

R2A2 QUALITY ASSURANCE (QA) PHYSICIAN

Roles:

- To contribute to the establishment and maintenance of an environment for research involving human subjects which protects the rights of subjects and promotes safety for subjects and clinical staff.
- Advise Laboratory Management on the quality assurance, safety, and care of human subjects and the credentialing and qualifications of the clinical staff.

Responsibilities:

- Chair the CRC Credentialing Committee to credential physicians, nurses and other clinical research staff who have contact with subjects.
- Chair the Clinical Research Quality Assurance Committee.
- Review and approve Adverse Event (AE) reports and determine that appropriate actions have been taken.
- Review protocols concerning research in voluntary human subjects to address issues relating to subject care.

Accountabilities:

- To the BNL Institutional Official for performances of the above tasks.

Authorities:

- Stop or interrupt a clinical study upon evidence of a hazard for the safety and/or rights for subject