Tool Summary Sheet

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| Tool: | CSOC Final Study Report Template |
| Purpose: | MS Word template to be used as a starting point for preparing the final CSOC report associated with a completed or terminated study |
| Audience/User: | Statisticians and Principal Investigators responsible for preparing final CSOC reports |
| Details: | This template includes a proposed structure for a CSOC final report as well as draft language and other guidance |
| Best Practice Recommendations: | * Customize this template to the specific needs and requirements of the study. * This template does not include a Table of Contents. You may choose to add one if your report includes additional sections or appendices. * 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 textas 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** | **09Jul2013** | **First approved version.** |
| **2.0** | **31Jul2013** | **Revised document title and modified formatting.** |
| **3.0** | **21Apr2014** | **Updated Executive Summary to revise Unanticipated Problems section and add Quality Management section** |

Clinical Study Oversight Committee

Final Study Report

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| 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 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 CSOC meeting> |
| Prepared By: | <Name of person who prepared the report  Person’s Title  Place of employment  Address> |

Protocol Synopsis

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| **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> 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 biospecimens 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: Final Study Disposition

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| **Key Issues for CSOC Meeting Discussion** | {Example text:}  No issues. This is to inform the CSOC of the final disposition of this <select one: completed or terminated> study. |
| **Study Site Status** | {Provide site-specific status information, including by-site information about sample processing and analysis, if applicable.  Example text:}  All sites completed subject recruitment and all study visits. Each site has processed all biospecimens/images and <shipped or stored> according to protocol. |
| **Enrollment and Retention Status** | {Provide detailed information about number enrolled and percent of target enrollment. If appropriate, include the same information for retention (e.g., clarify reasons for withdrawal/discontinuation). Specify study groups, if relevant, (e.g., case-control or adult-child).  Example text:}  500 participants, 400 cases and 100 controls, were enrolled. 488 subjects (393 cases and 95 controls) completed the final 6 month study visits.  Of those who did not complete the study, 3 subjects were lost to follow-up; 8 subjects withdrew consent; and 1 subject moved out of the area. |
| **Status of Outcome Measures and Biospecimens** | {Briefly summarize the overall status of biospecimens and key outcome measures for the study. Include a general statement about future use provisions, if applicable. If a genome-wide association study (GWAS), state that requests for data will be handled in accordance with NIH policy.  Example text:}  Key outcome measures were collected from 98% of enrollees; 99% meet quality control standards. Samples have been sent to the research lab and are being analyzed.  This study has stored 385 serum and 380 GCF specimens for future use at the DeGrange Laboratory in San Antonio, Texas. Specimens will be dispensed according to the data sharing plan that is detailed in this study’s Manual of Procedures. |
| **Major Protocol Changes Since Last CSOC Review** | {Specify yes or no. If yes, briefly describe major protocol changes and why such changes occurred. You may refer to an appendix for this item.} |
| **Unanticipated Problems** | {Briefly summarize any unanticipated problems (and AEs/SAEs if they are collected for this study). Example text:}  One serious adverse event occurred on the study: severe skin reaction to betadine used during a study visit that resulted in hospitalization. This allergy had not been previously diagnosed. This was also considered to be an unanticipated problem. This event was previously reported to the CSOC. |
| **Protocol Deviations** | {Summarize overall protocol deviations and those since the last CSOC meeting. Note any important events or trends that impact the interpretability of the study data.  Example text:}  A total of 15 protocol deviations occurred in this study, 3 since the last CSOC report. No deviations affected subject safety or the interpretability of the study data. |
| **Quality Management** | {Example text:}  Quality management reviews were performed quarterly and were last completed on July 8, 2013 and October 7, 2013. |
| **Identified Study Challenges and Solutions** | {Summarize challenges encountered since the last CSOC report along with measures taken to address issues.} |
| **Final Comments** | {Optional section for any final remarks or observations, including timelines to completion, disposition of any remaining safety issues, non-specific future plans for IP or follow-up studies, etc. Delete this row, if not applicable.} |