Tool **Summary** Sheet

|  |  |
| --- | --- |
| Tool: | CSOC Report Template for Clinical Studies |
| Purpose: | MS Word template to be used as a starting point for preparing a CSOC report  |
| Audience/User: | Statisticians and Principal Investigators responsible for preparing CSOC reports |
| Details: | This template includes a proposed structure for a CSOC report as well as draft language and other guidance.  |
| Best Practice Recommendations: | * Review this template several months prior to the date of the first CSOC 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} (“CROMS\_Instruction” style). 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 | 04May2011 | Approved version. |
| 2.0 | 28Nov2011 | NIDCR updates to better reflect reporting for non-interventional clinical studies |
| 3.0 | 04Jan2012 | Removed ‘Non-Interventional’ from title and added a Protocol Synopsis line item for describing the intervention if applicable. |
| 4.0 | 21Apr2014 | Revised instructional text for UPs to include AE/SAEs if applicable; corrected numbers in sample Enrollment tables; and added QM to Executive Summary and as a report section. |

CLinical STUDY Oversight COmmittee Report
FOR CLINICAL STUDIES

|  |  |
| --- | --- |
| Protocol Title: | <Insert title of the protocol> |
| Protocol Number: | <Insert protocol number> |
| PROTOCOL VERSION: | <Insert version number and date of current protocol> |
| Principal Investigator(s): | <Name of PIPI’s TitleInstitutionAddress> |
| 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 CSOC meeting>  |
| prepared by: | <Name of person who prepared the reportPerson’s TitlePlace of employmentAddress> |

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.}

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Protocol Synopsis

|  |  |
| --- | --- |
| Protocol Title | <Insert protocol title> |
| Principal Investigator | <Insert name of Principal Investigator> |
| Specific Study Aims | <List specific aims of the study> |
| Study Design | *{Describe study design using the criteria below. Refer to ClinicalTrials.gov* [*http://prsinfo.clinicaltrials.gov/definitions.html*](http://prsinfo.clinicaltrials.gov/definitions.html) *for additional information on data element definitions.}* |
| * **Study Model**
 | *{What is the primary strategy for participant identification and follow-up? Select which best fits the study structure: cohort, case-control, case-only, case-crossover, ecological or community study, family-based, or other (explain). Include number of study groups or cohorts.}* |
| * **Outcome Measures**
 | *{Specify primary and/or secondary outcome measurement(s) or observation(s) used to describe the patterns of disease, traits or associations with exposures or risk factors which are the focus of the study. If appropriate to study design, you may wish to include independent and dependent study variables.}* |
| * **Time Perspective**
 | *{What is the temporal relationship between the observation period and time of participant enrollment? Is the study prospective, retrospective, cross-sectional or other (explain)?}* |
| * **Enrollment**
 | *{What is the participant target enrollment - per site and study total?}*  |
| * **Inclusion Criteria**
 | <List inclusion criteria> |
| * **Exclusion Criteria**
 | <List exclusion criteria> |
| * **Intervention**
 | *{Describe intervention if there is an intervention}* |
| * **Biospecimens**
 | *{List each type of biospecimen (e.g., saliva, fixed/frozen tissue, and/or plasma) to be or being collected. Indicate the purpose for each sample type (e.g., Saliva is being collected for DNA extraction.). Will biospecimen be retained for future research?}* |
| Study Sites | <List name of each study site> |
| Study Activation Date | <Insert activation date of first site> |
| 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.)> |

Executive Summary

|  |  |
| --- | --- |
| **Key Issues for CSOC Meeting Discussion** | {Summarize key issues or questions you would like to discuss with the CSOC. If needed, further elaboration of these issues or questions may be provided within the body of the report as appropriate.} |
| **Study Site Status** | {Example text:}Two of the three study sites have started recruitment. The third will start this month. |
| **Enrollment and Retention Status** | {Include number enrolled and percent of target enrollment. If appropriate, include the same information for retention. Specify study groups, if relevant, (e.g., case-control or adult-child).Example text:} 276 participants, 176 cases and 100 controls, have been enrolled (55% of target enrollment) with 100% retention at 6 months.  |
| **Status of Outcome Measures and Biospecimens** | {Briefly summarize status of biospecimens and key outcome measures. Example text:} Key outcome measures were collected from 98% of enrollees; 99% meet quality control standards. Details are provided in Section 5. |
| **Major Protocol Changes Since Last CSOC** | {Specify yes or no. If yes, briefly describe major protocol changes and why such changes occurred.} |
| **Unanticipated Problems** | {Briefly summarize any unanticipated problems (and AEs/SAEs if they are collected for this study). Example text:} No unanticipated problems (UPs) have occurred.Eight adverse events have occurred in 2 subjects; all were considered mild. No serious adverse events have occurred. |
| **Protocol Deviations** | {Example text:} Three protocol deviations associated with five participants have been reported. Deviations did not affect participant safety. |
| **Quality Management**  | {Example text:}Quality management reviews are performed quarterly and were last completed on July 8, 2013 and October 7, 2013.  |
| **Identified Study Challenges and Solutions** | {Summarize challenges encountered thus far in the study. Identify measures taken to address issues. (Details can be provided in Section 10.0.)} |

{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 participants, listings may be more appropriate than summary tables.}

# Report Overview

{Provide introductory information. Include recommendations from the previous CSOC meeting and outcomes of those recommendations; also include any pending items from earlier CSOC meetings.

Example:}

The purpose of this report is to review major protocol changes and cumulative enrollment data for the participants enrolled in ‘Study Title’. This report reflects data from the study database as of <date>. Included are summary tables of enrollment, status of clinical biospecimens collected at each site, status of samples processed from the biospecimens, and unanticipated problems (UPs). Additional tables, listings, and figures referenced in this report are provided in Appendices A-C. There have been two CSOC meetings for this study. The last review was on April 10, 2011 and, at that time, the CSOC requested an update on enrollment within six months. This report was provided on November 8, 2011. Participants have been enrolled at 100% and 75% of targeted enrollment at Sites A and B respectively. Updated enrollment details have been provided in Section 3.0. Readers of this report are asked to maintain the confidentiality of the information provided in this report.

# Study Objectives and Timeline

{Describe key study objectives. Highlight any major changes since last CSOC.

Provide a timeline of the study’s principal target components, e.g., current status of recruitment/enrollment (using study specific parameters), biospecimen processing and testing, and data analyses as compared to original or previous projected timeline. This may be provided as a summary, a table of study milestones, or other graphic depiction, as appropriate.

Example of timeline:

Table #. Study Milestones Timeline- July 30, 2012

| Milestones | Projected Date | Status | Completion or Revised Projected Date |
| --- | --- | --- | --- |
| Recruitment Cases 50% | 5.1.2012 | 50% Enrolled | 4.15.2012 |
| Recruitment Cases 100% | 8.1.2012 | 75% Enrolled |  |
| Recruitment Controls 50% | 5.1.2012 | Delayed: 30% Enrolled\* | 7.1.2012\* |
| Recruitment Controls 100% | 8.1.2012 |  | 10.1.2012\* |
| Lab Biospecimen 100% DNA Processed | 11.1.2012 | 50% Completed |  |
| Genotyping for GWAS Analysis | 12.1.2012 |  |  |
| GWAS Analysis | 2.1.2013 |  |  |
| Whole Exome Sequencing Analysis | 3.1.2013 |  |  |
| Sequencing Analysis | 5.1.2013 |  |  |

Notes:

\*By 4.1.2012, only 10% targeted numbers of control participants had been recruited. Projected dates for recruitment of 50% and 100% control participants will be revised to 7.1.2012 and 10.1.2012, respectively. See Section 3.0 ENROLLMENT AND RETENTION STATUS below for details.}

# Enrollment and Retention Status

{Describe enrollment and provide a summary table. Include key study characteristics and relevant study groups (e.g., case-control status, adult-child, race/ethnicity breakdown). Provide enrollment statistics by site if the study involves multiple sites. If the study is enrolling, provide the recruitment target and estimated time to completion of enrollment. A figure showing expected/planned versus actual enrollment is helpful but not required.

*Examples:*

Table #. Cases- Inclusion/Enrollment

| Cases | Site A | Site B | Total | Target Enrollment | % of Target Enrollment |
| --- | --- | --- | --- | --- | --- |
| Total Enrollment | 65 | 85 | 150 | 250 | 60 |
| Sex: Female | 40 | 40 | 80 | 125 | 64 |
| Sex: Male | 25 | 45 | 70 | 125 | 56 |
| Race: African American | 25 | 10 | 35 | 65 | 54 |
| Race: Asian | 10 | 30 | 40 | 65 | 62 |
| Race: Caucasian | 30 | 45 | 75 | 120 | 63 |
| Hispanic/Latino ethnicity: Yes | 20 | 15 | 35 | 60 | 58 |
| Hispanic/Latino ethnicity: No | 45 | 70 | 115 | 190 | 53 |

Table #. Controls- Inclusion/Enrollment

| Controls | Site A | Site B | Total | Target Enrollment | % of Target Enrollment |
| --- | --- | --- | --- | --- | --- |
| Total Enrollment | 65 | 61 | 126 | 250 | 50 |
| Sex: Female | 40 | 40 | 80 | 125 | 64 |
| Sex: Male | 25 | 21 | 46 | 125 | 37 |
| Race: African American | 28 | 7 | 35 | 60 | 58 |
| Race: Asian | 0 | 43 | 43 | 60 | 72 |
| Race: Caucasian | 37 | 48 | 85 | 130 | 65 |
| Hispanic/Latino ethnicity: Yes | 15 | 22 | 37 | 65 | 57 |
| Hispanic/Latino ethnicity: No | 50 | 39 | 89 | 185 | 48 |

Figure #. Expected versus Actual Accrual

*}*

# Participant Status

{As relevant to the study design, describe where participants are in the study in relation to major milestones, such as the number who have completed the baseline visit, year 1 follow-up, and the final study visit. A summary table providing the study milestones and the number of participants who have completed those milestones is recommended. Also, provide the number of participants who completed the protocol or discontinued participation and why they discontinued participation (e.g., voluntary withdrawal, lost to follow-up, unanticipated problem, death).

Examples:

Table #. Participant Status, 2011-2012

| Participant | Site 1 | Site 2 | Total |
| --- | --- | --- | --- |
| Completed visit | 38 | 30 | 68 |
| Withdrawn after visit | 4 | 3 | 7 |

Table #. Participant Status, 2011-2012

| Participant | Site 1 | Site 2 | Total |
| --- | --- | --- | --- |
| Pregnancy visit | 38 | 30 | 68 |
| Birth | 38 | 30 | 68 |
| Follow-up Visit 1 | 36 | 28 | 64 |
| Follow-up Visit 2 | 36 | 27 | 63 |
| Withdrawn | 1 | 1 | 2 |
| Lost to follow-up | 1 | 1 | 2 |
| Discontinued by Study PI | 0 | 1 | 1 |

*}*

# Status of Outcome Measures

{Provide information regarding the collection status of outcome measures as described in the Study Design section of the PROTOCOL SYNOPSIS. For data analysis critical to the study’s aims, indicate the status of data collection and quality metrics, as appropriate.

*Example:*

Table #. Number and Percentage of Participants (N/%)
with Missing Data

| Participant | Site 1 | Site 2 | Study Totals |
| --- | --- | --- | --- |
| Outcome 1 | 1/0.7% | 0 | 1/0.3% |
| Outcome 2 | 3/2.3% | 2/1.3% | 5/1.8% |
| Covariate 1 |  2/1.5% | 0 | 1/0.7% |
| Covariate 2 | 4/3% | 2/1.3% | 5/1.8% |

*}*

# Biospecimen Status

*{Briefly describe the overall biospecimens testing and analysis plan. For biospecimen collection and analysis critical to the study’s aims, indicate biospecimen status as appropriate.}*

☐ Biospecimens being collected

*{State the type of biospecimens collected, status of biospecimen collection and processing, number of samples tested, and quality metrics as appropriate.*

*Example:*

Table #. Biospecimen Status

| *Biospecimen* | Site 1 | Site 2 | Study Totals |
| --- | --- | --- | --- |
| *Saliva for DNA: Number of participants with biospecimen(s) collected* |  |  |  |
| *Saliva for DNA: Number of biospecimens tested* |  |  |  |
| *Saliva for DNA: Average DNA quantity* |  |  |  |
| *Saliva for DNA: #/% biospecimens passing DNA quality metrics* |  |  |  |
| *Serum: Number of participants with biospecimens collected* |  |  |  |

*}*

☐ Laboratory analyses {e.g., genotyping, DNA sequencing} underway

Anticipated completion date:

☐ Laboratory analyses {e.g., genotyping/sequencing} completed

{Describe quality metrics as relevant, such as number/percent of run failures, average sequence coverage, call rate.}

# Unanticipated Problems

{Note: If adverse events (AEs) and serious adverse events (SAEs) are collected for this study, modify the section heading accordingly and include summaries/lists of those events in this section also.

Summarize or list unanticipated problems (UPs). Identify measures taken to address them including any protocol changes.

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 participant 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 participants 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 participants or others.}

# Protocol Deviations

{Summarize or list protocol deviations that have occurred since the previous CSOC report and over the course of the study. Identify measures taken to address them including any protocol changes.}

# Quality Management

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

# Study Challenges and Solutions

{Summarize issues noted during this study since the last CSOC meeting and identify measures used to address them including any protocol changes.}

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.}