National Institute of Allergy and Infectious Diseases NIAID Bethesda, MD USA	**Policy**	Version No.: 3.0 Version date: April 17, 2017 Page 1 of 9
	Effective Date: September 11, 2015 Release Date: July 31, 2015	

Title: NIAID Policy for Identifying Potential Conflict of Interest for Individuals Serving on Advisory Committees or as Independent Safety Monitors Responsible for Data and Safety Monitoring of Clinical Trials

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APPROVAL

	Approving Entity	**Date**
Approval Mechanism:	*NIAID Executive Committee*	*June 11, 2015*

PURPOSE

The purpose of this policy is to: (1) provide guidance to individuals responsible for data and safety monitoring of clinical trials regarding conflicts of interest (COI); and (2) set forth The National Institute of Allergy and Infectious Diseases (NIAID) Division and Center(s) requirements for operational policies which designate who is responsible for collecting COI information, what information is to be collected, and what actions to take should conflicts of interest be identified.

1.0 SCOPE

This policy applies to both Federal and non-Federal employees who are being considered for membership or who are members of NIAID data and safety monitoring boards (DSMB), safety monitoring committees (SMC), independent safety monitors (ISM), and is applicable to members' spouses, dependent children, household members, and relatives with whom they are deemed to have close personal relationships.[1]

2.0 BACKGROUND

The NIH Policy for Data and Safety Monitoring states all clinical trials require data and safety monitoring and that the method and degree of monitoring should be commensurate with the level of risk to study participants. Entities such as DSMBs, SMCs, and ISMs responsible for data and safety monitoring should have no outside associations or conflicts with the trial(s) under review that would affect the integrity of his or her services.[2] This policy also requires that each Institute and Center (IC) have policies that, to the extent possible, manage, reduce, or eliminate COI. NIAID Clinical Research Standard 1.2 requires all Divisions and Center(s) to have policies and/or standard operating procedures in many areas, one of which is COI review.

In situations where COI cannot be eliminated, this NIAID policy provides guidance on how to manage apparent or perceived COI and what actions to take. Using existing regulations as a basis, this policy proposes minimum standards under one overarching framework for NIAID Divisions and Center(s).

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1 https://policymanual.nih.gov/2400-04

2 http://grants.nih.gov/grants/guide/notice-files/not98-084.html

This policy addresses three key types of COI relevant to safety and data monitoring: Professional, Proprietary, and Financial (see Appendix 1).

3.0 DEFINITIONS

Conflict of Interest (COI) – A situation when someone has or is perceived to have competing professional obligations, proprietary conflicts and/or financial or other personal interests that would make it difficult to fulfill his/her duties fairly. The three types addressed in this policy are as follows[3]:

1. Professional: where the individual, their spouse, dependent children, other relatives with whom the individual has a close relationship[4], or household members acts as an officer, member, director, expert advisor, etc., of any organization whose study is under review. [5]

2. Financial: where the individual, their spouse, dependent children, other relatives with whom the individual has a close relationship, or household members have significant financial or equity interests in excess of $5,000[6] in any entity whose study is under review.

3. Proprietary: where the individual, their spouse, dependent children, other relatives with whom the individual has a close relationship, or household members own or otherwise control rights, including but not necessarily limited to intellectual property rights, relevant to the development and commercialization of any product being reviewed.

Data and Safety Monitoring Board (DSMB) – a committee of experts, independent of the trial investigators, pharmaceutical sponsor (if any), and funding agency, that periodically reviews the conduct and results of the trial and recommends continuation without change, continuation with change, or termination of the trial.[7]

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[3] http://ethics.od.nih.gov/Topics/coi.htm

[4] https://policymanual.nih.gov/2400-04

[5] http://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm

[6] http://grants.nih.gov/grants/policy/coi/fcoi_final_rule.pdf

[7] https://www.niaid.nih.gov/sites/default/files/dsmbpolicyv5.pdf

Protocol Specific DSMB – A Data and Safety Monitoring Board that is convened to review only one specific protocol.

Specialized DSMB - A Data and Safety Monitoring Board that addresses studies in certain scientific area, or geographic regions, such as Africa or Asia.

Independent Safety Monitor (ISM) - A physician or other appropriate expert who is independent of the study and available to review serious adverse events (SAEs) and other safety data in a timely fashion and recommends appropriate actions to the study team and NIAID.

Protocol - A document that describes the objective(s), design, methodology, statistical considerations, and organization of a trial. The protocol usually also gives the background and rationale for the trial, but these could be provided in other protocol referenced documents.[8]

Safety Monitoring Committee (SMC) - An independent group of experts that advises NIAID and the study investigators for some Phase I and most Phase II trials. The primary responsibility of the SMC is to monitor participant safety.

4.0 RESPONSIBILITIES

Each *Committee Member or ISM* is responsible for disclosing their COI status prior to their appointment; completing and signing the appropriate certification form; and certifying their COI status before each convened meeting in order to disclose any new/potential COI. If the minimum threshold is exceeded, the member is responsible for declaring the COI (see Appendix 2). Each member must comply with all Institutional and Division policies related to their participation as a committee member or ISM.

Division/Center Director is responsible for evaluating, managing and making the final decision on whether an identified conflict compromises the member's judgment, or is perceived to do so. This determination will be made before appointment as a DSMB/SMC member or ISM; and if the COI threshold is exceeded or if new/potential COIs are identified during the

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course of the appointment. In the event of a conflict, the Director will notify the Committee or Monitoring Board Chair. The Division/Center Director is encouraged to consult with the NIAID Deputy Ethics Counselor if there is uncertainty regarding the existence of a conflict of interest.

Executive Secretary, Committee or Monitoring Board Chair, or designee is responsible for collecting, reviewing, and evaluating COI certification forms in accordance with Divisional standard operating procedures (SOPs). They are responsible for ensuring that members submit updated documentation at least annually, verifying and documenting any COI prior to or at each review meeting, ensuring the acceptable participation level of all conflicted members, and maintaining COI certification forms and any other documentation related to the COI process. In addition, this individual may serve as a liaison between the Board or Committee and the Division/Center Director.

NIH Federal employees must comply with the NIH Policy Manual 2400-04[9] Managing Conflicts of Interests and the Introduction of Bias and the NIH Policy for Data and Safety Monitoring[10]. NIH federal employees may obtain additional information by contacting the NIAID Office of Ethics.

Non-federal employee members responsible for safety monitoring should contact their institutional or contracting office ethics official for additional information on COI requirements.

Each *NIAID Division and Center(s)* will develop written procedures for collecting, reviewing, and evaluating COI certification forms and their retention.

5.0 POLICY

Minimum standards for NIAID Divisions and Center(s) to follow regarding COI practices for data and safety monitoring entities:

5.1 DSMB, SMC, and ISM member COI certification: Member reviews and signs the certification form indicating:

[9] https://policymanual.nih.gov/2400-04

[10] http://grants.nih.gov/grants/guide/notice-files/not98-084.html

5.1.1 He/she does not have any professional, financial, proprietary or other conflict. or

5.1.2 He/she does have a professional, financial, proprietary or other conflict; certification form must be reviewed by the NIAID Division/Center Director for final eligibility determination.

6.1 DSMB, SMC, and ISM documentation management:

6.1.1 Division/Center Director will identify an individual responsible for collecting, evaluating, and maintaining documentation that review of COI has taken place, including documentation of the results of each review. Conflict of interest assessment documents should be maintained or archived per regulatory and/or appropriate records retention requirement timeframes.

6.1.2 Each NIAID Division and Center(s) will develop a written SOP that describes who collects COI information, how often it should be submitted, and how it is maintained.

6.2 DSMB, and SMC permitted levels of participation:

6.2.1 Eligible - May participate in all activities as DSMB or SMC member.

6.2.2 Ineligible - May not participate as DSMB or SMC member.

6.2.3 Consultant - If deemed appropriate by the Division/Center Director or DSMB/SMC vote, may provide expert comments, but may not participate in voting process.

6.3 ISM Permitted levels of participation:

6.3.1 Eligible - May participate in all activities as an ISM.

6.3.2 Ineligible - May not participate as an ISM.

6.0 REFERENCES

The below online information is current as of the effective date of this policy:

NIAID Clinical Research Standards
https://www.niaid.nih.gov/research/niaid-clinical-research-standards

NIAID Policy on Data and Safety Monitoring Board (DSMB) Operations
https://www.niaid.nih.gov/sites/default/files/dsmbpolicyv5.pdf

Code of Federal Regulations, Title 42, Part 50 Responsibility of Applicants for Promoting Objectivity in Research for Which PHS Funding Is Sought
http://grants.nih.gov/grants/policy/coi/fcoi_final_rule.pdf

NIH Policy for Data and Safety Monitoring
http://grants.nih.gov/grants/guide/notice-files/not98-084.html

Code of Federal Regulations, Title 45, Part 46 Protection of Human Subjects
http://www.ecfr.gov/cgi-bin/text-idx?tpl=/ecfrbrowse/Title45/45cfr46_main_02.tpl

Code of Federal Regulations, Title 45, Part 94 Responsible Prospective Contractors
http://grants.nih.gov/grants/policy/coi/fcoi_final_rule.pdf

Code of Federal Regulations, Title 21, Part 54 Financial Disclosure by Clinical Investigators
http://edocket.access.gpo.gov/cfr_2005/aprqtr/21cfr54.5.htm

Code of Federal Regulations, Title 45, Part 73.735-1002 Subpart J--Provisions Relating to Experts, Consultants and Advisory Committee Members
http://edocket.access.gpo.gov/cfr_2002/octqtr/45cfr73.735-1002.htm

A Guide to Preventing Financial and Non-Financial Conflicts of Interest in Human Subjects Research at NIH
https://ohsr.od.nih.gov/public/SOP_21_v4_10-20-15_AppD4-16-16.pdf

OHRP Final Guidance - Financial Relationships and Interests in Research Involving Human Subjects: Guidance for Human Subject Protections
https://www.hhs.gov/ohrp/regulations-and-policy/guidance/financial-conflict-of-interest/

NIH Ethics Program
https://ethics.od.nih.gov/policies.htm

National Academies - Policy on Committee composition and Balance and Conflicts of interest for Committees used in the development of reports
http://www.nationalacademies.org/coi/bi-coi_form-0.pdf

Federal Advisory Committee Act (FACA)
http://oma1.od.nih.gov/manualchapters/management/1810-1/

NIH Policy Manual 2400-04 Managing Conflicts of Interests and the Introduction of Bias
https://policymanual.nih.gov/2400-04

7.0 INQUIRIES/CONTACT INFORMATION

Questions and comments regarding this policy may be directed to NCRS Executive Secretary at ncrsexecsec@niaid.nih.gov

8.0 AVAILABILITY

This policy is available electronically on the NIAID Clinical Research Toolkit at https://www.niaid.nih.gov/sites/default/files/dsmbcoipolicypostexcom.pdf

9.0 CHANGE SUMMARY

This policy supersedes Version 1.0

10.0 APPENDICIES

Appendix 1- Identifying Potential Conflict of Interest for Individuals Serving on Advisory Committees Involved in Data and Safety Monitoring

Appendix 2- Sample Conflict of Interest Statement for Individuals Involved in Data and Safety Monitoring

11.0 REVIEW SCHEDULE/CHANGE SUMMARY

11.1 This policy will be reviewed 6 months after initial approval and every 2 years, and as needed, thereafter.

11.2 Complete the change summary table below when document is revised

Version #	Date	Replaces	Date of Revision	Rationale for Review/Revision/Retirement
2.0	June 11, 2015	1.0	June 11, 2015	• Revisions made with the scheduled 2year review • Section 4.0- Revisions to definition of "proprietary" (content per OTD recommendation), and definition of DSMB (to make it consistent with DSMB operations policy) • Updated links, including link to most recent DSMB operations policy • Minor punctuation and clarity revisions, NIAID logo updated • Section 6.1.1 and 6.1.2 wording changed for improved clarity • (Note: 6 month scheduled review was completed June 17, 2013 at NCRS meeting-no revisions requested at that time)
3.0	April 17, 2017	2.0	April 17, 2017	• Changes were made to update broken links for references.