QUALITY ASSURANCE/QUALITY IMPROVEMENT PROGRAM (QA/QIP)
Preparatory review for FDA Inspection

SOP#020 QA/QIP	Version # 1
Approval Date:	
Effective Date:	

1 PURPOSE:

1.1 This procedure establishes the actions QA will perform to prepare a site for an FDA inspection

1.2 The process begins when the QA/QIP is notified of a pending FDA inspection or FDA presence on site

1.3 The process ends after completion of all FDA related paperwork post FDA review.

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:

4.1QA/QIP will provide support to PI and site for preparation of FDA visit.

4.2 QA/QIP will provide support during FDA onsite visit.

4.3 QA/QIP will provide support past FDA visit until all requirements from the FDA are achieved.

5 RESPONSIBILITIES:

5.1 For new SOPs, the QA/QIP committee members execute this process.

6 PROCEDURE

6.1 Prior to FDA visit, QA will doe site review

6.1.1 Any identifiable issues will be addressed prior to FDA visit

6.1.2 If necessary, QA/QIP will support in development of CAPA

6.1.3 If necessary QA/QIP will support in execution of CAPA

6.1.4 Site re-review will be completed if deemed appropriate

6.2 QA/QIP will provide preparation procedures for FDA inspection to PI and study team

6.2.1 Assure PI has notified other person including but not limited to: IRB, ORRA, Sponsor, Sub-I, Medical Records, Coordinators.

6.2.2 Attempt to Obtain the following information regarding the visit:

6.2.2.1 Starting date and expected duration

6.2.2.2 FDA investigator name and contact information

6.2.2.3 Who/what is being inspected

6.2.2.4 Reason for inspection

6.2.2.5 Request for specific personnel or specific documents

6.2.3 Education of interview process, documents presentation is reviewed.

6.2.4 Recommendation of room selection, daily team meetings, and context will be reviewed.

6.2.5 Review of GCP, Protocol flow, protocol specific trainings for research team. Team aware of each other roles, individual interview, notes to files, adverse events, protocol deviations

6.2.6 IP/accountability logs, enrollment logs, source data availability: review comprehensiveness and accuracy

6.3 QA/QIP will be available for consultation throughout site visit.

6.3.1 Copy and list all documents which the FDA request

6.3.2 Designate point person for each inspector

6.3.3 Escort FDA inspector to meeting room. The inspector will present his/her credentials to the PI to verify. The inspector will preens the PI with the Notice of Inspection (FDA 482)

6.3.4 PI should set aside each day time to speak with the inspector.

6.3.5 Answering FDA questions: Listen carefully. Answer in honest complete manner. Be truthful, concise, positive and confident

DO NOT volunteer information, guess or speculate lie argue or panic.

DO NOT sign affidavits

6.3.6 Take notes of inspection and activities daily.

6.3.7 Provide only the documents requested

6.4 QA/QIP will work with PI to develop response to FDA 483 and /or established inspection report (EIR) if necessary

6.4.1 The FDA 483 response should be submitted within 15 calendar days

6.4.2 The EIR will be filed within 30 days.

7 MATERIALS:

7.1 Checklist

7.2 FDA prep review

8 REFERENCES:

8.1 FDA website: http://www.fda.gov/ICECI/Inspections/default.htm

8.2 GCP: QA Question and Answer Reference Guide

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