Drexel University

QUALITY ASSURANCE/QUALITY IMPROVEMENT PROGRAM (QA/QIP)
Pre-Review Process

GUIDANCE#016 QA/QIP	Version # 1
Approval Date:	
Effective Date:	

1 PURPOSE:

1.1 This procedure establishes the process to prepare for research study reviews

1.2 This procedure begins with the scheduling of the review.

1.3 This procedure ends with the beginning of the onsite 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 GUIDANCE:

4.1 For each scheduled review, preparation will occur prior to onsite visit. This preparation includes review of protocol and other relevant documents and collection of tools to be used for the review.

5 RESPONSIBILITIES:

5.1 The QA/QIP members execute this process.

6 PROCEDURE

6.1 Identify the type of review to be performed.

6.2 With the scheduling letter to the PI, request research study documents related to the type of review.

6.2.1 For routine reviews, request protocol and current IRB approved consent

6.2.2 For direct/for cause reviews, request protocol, current IRB approved consent. AS/SAE log, SAE submission to IRB and/or sponsor.

6.2.3 For requested reviews, request protocol, current IRB approved consents as well as any documents relevant to the reason for the request review.(i.e. if to prepare for monitor visit, request the last 3 monitor visit reports, if to prepare for audit, request audit notification to identify areas of focus)

6.2.4 The QA/QIP team has the right to request any additional information relevant to the review.

6.3 The requested documents are saved and filed per QA/QIP Records GUIDANCE009.

6.4 The requested documents are reviewed by the assigned reviewer to familiarize with the protocol and identify areas of potential concern.

6.6 The prepared documents are saved and filed per QA/QIP Records SOP009.
6.7 The prepared file is taken to the onsite review.

7 MATERIALS:

7.1 SOP 009 QA/QIP – Records
7.2 Checklist

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 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