



Quality Assurance - Standard Operating Procedures

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1. Overview

Purpose

Drexel University performs Quality Assurance and Improvement activities for the purposes of monitoring the safety of ongoing studies and measuring and improving human research protection effectiveness, quality, and compliance with organizational policies and procedures and applicable federal, state, and local laws. These assessments may involve referrals or collaborations with ancillary Drexel offices or external entities to thoroughly evaluate compliance, as applicable.

2. Procedures

2.1 External Monitoring, Audit, and Inspection Reports

The Drexel Human Research Protections (HRP) Office is responsible for reviewing investigator submitted reports from external monitors, auditors, or inspectors for issues that could impact the rights or welfare of human subjects, and for issues indicative of possible serious or continuing non-compliance which would be submitted as a “reportable new information” report to the IRB. In the event such issues are identified during review by Drexel’s Quality Assurance Program the researcher will also be instructed to submit a “reportable new information” report to the IRB. Such reports will be handled as described in the applicable HRP procedures for reportable events.

2.2 Investigator Compliance Reviews

Compliance reviews are conducted to assess investigator compliance with federal, state, and local law, and Drexel University policies, to identify areas for improvement, and to provide recommendations based on existing policies and procedures.

Drexel’s Quality Assurance Program, as described in ORI-601 Research Quality Assurance Reviews, can conduct post-approval directed (“for cause”) reviews as well as routine quality assurance reviews.

The results of directed compliance reviews will be reported to the requesting office, e.g., the Institutional Official, the HRP Executive Director and IRB Chairs, and will be shared with the investigator as appropriate. Any non-compliance will be handled in accordance with Drexel HRP procedures for reportable events.

If it is identified that subjects in a research project have been exposed to unexpected serious harm, the reviewer will promptly report such findings to the HRP Executive Director and/or IRB Chair for immediate action. The HRP Executive Director and IRB Chairs have authority to temporarily suspend research in cases where subjects may be exposed to harm.

If issues are identified that indicate possible misconduct in research, the University’s Research Misconduct and reporting procedures will be initiated.

Compliance reviews may include:

- Requesting progress reports from investigators;
- Examining investigator-held research records;
- Contacting research subjects;
- Observing research sites where research involving human research subjects and/or the informed consent process is being conducted;



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- e. Reviewing advertisements and other recruiting materials;
- f. Reviewing projects to verify from sources other than the investigator that no unapproved changes have occurred since previous review;
- g. Assuring that the consent documents include the appropriate information and disclosures about conflicts of interest;
- h. Monitoring HIPAA authorizations;
- i. Collaborating with external sites and/or IRBs to audit collaborative research;
- j. Conducting other monitoring or auditing activities as deemed appropriate by the HRPP or IRB.

2.3 IRB Compliance Reviews

The HRP Executive Director or designee and Quality Assurance Program with, or without, the assistance of an outside organization, will periodically review the activities of the IRB to assess compliance with regulatory requirements and to identify areas for improvement. Review activities may include:

- a. Review of the IRB minutes to determine that adequate documentation of the meeting discussion has occurred. This review will include assessing the documentation surrounding the discussion for protections of vulnerable populations as well as risk/benefit ratio and consent issues that are included in the criteria for approval;
- b. Review of the IRB minutes to assure that quorum was met and maintained;
- c. Review of IRB documentation, including IRB minutes, to assess whether privacy provisions, according to HIPAA, have been adequately reviewed, discussed, and documented;
- d. Evaluating the continuing review discussions to assure they are substantive and meaningful;
- e. Reviewing the IRB electronic system to assure retention of appropriate documentation and consistent organization of the IRB file according to current policies and procedures; and review of the IRB electronic system to assure all required fields are completed accurately.
- f. Reviewing single IRB-related documentation. When Drexel University is the reviewing IRB, verify that reliance agreements were executed prior to the IRB's approval and activation of relying sites.
- g. When Drexel University has ceded review, verifying that reliance agreements were executed and that Drexel University site-specific documents contain required language (e.g. subject injury language).
- h. Reviewing metrics (for example, time from submission to first review) to evaluate the quality, efficiency, and effectiveness of the IRB review process.
- i. Reviewing the workload of IRB staff to evaluate appropriate staffing level; and
- j. Other monitoring or auditing activities deemed appropriate.

The HRP Executive Director will review the results of IRB QA/QI reviews. If any deficiencies are noted in the review, a corrective action plan will be developed by the Executive Director as applicable, and in consultation with IRB Chairs and/or staff as applicable. The Executive Director (or designee) will have responsibility for implementing the corrective action plan, and for evaluating the results.

IRB noncompliance will be reported to the HRP Executive Director who will determine the appropriate course of action for documentation and remediation, including, but not limited to:

- completing a root cause analysis and instituting CAPA plan,



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- additional training and education for IRB reviewers and staff,
- documentation of noncompliance via note to file, and, when required,
- reporting to appropriate regulatory agencies.

Transparency regarding patterns of Drexel University IRB noncompliance will be achieved through briefing of the IRB Chairs, leadership, and IO.

3. Responsibilities

3.1 Office for Research & Innovation Responsibilities and Human Research Protections Responsibilities

The Office of Research & Innovation and Human Research Protections Office are responsible for maintaining and following these procedures, including review of reportable events, initiating compliance reviews, and completing ongoing quality assessment and improvement reviews. For inquiries regarding these procedures, please contact the Executive Director for Human Research Protections, as part of the Office for Research & Innovation (ORI).

4. Resources

- [Drexel University's Research Integrity and Research Misconduct Procedures/Reporting](#)
- [ORI-601 Research Quality Assurance Reviews](#)

5. Revision

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