Drexel University

QUALITY ASSURANCE/QUALITY IMPROVEMENT PROGRAM (QA/QIP)
Evaluation of Institutional Review Board (IRB) chair and committee

GUIDANCE#022 QA/QIP	Version # 1
Approval Date:	
Effective Date:	

1 PURPOSE :

1.1 This procedure establishes the process for the QA/QIP to conduct routine Institutional review Board (IRB) review.

1.2 The process begins when the QA/QI has identified the need for routine IRB review, or the IRB meets HRPP's criteria for QA/QIP-initiated routine review.

1.2.1 QA/QIP recommendation:

- As part of HRPP's requirement to review one IRB monthly
- New appointed IRB chair/and/or members

1.2.2 IRB Self-evaluation/review Department head initiated

- Apply tools to support compliance

1.3 The process ends when the QA/QIP has provided completed IRB visit information to the IRB chair.

2 SCOPE:

2.1 This process applies to all IRB conducted at Drexel University (DU) and applicable affiliates.

3 REVISIONS FROM PREVIOUS VERSION:

3.1 None

4 GUIDANCE:

4.1 The QA/QIP routine IRB review of meeting and meeting minutes is to ensure regulatory compliance.

4.2 The QA/QIP recommend corrective actions and offers quality improvement suggestions to facilitate best practices and enhance overall conduct.

5 RESPONSIBILITIES

5.1 Reference GUIDANCE 002 QA/QIP

6 PROCEDURE:

6.1 Schedule routine IRB review with each IRB chair

6.2 Forward review tools in advance as a checklist

6.3 Review corresponding IRB file and prepare onsite review tools using the Review Checklist

6.4 Review electronic and hard copy documentation (i.e. COEUS).

6.5 Provide IRB chair and other appropriate members of the IRB committee with preliminary findings and an opportunity to correct, explain, and/or ask questions.

6.6 Complete a visit report within 10 business days using QA/QIP Professional Report Template.

6.8 Follow the "GUIDANCE 009 QA/QIP – Records" to file correspondence to and from the QA/QIP.

6.9 Work with the IRB chair to implement recommendations and best practices and establish the need and schedule for a re-review in the future if applicable.

7 MATERIALS:

7.1 Review Checklist.

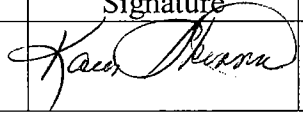
7.2 QA/QIP Professional Report

8 REFERENCES:

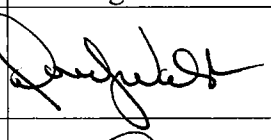
8.1 None

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