

# Working Group Report to the Advisory Committee to the NIH Director:

## Ethical Considerations for Industry Partnership on Research to Help End the Opioid Crisis

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TELECONFERENCE OF THE ADVISORY COMMITTEE TO THE DIRECTOR

APRIL 6, 2018

# Background

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- NIH and the Foundation for NIH (FNIH) have been in the planning stages with external partners to identify and outline options for collaboration to address the opioid crisis.
- Discussions have included dozens of companies, a few of which manufacture opioids and are the target of current litigation by several state Attorneys General and other entities.
- While there may be opportunity to advance addiction and treatment research with the financial, technical, and intellectual support of private sector companies, the ethics of accepting contributions from those companies that are perceived as having contributed to the crisis must be considered.

# Working Group Charge

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To make recommendations about considerations and appropriate ethical boundaries for engaging with and accepting resources from opioid producers, to support research to redress the opioid crisis.

To inform its deliberations, the working group may:

- Identify risks (including ethical, governance, reputational, and relationship risks) and benefits of accepting such resources
- Examine options for funding and/or governance structures that might mitigate ethical risks
- Identify concerns and real or perceived conflicts-of-interest
- Assess existing guidance for protecting the integrity of research funded by industries with real or perceived ethical conflicts

# Working Group Roster

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**M. Roy Wilson, M.D. (co-chair)**

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Retired Executive Vice President, Chief Scientific Officer  
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*With special thanks to Jackie Godin, Office of the  
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# Process of Deliberations

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- Two teleconferences and one in-person meeting over a period of four weeks
  - Reviewed publicly available resources along with an FNIH-produced white paper on the potential partnership
  - Presentations from academic and non-profit leaders involved in addiction and pain research and policy
- Deliberated on recommendations at meetings and via email
- Report to the ACD via public teleconference

# Recommendation #1 (Funding and Assets)

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**To mitigate the risk of real or perceived conflict of interest, it would be preferable if only Federal funds were used to support the research efforts included in this public-private partnership**

- Eliminates the perception of research bias
- If this is not possible, the WG offers additional parameters (subsequent recommendations) if funding from industry partners is accepted

# Recommendation #2 (Funding and Assets)

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**For any public-private partnership to address the opioid crisis, NIH should not accept funding from companies involved in litigation of concern related to the crisis**

- Ethical and reputational risks of accepting funds from these companies are too great
- NIH must define the level of “litigation of concern”
- Return financial resources if any company in the partnership becomes involved in future litigation (to extent possible under applicable laws, regulations, and policies)
- Funds generated as a “tax” on all member companies of a third-party or trade organization should not be accepted if the companies involved in litigation of concern would be contributors
- Ethically acceptable for NIH to accept settlement funds for research

# Recommendation #3 (Funding and Assets)

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**If a public-private partnership is established, any funding originating from industry partners (not precluded under Recommendation #2) that is to be provided to NIH, either directly or through FNIH, must be provided without conditions, other than being designated for the partnership, and must be received in full by NIH prior to NIH's announcement of any funding opportunity or other activity designated as part of the partnership.**

- Mitigates risk of undue influence or of having insufficient funds to complete the project
- Assures autonomy of NIH's decision-making



# Recommendation #4 (Funding and Assets)

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**Any company with assets (e.g., clinical and preclinical data, key chemical compounds) relevant to the research plan for a public-private partnership that NIH undertakes in response to the opioid crisis can contribute those assets to the partnership**

- All companies, even if excluded from funding or governance, encouraged to provide assets
- Assets shared freely, without any conditions or restraints on the use of the materials
- Assets with IP must be transferred without any conditions or claims arising from their ownership or IP on those assets, variants thereof, or future products that result from or are covered by the IP
- NIH must validate the assets and have a plan to mitigate risk of companies overvaluing the assets

# Recommendation #5 (Governance)

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**Any public-private partnership that NIH undertakes in its response to the opioid crisis should not involve governance participation from companies involved in litigation of concern related to the crisis**

- Companies excluded from funding should also be excluded from governance
- Prevents possibility of undue influence on partnership decision making
- These companies could share data and assets in accordance with Rec. #4

# Recommendation #6 (Governance)

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**In accordance with current practice, for projects that NIH funds using donations received under the partnership, NIH will solely govern the peer review process and have decision making authority with regard to the selection of projects, disbursement of funds, and monitoring and oversight of projects**

- Standard NIH peer review and post-award monitoring and report processes will apply for any applicable projects that the agency manages under the proposed public-private partnership
- Industry partners will not participate in the review, selection, or oversight of grants or cooperative agreements included within the partnership

# Recommendation #7 (Governance)

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**Governance structure(s) established to coordinate partners and to guide decision making about the overall strategy, direction, and goals of the public-private partnership should include a diverse group of stakeholders including public members**

- Ensures broad representation of perspectives in the partnership coordination and decision making
- Public members could include patients recovering from opioid addiction, patients afflicted with chronic pain, affected family members, and/or advocates for pain or addiction research and policy, among others

# Recommendation #8 (Governance)

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**NIH should augment its current vetting process for members of governance committee(s) to mitigate real and perceived conflict of interest**

- Process should be stringent and transparent
- Potential members who have direct or indirect relationships with the companies of concern should fully and transparently disclose those relationships
- NIH should employ strategies to appropriately manage such conflicts
- If a conflict cannot be fully managed, NIH should exclude that party from the governance

# Recommendation #9 (Governance)

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**Before moving forward with a public-private partnership, NIH should clarify and define a governance structure for each of the core initiatives of the proposed partnership or any subsequent core initiatives of collaboration**

- Different mechanisms needed for each initiative to ensure appropriate oversight and guidance
- NIH must address the appropriate level of industry involvement (if any) in the governance for each initiative
- Governance plans and planning should not include companies prohibited by Rec. #5

# Recommendation #10 (Transparency)

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**NIH should clearly communicate to the public the full extent of its research agenda related to opioids and where the partnership fits within NIH's comprehensive research strategy**

- NIH has an ongoing and wide-ranging research agenda to address opioid misuse and addiction and to develop non-addictive approaches for pain management
- Increased communication on this point will help stakeholders and the public understand the aims of a potential partnership in a broader context

# Recommendation #11 (Transparency)

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## **NIH should publicly disclose the research plan for the partnership**

- Product of extensive consultation with a range of expertise and perspectives
- To ensure transparency, NIH should disclose the research plan and the discussion participants to the public



# Recommendation #12 (Transparency)

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**To ensure public trust and alleviate concerns about real or perceived conflicts, NIH should employ increased transparency measures in the governance of the partnership (e.g., posting meeting summaries from governance committees; posting conflict of interest declarations of committee members)**

- Guiding principle must include increased transparency measures in all aspects of the partnership
- Document partnership governance thoroughly and in a form that is accessible to the public

# Concluding Observations

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- NIH-wide standards for public-private partnership development could aid future deliberations
- The Working Group recommends that moving forward, NIH should develop well-considered criteria and guidelines for developing public-private partnerships and partner engagement to apply across the agency.

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Questions?

