Quality Assurance & Improvement Program
Policy and Procedure

Table of Contents

I. Policy

A. This policy specifies the approach to quality assurance and continuous improvement for the Research Protection Programs (RPP) including the Office of the Institutional Review Board (OIRB), the Office of Clinical Research (OCR), and the Institutional Animal Care Program Office (IACP).

B. Overview

1. This procedure starts at regular intervals (weekly, monthly, quarterly and annual assessments) or by special request.

2. This procedure ends when the periodic results are used to progress research or strengthen processes in the OIRB, OCR, and IACP.

II. Procedure

A. The RPP undertakes regular monitoring to evaluate the strengths, weaknesses, efficiency and effectiveness of the services provided by the OIRB, OCR, and IACP.

B. Quality Assurance activities to assess program strengths and weaknesses

1. To maintain accreditation from the Association for the Accreditation of Human Research Protection Programs (AAHRPP), the UTHSCSA Human Research Protection Program undergoes a rigorous assessment every five years. The OIRB and OCR use the AAHRPP Evaluation Instrument on a regular basis to ensure the program continues to meet all the accreditation Standards and Elements.

2. An evaluation instrument to assess the OIRB and the OCR is available for use by the Office of Regulatory Affairs and Compliance. Audit results are shared with the Director and are used to identify areas for improvement.

3. The IACP and Institutional Animal Care and Use Committee (IACUC) conduct a program review and facility inspection twice per year, as required by the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals (Policy), Section IV.B.1.-3., the Guide for the Care and Use of Laboratory Animals (Guide), and the Animal Welfare Act (AWA) regulations, as applicable. Submission of semiannual reports to the Institutional Official is a condition of this institution's Animal

Welfare Assurance with the NIH Office of Laboratory Animal Welfare (OLAW). The program review includes an assessment of program changes, adherence, deficiencies, and deficiency corrections.

4. To maintain accreditation from the Association for Assessment and Accreditation of Laboratory Animal Care International, the UTHSCSA Institutional Animal Care and Use Program undergoes a rigorous assessment every three years.

C. Quality Improvement and Quality Control activities to improve program efficiency and effectiveness

1. Weekly and Monthly analyses are conducted of the data fields in the OIRB protocol database, IACP protocol database, and ORCA online protocol system to verify data entry accuracy. Items needing to be verified are identified by the Director and analyzed by the QA/QI Coordinator. When errors are found, the QA/QI Coordinator corrects or coordinates with the appropriate Associate Director or Compliance Manager who will direct staff to make the corrections. When recurring errors are identified, the Associate Director or Compliance Manager will schedule training sessions with staff to ensure data entry fields are completed as appropriate.

2. Quarterly analyses are conducted of the data fields in the OIRB protocol database and IACP protocol database to assess turnaround times for specific business items (such as median number of days from initial submission to IRB Full Board approval of a new study). The analyses are compiled into a report that is shared with the Director and used for benchmarking the OIRB, OCR, and IACP performance against other relevant organizations and identify and act upon areas needing improvement.

3. Quarterly analyses are conducted of the Research Regulatory Concierge Services Feedback Surveys. Concierge sessions are held several times per month and the research community who attend are invited to complete an anonymous feedback survey. The analyses are compiled into a report that is shared with the Director and used to improve the services offered by the OIRB, OCR, and IACP.

4. Quarterly analyses are conducted of the Research Regulatory Forum Feedback Surveys. Forum sessions are held several times per year and the research community who attend are invited to complete an anonymous feedback survey. The analyses are compiled into a report that is shared with the Director and used to improve the services and educational offerings of the OIRB, OCR, and IACP.

5. Quarterly analyses are conducted of the Research Regulatory Client Feedback Surveys. The Client Feedback Survey is posted on the OIRB, OCR, and IACP websites and the research community may complete this anonymous feedback survey at any time. The analyses are compiled into a report that is shared with the Director and used to improve the services, website content, and educational offerings of the OIRB, OCR, and IACP.

6. Quarterly analyses are conducted by the Office of Regulatory Affairs and Compliance (ORAC) to evaluate active IRB protocols. The Director is involved in this

evaluation process and notified of any critical issues or items needing follow-up per the Study Reviews for Human Research Policy.

7. An annual analysis of IRB and IACUC committee member meeting attendance and review assignments is conducted and compiled into a report that is shared with the Director. The Director and chairs of the IRB and IACUC committees use this report to evaluate the membership and composition of the committees and ensure all members are fulfilling the requirements including education requirements per the Evaluation of IRB Membership Policy and Procedure and the IRB Education Policy.

8. All Sponsor-Investigator studies are subject to a quality assurance review by the OCR. The OCR will randomly review primarily non-cancer related studies and also conduct any for-cause reviews or those voluntarily requested by Principal Investigators or researchers. The results will be documented using the Research Compliance Assessment Instrument (REDCap) and discussed with the PI. A written report of the findings and any corrective actions is then shared with the Director.

9. When the IRB determines that a protocol requires observation of the consenting process, the OCR or the ORAC coordinates with the Principal Investigator/ Coordinator in order to schedule and observe the informed consent process. After the observations are complete, the results are discussed with the PI. A written report of the findings and any corrective actions is then shared with the Director. As part of the corrective actions, the Principal Investigator is directed to follow the Informed Consent Process SOP, the Written Documentation of Consent SOP, and the Informed Consent Policy and Procedure. Should issues be noted by the observer as serious or continuing non-compliance, the Noncompliance Policy and Procedure would be followed.

10. Other reports and analyses are conducted per the Director, as needed, and as particular issues are identified.

11. Additionally, the OIRB Associate Director, IACP Associate Director, and OCR Compliance Manager conduct regular metrics reports of their analysts' work and performance to identify and act upon areas needing improvement.

12. As needed, the RPP utilize the services of the Department of Epidemiology & Biostatistics, specifically working with faculty with expertise in the Lean Six Sigma program. Collaborating with the Lean Six Sigma experts, special projects are identified in order to improve performance and reduce waste and redundancy.

13. As part of the Quality Improvement Program, Principal investigators conducting research will follow the PI Self Assessment Program Policy and Procedure.

D. Based on the QA/QI activities, if the RPP identifies issues pertinent to the responsibilities of other coordinating committees or offices, RPP will follow the Coordination with Other Committees or Offices Policy and Procedure.

III. References

A. Definitions (see Glossary)

B. Regulatory (see Policy on Policies Policy and Procedure)