QUALITY ASSURANCE/QUALITY IMPROVEMENT PROGRAM (QA/QIP)
Follow-up Reviews

GUIDANCE#014 QA/QIP	Version # 1
Approval Date:	
Effective Date:	

1 PURPOSE:

1.1   This procedure establishes the process for the follow up reviews.

1.2   The QA/QIP Committee retains the right to increase the length of review for complex protocols which demand a more thorough overview.

2 SCOPE:

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

3 REVISIONS FROM PREVIOUS VERSION:

3.1 None.

4 GUIDANCE:

4.1   Initial reviews resulting in PI/SC site CAPA will be reviewed to assure the accepted plan has been executed.

4.2   This process will ensure a successful evaluation of the correction or adjustments related to the study.

5 RESPONSIBILITIES:

5.1 The QA/QIP committee members execute this process.

6 PROCEDURE

6.1   In response to the initial report, the PI will submit Corrective and Preventive Action (CAPA) Plan to QA/QIP within 20 business days.

6.1.1 If CAPA not received within time frame, QA/QIP will alert PI

6.1.2 QA/QIP has right to determine an extension date or present options for PI.

6.2   QA/QIP will schedule review with PI after the last date referenced in the submitted and approved (CAPA) Plan. The date should be no greater than 6 months after the last dates

6.3   If the CAPA is exclusively change in paperwork or communication, the QA/QIP representative may opt to review the paperwork to confirm compliance.

6.4   If the CAPA involves safety or regulatory issues, a site visit to assure compliance and safety is necessary.

6.5   Unresolved Plan of Action Tasks will be discussed at the monthly QA/QIP meeting and any further necessary follow up will be decided on at that time.

6.5.1 Possible recommendations for post-review sessions:

6.5.1.1 Training/Re-training:
- Training sessions will be recommended and developed by the CRG to target problematic areas, if applicable.
- These training sessions will be discussed with the PI/CRC
- Dates for training arranged

6.5.1.2 Reporting outstanding items (especially safety) to the regulatory bodies

6.5.1.3 Reporting outstanding items to the Sponsor, where applicable

6.5.1.4 Review of processes. Revise as deemed necessary.

6.5.1.5 Review and revise SOP/guidelines if deemed appropriate.

6.5.1.6 Use of QA/QIP support services

7 MATERIALS:

7.1 Review Checklist

7.2 QA/QIP Activity Tracking Log

7.3 QA/QIP Professional Report Form

8 REFERENCES:

8.1 None

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 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