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| **AUDIT/INSPECTION INTAKE FORM** | |
| **Date of Call:** Click or tap to enter a date. | **Person Taking the Call:** Click or tap here to enter text. |

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| **AUDITOR/INSPECTOR INFORMATION** |
| **Number of Auditors/Inspectors Expected:** Click or tap here to enter text. |
| **Name(s):** Click or tap here to enter text. |
| **Title(s):** Click or tap here to enter text. |
| **Contact Information:** Click or tap here to enter text. |

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| **AUDIT/INSPECTION VISIT INFORMATION** *(Wait for answers. Do not make suggestions)* | |
| **Anticipated Start Date**: Click or tap to enter a date. | **Expected Duration**: Click or tap here to enter text. |
| **Purpose of the Inspection**:  Pre-Approval (NDA/ANDA)  Routine (IND, Manufacturer)  Follow-Up (483, warning letter)  Directed/For-Cause  Other | **Who/What is Being Inspected**:  Clinical Trial(s): Click or tap here to enter text.  PI/Co-I(s): Click or tap here to enter text.  Site: Click or tap here to enter text.  Other: Click or tap here to enter text. |

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| **ADDITIONAL INFORMATION** *(Ask the auditor/inspector. Do not make suggestions)* | |
| **Does the auditor/inspector want/need to tour the facility?** Yes  No | |
| **Does the auditor/inspector want specific personnel available?** Yes  No | |
| ***If Yes*, Who:**  Click or tap here to enter text. | **When:**  Click or tap here to enter text. |
| **Does the auditor/inspector want specific documents available?** Yes  No | |
| ***If Yes*, What Documents**: *(Ask for confirmation of requested documents in writing)*  Click or tap here to enter text. | |

*This document has been created by the LSUHSC-NO IRB and CTO as guidance to help investigators and research staff throughout the process of a Food and Drug Administration (FDA) inspection. It is important to take detailed notes during all communication and interaction with the inspector/auditor. Once you have been notified of an audit/inspection, please send a copy of this form to* [*IRBOffice@lsuhsc.edu*](mailto:IRBOffice@lsuhsc.edu) *and* [*CTO@lsuhsc.edu*](mailto:CTO@lsuhsc.edu)