National Center for Complementary and Integrative Health

Tool Summary Sheet

Tool: FDA Document History Log

Purpose: To record all documents submitted to the FDA

Audience/User: Study coordinators, principal investigators, other site staff, clinical monitor

Details: This tracking log should provide a comprehensive list of all documents submitted to the FDA. This document should be used for all studies that are regulated by the FDA.

The set of columns are suggestions and can be customized to meet the needs of the study.

Best Practice Recommendations: Record documents in the history log as they are submitted, to ensure completeness and accuracy of the data.

- Number each page and maintain this log in the Essential Documents Binder, behind the Study Communication tab. (Synonyms for this binder include Investigator Binder, Regulatory Binder, Investigator Site File [ISF], and Study File.)
- Store pages in reverse chronological order, with the newest pages of the log placed at the front of the section.
- At the conclusion of the study, identify the final page of the log by checking the box in the footer.
- Remove this Tool Summary Sheet before use of the log.

Tool Revision History:

Version		
Number	**Date**	**Summary of Revisions Made:**
3.0	24Apr2013	Minor formatting revisions made to document, summary sheet added
2.0	02Mar2010	First approved version

FDA Document History Log

Investigator Name:	Protocol:	IND Number:

List all documents submitted to the FDA.

Date of Correspondence	Type of Correspondence (e.g., submission, contact report)	Serial Number (if applicable)	Description

Check if final page of log: ☐