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SUBJECT: Clinical Protocol Coordinator (CPC)	REVIEWED BY: F. HENN	
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1.0 POLICY

• It is the policy of the CRC to have a Clinical Protocol Coordinator (CPC) who provides support to the PIs doing human subjects research in the preparation of the IRB submission and study documentation.

The CPC is responsible for providing internal Quality Assurance (QA) within the research team ensuring the accuracy and completeness of the subjects' medical records, Consent Forms and Case Report Forms.

2.0 QUALIFICATIONS

The CPC shall have the following qualifications:

- Must have knowledge of Good Clinical Practice (GCP) and other federal regulations.
- Must have knowledge of maintenance of study documents (i.e. Case Report Forms (CRF), source documents, Investigator files and research protocols).
- Knowledge of Department of Energy, National Institutes of Health, BNL and Medical Department Policies and Procedures regarding human subject protection in clinical research.

3.0 RESPONSIBILITIES (R2A2 ATTACHMENT F)

The CPC shall report to the PI for performance of the above tasks and to the head of the clinical research group as appropriate for assisting the PI in carrying out human subjects research.

The CPC shall have the following duties:

3.1Assist PIs in preparation of protocol, IRB application and consent forms for new protocol

3.2Assist PIs in preparation of protocol addendums, consent forms, IRB submission and recertification (including subject accrual reconciliation) for existing protocol. Assist PIs in updating the protocol by incorporating the approved addendum and distributing the updated protocol to ORA and the related research facilities (MRI/PET). Act as a liaison between the research team, CRC and IRB.

3.3 Assist PIs in preparation and maintenance of Investigator's files.

3.4 Assist PI and RP in preparation of study documentation for each new protocol and updating the study documentation for each approved protocol and each approved addendum.

3.5 Keep informed of good clinical practice and regulatory requirements for human subjects research.

3.6 Assist PI's in the continuous review of subject records to ensure the accuracy and completeness of all subjects' records, Consent Forms, and Case Report Forms.

3.7 Report to the PI any issues involving record keeping or protocol compliance and assist the PI in implementing corrective actions.

3.8 Coordinate clinical studies as assigned by PI's. Coordinate subject scheduling and study details with CRC administrative staff.

3.9 Assist PI's in completing medical records and ensuring that all records are returned to CRC in a timely manner.

4.0 REPORTING STRUCTURE

The Clinical Protocol Coordinator shall be responsible to the Clinical Head and/or Program Director of the associated group.