



Tool Summary Sheet

Tool: IMC Charter Template

Purpose: MS Word template to be used as a starting point for preparing a IMC Charter

Audience/User: IMC Chair or designee responsible for preparation of IMC Charter

Details: This template includes a proposed structure for a IMC Charter as well as draft language and other guidance.

Best Practice Recommendations:

- Review this template and customize to the specific needs and requirements of the IMC. Sample text may be updated as needed.
- In the template, the instructions and explanatory text are indicated by *{blue italics}*. Instructional text will also be enclosed in braces to signify this text for screen-readers used by the visually impaired.
- Text enclosed with <> is a placeholder for a specific detail (e.g., <protocol title>); replace as appropriate.
- Delete template-specific *instructional text* as well as this Tool Summary Sheet during the Charter development process.
- Leave the template version information in the lower left hand corner of the document.
- It is easiest and cleanest to use the styles that are embedded in the document, rather than to create your own. (In MS Word 2010: From the Home menu, select the bottom right arrow key to bring up the styles box, select “Options”, under “Select Styles to Show” select “in current document”.)
- Ensure that all placeholder and example text is replaced with the study specific information.
- A IMC may be constituted for a single protocol or for a clinical area. Update this document to reflect this distinction.

Tool Revision History:

Version Number	Version Date	Summary of Revisions Made:
1.0	13Apr2016	IMC-specific version of DSMB Charter Template v1.0

INDEPENDENT MONITORING COMMITTEE CHARTER

<Insert protocol title here>

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PI NAME	<Insert PI Name(s) here>
NAME OF SPONSOR:	National Center for Complementary and Integrative Health (NCCIH)
PROTOCOL NUMBER: <i>{Remove this row if the IMC is responsible for multiple studies}</i>	<Insert protocol number>
DATE OF CHARTER:	<Version x.x; Date Charter is issued>

CONFIDENTIAL

This is an NCCIH document that contains confidential information. Nothing herein is to be disclosed without written consent.

Note: This Charter will serve as the Standard Operating Procedure (SOP) for the IMC

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1 INTRODUCTION

The following document summarizes National Center for Complementary and Integrative Health (NCCIH) guidelines concerning the establishment, responsibilities, and operating procedure of Independent Monitoring Committees (IMC).

The IMC will act in an advisory capacity to NCCIH and grantee institution to monitor patient safety, and the performance of the clinical study in meeting its stated objectives. [PI/network], [institution], is conducting a clinical study entitled, [name of study]. This study is being funded by the NCCIH.

2 IMC RESPONSIBILITIES

The initial responsibility of the IMC will be to approve the initiation of this clinical study. After this approval, and at periodic intervals during the course of the study, the IMC responsibilities are to:

- review the research protocol, informed consent documents and plans for data safety and monitoring, including all proposed revisions;
- 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, the ethics of the study or a subject's willingness to participate;
- protect the safety of the study participants;
- report on the safety and progress of the study;
- make recommendations to the NCCIH, the Grantee Institution, the Principal Investigator (PI), and, if required, to the Food and Drug Administration (FDA) and the Institution Review Board (IRB) concerning continuation, termination or other modifications of the study;
- if appropriate, conduct interim analysis of efficacy in accordance with stopping rules which are clearly defined in advance of data analysis and have the approval of the NCCIH and the IMC;
- ensure the confidentiality of the study data and the results of monitoring;

- assist the NCCIH by commenting on any problems with study conduct, enrollment, sample size and/ or data collection

3 MEMBERSHIP

The IMC will consist of at least [#] members. [#] members will constitute a quorum. The members have been approved by the NCCIH and will include at least one member with human subject research monitoring expertise, at least one member with relevant disease expertise (such as an M.D. or equivalent), at least one member with expertise in the intervention or observation technique under study, and a Ph.D.-level biostatistician.

Members of the IMC shall have no financial, scientific, or other conflict of interest with the study. Current or past (within 3 years) collaborators, including any individual involved in the design, conduct or analysis of the study, associates and direct reports of the PI are not eligible to serve on the IMC.

Dr. [name] of the [institution] has been selected to serve as the IMC Chair.

The safety officer, [name] M.D., will be the contact person for any safety issues related to the study, including adverse event reporting.

4 COMMITTEE PROCESS

The IMC will meet a minimum of once a year at the call of the Chair.

Meetings shall be closed to the public because discussions may address confidential patient data. Meetings are attended, when appropriate, by the study principal investigators (PI(s)) and members of the study team. Meetings may be convened as conference calls as well as in person. An emergency meeting of the IMC may be called at any time by the Chair or by NCCIH should questions of patient safety arise.

5 MEETING FORMAT

An appropriate format for IMC meetings may consist of an open and a closed session. This format may be modified as needed.

5.1 Open Session:

The open sessions are attended by the IMC, study PI (s), and study team members, including the study biostatistician. The IMC may limit the number of non-board members in attendance. The number of non-IMC members in attendance should be limited, as they are observers to the proceedings, so as not to overwhelm free and open exchange among IMC members. Occasionally, NCCIH Program Official (s) for the study will attend open sessions. Issues discussed in open sessions usually include conduct and progress of the study, including patient

accrual, compliance with protocol, general safety issues, and any other problems encountered. **Patient-specific data and treatment group data will not be presented in the open session.**

5.2 Closed Session:

Closed sessions are attended by the IMC. NCCIH staff participation in closed sessions when unmasked data will be discussed is restricted.

All study progress and safety data, as well as planned interim analyses are presented at this session. The IMC may choose to review masked group data, or may request review of unmasked data during the study. Access to unmasked data must be limited to IMC members and a small group of additional individuals who are to be determined at the onset of the study. Generally, these data are prepared by and presented to the IMC by the unmasked study biostatistician. The discussion at the closed session is completely confidential.

5.3 Executive Session:

Executive sessions are attended by the IMC members. On occasion, and by request, the IMC Chair may request other NCCIH Staff participate in the Executive Session. The IMC Chair will record minutes/recommendations during the executive session. In the executive session, the IMC will discuss the general conduct of the study and all outcome results, including adverse events. IMC recommendations are developed and finalized in the executive session.

The IMC will discuss information presented during the closed and open sessions and provide comments and recommendations regarding study progress and continuation. The IMC will specifically discuss whether to recommend continuation or termination of the study. The IMC will also discuss whether protocol modification or other changes should be implemented in the study.

Should an IMC member make a recommendation for study termination, a full vote of the IMC will be required. The final results of the vote will be presented to the Grantee Institution and to NCCIH for consideration. In the event of a split vote, majority vote will rule and a minority report should be appended. Reasons for early termination include:

- Serious adverse effects in entire intervention group or in a dominating subgroup;
- Greater than expected beneficial effects;
- A statistically significant difference by the end of the study is improbable;
- Logistical or data quality problems so severe that correction is not feasible.

5.4 Final Open Session (optional):

The final session may be attended by voting IMC members, the study PI(s), the study biostatistician or other study members, and NCCIH staff (if applicable).

The Chair of the IMC shall report on the recommendations of the IMC regarding study continuation and concerns regarding the conduct of the study. Requests regarding data presentation for subsequent meetings will be made. Scheduling of the next IMC meeting may also be discussed.

6 DATA PRESENTATION

At the first IMC meeting, the IMC Chair will inform the study team regarding their preference for the format of the closed report (data may be presented by either masked intervention groups (e.g. Group A vs. Group B) or in an unmasked fashion). The IMC may routinely review data in a masked fashion to prevent any potential compromise to the study blind. The IMC may request access to unmasked data throughout the duration of study oversight, on a one time or continuous basis. The IMC can request unmasking by the unmasked study statistician if a majority vote of the IMC agrees that data trends warrant further information on group assignment. Generally, these data would be prepared by and presented to the IMC by the unmasked study biostatistician. Discussion and deliberation of the unmasked data should be limited to members of the IMC only with select attendance by unmasked members of the study team, as requested.

7 REPORTS

7.1 Interim Reports:

Interim reports will be prepared by the study team. The reports will be distributed to the IMC at least 10 days prior to a scheduled meeting. The contents of the report are determined by the IMC. Additions and other modifications to these reports may be directed by the IMC on a one-time or continuing basis. Interim data reports generally consist of two parts:

7.1.1 Part 1 (Open Session Report)

This report provides information on study aspects such as accrual, baseline characteristics, and other general information on study status. This report is generally shared with all investigators involved with the clinical study. The reports contained in this section will include:

- o Comparison of Target Enrollment to Actual Enrollment by Month
- o Overall Subject Status by Site, including: Subjects Screened, Enrolled, Active, Completed and Terminated
- o Demographic and Key Baseline Characteristics by Group
- o Treatment Duration for Subjects who Discontinue Therapy
- o Unanticipated Problems/Adverse Events/Serious Adverse Events by Site and Subject

7.1.2 Part 2 (Closed Session Report)

This report may contain data on study outcomes (if pre-specified and approved by NCCIH and the IMC), safety data, serious adverse events or termination. Data will be presented by masked treatment groups; however, the IMC may request that the treatment groups be unmasked. The Closed Session Report is confidential and should be destroyed at the conclusion of the meeting. Data files to be used for interim analyses should have undergone established editing procedures to the extent possible. **This report should not be viewed by any members of the clinical study team, except the designated unmasked study statistician who prepared the report.**

8 REPORTS FOR THE IMC

A formal report containing the recommendations for continuation or modifications of the study, prepared the IMC, will be sent to the study PI (s). It is the responsibility of the study PI (s) to distribute this report to all co-investigators and the NCCIH and to ensure that copies are submitted to all the IRBs associated with the study.

Each report should conclude with a recommendation to continue or to terminate the study. This recommendation should be made by formal majority vote. A termination recommendation may be made by the IMC at any time by majority vote. In the event of a split vote in favor of continuation, a minority report should be contained within the regular IMC report. The report should not include unmasked data, discussion of the unmasked data, or any other confidential data.

9 MAILINGS TO THE IMC

On a scheduled basis, [usually on a quarterly basis] (as agreed upon by the IMC) masked safety data should be communicated to all IMC members and the designated safety officer.

10 NCCIH CONTACT FOR IMC QUESTIONS AND COMMENTS

IMC Member and Safety Officer concerns related to the conduct of the study may also be directed to the assigned NCCIH Program Official

11 CONFIDENTIALITY

All materials, discussions and proceedings of the IMC are completely confidential. Members and other participants in IMC meetings are expected to maintain confidentiality.

APPENDIX A: IMC Member Signature Page

Member Information

Role: IMC Chair _____ Member _____

Voting Rights: Yes _____ No _____

Name:

Affiliation:

Phone:

Fax:

E-mail address:

Re: IMC Charter Version Date: _____

I have reviewed the attached IMC Charter and approve it as written. I understand my role as a member of this IMC.

Signature: _____ **Date:** _____

{Due to the geographically dispersed IMC, a separate signature page will be issued and collected from each IMC member.}

APPENDIX B: Dynamic References List

{If used, this section includes a list of documents that are maintained and updated separately from this Charter but are referenced herein. For example, the Membership list could be maintained as a dynamic reference. If dynamic references are not used, please delete this section.}