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1. Overview

Purpose

The purpose of these procedures is to describe the process by which the Office of Research & Innovation (ORI) conducts research quality assurance (QA) reviews or audits at Drexel University. The intent of the reviews is to evaluate compliance with applicable laws and regulations, institutional policies and procedures, guidelines, funder requirements, and approved protocols, as applicable under the ORI. Reviews may include but are not limited to human subjects research, animal research, research integrity, conflict of interest, export compliance, and as requested by the Institutional Official (IO).

Continuing oversight of research activities is required by federal laws, regulations, policies and guidelines. Quality assurance reviews ensure compliance with the regulatory and ethical standards governing research activities, as well as guide the University in identifying opportunities for improvement and provide recommendations on how to achieve improvement. Quality assurance reviews also support ongoing education and training initiatives of the ORI.

Quality assurance reviews promote regulatory compliance as well as facilitate communication and collaboration between researchers and the ORI, promoting a culture of compliance institution wide. Some benefits that may be gained from quality assurance reviews, include, but are not limited to:

- Increased understanding of the regulations that guide research projects and procedures.
- Increased communication concerning Federal regulations and University policies.
- Access to an individual to clarify the Federal regulations and University policies.

The types of quality assurance reviews under the purview of these procedures include:

- Routine quality assurance reviews
- Directed (for-cause) quality assurance reviews
- Requested (by the PI or responsible individual) quality assurance reviews

Scope

The scope of these procedures encompasses evaluating the processes, practices, and outputs of research activities to ensure compliance with applicable laws and regulations, institutional policies and procedures, guidelines, funder requirements, and approved protocols. This may include post-approval review of specific protocols or projects, as well as ORI processes and procedures, e.g., review of IRB, IACUC, or COI processes. These procedures do not exclude or limit other University units from conducting reviews, taking actions, making recommendations, or imposing additional requirements.

All individuals involved in a research project under QA Review are expected and required by Drexel to fully cooperate in the QA review or audit. No individual may act in a manner that obstructs or hinders the conduct of a QA review or audit.

2. Definitions

Audit – a systematic and independent examination of records, including but not limited to research records, financial records, documents, and processes to ensure compliance with established requirements, e.g., regulations, good clinical practice (GCP) guidelines, institutional procedures, or approved protocols.

Corrective and Preventive Action (CAPA) – a systematic approach to identifying, investigating, and addressing problems in products, processes, and systems to correct a problem or prevent future occurrences.

Human Research Protection Program (HRPP) – serves as the governing program for the conduct and review of human research and is a collaborative effort that ensures the rights and welfare of research participants are protected. The Drexel University HRPP consists of various individuals and committees such as: the Institutional Official, the Institutional Review Board, the Institutional Biosafety Committee, the Radiation Safety Committee, Office of Sponsored Programs, Quality Assurance Program, Office of General Counsel, Conflict of Interest group, investigators, research staff, and health and safety staff.

Investigational Device Exemption (IDE) – an **IDE** allows the investigational device to be used in a clinical study in order to collect safety and effectiveness data.

Investigational New Drug (IND) – an **IND** application is a request to the FDA for permission to administer an investigational drug or biologic to humans.

Institutional Animal Care and Use Committee (IACUC) – is responsible for oversight of the animal care and use program and its components as described in the Animal Welfare Act, Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals, and the Guide for the Care and Use of Laboratory Animals. Its oversight functions include an ongoing assessment of animal care and use and serve an important role in ensuring the ethical and humane care of animals.

Institutional Review Board (IRB) – is an appropriately constituted independent group formally designated to review and monitor research involving human subjects. In accordance with regulations, an IRB has the authority to approve, require modifications in (to secure approval), or disapprove research. This group reviews human subjects research and serves an important role in the protection of the rights and welfare of human research subjects (Per FDA and OHRP consideration).

Institutional Official (IO) – a person who is legally authorized to act on behalf of an institution in research. The IO is responsible for ensuring that the institution complies with all relevant requirements for research, including those involving human subjects or animals.

Phase 1 Project - tests the safety, side effects, best dose, and timing of a new treatment in a small group of people (20–80) for the first time. The purpose is to study the treatment to learn about safety and identify side effects.

Principal Investigator (PI) – is the individual responsible for preparing, conducting, and administering a protocol, research project, research grant, cooperative agreement, training or public service project, contract, or other sponsored project.

Quality Assurance – a set of systems, techniques, and resources that ensure research is conducted responsibly and ethically.

3. Routine Quality Assurance Reviews

Routine quality assurance reviews ("Routine Reviews") are systematic evaluations completed to ensure that research projects and processes meet predefined quality standards (e.g., IRB and IACUC approvals, federal regulations, funders expectations, Good Clinical Practice). These reviews are a proactive approach, integral to maintaining consistency, preventing errors, and continuously improving the overall quality of the work. Routine Reviews generally cover a broad range of processes, procedures, documentation and research activities with the purpose of making recommendations for improvements to enhance research quality and compliance.

Routine Reviews conducted by ORI do not replace an investigator's responsibility for implementing quality assurance systems and procedures or for conducting their research projects in compliance with applicable governmental laws and regulations and with Drexel policies.

3.1 Routine Review Selection Criteria

Routine Reviews will be identified and prioritized by the Executive Director for Research Quality Assurance using the following criteria:

- Investigators or Drexel holding an IND/IDE on an FDA-regulated study
- Project status (e.g., currently enrolling, ongoing research activities)
- Phase 1 projects
- Projects with high participant enrollment (e.g., multisite projects where Drexel is enrolling a high number of participants)
- Investigators with a high number of projects (3 or more), conflict management plans, or intellectual property
- Projects involving a vulnerable population
- Projects with significant reported deviations or safety reports
- Federally funded/federally regulated projects without external monitoring
- Department/College research portfolio representation (e.g., a College or department otherwise infrequently selected for quality assurance reviews)
- New/first-time investigator
- IACUC protocols with a higher pain category (e.g., category E versus C)
- IACUC protocols with USDA covered species
- IACUC protocols with major survival surgery, prolonged restraint, or food/fluid restriction

3.2 Routine Review Preparation

1. Notify the project PI or responsible individuals of the upcoming Routine Review.
    - Copy the area/division chairperson, Associate Dean for Research, or Dean
    - Copy the Associate Vice Provost for Research Compliance and Regulatory Affairs
2. Initial notification will include:

- The scope of the review, (e.g., full quality assurance review, documentation of informed consent, participant eligibility)
- List of required documents for review, (e.g., regulatory files, training documentation, source documents)
- Timeframe for review (within 4 weeks unless extenuating circumstances are under consideration),
- Review location (e.g., fully remote review request via SharePoint document sharing, requesting an available room to complete the review on-site)

3. Prior to the scheduled review period, preliminary review preparation may include the review of electronic submissions (e.g., COEUS, DragonSpot, Novelution), protocol/project procedures/terms, communications with federal agencies and funding sources, discussions with project personnel.

3.3 Routine Review Visit Expectations

It is expected that the requested documents will be made available for review on the scheduled review date. The reviewer and researchers will maintain communication of any scheduling changes or limitations for completing the review or providing the requested materials.

The requested materials will be reviewed in accordance with the applicable laws and regulations, institutional policies and procedures, guidelines, and approved protocols. Additional materials may be requested during the course of the review. Personnel may be interviewed or asked additional process information.

Documentation can be generated, provided they are substantiated by original verifiable source materials, and include appropriate versioning and a clear "origination date" and MUST never make false representations (e.g., back-dating reviews or signatures, signing on behalf of another individual) and MUST always be backed up by alternate documentation that can be considered source information (e.g., using emails, existing records or files to support the documentation in lieu of having a formal log). If a particular document or set of documentation was previously unavailable and is newly generated for the audit, an accompanying note-to-file should be included outlining the following fields:

1. Reason for the Error/Omission:
   - Provide an explanation of why the error or omission occurred (e.g., human error, technical glitch, oversight).
   - If the root cause is unknown at the time of the note, indicate that a further investigation will follow.
2. Description of the document generation:
   - What Happened: Provide a precise explanation of the missing documentation or error.
   - Where It Occurred: Identify the specific document, system, or record where the error or omission was found.
   - When It Was Identified: Include the date when the issue was discovered and by whom.
3. Corrective Action:
   - How the Error Was Corrected: Describe the steps taken to correct the error or fill in the omission.

- Who Implemented the Correction: Identify the person(s) responsible for making the correction and how information was disseminated to study staff, as applicable.
- Date of Correction: Record the date when the correction was made.

4. Preventive Action:
   - Outline any steps that will be taken to prevent the error or omission from recurring in the future.
   - This could include training, process changes, or system upgrades.
5. Supporting Documentation:
   - Attach copies of any relevant documentation that supports the identification of the error, the documentation, and the corrective action taken.
   - This could include the original, erroneous document and the corrected version, along with any other relevant records, such as email correspondence or meeting notes.
6. Approval or Acknowledgment:
   - If applicable, include date and signatures from relevant parties (e.g., PI, Associate Dean for Research, supervisors) who have reviewed and approved the note-to-file.
   - This adds a layer of accountability and formal acknowledgment of the resolution.
7. Reference to Applicable Policies or Regulations:
   - If the error or omission impacts regulatory compliance, reference the relevant guidelines, policies, or regulations that dictate the correction procedure.
   - This ensures that the correction process aligns with necessary standards.
8. Impact Assessment:
   - Evaluate and document whether the error or omission had any impact on downstream processes, decisions, outcomes, or other programs.
   - Include an assessment of whether the error affected regulatory compliance or participant rights or welfare and is reportable to the IRB, IACUC, funding agency, Human Resources, Office of General Counsel, or any other relevant office or agency.

If during the review preparations, the investigator or other individual identifies an event requiring prompt reporting (e.g., to the IRB, IACUC, funder), they must proceed to follow the reporting requirements as applicable (e.g., submitting a reportable new information (RNI) report to the IRB within 7 days). Documentation of this report should be provided to the QA Program personnel at the time of the review.

During the course of the review, if any review findings indicate immediate safety or welfare concerns, the findings will be communicated to the Associate Vice Provost for Research Compliance and Regulatory Affairs and may be reported to the IRB, IACUC, Research Integrity Officer, Institutional Official or other applicable groups.

If any review findings fall outside of the initial scope of the review, the review may be expanded to include other focus areas under the ORI or may include the review of additional projects as needed. In addition, if any review findings fall outside of the scope of the ORI, additional University offices may be notified, as applicable (e.g., Internal Audit, Privacy Program Services, Civil Rights Compliance, Corporate Compliance, Office of Graduate Studies, etc.).

3.4 Routine Review Procedures

Routine Review procedures will vary depending on the scope or focus of the review. The scope of the review will be communicated to the PI or responsible individual prior to the review along with a list of required documents for review.

Quality assurance reviews may consist of, but are not limited to, the review of:

- Regulatory records and documentation
- Conflict of interest and financial disclosure(s)
- Training records
- Source records and protocol compliance
- Investigational product accountability records

The initial scope of the review may be expanded to include additional focus areas or other projects. Any changes to the review scope will be communicated to the PI or responsible individual and the Associate Vice Provost of Research Compliance & Regulatory Affairs.

3.5 Routine Review Close Out Procedures

Upon completion of the review, a close-out meeting with the project personnel will be scheduled to review and discuss the findings.

The review results will be documented in the form of a written report, including detailed findings, applicable regulations, guidelines, and policies, and proposed action plans to address any findings. The final report will be sent to the project Principal Investigator or responsible individual, the Dean, Department Chair/Head, Associate Dean for Research of the applicable department/college, the Associate Vice Provost for Research Compliance and Regulatory Affairs, the Institutional Official, and other relevant Drexel offices as applicable within 10-15 business days of completion of the review.

The report will include suggested action plans for follow-up, either action items or full corrective and preventive action (CAPA) plans. The report findings and suggested action plans are guidance based on case-by-case or project-specific observations; however, it is under the discretion and responsibility of the PI or responsible individual to determine the appropriate actions and if corrective measures should be applied to other projects under their oversight. If the PI disagrees with the findings of a report, the PI may submit this information along with additional supporting documentation with their written response to the report. A report response must be submitted within 30 days of receipt of the report to the QA reviewer who provided the report. If additional time is needed for responses, a request must be made and permitted by ORI leadership, as applicable. Please note, that protocols falling under the HRPP/IRB or IACUC may have shorter reporting windows. Any requirement to report findings to the HRPP/IRB or IACUC will be specified in the report. In addition, the reviewing committee (e.g., IRB or IACUC) may request or impose additional actions during their review of reportable events. All other items should be addressed, or a plan for ongoing implementation of corrective and preventive actions is communicated to the quality assurance reviewer.

If an observation meets additional reporting criteria, e.g., prompt reporting to the IRB or IACUC, and the study team or applicable party fails to submit the information per the reporting criteria, the Executive Director for Research Quality Assurance will escalate the request to the Department Chair, Associate Dean for Research, Dean, or Institutional Official as appropriate.

When applicable, a follow-up review may be required to ensure implementation of the CAPA plan. The follow-up review may include, but is not limited to a full audit, a focused audit based on the previous audit findings and implemented CAPA plans, or review of a different protocol.

4. Directed or "For-Cause" Quality Assurance Reviews

Directed quality assurance reviews ("Directed Reviews"), also considered "for-cause" audits, may be requested by the Institutional Official, HRPP/reviewing IRB, IACUC, or other regulatory office. Directed Reviews may be triggered by specific concerns, incidents, or deviations, including complaints or observations of noncompliance. Directed Reviews may be focused on a specific area of concern or may extend to related processes and documentation. All requests for Directed Reviews shall be forwarded to the Executive Director for Research Quality Assurance.

4.1 Directed Review Selection Criteria

The selection of a Directed Review will be at the discretion of the individual or office requesting the review.

4.2 Directed Review Preparation

The PI or responsible individual and the QA Program will be notified of the Directed Review by the party requesting the review (e.g., IRB, IACUC, IO). The requestor will provide the name of the PI or responsible individual, department name, specific projects (if applicable), and the scope of the review in writing to the Executive Director of Research Quality Assurance. The QA Program personnel will then contact the PI or responsible individual to establish dates and procedures for the review.

Preparation procedures will include:

1. Notifying the project PI or responsible individuals of the upcoming quality assurance review.
   - Copy the area/division chairperson, Associate Dean for Research, or Dean
   - Copy the Associate Vice Provost for Research Compliance and Regulatory Affairs
2. Initial notification will include:
   - The scope of the review, (e.g., full quality assurance review, documentation of informed consent, participant eligibility)
   - List of required documents for review, (e.g., regulatory files, training documentation, source documents)
   - Timeframe for review (typically within 1 week unless extenuating circumstances are under consideration),
   - Review location (e.g., fully remote review request via SharePoint document sharing, requesting an available room to complete the review on-site)
3. Prior to the scheduled review period, preliminary review preparation may include the review of electronic submissions (e.g., COEUS, DragonSpot, Novelution), protocol/project

procedures/terms, communications with federal agencies and funding sources, discussions with project personnel.

4.3 Directed Review Visit Expectations

It is expected that the requested documents will be made available for review on the scheduled review date. The reviewer and researchers will maintain communication of any scheduling changes or limitations for completing the review or providing the requested materials.

During a directed review, investigators and any other Drexel personnel shall not alter, delete or create information or documentation in preparation of or during the audit. This will be communicated to the PI or responsible individual when the audit is scheduled. If the PI or responsible individual identifies a deviation or documentation error, this must be communicated to the QA Program reviewer at the time of the audit.

If during the review preparations, the investigator or other individual identifies an event requiring prompt reporting (e.g., to the IRB, IACUC, funder), they should proceed to follow the reporting requirements as applicable (e.g., submitting a reportable new information (RNI) report to the IRB within 7 days). Documentation of this report must be provided to the QA Program personnel at the time of the review.

The requested materials will be reviewed in accordance with the applicable laws and regulations, institutional policies and procedures, guidelines, and approved protocols. Additional materials may be requested during the course of the review. The scope of review may be expanded or modified at the discretion of the QA personnel during the review. Personnel may be interviewed or asked for additional process information.

During the course of the review, if any review findings indicate immediate safety or welfare concerns, the findings will be communicated to the Associate Vice Provost for Research Compliance and Regulatory Affairs and may be reported to the IRB, IACUC, Research Integrity Officer, Institutional Official or other applicable groups.

If any review findings fall outside of the initial scope of the review, the review may be expanded to include other focus areas under the ORI or may include the review of additional projects as needed. In addition, if any review findings fall outside of the scope of the ORI, additional University offices may be notified, as applicable (e.g., Internal Audit, Privacy Program Services, Civil Rights Compliance, Corporate Compliance, Office of Graduate Studies, etc.).

4.4 Directed Review Procedures

Review procedures will vary depending on the scope or focus of the review as identified by the requestor. The scope of the review will be communicated to the PI or responsible individual prior to the review along with a list of required documents for review.

Directed Reviews may consist of, but are not limited to, the review of:

- Regulatory records and documentation
- Conflict of interest and financial disclosure(s)

- Training records
- Source records and protocol compliance
- Investigational product accountability records

The initial scope of the Directed Review may be expanded to include additional focus areas or other projects. This may be done as a result of preliminary review findings or new information. In addition, the party requesting the review may expand or revise the scope of the audit. Any changes to the review scope will be communicated to the PI or responsible individual and the Associate Vice Provost of Research Compliance & Regulatory Affairs.

4.5 Directed Review Close Out Procedures

The Directed Review results will be documented in the form of a written report, including detailed findings, and applicable regulations, guidelines, and policies. The final report will be provided to the requesting Office who will disseminate the reported information as appropriate or an alternate plan as identified by the requesting Office, e.g., the QA Program may disseminate the report to the PI, applicable department, etc. as requested by the IRB who requested the directed review.

The timeline for completion of the review and report submission will vary depending on the scope and complexity of the review.

The requesting office shall disseminate the report to the principal investigator or responsible individual at their discretion and will require responses and/or corrective actions, as applicable. In general, it is expected that audit findings will be provided to the PI, responsible party, Dean, Department Chair/Head, and Associate Dean for Research of the applicable college/department unless dissemination of the findings is precluded by other policies or procedures. The timeline for the report response and requested actions will be communicated to the investigator or responsible individual.

The requesting party may require a follow-up review to ensure implementation of the CAPA plan(s), as applicable. The requesting party should notify the principal investigator or responsible individual and the QA Program of the follow-up review. The follow-up review may include, but is not limited to a full audit, a focused audit based on the previous audit findings and implemented CAPA plans, or review of a different protocol and will be completed at the direction of the requestor.

5. Requested Quality Assurance Reviews

Investigators or Offices may voluntarily request the QA Program complete a review of a project or process (“Requested Review”). Investigators may consider a Requested Review beneficial if the study sponsor has indicated the site has a high likelihood of an FDA or agency inspection, if there are concerns about regulatory compliance, or for a review of best practices. Requested Reviews should not be used to satisfy a project’s monitoring plan or Data Safety Monitoring Plan (DSMP).

5.1 Requested Review Selection Criteria

The QA Program will make every effort to assist with a Requested Review. Requested Reviews may be subject to availability of personnel or a risk-level assessment of priority.

5.2 Requested Review Preparation

The QA Program personnel will discuss the scope of the Requested Review with the requesting individual. This may vary depending on the reason for the Requested Review (e.g., full review of GCP procedures or concerns about data integrity, etc.). The QA Program personnel will communicate the required documents for review and work with the requestor to arrange the timeframe and location of the review.

Prior to the scheduled review period, preliminary review preparation may include the review of electronic submissions (e.g., COEUS, DragonSpot, Novelution), protocol/project procedures/terms, communications with federal agencies and funding sources, discussions with project personnel.

5.3 Requested Review Visit Expectations

It is expected that the requested documents will be made available for review on the scheduled review date. The reviewer and researchers will maintain communication of any scheduling changes or limitations for completing the review or providing the requested materials.

The requested materials will be reviewed in accordance with the applicable laws and regulations, institutional policies and procedures, guidelines, and approved protocols. Additional materials may be requested during the course of the review. Personnel may be interviewed or asked additional process information.

While documentation can be generated to record relevant or pre-existing information, generated documentation should never make false representation (e.g., back-dating reviews or signatures, signing on behalf of another individual) and should always be able to be backed up by alternate documentation that can be considered source information (e.g., using emails, existing records or files to support the documentation in lieu of having a formal log). If a particular document or set of documentation was previously unavailable and is newly generated for the audit, an accompanying note-to-file should be included outlining the following fields:

1. Reason for the Error/Omission:
   - Provide an explanation of why the error or omission occurred (e.g., human error, technical glitch, oversight).
   - If the root cause is unknown at the time of the note, indicate that a further investigation will follow.
2. Description of the document generation:
   - What Happened: Provide a precise explanation of the missing documentation or error.
   - Where It Occurred: Identify the specific document, system, or record where the error or omission was found.
   - When It Was Identified: Include the date when the issue was discovered and by whom.
3. Corrective Action:

- How the Error Was Corrected: Describe the steps taken to correct the error or fill in the omission.
- Who Implemented the Correction: Identify the person(s) responsible for making the correction and how information was disseminated to study staff, as applicable.
- Date of Correction: Record the date when the correction was made.

4. Preventive Action:
   - Outline any steps that will be taken to prevent the error or omission from recurring in the future.
   - This could include training, process changes, or system upgrades.
5. Supporting Documentation:
   - Attach copies of any relevant documentation that supports the identification of the error, the documentation, and the corrective action taken.
   - This could include the original, erroneous document and the corrected version, along with any other relevant records, such as email correspondence or meeting notes.
6. Approval or Acknowledgment:
   - If applicable, include date and signatures from relevant parties (e.g., PI, Associate Dean for Research, supervisors) who have reviewed and approved the note-to-file.
   - This adds a layer of accountability and formal acknowledgment of the resolution.
7. Reference to Applicable Policies or Regulations:
   - If the error or omission impacts regulatory compliance, reference the relevant guidelines, policies, or regulations that dictate the correction procedure.
   - This ensures that the correction process aligns with necessary standards.
8. Impact Assessment:
   - Evaluate and document whether the error or omission had any impact on downstream processes, decisions, outcomes, or other programs.
   - Include an assessment of whether the error affected regulatory compliance or participant rights or welfare and is reportable to the IRB, IACUC, funding agency, Human Resources, Office of General Counsel, or any other relevant office or agency.

If during the review preparations, the investigator or other individual identifies an event requiring prompt reporting (e.g., to the IRB, IACUC, funder), they should proceed to follow the reporting requirements as applicable (e.g., submitting a reportable new information (RNI) report to the IRB within 7 days). Documentation of this report should be provided to the QA Program personnel at the time of the review.

During the course of the review, if any review findings indicate immediate safety or welfare concerns, the findings will be communicated to the Associate Vice Provost for Research Compliance and Regulatory Affairs and may be reported to the IRB, IACUC, Research Integrity Officer, Institutional Official or other applicable groups.

If any review findings fall outside of the initial scope of the review, the review may be expanded to include other focus areas under the ORI or may include the review of additional projects as needed. In addition, if any review findings fall outside of the scope of the ORI, additional

University offices may be notified, as applicable (e.g., Internal Audit, Privacy Program Services, Civil Rights Compliance, Corporate Compliance, Office of Graduate Studies, etc.).

5.4 Requested Review Procedures

Review procedures will vary depending on the scope or focus of the review. The scope of the review will be based off the purpose for the Requested Review, as indicated by the requestor. The QA Program will provide a list of required documents for review to the PI or responsible individual.

Quality assurance reviews may consist of, but are not limited to, the review of:

- Regulatory records and documentation
- Conflict of interest and financial disclosure(s)
- Training records
- Source records and protocol compliance
- Investigational product accountability records

The initial scope of the review may be expanded to include additional focus areas or other projects. Any changes to the review scope will be communicated to the PI or responsible individual and the Associate Vice Provost of Research Compliance & Regulatory Affairs.

5.5 Requested Review Close Out Procedures

Upon completion of the review, a close-out meeting with the project personnel will be scheduled to discuss the findings.

The review results will be documented in the form of a written report, including detailed findings, applicable regulations, guidelines, and policies, and proposed action plans to address any findings within 10-15 business days of completion of the review. Reports for Requested Reviews will only be sent to the PI and/or personnel requesting the review unless observations suggest increased risk of harm, require additional immediate escalation, or require reporting outside of the purview of ORI.

The report will include suggested action plans for follow-up, either action items or full corrective and preventive action (CAPA) plans. The report findings and suggested action plans are guidance based on case-by-case or project-specific observations; however, it is under the discretion and responsibility of the PI or responsible individual to determine the appropriate actions and if corrective measures should be applied to other projects under their oversight. A report response is required within 30 days of receipt of the report. If additional time is needed for responses, a request must be made and permitted by ORI leadership, as applicable. Please note, that protocols falling under the HRPP/IRB or IACUC may have shorter reporting windows. Any requirement to report findings to the HRPP/IRB or IACUC will be specified in the report. In addition, the reviewing committee (e.g., IRB or IACUC) may request or impose additional actions during their review of reportable events. All other items should be addressed, or a plan for ongoing implementation of corrective and preventive actions is communicated to the quality assurance reviewer.

If an observation meets additional reporting criteria, e.g., prompt reporting to the IRB or IACUC, and the study team or applicable party fails to submit the information per the reporting criteria, the Executive Director for Research Quality Assurance will escalate the request to the Department Chair, Associate Dean for Research, Dean, or Institutional Official as appropriate.

When applicable, a follow-up review may be required to ensure implementation of the CAPA plan. The follow-up review may include, but is not limited to a full audit, a focused audit based on the previous audit findings and implemented CAPA plans, or review of a different protocol.

6. Responsibilities

6.1 Office of Research & Innovation Responsibilities

The Office of Research & Innovation is committed to ongoing quality assurance and research compliance. The QA Program, as part of ORI, is responsible for maintaining these procedures, applicable tools, and completing quality assurance reviews. For inquiries regarding these procedures, please contact the Associate Vice Provost for Research Compliance and Regulatory Affairs in ORI.

6.2 Principal Investigator Responsibilities

As applicable, the Principal Investigator (PI) is responsible for ensuring that all aspects of an approved protocol are understood and followed by all personnel involved in the conduct of the project. The PI will be responsible for facilitating quality assurance reviews as requested, and for ensuring audit observations are appropriately resolved following review. In the event that a PI has left the institution and/or is unable to facilitate the quality assurance review, the PI's department may be responsible for identifying an individual to facilitate the review and implement any applicable actions.

6.3 Other Personnel Responsibilities

When quality assurance reviews are focused on ORI processes, areas, or offices (e.g., IRB, IACUC, COI) other responsible individuals may be identified to comply with a QA Program audit (e.g., the Executive Director of Human Research Protections may be the responsible individual for facilitating a QA review of consent form approvals and required elements). The QA Program will identify and communicate with responsible individuals regarding the scope of the review and responsibilities for facilitating the QA reviews.

7. Resources

- Good Clinical Practice Guidelines (R2)
- Good Clinical Practice Guidelines (R3, 01/06/2025)
- 45 CFR 46 Office for Human Research Protections
- AAHRPP Accreditation Procedures
- SMART IRB Agreement, Sections 5.12 and 6.13
- Public Health Service Policy on Humane Care and Use of Laboratory Animals [NIH-OLAW]
- Guide for the Care and Use of Laboratory Animals (8th Edition)
- Animal Welfare Act and Animal Welfare Regulations

- AAALAC Rules of Accreditation

8. Revision and Workgroup Members

8.1 Revision

Version 001/Effective Date 03/12/2025 - Original Document – Research Quality Assurance Reviews

8.2 Workgroup Member

The Office for Research and Innovation appreciates the following individuals who served as Workgroup Members:

Workgroup Members	
Marisa Corbett, BA, CCRC Executive Director for Research Quality Assurance Office of Research & Innovation	**Cassandra Myers, BS** Associate Vice Provost Research Compliance and Regulatory Affairs Office of Research & Innovation
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Alison Dougherty, Ed.D. Assistant Vice President, Title IX & EO Coordinator Office for Institutional Equity & Inclusive Culture	**Alice Reuther** Director of Contracts and Subawards Office of Research & Innovation
Victoria Egan, MPH Director of Research Administration Dornsife School of Public Health	**John Roberts, BA, CIP** Executive Director of Human Research Protections Program Office of Research & Innovation
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Elizabeth Hann, BS Director of Animal Welfare, Radiation Safety, and IBC Office of Research and Innovation	**Tamara Sobkow** Human Resources Business Partner Office of Human Resources
Lacee Harris, PhD Executive Director, Research Compliance Office of Research & Innovation	**Jacqueline Stults, MBA, BS** Research Quality Assurance/Quality Improvement Office of Research & Innovation

Janet Matthews, MSN, RN Senior Director, Research Program Development College of Medicine	**Melissa Whitney, BS** Animal Welfare Specialist Office of Research & Innovation
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