

# Sample Independent Data Monitoring Committee (IDMC) Charter

(Adapted from National Heart, Lung, and Blood Institute documents and other sources)

## The *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD)



**Official Charter of the  
Independent Data Monitoring Committee for the  
*[Insert Study title]***

***[Insert date]***

***[Insert version number]***

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**Committee Chairperson Name**

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**Committee Chairperson Signature**

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**Date**

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# Charter for the Independent Data Monitoring Committee for the *[insert study title], [insert date]*

## 1. Introduction

This document constitutes the Independent Data Monitoring Committee (IDMC) Charter for the *[insert Study title]*, also referred to by the identifier *[insert Trial Number]*, to be conducted at *[insert locations for the study]* from *[insert Start date]* to *[insert Planned End Date]*.

This Charter is a living document and will be reviewed periodically by the IDMC to determine whether any changes in procedure(s) are needed throughout the duration of the study. All version updates to this document are tracked in the table below.

Version Number	Date Need for Change Was Identified	Details of Change	Date Change was Finalized
1.0		Drafted Initial Charter	

Each member of this IDMC must agree to the terms outlined in this Charter. Each member will sign the *Acceptance of IDMC Terms and Conditions Form* to illustrate this agreement. Once this Charter is finalized, it is to be reviewed in an IDMC meeting, signed by all members, and the signed copies provided to the NICHD Executive Secretary, *[insert name]*, for the study.

## 2. Purpose and Responsibilities of the IDMC

The members of the IDMC identified in this Charter for *[insert Study title]* are responsible for safeguarding the interests of study participants, assessing the safety and efficacy of all study procedures, and shall monitor the overall conduct of the *[insert Study title]*. This Committee will serve as an independent advisory group to the Director of the NICHD and is required to provide recommendations about starting, continuing, and stopping the *[insert Study title]*. The Committee will:

- Review the research protocol, review model informed consent documents, and plans for data and safety monitoring, including all proposed revisions;
- Review methodology used to help maintain the confidentiality of the study data and the results of monitoring by reviewing procedures put in place by investigators to ensure confidentiality;
- Monitor study design, procedures and events that will maximize the safety of the study participants and minimize the risks ;
- Evaluate the progress of the study, including periodic assessments of data quality and timeliness, participant recruitment, accrual and retention, participant risk versus benefit, performance of the study site(s), and other factors that may affect study outcome;
- Consider factors external to the study when relevant information becomes available, such as scientific or therapeutic developments that may have an impact on the safety of the participants or the ethics of the studies;
- Review serious adverse event documentation and safety reports and make recommendations regarding protection of the safety of the study participants;

- Report to the NICHD *[and the study sponsor]* on the safety and progress of the study;
- Evaluate and report to the NICHD *[and the study sponsor]* on any perceived problems with study conduct, enrollment, sample size, and/or data collection;
- Provide to the NICHD *[and the study sponsor]* a recommendation regarding continuation, termination or other modifications of the study based on the cumulative experience including the observed beneficial or adverse effects of the treatment under study;

This Committee is responsible for identifying mechanisms for the completion of various tasks that will impact the safety and efficacy of all study procedures and overall conduct of the study. The table below identifies the key areas for which oversight is necessary and the ways in which the Committee for the *[insert Study title]* will complete those tasks.

Basic Responsibility of IDMC	Method IDMC for the <i>[insert Study]</i> will use to complete task
Familiarize themselves with the study protocol	
Monitor adverse events	
Monitor data quality	
Oversee participant recruitment and enrollment	
Develop an understanding of the Study's risks and benefits	
Ensure the proper reporting occurs	
Review confidentiality procedures	
Recommend study disposition	

### 3. IDMC Members, Organizational Chart, and Communications

#### Members

The IDMC for the *[insert Study title]* is composed of the members listed in the table below. In addition, their high level roles and responsibilities are identified in the table.

Name of Member	Role on IDMC	High Level Responsibilities
<i>[insert name]</i>	Chair of IDMC	<i>[insert basic responsibilities]</i>
<i>[insert name]</i>	Voting member (repeat for all)	<i>[insert basic responsibilities]</i>
<i>[insert name]</i>	Advisory member (repeat for all)	<i>[insert basic responsibilities]</i>

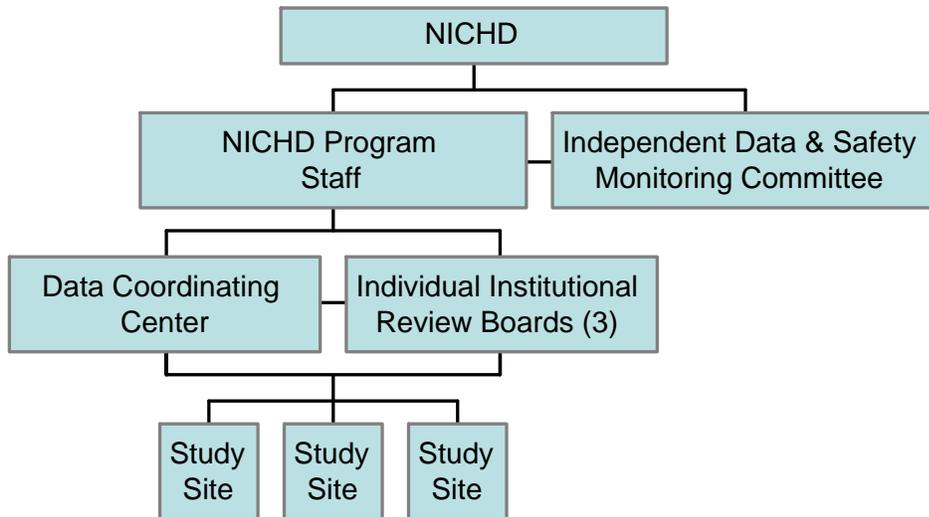
*[Choose one: Only / Both]* Voting members and Advisory members for this IDMC may attend closed sessions for this Committee. In addition, *[choose one: Only / Both]* Voting members and Advisory members will have access to *[specify certain data points if there are restrictions]* for this Committee.

In addition, this IDMC has identified an Executive Secretary (ES) to provide an unbiased staff interface for the IDMC, especially during executive sessions. The ES is responsible for assuring the accuracy and timely transmission of the final recommendations and IDMC minutes.

- *[Insert name]*, Executive Secretary, (ES)

## Organizational Chart

The following diagram illustrates the relationship between the IDMC and other entities in the *[insert Study title]*. *[Insert diagram depicting the relationship of the IDMC and other entities. The diagram should depict lines of communication, review and any hierarchical relationships. Sample is provided below.]*



## Communication

Communication members for this IDMC will be primarily through the NICHD Program Office and, when applicable, the Data Coordinating Center (DCC). Investigators from the *[insert Study title]* will not communicate directly with IDMC members about the study, except when making presentations or responding to questions at IDMC meetings or during scheduled conference calls.

## 4. Conflict of Interest (COI) and Compensation

It is extremely important that all members of the IDMC state any real or apparent COIs at the onset of the study. Members of the IDMC shall read the NICHD Clinical Research Guidance Document regarding COI and will provide their signed summary of any COIs to the ES, *[insert name]* for the study, at its onset. A table summarizing any COI within the IDMC is provided below.

IDMC Member Name	Date Submitted Signed COI Policy	Was a COI Identified?	Will the Member Remain part of the Committee?

Prior to each meeting, all members of the *[insert study name]* IDMC will have an opportunity to state whether they have developed any new COIs since the pervious meeting. As a new COI is

identified, it must be documented in the table above and a new signed summary of the COI should be provided to the ES for the study.

If a new conflict is reported, the Chair and staff will determine if the conflict limits the ability of the IDMC member to participate in the discussion.

All IDMC members *[choose one: will / will not]* be compensated for their role in supporting the committee. Compensation will include *[insert description of compensation]*.

## 5. Scheduling, Quorum, and Organization of Meetings

The purpose of the first meeting for the IDMC for the *[insert Study title]* is to:

- Draft, review, discuss and sign the Charter;
- Provide an overview of *[insert Study title]* activities;
- Review and make recommendations about the study protocol(s); and
- Determine the frequency of interim analyses and whether data will or will not be masked to identity of randomized groups.

In addition to familiarizing the committee with the *[insert Study title]* study at the first meeting, the IDMC will determine logistics for following meetings (both in person and teleconferences), which are documented in the table below.

Meeting / Review Type	Scheduled Time	Purpose	Required Attendees
Kickoff Meeting	Prior to enrollment of study participants	<ul style="list-style-type: none"> <li>• Review charter template and draft Study specific information</li> <li>• Identify data for review at future meetings and how it should be presented at future meetings</li> <li>• Review protocol including review of statistical analysis plan</li> </ul>	All
Regularly scheduled in person meetings	<i>[insert dates or Study milestones]</i>	<i>[insert goals for meetings]</i>	<i>[insert expected attendees]</i>
Regularly scheduled conference calls			
Ad hoc Conference calls			
Review of interim data analyses			
<i>[insert other necessary reviews or meetings]</i>			

It is expected that all IDMC members who are identified in the table above will attend every meeting. However, it is recognized that this may not always be possible. Therefore, the IDMC for *[insert study name]* has established the following quorum for voting. *[Complete as needed: A quorum of this IDMC is considered to be [insert number of members].* Quorum must be reached in order for an item to be voted on.

## **7. Materials and Protocol for IDMC Meetings**

The agenda for IDMC meetings and calls will be drafted by the Data Coordinating Center (DCC) in consultation with NICHD staff. The IDMC Chair will review the finalized agenda prior to distribution to the group.

The agenda and meeting materials will be distributed to the IDMC by the DCC *[insert time period]* before each meeting or call to allow members adequate time to prepare for the meeting. Meeting materials will include the following reports and data:

- Adverse event data
- Other safety data
- Quality and completeness of study data
- Enrollment data
- *[insert additional required reports / data]*

The IDMC will review the above information at each meeting to ensure proper conduct of the study.

### **Meeting Protocol**

IDMC meetings and calls for the *[insert study name]* will be organized into open, closed, and executive sessions. Definitions for each meeting type are included below. The meeting type will be identified by the DCC when it provides the IDMC Chair with the meeting agenda.

- **Open sessions:** Information will be presented to the IDMC by the DCC, study investigators, and NICHD staff as appropriate, with time for discussion.
- **Closed sessions:** The IDMC, DCC, and NICHD staff will discuss confidential data from the study, including information on efficacy and safety by treatment arm.

The IDMC may decide whether to remain masked to the treatment assignments at each meeting. If the closed session occurs on a conference call, steps will be taken to ensure that only the appropriate participants are on the call and to invite others to re-join the call only at the conclusion of the closed session.

- **Executive sessions:** Only the IDMC members and NICHD ES are present to discuss study issues independently. Voting on recommendations will follow Roberts' Rules of Order (Robert's Rules of Order Newly Revised (10th Edition) by Henry M. Robert III, William J. Evans (Editor), Daniel H. Honemann (Editor), Thomas J. Balch (Editor), Sarah Corbin Robert, Henry M. Robert III, General Henry M. Robert).

If the executive session occurs on a conference call, steps will be taken to ensure that only the appropriate participants are on the call and to invite others to re-join the call only at the conclusion of the executive session.

At the conclusion of the closed and executive sessions, all participants will re-convene so that the IDMC Chair can provide a summary of the IDMC's recommendations. This process provides an opportunity for study investigators, the DCC, and NICHD staff to ask questions to clarify the recommendations. The meeting is then adjourned.

## **9. Reporting Requirements for the *[insert study title]* IDMC**

Proper records will be collected at each IDMC meeting to ensure that there is a physical record of any and all decisions and recommendations. The required documentation for IDMC meetings for the *[insert study name]* includes the following:

- **Initial summary:** The NICHD ES is responsible for assuring the accuracy and transmission of a brief summary of the IDMC's discussion and recommendations for the NICHD Director within 48 hours of the meeting or call. The Director or designee will review this summary and approve/disapprove the recommendation(s) or request additional information. The recommendations will then be sent to the DCC and the clinical investigators.
- **Formal minutes:** The NICHD ES is responsible for the accuracy and transmission of the formal IDMC minutes to the NICHD Director within 30 days of the meeting or call. These minutes are prepared to summarize the key points of the discussion and debate, requests for additional information, response of the investigators to previous recommendations, and the recommendations from the current meeting.
- **Action plan:** If the IDMC's recommendations require significant changes or followup, NICHD staff and the DCC will collaborate to prepare an action plan outlining the steps required to implement the recommendations.

*[Insert review process for meeting minutes; a sample review process for meeting minutes is as below]*

Minutes will be reviewed by NICHD staff, key study personnel, and the DCC before being forwarded to the IDMC Chair for final review and approval. The IDMC Chair may sign the minutes or indicate approval electronically via e-mail. Then, the minutes are sent to the NICHD Office of the Director approval. Subsequently, the minutes are sent back to the DCC and the relevant investigators and are included in the materials for the subsequent IDMC meeting to be approved by voice vote at that meeting. Once they have been voted and approved by the Board, they are considered final and archived with other IDMC documentation.

## 10. Reports of IDMC Proceedings for IRBs

*[Section can be removed if this is not a multi-center study]*

If an IDMC is convened for a multi-center study, this Committee is required to submit reports to IRBs at each of the participating sites. The participating sites for this study are outlined in the table below.

Site of Study	Point of Contact at each Clinical Site for Reporting
<i>[insert study site]</i>	<i>[Insert point of contact at Study site for reporting]</i>

If the IDMC does not identify any safety or other protocol-related concerns within 30 days after a IDMC meeting, the NICHD Program Officer will prepare a summary report stating that:

- A review of outcome data, adverse events, and information relating to study performance (for example, data timeliness, completeness, and quality) across all centers took place on *[insert date of meeting]*; the observed frequency of adverse events did not exceed what was expected and indicated in the informed consent;
- A review of recent literature relevant to the research took place; and
- The IDMC recommended that the study continue without modification of the protocol or informed consent.

If concerns are identified, the report to the clinical centers will outline those concerns, the IDMC discussion of the concerns, and the basis for any recommendations that the IDMC makes in response to the concerns.

The report will be distributed by the *[insert appropriate party]* to each clinical center involved in the study. It is the responsibility of each clinical center to forward this information to the local IRB.



# Conflict of Interest Statement

I, \_\_\_\_\_, assuming the role of \_\_\_\_\_

(Insert role, for example: IDMC member)

for the \_\_\_\_\_

(Insert project or study name)

agree to the following statements.

I agree to:

- Protect the interests and safety of study participants;
- Uphold the integrity of the research process, including data collection and analysis, to be as free from bias and preconception as I am able;
- Adhere to the highest scientific and ethical standards, comply with all relevant regulations, and eliminate or disclose, during my involvement with the proposed clinical research project, any real or apparent conflicts of interest.

In addition:

I declare that I, my spouse or dependent children, or organization with which I am connected, **[select one: do/does not]** have any financial interest in the \_\_\_\_\_ study, where financial interested is defined by the U.S. Department of Health and Human Services (DHHS), as anything of monetary value, including but not limited to, salary or other payments for services (for example, consulting fees or honoraria); equity interests (for example, stocks, stock options or other ownership interests); and intellectual property rights (for example, patents, copyrights and royalties from such rights).

The financial interest term does not include various items which can be found in The Federal regulation, Public health Service (PHS), DHHS Part 50: Policies of General Applicability, Subpart F: *Responsibility of Applicants for Promoting Objectivity in Research for Which PHS Funding Is Sought*.

For federal employees, financial interests that are allowable and require disclosure are:

Financial Interest Disclosure: *Financial interest that require disclosure are stock holdings in pharmaceutical firms, medical device manufacturers, and biotechnology companies*

Allowable Financial Interests: *In a company that produces a product that is being evaluated by a study, participants may hold up to \$15,000 of stock: and, up to an aggregate of \$25,000 of the stock of that company and its competitors who produce that (or a similar) product. As an alternative to individual stock holdings, participants may hold up to an aggregate of \$50,000 in sector mutual funds-including pharmaceutical/health care sectors.*

*For holdings in excess of these de minimus levels, a conflict of interest analysis needs to be conducted by NIH regarding the holding, the company producing the product being evaluated under the study, and its competitors, and, if a conflict exists, could lead to the need to withdraw from the study.*

I agree not to withhold any data related to the \_\_\_\_\_ study or to interfere with the analysis or publication of the study's results.

I will not engage in activities that could be viewed as real or apparent conflict of interest, including but not limited to:

- Having a part-time, full-time, paid, or unpaid employee status of any organizations that are: (a) involved in the study under review; (b) whose products will be used or tested in the study under review, or whose products or services would be directly and predictably affected in a major way by the outcome of the study;
- Being an officer, member, owner, trustee, director, expert advisor, or consultant of such organizations;
- Being a current collaborator or associate of the principal investigator (applicable to potential members of data safety and monitoring boards);
- Having a scientific interest beyond that required for my role, for which scientific interest is defined as having influence over the protocol, the study design, conducting the study analysis, or any reporting related to the investigation (applicable to potential members of data safety and monitoring boards).

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Signature

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Printed Name

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Date

## ***Independent Data Monitoring Committee Confidentiality Agreement***

I understand that I will be provided with information from the Data Coordinating Center and/or study sites or similar organizations for the *[insert Study title]*, including proprietary and confidential information.

I understand that I will have access to these records in order to participate in the Independent Data Monitoring Committee for the *[insert Study title]*.

In my role as the \_\_\_\_\_, *[insert Committee role]*, I \_\_\_\_\_, *[insert name]* hereby agree that I shall not release, publish, or reproduce these records. I further agree that I shall not make any use of these records except for the limited purpose of participation in the Independent Data Monitoring Committee for the *[insert Study title]*.

I will take reasonable precautions to prevent access by any other persons to these confidential records or to work products that result from review of those records. I will retain any confidential documentation until the conclusion of the study and will return the documents and all related materials to the Executive Secretary for this study.

I have read the terms of this agreement and agree to abide by its terms.

Signed: \_\_\_\_\_ Date: \_\_\_\_\_

[Name], [Title]