

# Tool Summary Sheet

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| 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:**

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| --- | --- | --- |
| ****Version**** | |  |
| Number | Date | Summary of Revisions Made: |
| 1.0 | 24Apr2013 |  |
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# NCCIH Document History Log

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| Investigator Name: | Protocol: | IND Number: |

List all documents submitted to the FDA.

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| Date of Correspondence | Type of Correspondence  (i.e., submission, contact report, etc.) | Serial Number (if applicable) | Description |
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Check if final page of log: Checkbox.