



Chicken Soup

for the Busy Coordinator



SEPTEMBER 2025

Managing Study Team Changes (Co-Investigators)

New Co-Investigator (Co-I) Dr Charles

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The Principal Investigator (PI) was notified that Co-Investigator Dr Bruce will be leaving the study team. Dr Charles will be added as a new Co-Investigator to take over Dr Bruce's responsibilities.

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WHAT'S NEXT?

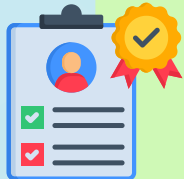


Ensure compliance with requirements to prevent non-compliance

New Co-Investigators must have IRB approval, meet qualifications, and complete mandatory training before commencing their research duties

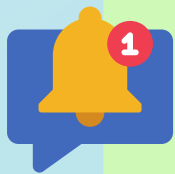
Before Dr Charles take over Dr Bruce's responsibilities and be Co-I;

Ensure Qualification and Training Requirements are Met



- Has Dr Charles met the relevant qualification and minimum training requirements set by the reviewing IRB and/or Research Institution? (where applicable)
- Have Dr Charles's minimum training certificate/reports been validated and minimum training labels applied? For more information, refer [here](#).
- Has Dr Charles received adequate protocol training on all delegated tasks by the PI?

Notify Key Stakeholders



- Has a study amendment been submitted to the IRB to add Dr Charles and remove Dr Bruce?
- Are sponsors notified? (If applicable)

Ensure Proper Documentation



- Is a copy of Dr Charles's latest CV and completed minimum training certificate/reports maintained in the Investigator File?
- Is the study delegation log updated to end Dr Bruce's participation and to start Dr Charles participation in the study?
- Has Dr Charles's protocol training been documented and maintained in the Investigator File?

References: PCR SOP 501-A02 Responsibilities of the Research Team
501-A03 Training and Education
501-B05 Documentation
509-002 Study Responsibility or Delegation Log
NHG Health Investigator's Manual Chapter 3: The Study Team

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