



# Study Chair Responsibilities

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# Study Chair Responsibilities

- Protocol development
  - Protocol monitoring
  - Protocol analysis
  - Publication of results
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## Study Chair Responsibilities

- Ethical Conduct of Research
    - Affirmation of integrity
    - Training in human subjects protection (required as of 10/1/00)
    - Conflict of interest disclosure
    - CTSU registration
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## Patient Confidentiality: HIPAA

- Study chair is responsible for protecting patient confidentiality
  - Designees of study chair are also bound by HIPAA
    - Secretary who organizes patient files
    - Staff who contacts patients for follow-up questionnaires
    - Study Co-chair/research nurse who assists in case evaluation process
  - Use appropriate medium to maximize privacy
    - Fax, e-mail, land mail, phone
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## Study Chair Responsibilities

- Protocol Development
    - Protocol document and forms
    - All components of the study
    - Communication
      - Protocol Coordinator, Data Coordinator, Statistician, Committee Chair, Executive Officer
    - Informed Consent and HIPAA Authorization
    - IRB Request for Waiver of Authorization
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## Study Chair Responsibilities

- All “official” communications with NCI go through the Central Office
  - All drug distribution and contract negotiations conducted by Central Office
  - Performance monitored by Protocol Coordinators and Executive Officers
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## Central IRB

- Convened by NCI; approved by OHRP
  - Reviews all Phase III treatment trials from adult cooperative groups
  - Full CIRB approval required prior to protocol activation
  - Study chair must assist in CIRB submission and be available on telephone during review
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## Cancer Trials Support Unit

- Administrative unit supported by NCI
  - Responsible for all regulatory affairs for cooperative groups including investigator credentials; IRB documentation; IND documentation; financial disclosure
  - Conducts cross group registration for all Phase III trials
  - Provides salary support for Study Chairs, Statistical Center, and per case payments
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## Study Chair Responsibilities

- Grant Applications
    - Review by Statistical Center, Central Office, and Executive Committee required
    - Budget components for Statistical Center and Central Office required; PCO, ICL, or other infrastructure if appropriate
    - Letter of support from Group Chair important
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## Study Chair Responsibilities

- Pharmaceutical Company Collaborations
    - Initiate contact early; negotiations handled by Central Office
    - Key Issues:
      - IND holder
      - Data requirements
      - Audit requirements
      - Drug distribution
      - Level of support
      - Drug or drug + money
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## Study Chair Responsibilities

- *Protocol Analysis*
  - Case evaluations
  - Statistical analysis
- *Publication Policy*
  - Timeliness
  - Review process
  - Acknowledgments
  - CTEP review
- *Presentations*
  - Use summary data only
  - CTEP review
  - Review by sponsors and collaborators

## Eligibility Waivers

- Study chairs may not grant eligibility waivers under any circumstances.
  - Eligibility waivers may be granted only by the Group Chair or Executive Officer.
  - Questions about eligibility should be resolved by protocol amendment.
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