

Clinical Research Site (CRS) Quality Assurance (QA) Summary Report

OMB Control #: 0925-0668
Expiration Date: 1/31/2016

Site Name _____ Site Number _____

Role of Person Preparing Report _____ Date of QA Report _____

Period of Review: (Date) _____ to (Date) _____

1. Composition of PIDs reviewed;

- a. Number of newly enrolled PIDs at CRS during this period (=m) _____
- b. Number of new PIDs reviewed (=n) _____
- c. Total number of PIDs reviewed (old PIDs +Newly enrolled PIDs=x) _____
- d. Total enrollment at CRS (y) _____
- e. Percent of newly enrolled PIDs reviewed ($=n/m * 100$) _____
- f. Percent of total PIDs reviewed ($=x/y * 100$) _____

(Please remember to increase percent reviewed based on newly enrolling protocols, complex protocols, records completed by new staff, etc.)

Burden Disclosure: Public reporting burden for this collection of information is estimated to average 15 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA# 0925-0668. Do not return the completed form to this address.

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2. Summary of protocols reviewed

Note: Complete only for protocols of PIDs reviewed for chart Review. All cells may not need to be completed

Protocol	First participant enrolled (yr)	Number of records reviewed

3. List Quality Control (QC)/Quality Assurance Tools used for this review

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4. Summary of key quality indicators and number of findings

Indicators	Number of findings

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5. Summary of deficient key indicator and criteria(s)

PID #	Protocol #	Deficient key indicator(s) identified	List the criteria identified for corresponding indicator	Corrective action implemented? Describe	Is corrective action effective?

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PID #	Protocol #	Deficient key indicator(s) identified	List the criteria identified for corresponding indicator	Corrective action implemented? Describe	Is corrective action effective?

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PID #	Protocol #	Deficient key indicator(s) identified	List the criteria identified for corresponding indicator	Corrective action implemented? Describe	Is corrective action effective?

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Regulatory File Review

Based on findings identified in the Quarterly Clinical Quality Management Regulatory File Review Tool, complete the following questions

1. Was a Quality Assurance review of the Regulatory File conducted during this quarter? Y _____ N _____

2. If no, provide an explanation

3. If yes, specify associated protocol and complete table below per protocol(s) reviewed

Protocol reviewed	Identified issues (list and describe)	Corrective action(s) implemented, per issue identified	Comments

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Protocol reviewed	Identified issues (list and describe)	Corrective action(s) implemented, per issue identified	Comments

4. Clinical Quality Management Plan (CQMP) Revision

- a. Does the CQMP need revision based on the findings of this Quality Assurance audit? Y _____ N _____
- b. If yes, please specify areas to be revised