Clinical Research Operations

The Office of the Clinical Director serves as the interface between CCR clinical investigators and the NIH Clinical Center where CCR clinical trials take place. The Clinical Director, Dr. James Gulley, oversees and assures the quality of medical care delivered to patients treated on CCR clinical trials. The Office of the Clinical Director is also responsible for:

- Biostatistical expertise for clinical trial design and analysis
- Administrative support for the protocol review and monitoring process
- Training and continuing education for clinical research staff
- Data management, auditing and monitoring of NCI intramural and multi-institutional trials
- An outreach program to promote patient accrual
- Informatics for data collection and storage

This site was developed to support CCR clinical operations staff and is organized into the following sections:

1. Biostatistics and Data Management – Consultation for clinical trial design, review, conduct, monitoring and analysis
2. CCR Scientific Review – Information about meetings, scientific review procedures, and link to sign up for listserv
3. Clinical Informatics – Links to login pages, policies, applications support, updates, training schedules, user groups and other resources
4. Office of Education and Compliance (OEC) – New hire orientation, continuing education, seminars and helpful resources
6. NIH Institutional Review Board (IRB)
7. Office of Research Nursing (ORN) –
8. Office of Sponsor and Regulatory Oversight
9. CCR SOPs, Related Forms and Guidelines – Access to NCI-CCR standard operating procedures (SOPs), related forms (i.e., delegation log, protocol specific training documentation), and guidelines.
10. Medical Oncology Service (MOS) Policies and Guidelines –
11. Protocol Support Office (PSO) – Assistance to CCR clinical investigators in preparing and submitting clinical protocols to various regulatory bodies such as the IRB, RSC and IBC through the lifetime of the protocol
12. CCR IND/IDE Management –
13. Resources – Clinical trials resources, professional associations, training, terminology, and MORE . . .
14. Data Sharing –
15. Collaboration with Walter Reed National Military Medical Center Murtha Cancer Center - Consultation and treatment of NCI patients at WRNMMC, credentialing, clinical collaboration and tissue requests

Related Links

CCR Staff Intranet