GUIDANCE#013 QA/QIP	Version # 1
Approval Date:	
Effective Date:	

1 PURPOSE:

1.1 This procedure establishes the timeline from the initial report from QA/QIP committee received by the PI to evidence of execution of plan of action.

1.2 The QA/QIP Committee retains the right to extend deadlines the length for complex protocols which demand intensive action plans.

2 SCOPE:

2.1 This process applies to all industry sponsored, government funded and investigator initiated studies conducted at Drexel University and applicable affiliates.

3 REVISIONS FROM PREVIOUS VERSION:

3.1 None.

4 GUIDANCE:

4.1 To create consistent workflow of response process

5 RESPONSIBILITIES:

5.1 The QA/QIP committee maintain calendar log of contact, report dates, receipt of response dates to maintain process flow.

6 PROCEDURE

6.1 Response by PI/CRC to be received within 20 business days.

6.2 QA/QIP committee will review report (refer to flowchart)

6.2.1 PI/CRC/ & QA/QIP <u>Agree</u> on Response: QA/QIP plans follow up review visit after last target completions date identified on action plan(step 6.3).

6.2.2 PI/CRC/ & QA/QIP <u>Disagree</u> with evaluation/or PI/CRC does not <u>respond</u> to report:

6.2.2.1 PI/CRC must supply the reason for disagreeing or not responding to report.

6.2.2.2 If PI/CRC does not agree, the following process will be followed:

6.2.2.2.1 QA/QIP will send a follow up request and clarify the mission

of QA/QIP, and offer a chance for further discussion with the committee within 5 business days.

6.2.2.2.2 PI/CRC to respond to second request within 5 business days.

6.2.2.2.3 If no response to second request; contact will be made with appropriate department head to discuss assistance with compliance and report is escalated to Chief Operating Officer (COO) at CRG.

6.2.2.2.4 If the review elicits safety issue, the PI will be directed to report per protocol and regulations to appropriate authorities within 3 business days. The QA QIP committee will request evidence of the report. If no evidence is received, the QA/QIP will report safety issues to COO at CRG.

6.3 QA/QIP plans follow up review visit after last target completions date identified on action plan.

6.3.1 If action plan not completed successfully, QA/QIP will work with PI to implement recommendation and best practices.

6.3.2 If Action plan implemented successfully, no further action necessary.

6.3.3 If PI non-compliant or safety issues exist, COO of CRG is notified.

7 MATERIALS:

7.1 Calendar

7.2 QA/QIP Activity Tracking Log

7.3 QA Professional Report

8 REFERENCES:

8.1 References

Approvals

Signature of author signifies that this document accurately reflects the current process.

Author(s)	Title	Signature	Date
Karen Skinner	QA\QIP Director	*[signature]*	11/30/12

Signature of the approvers signifies agreement that this guidance document should be effective within Drexel University, Drexel University College of Medicine, and applicable affiliates.

Approval	Title	Signature	Date
Donna Walsh	Executive Director, Human Research Protection Program	*[signature]*	11-30-12
Michael Edwards	Senior Associate, Vice Provost for Research	*[signature]*	12/12/12

Revision History

Version	Effective Date	Change

Drexel University
Drexel University College of Medicine
QUALITY ASSURANCE/QUALITY IMPROVEMENT PROGRAM (QA/QIP)
Timeline for Response Process

PI receives initial report from QA/QIP

PI has 20 business days to submit response to QA/QIP

QA/QIP agrees or disagrees with response or absence of response

Disagrees with report or absence of report

QA/QIP will contact PI for reason for no response

If PI disagrees, QA/QIP will send request, clarify mission and offer change for PI to further discussion in 5 business days

Agree or disagree

Agrees and accepts follow up response plan

Second request sent for response within 5 business

Agree or disagree

Follow up Review visit is scheduled and performed after last target date identified on the action plan

If safety issues exist, PI has 3 business days to notify appropriate authorities

Non-compliance? Action plan implemented successfully? Additional support necessary? no immediate safety issue exist

York with PI to implement amendations and best practices.

No further action required if corrective action plan is implemented successfully

If PI is non-compliant or safety issues exist, communicate finding with the COO of CRG as well as investigator