National Center for Complementary and Integrative Health

Tool Summary Sheet

Tool: Independent Monitoring Committee (IMC) Report Template

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

Audience/User: Statisticians and Principal Investigators responsible for preparation of IMC reports

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

Best Practice Recommendations:

- Review this template several months prior to the date of the first IMC meeting, and customize to the specific needs and requirements of the study.
- 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 report 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 2007: 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.

Tool Revision History:

Version Number	Version Date	Summary of Revisions Made:
1.0	13Apr2016	First approved version

INDEPENDENT MONITORING COMMITTEE REPORT

PROTOCOL TITLE: <Insert title of the protocol>

PROTOCOL NUMBER: <Insert protocol number>

PROTOCOL VERSION: <Insert version number and date of current protocol>

PRINCIPAL INVESTIGATOR: <Name of PI
PI's Title
Institution
Address>

MEETING DATE: <Insert date of the scheduled meeting>

DATE REPORT ISSUED: <Insert date that the report is being issued>

DATA CUTOFF DATE: <Insert the date of the data snapshot for the analyses in this report>

DATE OF LAST DATA REVIEW: <Insert date of last IMC meeting>

PREPARED BY: <Name of person who prepared the report
Person's Title
Place of employment
Address>

Table of Contents

{This table uses the Table of Contents function in Microsoft Word that will automatically update headings and page numbers used in the body of the report. In the body of the report, add, delete, or modify headings as needed in order to best reflect your study.}

Executive Summary

{Add, delete, or modify summary topics as needed.}

Report Overview	*{Example text:}* This report reviews enrollment and safety data available in the study database as of April 19, 2015. Summary tables are provided in the body of the report. Additional tables and figures referenced in the report are provided in the Appendices.
Study Site Status	*{Example text:}* Two of the 3 study sites have been activated. The third will be activated this month.
Enrollment Status	*{Example text:}* • 100 subjects have been screened for this study. • 20 subjects have been enrolled.
Subject Status	*{Example text:}* • 5 subjects are awaiting dosing. • 5 subjects have completed Month 1 follow-up. • 5 subjects have completed Month 2 follow-up. • 5 subjects have completed the protocol. • No treated subjects have been discontinued (withdrawn) from the study.
Stopping Rules **<or Halting Rules or Suspension Guidelines>** *{Use terminology that matches the protocol throughout this report}*	*{Example text:}* No stopping rules have been met since the previous IMC review. Or There are no new “Alerts” since the previous IMC review.

Safety Summary	*{Example text:}* • 100 adverse events have occurred in 7 subjects. • 50 adverse events were reported in the previous IMC report. • There have been no additional serious adverse events since the last IMC meeting. • Of the 50 adverse events, all were considered either mild or moderate.
Protocol Deviations	*{Example text:}* • 50 protocol deviations associated with 5 subjects have been reported. • None of the deviations has impacted subject safety. • 5 deviations have impacted scientific integrity
Quality Management	*{Example text:}* Quality management reviews are performed quarterly and were last completed on July 8, 2015 and October 7, 2015.

Protocol Synopsis

{Add, delete, or modify protocol headings as required. Enter appropriate information in second column; some clarification guidance has been provided.}

Protocol Title	<Insert protocol title>
Principal Investigator	<Insert name of Principal Investigator>
Study Sites	<List name of each study site>
Study Activation Date	<Insert activation date of first site>
Planned Accrual	<Insert planned number of participants to be enrolled>
Planned Accrual Period	<Insert time (months, years, etc.)>
Planned Duration	<Insert time from first participant-first visit to last participant-last visit (months, years, etc.)>
Study Design	<Briefly describe study design>
Study Objectives	<Briefly describe study objectives>
Treatment Description	<Briefly describe study treatment(s)>
Inclusion Criteria	<List inclusion criteria>
Exclusion Criteria	<List exclusion criteria>
Study Outcomes	<Briefly describe study outcomes>
Study Stopping Rules <or Halting Rules or Suspension Guidelines> *{Use terminology that matches the protocol throughout this report. Replace headings as appropriate.}*	<Clarify stopping rules or suspension guidelines>

{Add, delete, or modify headings as needed in order to best reflect your study. Place summary tables, listings, and figures within the body of the report; however, if the tables, listings, or figures are long, place them in the Appendices. For small numbers of subjects, listings may be more appropriate than summary tables.}

1.0 REPORT OVERVIEW

{Example text:}

The purpose of this report is to review cumulative enrollment and safety data for the subjects enrolled in the Excellent study. This report reflects data from the study database as of April 19, 2015. Within the body of the report are summary tables of enrollment, demographic characteristics, and adverse events. Additional tables, listings, and figures referenced in this report are provided in Appendices A-C. There have been five IMC meetings for this study, and the last review was on April 10, 2014. At that time, the IMC concluded that the available safety data supported the continuation of the trial. Readers of this report are asked to maintain the confidentiality of the information provided in this report.

2.0 RESPONSE TO MOST RECENT IMC RECOMMENDATIONS/REQUESTS

{Identify IMC recommendations/requests from the last meeting and clarify how those requests have been handled in the report and/or elsewhere. If this is the first IMC meeting for this protocol or no previous recommendations/requests were made, indicate as such in this section. Doing so will provide a future reminder to the author who is likely to use the previous report as a starting point for the subsequent report.}

3.0 ENROLLMENT STATUS

{Describe enrollment and provide a summary table (see example below). Provide enrollment statistics by site if the study involves multiple sites. If the study is enrolling, provide the subject accrual target and estimated time to completion of enrollment. A figure showing expected/planned versus actual enrollment is helpful (see example on next page).

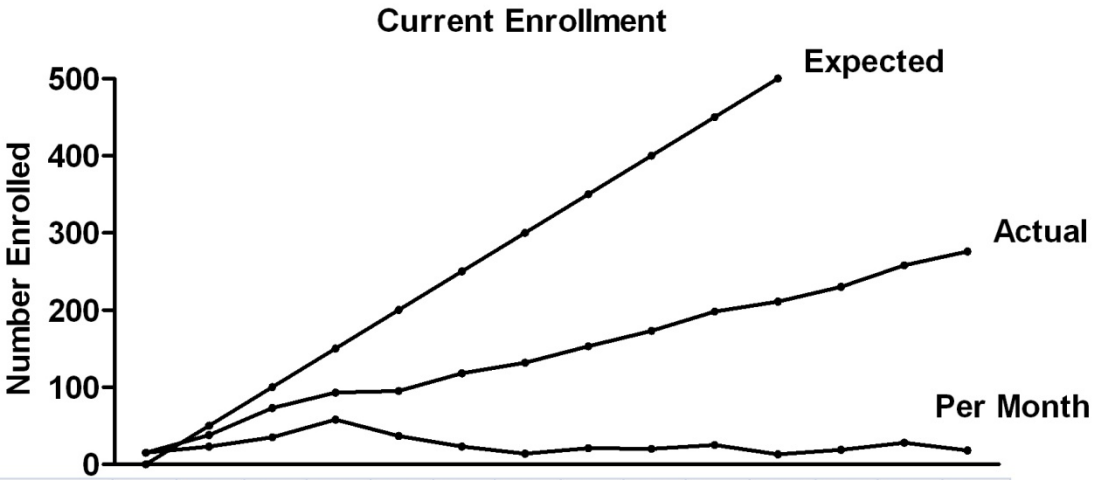
Sample Table:}

Table #. Subject Enrollment Status for All Subjects

Type	Site A	Site B	Total
Pre-Screened	100	100	200
Consented and Screened	50	50	100
Eligible	35	40	75

{Sample Figure:}

Figure #. Expected versus Actual Accrual



	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
Expected	0	50	100	150	200	250	300	350	400	450	500			
Actual	15	38	73	93	95	118	132	153	173	198	211	230	258	276
Per Month	15	23	35	58	37	23	14	21	20	25	13	19	28	18

4.0 SUBJECT STATUS

{Describe where patients are in the study in relation to major milestones, such as the number of subjects who have completed the baseline visit, the dosing visit, year 1 follow-up, and the final study visit. A summary table providing the study milestones and the number of subjects who have completed those milestones is recommended.

Also, provide the number of subjects who were terminated and the reason for their termination, such as voluntary withdrawal, death, lost to follow-up, adverse event, or completed the protocol. A summary table of subject disposition is also recommended. For some protocols, it is important

to distinguish between subjects who withdrew early from the study and those who discontinued treatment but may or may not still be followed.}

5.0 DEMOGRAPHICS (AND BASELINE CHARACTERISTICS IF APPROPRIATE)

{Describe the demographic characteristics (age, race, and ethnicity) and key baseline characteristics of enrolled subjects (if appropriate). Provide a summary table (see example on the next page) or a listing of the data. Listings are preferable over summary tables if only a few subjects have been enrolled. However, avoid listing any information that could potentially lead to the identification of a participant.

Sample Listing:}

Listing #. Listing of Demographic Information for All Consented Subjects

Subject ID	Age (yrs)	Gender	Race	Ethnicity
001	60	Female	Black	Not Hispanic or Latino
002	65	Female	Black	Not Hispanic or Latino
003	64	Male	White	Hispanic or Latino
004	72	Male	White	Not Hispanic or Latino
005	45	Male	Alaskan Native	Not Hispanic or Latino
006	70	Male	White	Not Hispanic or Latino

6.0 SAFETY SUMMARY

6.1 Stopping Rules

{List and describe any stopping rules that have been triggered since the previous IMC report and over the course of the study.}

6.2 Deaths

{List and describe any deaths that have occurred since the previous IMC report and over the course of the study.}

6.3 Unanticipated Problems

{Summarize or list unanticipated problems. The Office for Human Research Protections (OHRP) considers unanticipated problems, in general, to include any incident, experience, or outcome that meets all of the following criteria:

1. *Unexpected (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the protocol-related documents, such as the IRB approved research protocol and informed consent document, and (b) the characteristics of the subject population being studied;*
2. *Related or possibly related to participation in the research (in this guidance document, possibly related means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research); and*
3. *Suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.*

OHRP notes that an incident, experience, or outcome that meets the three criteria above generally will warrant consideration of substantive changes in the research protocol or informed consent process/document or other corrective actions in order to protect the safety, welfare, or rights of subjects or others.}

6.4 Adverse Events

{Summarize or list the adverse events (AEs) that have occurred since the previous IMC report and over the course of the trial. Provide information on severity and relatedness to treatment and study procedures (see an example of a summary table below). Please ensure that categories summarized match those in the protocol. For instance related/unrelated vs. the 5 category delineation.

In addition, a summary table or listing of subjects experiencing adverse events by treatment group, system organ class, and preferred term should be considered. Extensive listings may be placed in the Appendix.

Sample Table:}

Table #. Summary of All Adverse Events for Consented Subjects

Topics	Site A	Site B	Total N=12
Number of AEs reported	38	30	68
Number of Subjects with AEs [1]	4	3	7
Number of SAEs reported	1	0	1
Number of Subjects with SAEs [1]	1	0	1
Number of AEs by Severity*	**Site A**	**Site B**	0

Topics	Site A	Site B	Total N=12
Mild	31 (81.1%)	24 (80.0%)	55 (80.9%)
Moderate	7 (18.9%)	3 (10.0%)	10 (14.7%)
Severe	0 (0.0%)	3 (10.0%)	3 (4.4%)
Subjects with AEs by Severity [2]**			
Mild	4 (100.0%)	3 (100.0%)	7 (58.3%)
Moderate	3 (100.0%)	2 (66.7%)	5 (41.7%)
Severe	0 (0.0%)	1 (33.3%)	1 (8.3%)

Number of AEs by Relatedness to Treatment*	Site A	Site B	Total N=12
Unrelated	25 (64.9%)	23 (76.7%)	48 (70.6%)
Unlikely	9 (24.3%)	4 (13.3%)	13 (19.1%)
Possible	4 (10.8%)	3 (10.0%)	7 (10.3%)
Probable	0 (0.0%)	0 (0.0%)	0 (0.0%)
Definite	0 (0.0%)	0 (0.0%)	0 (0.0%)
Subjects with AEs by Relatedness to Treatment [2]**	**Site A**	**Site B**	**Total N=12**
Unrelated	4 (100.0%)	3 (100.0%)	7 (58.3%)
Unlikely	3 (100.0%)	2 (66.7%)	5 (41.7%)
Possible	2 (66.7%)	2 (66.7%)	4 (33.3%)
Probable	0 (0.0%)	0 (0.0%)	0 (0.0%)
Definite	0 (0.0%)	0 (0.0%)	0 (0.0%)
Number of AEs by Relatedness to Study Procedures	**Site A**	**Site B**	**Total N=12**
Unrelated	26 (67.6%)	21 (70.0%)	47 (69.1%)
Unlikely	5 (13.5%)	4 (13.3%)	9 (13.2%)
Possible	4 (10.8%)	4 (13.3%)	8 (11.8%)
Probable	1 (2.7%)	1 (3.3%)	2 (2.9%)
Definite	2 (5.4%)	0 (0.0%)	2 (2.9%)
Subjects with AEs by Relatedness to Study Procedures [2]**	**Site A**	**Site B**	**Total N=12**
Unrelated	4 (100.0%)	3 (100.0%)	7 (58.3%)
Unlikely	2 (66.7%)	2 (66.7%)	4 (33.3%)
Possible	3 (100.0%)	3 (100.0%)	6 (50.0%)
Probable	1 (33.3%)	1 (33.3%)	2 (16.7%)
Definite	2 (66.7%)	0 (0.0%)	2 (16.7%)

[1] Subjects who experience one or more AEs or SAEs are counted only once.
[2] Subjects are counted only once within a particular severity grade or relatedness category.
*** Percentages are based on number of AEs reported for each treatment group.**
**** Percentages are based on N for each treatment group.**

6.5 Serious Adverse Events

{Summarize or list all serious adverse events (SAEs) that have occurred since the previous IMC report and over the course of the trial. Provide information on expedited reports, and include MedWatch forms in the Appendix if applicable.}

6.6 Laboratory Findings

{Summarize results from any clinical laboratory tests that are being monitored for subject safety. Laboratory results may be presented as summary tables, listings by subject, or plots. Depending on the study, identify by subject any significant changes from baseline, results that are clinically significant, or results that are considered adverse events.}

6.7 Other Clinical Tests

{You may list types of tests, such as imaging or physical examinations, as separate headings.

Summarize any other clinical tests that are being monitored for subject safety. Depending on the study, identify by subject any significant changes from baseline, results that are clinically significant, or results that are considered adverse events.}

7.0 PROTOCOL DEVIATIONS

{Summarize or list protocol deviations that have occurred since the previous IMC report and over the course of the study.}

8.0 QUALITY MANAGEMENT

{Provide details regarding quality management activities completed since the last IMC review, including frequency. Summarize or list findings and identify measures or corrective actions taken to address the findings or issues.}

9.0 OUTCOMES DATA

{As a general rule, interim results should not be performed or presented unless interim analyses are described in the protocol or the IMC has requested an interim analysis to assess a safety concern or study futility. The decision whether or not to present interim or final results in this report, or to present results in an open or closed session, should be discussed with the IMC and the study sponsor.}

Appendix A: Additional Summary Tables

{It is likely that these Appendices will originate as separate electronic files created by SAS or some other statistical software. If you are creating an electronic version of the full report, use Adobe pdf (or equivalent) to combine the files with this document in a "published" Adobe report. It is very useful to include a Table of Contents or, at a minimum, a list of items contained within each Appendix (e.g., a list of table numbers and names).

Page numbering of the contents of the Appendices are at the discretion of the document owner. Each Appendix file can 1) begin at page 1 or 2) can be numbered contiguously with this document. The second option is advantageous but more difficult to achieve.

A subset of these items may also have been inserted into the report. It is acceptable to also include those items in the corresponding appendix. All other displays that are not inserted into the body of the report should be included herein. It is good practice to ensure that all post-text displays are referenced somewhere in the body of the report.

Include post-text Summary Tables here.}

Appendix B: Additional Figures

{Include post-text Figures here.}

Appendix C: Additional Data Listings

{Include post-text Data Listings here.}