National Center for Complementary and Integrative Health

Tool Summary Sheet

Tool: NCCIH 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 NCCIH.

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:**
1.0	24Apr2013	

NCCIH Document History Log

Investigator Name:	Protocol:	IND Number:

List all documents submitted to the FDA.

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

Check if final page of log: ☐