

R2A2 CLINICAL PROTOCOL COORDINATOR

Clinical Protocol Coordinator (CPC)

Role

- Provide technical and regulatory information and support to the Principal Investigators carrying out Human Studies

Responsibilities

- Assist PI's in preparation of forms, IRB application and consent forms for new protocols.
- Review regulatory requirements annually and make recommendations to the Principal Investigator/Responsible Physician to ensure regulatory compliance.
- Assist in the preparation of the package to be submitted to the IRB for annual review .(including subject accrual reconciliation)
- Assist in the continuous review of investigator files and medical records.
- Report to the Principal Investigator any problems in record keeping or protocol compliance.

Accountability

- To the Principal Investigator for performance of the above tasks
- To the Chair of the Medical Department for assisting the Principal Investigator in carrying out Human Studies Research

Authorities

- To take action needed to ensure that Human Studies Research is carried out in compliance with regulatory policies

