Operations Manual

Document: 416-F

Audit Indicators Assessment

Instructions:

Use this form to determine whether or not a newly approved study has KRI's that warrant an auditing plan by the Research Quality Assurance Program.

Study Details:

Date of Review:	**DR-5 Date:**	**RQAP Reviewer (initials):**
Protocol Title:		**LCID:**
Sponsor:		**Site:**
PI:	**CRC:**	**RN:**
IRB of Record:	***IRB approval date:*** ****Lahey Admin Approval*:**	

Overall Risk Assessment (per assessor's discretion):

Risk	Study Description	X (if Yes)
High	*Phase I-III; Investigator IND/IDE; interventional; invasive; categorized as more than minimal risk, etc.*	
Medium	*Phase IV; Post Market; may be more than minimal risk or minimal risk category, etc.*	
Low	*Non-interventional; data collection only; observational; repository; registry; database; categorized as minimal risk; waiver of informed consent, etc.*	

KRI Assessment:

Assessment	X (if Yes)
RQAP feels this study DOES NOT merit an audit plan	
RQAP feels this study DOES merits an audit plan*	

*** 1) Complete the next 2 sections on Key Risk Indicators (KRIs) and Audit Plan**
2) Add to corresponding Audit Tracking Log

An Audit is warranted due to the following KRI's (select all that apply):

Key Risk Indicator	X (if Yes)
1. New investigator/clinical research coordinator (CRC)	
2. No CRC or research nurse support	
3. Appearance of lack of staff support, lack of resources or high staff turnover (potentially compromising study integrity and/or patient safety)	
4. PI/CRC has history of cumulative protocol deviations and/or noncompliance	
5. The study is investigator-initiated and not otherwise monitored	
6. The study will not be routinely monitored by a sponsor or contract research organization (CRO)	
7. The study is a Phase I or II	
8. The study has vulnerable populations	
9. The investigator has high number of protocols (potential for lack of adequate oversight)	
10. The protocol has high enrollment (potential for missed oversight)	
11. The study has a conflict of interest (COI) management plan	
12. Study has an NIH Data Management and Sharing Plan/ or is federally-funded and not otherwise monitored	
13. Ceded review and history of noncompliance or lack of resources	
14. A Member Organization site (potential for lack of experience/oversight)	
15. Other (describe)	

Audit Plan (if applicable):

Audit Plan Timeframe	X (if Yes)
After first patient is enrolled	
After 10% enrollment goal is met	
Within 3 months of first patient being enrolled	
Other (Describe):	

Comments: