

QUALITY ASSURANCE/QUALITY IMPROVEMENT PROGRAM (QA/QIP)

Scheduling Routine, Random reviews

GUIDANCE#021 QA/QIP

Version # 1

Approval Date:

Effective Date:

1 PURPOSE:

- 1.1 This procedure establishes the process to create the schedule of random routine reviews.
- 1.2 The process begins during the fourth quarter of the calendar year.
- 1.3 The process ends when the schedule for the calendar year following the fourth quarter is completed.

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 A schedule for routine random audits will be established annually.
- 4.2 This preparation is completed during beginning of 4th quarter of previous calendar year for each year
- 4.3 The identified selection criteria will remain consistent throughout each calendar year.
 - 4.3.1 The focus for determining the scheduling of random reviews for upcoming following calendar year will be determined during 4th quarter of current year.
 - Pending the result of data collected, the schedule may select from the list of open studies, those with new PI or frequently changing research personnel, high enrollment, frequent SAE's or protocol deviations.
 - The selection criteria may be reflective of trends noted from external audits or internal aggregated data.

5 RESPONSIBILITIES:

- 5.1 QA/QIP will review collected data from internal reviews
- 5.2 QA/QIP will review external communication/publications of auditing trends
- 5.3 Upon review of above date, QA/QIP will identify criteria for random scheduling for the following year
- 5.4 QA/QIP will identify PI/Protocol meeting identified criteria
- 5.5 QA/QIP will send our letters using template informing the PI/study team of scheduled review visit.

6 PROCEDURE

- 6.1. QA/QIP will identify criteria used to select random review for the next

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calendar year

- 6.2. PIs/Protocols matching the selected criteria will be identified
- 6.3. Of the identified group, a rotation among departments will be assigned to each calendar month.
- 6.4. Using the template letters, the PI and study team will be informed of routine review and scheduling.
- 6.5. The PI/study team will respond to confirm review date and arrangements for visit

7 MATERIALS:


- 7.1 Template PI letter Routine Review

8 REFERENCES:

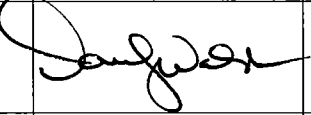
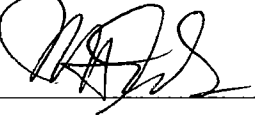
- 8.1 AAHRPP standards

Approvals

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

Author(s)	Title	Signature	Date
Karen Skinner	QA/QIP Director		11/20/12

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		11-30-12
Michael Edwards	Senior Associate, Vice Provost for Research		12/12/12

Revision History

Version	Effective Date	Change