if needed.
- Attend and participate in the scheduled meetings of the PPP or consortium.
- Promote good science through rigorous, detailed discourse with the members of the PPP or consortium.
- Inform and help the PPP or consortium participants to understand how CDER operates and its current thinking on precompetitive domain issue(s).
- Provide clarification of regulations, guidances, policies, and practices.
- Provide general perspective on the relative strength of the types of evidence that are present, or if there is a gap in the evidence.
- Educate PPP or consortium participants on issues CDER reviewers are likely to consider important for pre-competitive projects under development.
- Explain potentially important issues to the PPP or consortium participants and discuss why the issues may have importance to the CDER regulatory community.
- Promptly inform the Office Director, Center Director, and CDER PPP Coordinator of any suspected violations of the assurances by the PPP Convener.
- Promptly discuss with immediate supervisor any potential need to be recused from participating in a PPP or consortium activity or regulatory review activity.

CDER PPP Liaison(s) will not:

- Begin his or her participation in a PPP or consortium activity until the activity has been approved by the Center Director and the Center Office Director has officially assigned the employee as a CDER PPP Liaison to the activity.
- Violate the Trade Secrets Act (18 USC 1905), the Administrative Procedure Act (5 USC 551 et seq.), the Privacy Act of 1974 (5 USC 552a), or other laws related to protection of confidential information or personally identifiable information or other laws related to confidential information by discussing confidential regulatory information or other non-public information with the PPP or consortium participants. Such violation could be subject to civil or criminal penalties.
- Violate the Administrative Procedure Act (5 USC 551 et seq.) or other laws related to public communication during rulemaking and other administrative processes.

- Provide specific opinions on the quality and quantity of scientific evidence for regulatory decision-making. Provide opinions on what conclusions an official regulatory review might reach based on the scientific evidence.
- Provide any recommendations or comments on submissions intended for the FDA review teams.
- Provide official opinions on allocation of the PPP's or consortium's resources, such as membership fees, administrative costs, grants, and contracting services.
- Have any fiduciary role with the PPP or consortium. For example, CDER employees should make no decisions associated with the internal business decisions of the convening organization, its member organizations, or private and regulated entities, and should not make decisions associated with the obligation or disbursement of private resources.
- Give advice on a specific proprietary drug development program.

PROCEDURES

Initiation of PPP and Consortium Activities:

If a CDER employee is approached by an external organization to participate in his or her official capacity in a PPP or consortium activity, the employee first discusses the request with his or her supervisor.

If the Office Director (or designee) expresses initial interest in participating in the PPP or consortium activity, the CDER employee requests the PPP Convener submit a *Request for CDER Participation in a PPP or Consortium Activity Form* to the CDER PPP Coordinator's email inbox (OTS-PPPCoordinator@fda.hhs.gov).

When the CDER Center Director is approached by an external organization requesting CDER's participation in a PPP or consortium activity, he or she similarly requests the Convener complete and submit a *Request for CDER Participation in a PPP or Consortium Activity Form* to the CDER PPP Coordinator's email inbox (OTS-PPPCoordinator@fda.hhs.gov).

Evaluation of CDER's Participation in the PPP or Consortium Activity

The CDER PPP Coordinator forwards the completed *Request for CDER Participation in a PPP or Consortium Activity Form* to the appropriate CDER Office Director and to the Center Director.

The CDER Office Director and Center Director assess the value to CDER of participating in the PPP or consortium activity based on the following criteria:

- Relevance of the topic to CDER's mission.
- Potential impact on public health.
- Whether the particular opportunity is unique.
- The role of CDER employee(s) in the activity.
- Costs, including travel, for CDER employee participation.

- Whether the CDER Office has the resources to support such an activity.
- Whether participation in the proposed activity would raise actual or apparent conflicts of interest or other legal or ethical issues for CDER.

Center Director's Approval of CDER's Engagement in the PPP or Consortium Activity and Office Director's Appointment of the CDER PPP Liaison

1. The Office Director confirms the value of the PPP or consortium activity for his or her Office, identifies a CDER employee(s) to serve as CDER PPP Liaison(s) to support the designated activity, and confers with the Center Director.
2. Upon evaluation of the PPP or consortium request, the Center Director consults with FDA Division of Ethics and Integrity, FDA OGC, CDER ORP, the Office Director, or the FDA Office of Chief Counsel, as appropriate.
3. The Center Director approves or disapproves the proposed PPP or consortium activity by signing the appropriate clearance form, and submitting it to the CDER PPP Coordinator.

Initiation of PPP and Consortium Activities

1. The CDER PPP Coordinator communicates to the PPP Convener the CDER decision regarding participation in the PPP or consortium and the name(s) of the designated CDER PPP Liaison(s).
2. The appointed CDER PPP Liaison(s) completes and submits the *CDER PPP Liaison Initiation Form*, acknowledging their understanding of roles and responsibilities.
3. The appointed CDER PPP Liaison(s) begins engagement with the PPP or consortium.

Annual Reporting of PPP and Consortium Activities

1. The CDER PPP Liaison completes and submits the *CDER PPP Liaison Annual Update Form,* within two weeks of the start of the fiscal calendar, to provide feedback on the ongoing value of the liaison activity to CDER.
2. The CDER PPP Liaison promptly informs their immediate supervisor and the CDER PPP Coordinator of any suspected violations of the assurances.
3. The CDER PPP Coordinator updates the Center Director on the ongoing value of the PPP or consortium activities on an annual basis.
4. The CDER PPP Coordinator raises concerns regarding CDER's continued engagement with a PPP or consortium on an ongoing basis.
5. The CDER PPP Coordinator maintains a database and a website to track CDER PPP and consortium activities.

REFERENCES

1. Food and Drug Administration Amendments Act of 2007, Public Law 110-85.
2. FDA, 2004, Critical Path Initiative.
3. FDA, 2010, Advancing Regulatory Science for Public Health.
4. FDA, 2013, Center for Drug Evaluation and Research, MAPP 4510.2, Clearance of FDA-Related Articles, Speeches, and Other Publications.
5. Legal memorandum of August 8, 2002, entitled, "Co-Sponsorship Guidance," issued by the HHS Designated Agency Ethics Official.
6. FDA, 2016, Center for Drug Evaluation and Research, MAPP 4100.1, CDER Co-sponsorship Agreements for Events.
7. 31 USC Sec 6301-6308. Using Procurement Contracts and Grants and Cooperative Agreements.
8. 15 USC 3710A. Cooperative Research and Development Agreements.

DEFINITIONS

CDER PPP Liaison(s): CDER employee(s) appointed to a PPP or consortium where CDER views the activity objectives as a valuable effort consistent with the FDA mission, and the CDER employee has the potential to aid the PPP or consortium in achieving those objectives. The CDER PPP Liaison's participation is part of his or her official duties. A CDER PPP Liaison does not direct internal operations of a PPP or consortium.

Committee: For the purposes of this MAPP, a committee or working group is a collection of individuals convened or appointed to act upon a particular matter or accomplish an objective (e.g., to conduct a scientific study, perform a literature review, or develop a report). Committees and working groups can be organized by a PPP (or consortium) to accomplish a specific goal in support of the PPP's mission.

Consortium: See definition of public-private partnership (PPP), below.

Co-Sponsorship Event: A single event such as a joint conference, seminar, symposium, educational program, public information campaign, or similar event related to the mission of CDER. This event involves CDER and one or more co-sponsors, who provide relevant expertise and share a mutual interest and benefit in the subject matter. These events may not generate monetary profits for any of the co-sponsors involved.

CDER PPP Coordinator: CDER employee designated by the Director of the Office of Translational Sciences (OTS) to coordinate reporting of collaborative activities on behalf of CDER.

Official Duty Activities: Activities performed by an employee as part of, or as an extension of, regular official responsibilities. For more information, visit the FDA Division of Ethics and Integrity Program website.

PPP Convener: A non-U.S. Government, nonprofit organization and coordinator of the PPP or consortium. The PPP Convener is responsible for submitting a request for CDER staff participation in a PPP or consortium activity and for providing certain assurances to CDER regarding the proposed activity.

Precompetitive Domain: For the purposes of this MAPP, the precompetitive domain includes activities, including research, aimed at bridging knowledge gaps in discovery, clinical research, and medical product development. Such activities are neither proprietary in nature nor product specific, and therefore do not present a greater advantage to one stakeholder over another. In the precompetitive domain, all stakeholders benefit from added knowledge, tools, and data to enhance the efficiency of product development and the regulatory process.

Public-Private Partnership (PPP): For the purposes of this MAPP, a PPP or a consortium is an on-going collaborative group managed by a convening or coordinating organization involving multiple stakeholder organizations including at least one non-profit or 501(c)(3) organization (e.g., academia, government, or foundation) and at least one for-profit organization (e.g., pharmaceutical, biotechnology, or medical device company). A PPP may involve multiple committees and working groups.

Not-For-Profit: An organization, such as a professional society, academic institution, or science based foundation, which may serve as a third party convener of the collaborative activities (e.g., government, academia, science-based foundations, professional societies and patient advocacy groups).

Working Group: See definition of committee, above.

EFFECTIVE DATE

This MAPP is effective upon date of publication.

CHANGE CONTROL TABLE

Effective Date	Revision Number	Revisions
1/3/17	Initial	n/a
4/19/23	n/a	Document recertified. Updated forms.

ATTACHMENT 1: FAQs - CDER PPP Liaison Roles and Responsibilities

Purpose of Document

This document is specifically for CDER staff involved in discussions with PPPs and consortia convened by external entities. This document provides direction to the CDER staff participating in various partnership efforts as official CDER PPP Liaisons to facilitate, inform, and help the external groups to understand CDER's current thinking in a role separate from any regulatory review process.

While this document is specifically applicable to CDER staff, external partnership activities may sometimes involve other FDA Centers. In such instances, this document will apply only to the CDER staff, even when activities involve participants from other FDA Centers. However, similar principles to those laid out in this document may also apply to the other Center staff and those staff should consult with their Center management.

1. Under what circumstances can a CDER employee serve in the role of CDER PPP Liaison?

A CDER employee may serve in an official capacity if a federal statute expressly authorizes such service with the organization and the activity has been assigned to him or her by the Office Director as an official duty. In some cases, consultation with OCC, ORP, or the FDA Division of Ethics and Integrity may be required.

2. When participating in the role of a CDER PPP Liaison, are the collaborative activities considered to be outside activities for purposes of 5 CFR 5501.106?

No. If a CDER employee is participating in a PPP or consortium activity in his or her official Liaison role, these activities are not considered to be outside activities. The CDER staff member does not need to seek additional approval for his or her participation in the activity as an outside activity.

3. When and how are CDER PPP Liaisons designated for collaboration with external organizations?

CDER PPP Liaisons are appointed to PPP or consortium activities where CDER views the project objectives as a valuable effort consistent with the FDA mission and the Center Director and Office Director have approved and confirmed the activity, respectively, consistent with MAPP 4100.2.

4. What are CDER's expectations of the CDER staff serving in the role of CDER PPP Liaison?

The role of the CDER PPP Liaison is separate from the role of CDER reviewers of regulatory submissions. A CDER PPP Liaison should educate the convener of the collaboration and other participants of the PPP or consortium regarding this and the consequent limits on the content and specificity of the CDER PPP Liaison's advice. The

PPP Liaison should consult his or her supervisor regarding what information he or she may discuss. While the CDER PPP Liaison can have general regulatory discussions with the participants of the PPP or consortium, the CDER PPP Liaison will not engage in discussions directly related to any regulatory submissions, which are the responsibility of the CDER reviewers in the review team. Similarly, the CDER PPP Liaison will not discuss other confidential or non-public information.

5. When should a CDER PPP Liaison seek recusal from participating in the review activity involving regulatory decision making? What are the Liaison responsibilities when recusal from review activities is warranted?

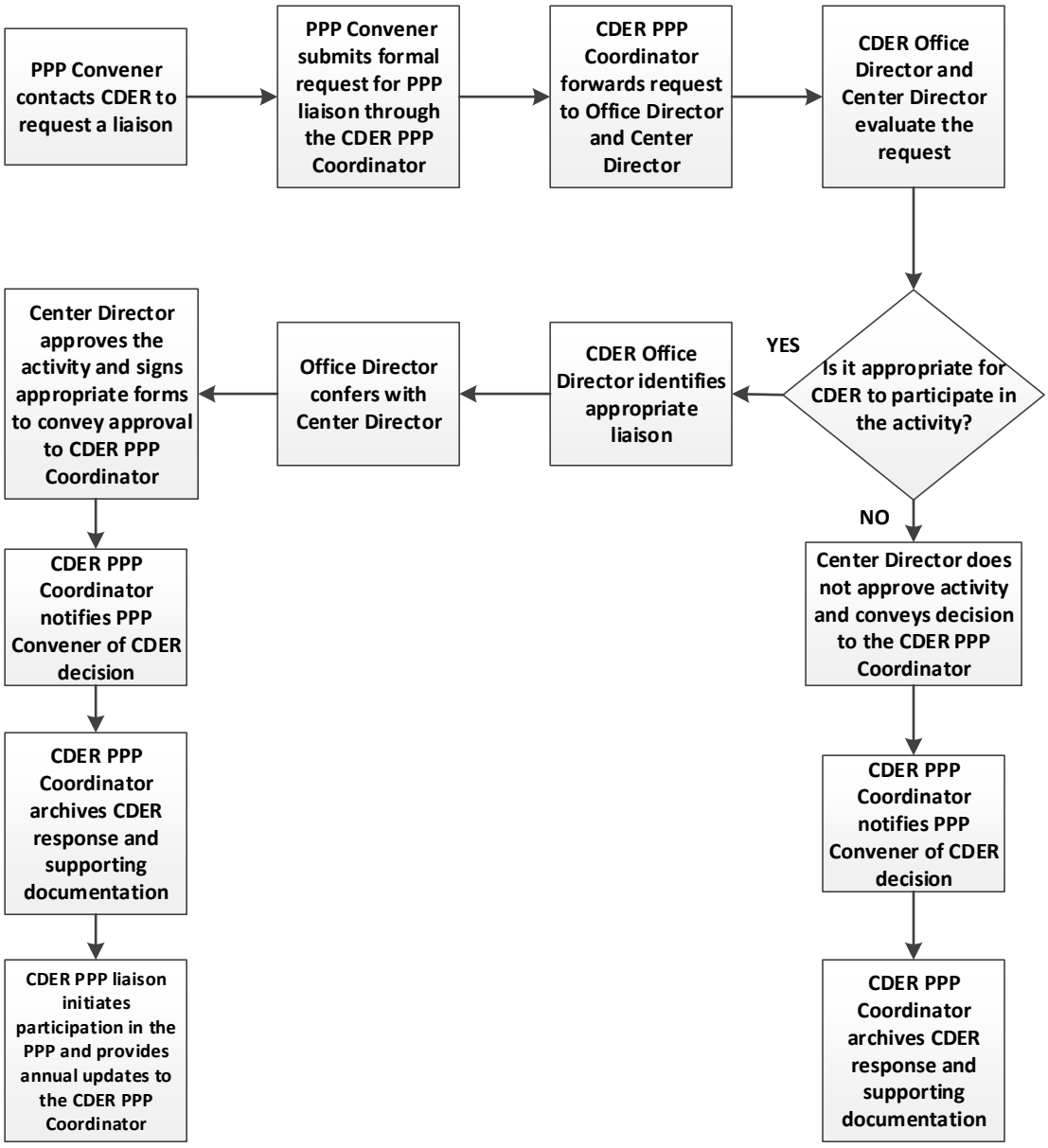
If a CDER PPP Liaison has participated in any of the activities described in MAPP 4100.2 as responsibilities of the CDER PPP Liaison with the PPP or consortium, recusal from the regulatory review activity may be warranted. There may be additional circumstances that could result in recusal being required. A CDER PPP Liaison should consult his or her supervisor, the CDER Office Director and the FDA Division of Ethics and Integrity to assess the need for recusal.

CDER staff may function as the CDER PPP Liaison, as well as a reviewer of regulatory submissions that are unrelated to the PPP activity. The distinction between the role of the CDER PPP Liaison from that of the reviewer is determined by CDER leadership.

6. Can a CDER employee participate in fund raising activities? Solicit funds?

No. CDER employees are prohibited from using their status as representatives of the federal government to solicit private funds. Furthermore, PPP partners are similarly prohibited from appearing to solicit funds on behalf of CDER, FDA, or the federal government. Partners are also prohibited from soliciting funds on government property.

ATTACHMENT 2: PPP Clearance Flow Chart



ATTACHMENT 3: Request for CDER Participation in a PPP or Consortium Activity Form

ATTACHMENT 4: CDER PPP Liaison Initiation Form

ATTACHMENT 5: CDER PPP Liaison Annual Update Form