

NIH Quality Improvement Assessment (QIA)

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QIA—Scope

- 80 protocols of the 810 protocols that were actively enrolling participants as of January 1, 2017 were assessed
 - Excluded training, screening and repository protocols
- 10 participants or less per protocol for a total of 468 participant records
- Focused review:
 - Informed consent process
 - Eligibility
 - Problem Reporting

QIA—Scope (continued)

- Assessment was performed by Pharmaceutical Product Development (PPD)
- PPD was chosen using a competitive process and is a global contract research organization that provides comprehensive clinical research support to industry, academic and government organizations

QIA—Scope (continued)

18 Institutes

Sites included:

- Bethesda Campus,
- Baltimore,
- Research Triangle Park,
- Phoenix
- Detroit

Protocols included:

- FDA regulated trials (IND/IDE),
- Observational studies,
- Natural history studies,
- Clinical trials
- Thematic protocols

Critical Findings—Informed Consent

- Total of two (2) findings out of 468 records that were reviewed
- For one protocol a participant was consented with the wrong consent based on their participation type (donor vs recipient)
- For one protocol an individual not listed as an Investigator or delegated with the role of obtaining consent administered consent to a participant on the study

Trends: Informed Consents

- Documentation of the informed consent process in the medical record was sometimes incomplete or not present
- Solution: A policy will be developed to ensure that the consent process will be supplemented by a complete and accurate informed consent note in the medical record

Critical Findings--Eligibility

- Total of three (3) findings out of 468 records that were reviewed.
- 2 findings were for required tests to determine eligibility not being performed or performed after the participant was enrolled on the study
- 1 finding was for a protocol where participants were required to have more than 4 weeks since their last treatment for disease before enrolling and they were enrolled before the 4 weeks passed

Trends--Eligibility

- PPD was unable to verify eligibility due to inadequate or missing documentation in the medical record
- Solution: A policy will be developed to ensure that eligibility criteria checklist data will be documented in the medical record

Critical Findings--Problem Reporting

- Total of two (2) out of 468 records that were reviewed
- One Problem report was classified incorrectly—after submission the IRB corrected the Problem Report
- One Serious Protocol Deviation was not reported to the IRB. The PI submitted the problem report as required by the NIH HRPP SOPs when notified by the QIA review

PPD noted several processes that work well

- Protecting the health safety and welfare of human research participants is a clear priority of the staff as demonstrated by the few safety and critical events identified
- Staff was collaborative and receptive to feedback, planned to implement best practices going forward and many were interested in future review and training

PPD noted areas that need improvement

NIH should:

- Have one centralized IRB with standardized policies and procedures
- Develop additional role based Good Clinical Practice Guidelines training to promote improved study practices

Future Plans

- Expand current committees to address identified areas that need improvement
 - Training Committee
 - QAPAC
- Continue the QIA to include annual deep dive audits of protocols
- Utilize the QAPAC (Quality Assurance Professionals Advisory Committee) to establish common guidelines for best practices (e.g. delegations logs) and to adjust IC monitoring plans for 2018 using results from the QIA