



Amendments to Study  
Documentation



Breach of Participant  
Confidentiality in Research Studies



Clinical Trial Sample Analysis  
in University Laboratories



Complaints from Research  
Participants



Contracting for CTIMPs



Convening of Trial Steering Committees and  
Data Monitoring Committees for Clinical Trials



Creation, Control, Amendment  
and Storage of SOP's



Data Management: Collection,  
Validation and Storage



Delegation of Responsibilities



Development and Review of  
Research Plan / Study Protocol



Education, Training and  
Experience



End of Study Declaration, Early  
Termination and Final Report



The Ethical Approval of Re-  
search



Indemnity and Sponsorship of  
UK research studies



Informed Consent for  
Research



Maintaining Laboratory  
Books



Matters of Non-compliance  
with Study Protocol



Monitoring of Research  
Studies



Preparation, Completion, Signing  
and Correcting Case Report Forms



Production of Progress  
Reports



Registration of Clinical Trials



Reporting and Managing  
Research Related Adverse Events



Research Governance Audit



Risk Assessment of Research  
Studies



Setting Up, Maintaining and  
Archiving Research Files



Sponsor Green Light

