



**QUALITY ASSURANCE/QUALITY IMPROVEMENT PROGRAM (QA/QIP)
TIMELINE FOR REVIEW PROCESS**

Guidance # QAQIP 012

Version # 002

Approval Date:

Effective Date:

Purpose:

- 1.1 This procedure establishes the timeline from the initial contact between PI and QA/QIP committee to completion of final reports and evidence of execution of plan of action.
- 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 and applicable affiliates.

3 REVISIONS FROM PREVIOUS VERSION:

- 3.1 None.

4 POLICY:

- 4.1 To create consistent workflow of review process

5 RESPONSIBILITIES:

- 5.1 QI/QIP members maintain log of contact, review dates, response dates to maintain process flow

6. GUIDANCE

6.1 Contact made

- 6.1.1 QA/QIP to PI/CRC (Routine Review or For Cause Review)
- 6.1.2 PI/CRC Contacts QA/QIP
- 6.1.3 IRB contact QA/QIP
- 6.2 Within 10 business days of request QA/QIP will arrange date for a routine review
 - 6.2.2 Within 2 business days of request QA/QIP will arrange date for a for cause review
- 6.3 Routine/Requested Review is completed at the study site within 40 days of review request
- 6.4 For cause Review is completed within 5 business days of review request.
- 6.5 Upon QA/QIP Director Approval, a Quality Assurance Report is delivered to the PI/CRC within 30 business days of review
 - 6.5.2 Upon QA/QIP Director Approval, the For cause Quality Assurance Report is delivered IRB/designees or Executive Director or Institutional Official within 10 business days of review.
 - 6.5.3 The IRB is responsible to share findings with PI or recommend PI utilize QA/QIP services for CAPA
- 6.6 PI/CRC has 20 business days to respond to QA Report

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- 6.5.1 Plan of Action discussed and dates arranged for completion of these tasks
 - 6.6 Follow up visit is conducted
 - 6.6.1 Quasi-review of all plan of action tasks
 - 6.6.2 Status determined
 - 6.6.2.1 If tasks are completed :
 - 6.6.2.1.1 Final report with completed plan of action is delivered to PI/CRC and CRG
 - 6.6.2.2 If task not completed:
 - 6.6.2.2.1 New date arranged and plan of action reviewed and date set for final follow up
- Decision by QA/QIP will stand

7. MATERIALS:

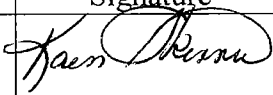
- 7.1 Review Checklist
- 7.2 Calendar

8. References

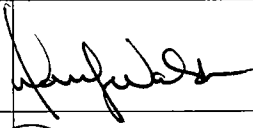

- 8.1 None

Approvals

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

Author(s)	Title	Signature	Date
Karen Skinner	QA/QIP Director		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		11-30-12
Michael Edwards	Senior Associate, Vice Provost for Research		12/12/12

Revision History

Version	Effective Date	Change

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