

**Clinical Research Office (CRO)  
of the  
Robert H. Lurie  
Comprehensive Cancer Center  
of Northwestern University**

# Who uses the Clinical Research Office (CRO)?

- Services are available to anyone conducting research involving cancer patients
- The Cancer Center is the central cancer research site for the following groups:
  - Northwestern Memorial Hospital
  - Evanston Northwestern Healthcare
  - Children's Memorial Hospital
  - Jesse Brown VA Medical Center
  - The Rehabilitation Institute of Chicago

# CRO Services in support of cancer trials

- Scientific review and approval of cancer clinical trial protocols and amendments prior to IRB submission
- Develop clinical trial budgets, liaison with sponsors on contract issues, provide ongoing account maintenance
- Provide regulatory support services (initial and ongoing IRB submissions)
- Provide study coordination and data management
- NCI-approved data and safety monitoring committee, including ongoing monitoring of investigator-initiated trials

# Clinical Research Office (CRO) Scientific Review & Approval

- NCI mandate for comprehensive cancer centers
- Which studies require this approval?
  - All studies not already approved by an NCI approved review body
    - Investigator-initiated studies
    - Pharmaceutical sponsored trials
    - Contact the CRO for a listing of NCI-approved scientific review bodies

# Scientific Review Process Requirements

- A letter of intent (LOI), if the study has been developed by a Northwestern investigator
- A new protocol submission form with all required signatures and attachments (protocol, consent, etc.)
- An electronic copy of the informed consent (and preferably the protocol), if CRO will prepare IRB submission

NOTE: The IRB submission form must be signed by the CRO before the IRB will accept any cancer study.

# Who Needs to Sign the CRO Forms Before they are Submitted?

- The letter of intent must be signed by the principal investigator
- The CRO New Protocol Submission Form must be signed by
  - The disease section leader or department chair
  - Any special disease modality leader who would be involved in the study (e.g., radiation oncology, surgery, nuclear medicine)

# Where are the CRO Forms Submitted?

- Forms should be submitted to the CRO's Clinical Protocol Scientific Review and Monitoring Committee (CPSRMC) Coordinator
  - Becky Thulson
  - 676 North St. Clair, Suite 1200, Chicago, IL or
  - Via email to [r-thulson@northwestern.edu](mailto:r-thulson@northwestern.edu) with signed CRO form faxed to (312) 695-1352

# How Long Does it Take for the CRO to Approve a New Study?

- LOIs are reviewed at weekly meetings, and complete new study applications are reviewed twice each month
- New study applications are reviewed by a committee approximately two weeks after they are submitted
- The committee's findings are usually returned to the PI within a week after review

# Where Do I Get the Forms?

- All required forms can be found on the CRO web page at:  
[www.cro.lurie.northwestern.edu/Administrative/](http://www.cro.lurie.northwestern.edu/Administrative/)
  - (see “Forms & Templates”)

# Clinical Research Office (CRO)

- Budget and contracting services include:
  - Budget development and negotiation with the sponsor
  - Work with the Office of Sponsored Research and will serve as the liaison between the sponsor and the OSR
  - Manage clinical trial accounts
    - Pay bills, reconcile accounts, contact sponsors for payment, etc.

# Clinical Research Office (CRO)

- Regulatory services provided include:
  - Consent form finalization, HIPAA form development
  - Completion of all IRB paperwork for new and ongoing submissions
    - Amendments, periodic review, safety reporting, study completion, etc.
  - Primary contact with sponsors for all trials
    - Maintain regulatory binders, send required paperwork, etc.

# Clinical Research Office (CRO)

- Study coordination and data management:
  - Screening
  - Assist in consent process
  - Manage protocol requirements
    - Ensure medical team knows and follows protocol requirements
  - Complete all required data
  - Complete SAEs for IRB submission

# Questions? Contact the Clinical Research Office (CRO)

- For questions about the study submission or the scientific review processes, contact the CPSRMC Coordinator, Becky Thulson, at 312-695-1369
- For administrative questions, contact the Administrative Director, Renee Webb, at 312-695-1301