QUALITY ASSURANCE/QUALITY IMPROVEMENT PROGRAM (QA/QIP)
Criteria for Documents Review

GUIDANCE# 002 QA/QIP	Version #1
Approval Date:	
Effective Date:	

1 PURPOSE :

1.1 The Quality Assurance/Quality Improvement Program (QA/QIP) reviews human research conducted at Drexel University (DU) to assure the Best Practice is adhered to, in order to achieve excellence in research.

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 The QA/QIP performs onsite review of study documentation to ensure regulatory compliance, including protocol adherence, accurate record keeping, and appropriate informed consent process. The types of review include routine, self-monitoring, and for cause.

4.2 The QA/QIP suggests corrective actions and offers quality improvement recommendations to facilitate best practices and enhance overall study conduct.

5 RESPONSIBILITIES:

5.1 IRB Chair or designee or Executive Director of HRPP

5.1.1-Submits all request for cause reviews

5.2 Principal Investigator (PI)

5.2.1 Submits request for review (if applicable)
5.2.2 Submits request for support preparation for external audit.
5.2.3 Be available for interview and clarifications

5.3 Study Coordinator (SC)

5.3.1 Submits request for review (if applicable)
5.3.2 In preparation for the visit, gets the requested essential binder items ready for review. These may include but not limited to:

- Regulatory binders:
  - Protocol
  - Informed Consent Documents
  - AE/SAE reports/monitoring log

- Protocol Deviations
- Completed CRF's (to compare to source documents)
- Sample CRF's
- FDA 1572/ Conflict of Interest
- Drug/Device Accountability
- CV's
- Correspondence with IRB
- Monitoring logs
- Delegation of Authority
- Training records
- Laboratory Licenses/ Accountability
- Investigator Brochure
- Sample Storage
- Equipment Maintenance log

o Subject binders

5.3.3 Establishes a planned time to meet with reviewer and provides a space for the review.

5.4 QA/QIP

5.4.1 Supports PI and Research Team in preparing for external audit or inspection

5.4.2 Conducts internal review

5.4.2 Provides response in a timely manner

5.4.3 Insures that all applicable and selected corrective actions are implemented

5.4.4 Provides resources to ensure continued audit readiness

6 PROCEDURE:

6.1 Identify if review falls into "routine" or "for cause" review

6.2 Refer: GUIDANCE 003 QA/QIP – Routine Review
GUIDANCE 004 QA/QIP – For Cause Review

7 MATERIALS:

7.1 Service request form

7.2 PI notification letter of upcoming review

7.3 Review Checklist

7.4 QA/QIP Professional Report

8 REFERENCES:

8.1 QUA 102 External Audit and Inspection

8.2 21 CFR 312

8.3 ICH GCP Guidelines E6

Approvals

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

Author(s)	Title	Signature	Date
Karen Skinner	Director QA\QIP		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