

ECHO Cohort Conflicts of Interest Policy

I. Introduction and Purpose

One of the NIH Environmental influences on Child Health Outcomes (ECHO) Program’s guiding principles is responsibility. The ECHO Cohort Consortium (consortium) considers responsibility to include ensuring that its members conduct ethical, unbiased, and transparent scientific research. Conflicts of interest (conflicts) exist when secondary interests have an opportunity to influence professional judgment. Without proper management, these conflicts can undermine responsibility. While not all conflicts are impermissible, consortium members must disclose all conflicts identified by this policy so that the consortium and its committees, task forces, and members can manage them appropriately.

Therefore, the purpose of this policy is to guide the consortium’s process of managing conflicts by disclosure, recusal when necessary, and documentation to preserve transparency, independent decision-making, protection of research participants, and research integrity.

This policy aligns with the Code of Federal Regulation ([42 CFR 50](#)) and the [NIH Grants Policy Statement](#). This policy and the consortium process it governs do not replace any other conflict reporting requirements. Consortium members must comply with their own local institutional requirements as well as with all federal requirements.

II. Scope

This policy applies to members of the Consortium governing bodies that have influence over Consortium decisions (“groups”). These groups include the Steering Committee, Operations Committee, and other committees or task forces that the Steering Committee, Operations Committee, or NIH consider appropriate for inclusion under the scope of this policy. Currently, these are the Protocol Task Force, Biospecimen Assay Task Force, Return of Results Task Force, and Genetics Task Force.

This policy does not apply to the Publications Committee or Opportunities and Innovation Fund (OIF) because they have existing processes for disclosure and management conflicts of interests. Consortium working groups and writing teams should disclose and manage conflicts of interests themselves and in accordance with scientific journal policies during manuscript submission.

This policy governs the disclosure and management of two types of conflicts:

- A. Financial
- B. Professional

A. Financial Conflicts

Definition: Conflicts arising from significant financial interests or vested interests. According to this policy, *financial conflicts* include, any single investment valued over \$5,000, annual payment(s) from a company or entity of more than \$5,000, and any intellectual property rights and interests after the time of first financial payment.

B. Professional Conflicts

Definition: Conflicts arising from relevant professional, personal, or institutional affiliations. According to this policy, *professional conflicts* include any that reasonably have the potential to alter, compromise, or bias consortium members' judgement or objectivity. Examples include, but are not limited to board memberships, close family member affiliations with suppliers or vendors, and academic or intellectual contribution to research tools or other enterprises in research and development.

III. Definitions

Refer to the [ECHO Glossary](#) for full list of ECHO terminology.

IV. Policy

Conflict management consists of disclosure, recusal, and documentation.

A. When to Disclose

Planning teams of the groups identified under the scope of this policy should determine if disclosure of conflicts of interest are necessary for decision-making or recommendation processes undertaken by the committee or task force. Decision-making processes requiring conflict disclosure include but are not limited to those related to the expenditure of consortium resources, such as the selection or purchase of proprietary measures, instruments, or tools for the ECHO Cohort Data and Biospecimen Collection Protocol; the selection of proprietary software, platforms, or tools for consortium business or communication; the selection of consortium affiliations or partnerships. If such processes are already underway, the groups should disclose related conflicts of interest as soon as possible. Members should disclose at least annually for the duration of involvement in decision-making processes that take longer than one year.

B. Disclosure

The chairs and members of groups involved in relevant decision-making processes should disclose their conflicts verbally to their group. Members of consortium committees or task forces should disclose their conflicts verbally to their committee or task force. After disclosure, the discloser can participate in the group's discussions involved in decision making. If the same disclosure pertains to multiple meetings, the discloser may elect to have the planning team use a disclaimer slide or word document to provide disclosure reminders to the group.

C. Recusal When Necessary

Recusal is necessary only when voting is part of a relevant decision-making process. If the group deems that a disclosure is a conflict, then the discloser must recuse themselves from voting if the group votes during the course of a relevant decision-making process.

D. Documentation

After the first meeting involving a verbal disclosure—whether or not voting and recusal occurs—the discloser must complete a short disclosure form provided and kept securely by the ECHO Coordinating Center. The disclosure form documents a) the disclosing consortium member’s name; b) the relevant decision-making process to which the disclosure pertains, including whether recusal from voting took place; c) the entity(ies) from which the secondary interest arises, e.g., company name or intellectual property rights; and d) the type of conflict, i.e., financial conflict, professional conflict, or both. In cases of financial conflicts, disclosures should note the approximate value as \$5K–\$50K, \$50K–\$500K, or >\$500K. The ECHO Coordinating Center must keep records of disclosure documentation for a minimum of five years in case review of the Consortium’s decision-making processes becomes necessary.

E. Additional Considerations

1. NIH Oversight

To help NIH assure the responsibility of ECHO’s research, the Program Office may periodically ask groups to report to NIH the disclosures, types of conflicts, and management strategies that the groups have undertaken in the current calendar year.

2. Failure to Comply

If consortium members do not appropriately adhere to conflict management strategies that this policy prescribes, the consortium member(s) may be subject to corrective actions decided by the ECHO Cohort Steering Committee or ECHO Cohort Operations Committee, as well as subject to negotiations between NIH and the consortium members’ home institutions regarding management of the failure to comply.

3. Disputes and Appeals

Consortium members may dispute a conflict management action, e.g., vote recusal. The Steering Committee or Operations Committee hears such disputes *ad hoc*. If a dispute remains unresolved after Steering Committee or Operations Committee hearings, consortium members may ask the ECHO Program Office to convene a Dispute Resolution Committee according to the Dispute Resolution Clause in the Cooperative Agreement Terms and Conditions of Award.

V. Review and Revision

Review of ECHO Program Manual documents occurs every three years; however, if processes change substantially in the interim, NIH may decide to edit the document sooner.

VI. Supporting Documents

None

VII. References

- [42 CFR 50, Subpart F Promoting Objectivity in Research](#)

- [NIH Grants Policy Statement 4.1.10 Financial Conflict of Interest](#)

VIII. Attachments

Figure 1: Approach to Managing Conflicts of Interest in Real Time

IX. History of Change

Version Number	Effective Date	Section Affected	Summary of Changes
3.1	18/Feb/2025	IV.A.	Clarified that group members should update disclosures at least annually if they are involved in decision-making processes taking longer than one year.
3.0	19/Dec/2024	Entire Policy	Revised to facilitate management of Conflicts of Interest in real-time
2.0	11/Dec/2023	Entire Policy	Revised policy to support ECHO Cycle 2.
1.1	08/May/2019	N/A	New Policy



ECHO

Environmental influences
on Child Health Outcomes

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Approval Page

Name/Title	Approval Date
NIH ECHO Program Office	February 18, 2025



X. Attachments

Figure 1: Approach to Managing Conflicts of Interest in Real Time

ECHO Approach to Managing Conflicts of Interest

