GUIDANCE#008 QA/QIP	Version # 1
Approval Date:	
Effective Date:	

1 PURPOSE:

1.1 This procedure establishes the process to manage information reported to QA/QIP that represents potential Non-Compliance, including the following:

- Unanticipated Problems Involving Risk to Participants or Others
- Suspensions of IRB Approval
- Terminations of IRB Approval
- Other non-compliance/Risk information not mentioned above that could compromise the protection and welfare of trial participants.

1.2 The process begins when the QA/QIP receives a "Report of Requests Form" with "**for cause**" checked.

1.3 The process ends when the information item is addressed and documented.

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 DEFINITIONS:

4.1 Serious Non-Compliance: Non-Compliance that affects the rights or welfare of participants.

4.2 Continuing Non-Compliance: Non-compliance identified previously without evidence or corrective action implemented

4.3 Non-series Continuing Non-Compliance: Non-compliance identified previously without evidence or corrective action implemented not directly affecting the rights or welfare of participants

4.4 Reference GUIDANCE 011 Definitions for further details

5 GUIDANCE:

5.1 Only the IRB chair/designee or Executive Director or Organizational Official may request assistance from the QA/QIP to gather additional information, when, in their opinion, it is needed to answer a question related to concern for safety and welfare of subjects.

5.2 The requester receives a report of review findings. It is the requester's responsibility to share results with PI. The IRB may recommend the PI utilize QA/QIP services

5.3 The Principal Investigator (PI) is responsible for formally reporting identified safety issues to the IRB, as required by the regulations

5.3.1 The PI is to copy QA/QIP on report(s) to IRB or any other required

regulatory agencies. Without evidence of self-report within the timeline given to the PI on such reports to the IRB, the QA/QIP will inform IRB, as well as CRG management.

6 RESPONSIBILITIES:

6.1 The QA/QIP members execute this process.

7 PROCEDURE

7.1 QA/QIP reviews the incoming information and answers the following questions:

7.1.1 Is this an Allegation of Non-Compliance?
7.1.2 Is this a Finding of Non-Compliance?
7.1.3 Is this an Unanticipated Problem Involving Risk to Participants or Others?
7.1.4 Is this a Suspension or Termination of IRB Approval?

7.2 Schedule review per GUIDANCE

See attached flowchart for a diagram of the flow of this procedure

7.3If the notification involves a participant becoming a prisoner in a study not approved by the IRB to involve prisoners inform the investigator that all research interactions and interventions with, and obtaining identifiable private information about, the now-incarcerated prisoner-participant must be stopped immediately until the regulatory requirements for research involving prisoners are met, unless the investigator asserts that it is in the best interests of the subject to remain in the research study while incarcerated and promptly submits a modification to the IRB to include prisoners.

7.4Take any additional actions required to resolve any concerns or complaints associated with the information.

7.5 Document findings supporting decision and actions.

7.5.1 Communicate findings to PI and CRC

7 MATERIALS:

7.1 CHECKLIST: Review of Regulatory and chart
7.2 GUIDANCE 003 QA/QIP- Routine Review
7.3 GUIDANCE 004 QA/QIP – For Cause Review
7.4 GUIDANCE 009 QA/QIP – Records
7.5 GUIDANCE 012 QA/QIP - Timeline of Review Process (with flowchart)
7.6 GUIDANCE011 QA/QIP-Definitions
7.7 GUIDANCE 013 QA/QIP - Timeline of Response Process (with flowchart)

8 REFERENCES:

8.1 AAHRPP Evaluation Instrument for Accreditation: I.3.B
8.2 21 CFR §56.108(b)

8.3 7.3 45 CFR §46.103(b)(5), 45 CFR §46.108(a)

Approvals

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

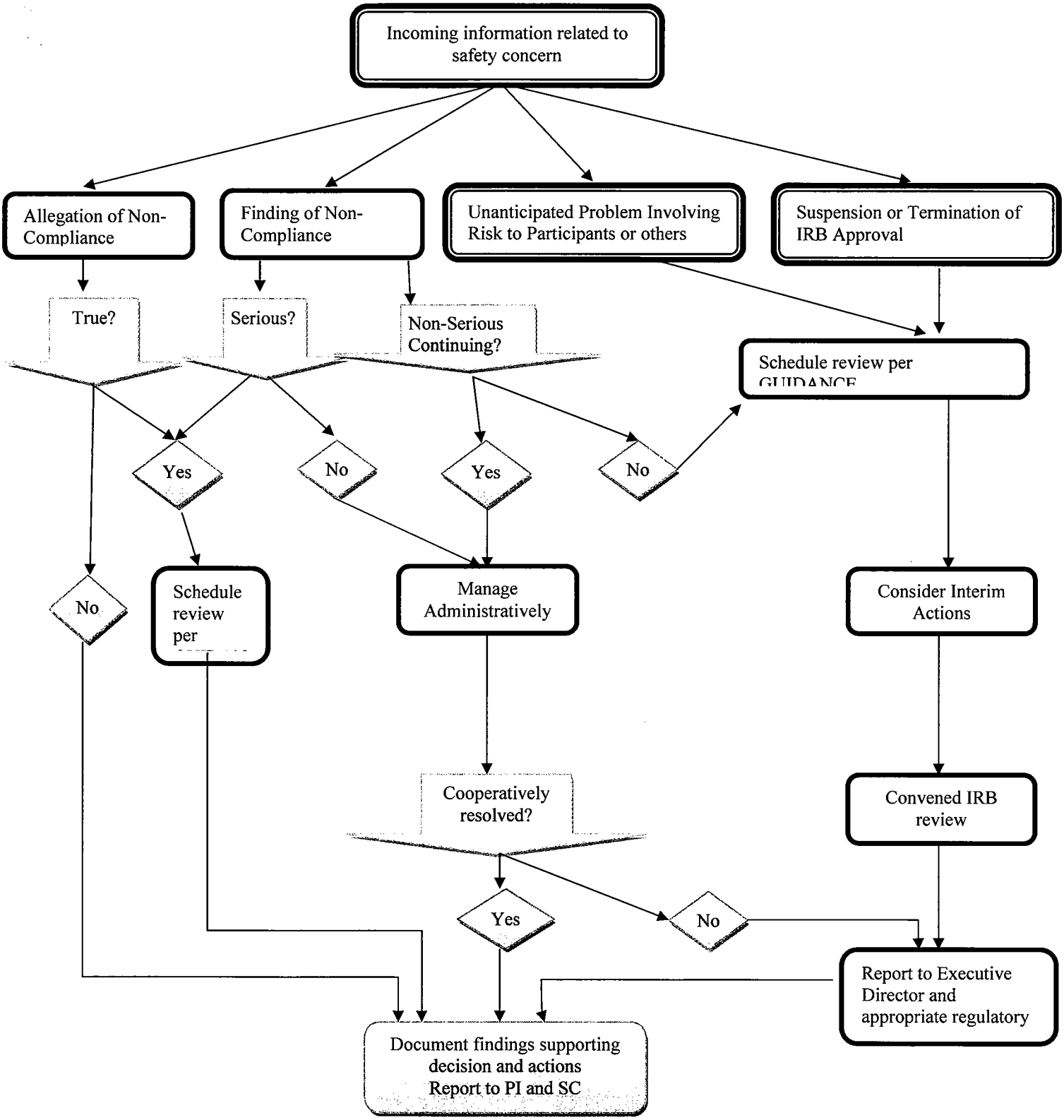
Author(s)	Title	Signature	Date
Karen Skinner	Director QA\QIP		11/30/12

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


Incoming information related to safety concern
Allegation of Non-Compliance
Finding of Non-Compliance
Unanticipated Problem Involving Risk to Participants or others
Suspension or Termination of IRB Approval
True?
Serious?
Non-Serious Continuing?
Schedule review per GUIDANCE
Yes
No
Yes
No
No
Schedule review per
Manage Administratively
Consider Interim Actions
Cooperatively resolved?
Convened IRB review
Yes
No
Report to Executive Director and appropriate regulatory
Document findings supporting decision and actions
Report to PI and SC