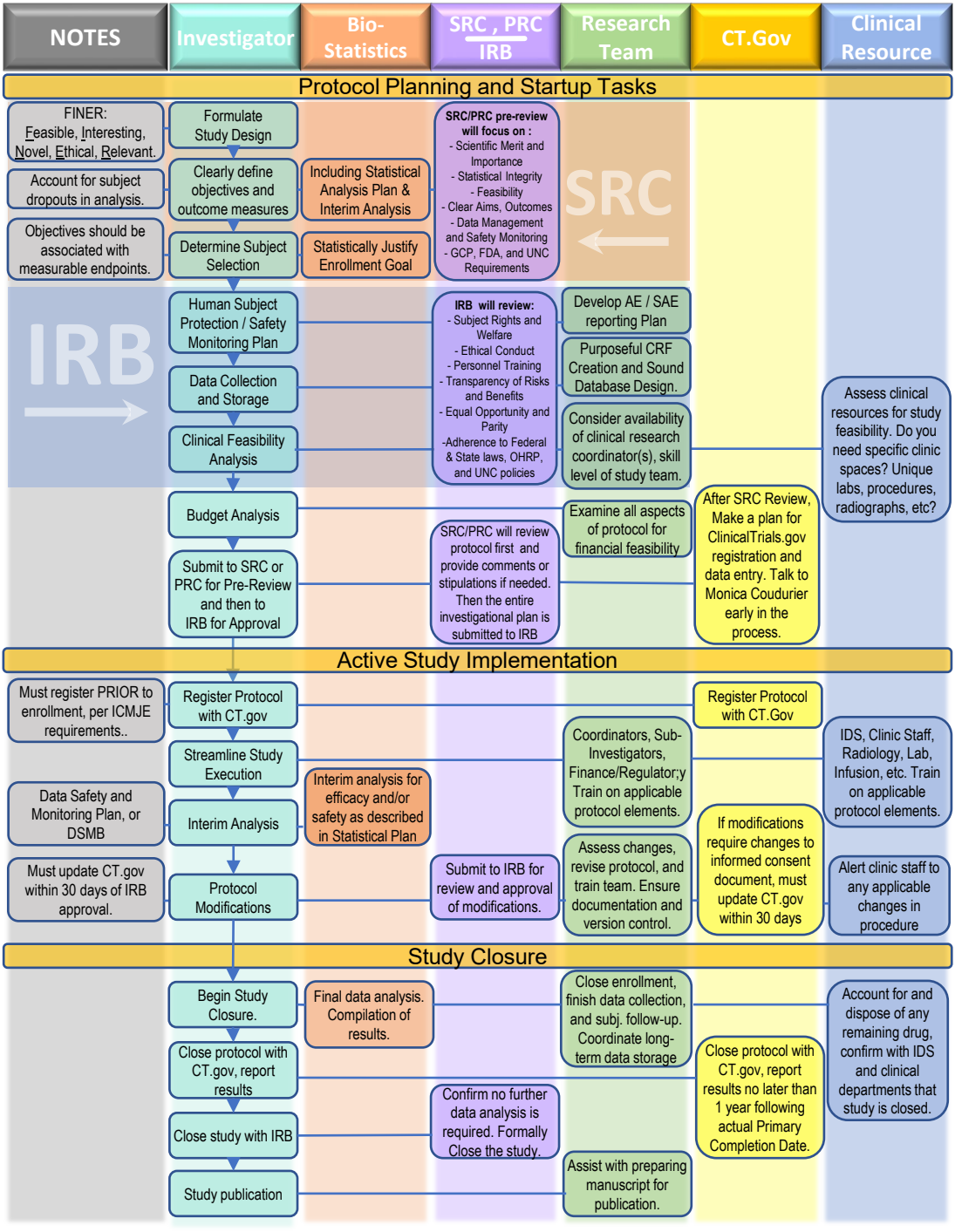
NOTES
Investigator
Bio-Statistics
SRC , PRC IRB
Research Team
CT.Gov
Clinical Resource
Protocol Planning and Startup Tasks
FINER: Feasible, Interesting, Novel, Ethical, Relevant.
Formulate Study Design
SRC/PRC pre-review will focus on : - Scientific Merit and Importance - Statistical Integrity - Feasibility - Clear Aims, Outcomes - Data Management and Safety Monitoring - GCP, FDA, and UNC Requirements
SRC
Account for subject dropouts in analysis.
Clearly define objectives and outcome measures
Including Statistical Analysis Plan & Interim Analysis
Objectives should be associated with measurable endpoints.
Determine Subject Selection
Statistically Justify Enrollment Goal
IRB
Human Subject Protection / Safety Monitoring Plan
IRB will review: - Subject Rights and Welfare - Ethical Conduct - Personnel Training - Transparency of Risks and Benefits - Equal Opportunity and Parity -Adherence to Federal & State laws, OHRP, and UNC policies
Develop AE / SAE reporting Plan
Data Collection and Storage
Purposeful CRF Creation and Sound Database Design.
Clinical Feasibility Analysis
Consider availability of clinical research coordinator(s), skill level of study team.
Assess clinical resources for study feasibility. Do you need specific clinic spaces? Unique labs, procedures, radiographs, etc?
Budget Analysis
Examine all aspects of protocol for financial feasibility
After SRC Review, Make a plan for ClinicalTrials.gov registration and data entry. Talk to Monica Coudurier early in the process.
Submit to SRC or PRC for Pre-Review and then to IRB for Approval
SRC/PRC will review protocol first and provide comments or stipulations if needed. Then the entire investigational plan is submitted to IRB
Active Study Implementation
Must register PRIOR to enrollment, per ICMJE requirements..
Register Protocol with CT.gov
Register Protocol with CT.Gov
Streamline Study Execution
Coordinators, Sub-Investigators, Finance/Regulator;y Train on applicable protocol elements.
IDS, Clinic Staff, Radiology, Lab, Infusion, etc. Train on applicable protocol elements.
Data Safety and Monitoring Plan, or DSMB
Interim Analysis
Interim analysis for efficacy and/or safety as described in Statistical Plan
If modifications require changes to informed consent document, must update CT.gov within 30 days
Must update CT.gov within 30 days of IRB approval.
Protocol Modifications
Submit to IRB for review and approval of modifications.
Assess changes, revise protocol, and train team. Ensure documentation and version control.
Alert clinic staff to any applicable changes in procedure
Study Closure
Begin Study Closure.
Final data analysis. Compilation of results.
Close enrollment, finish data collection, and subj. follow-up. Coordinate long-term data storage
Account for and dispose of any remaining drug, confirm with IDS and clinical departments that study is closed.
Close protocol with CT.gov, report results
Close protocol with CT.gov, report results no later than 1 year following actual Primary Completion Date.
Close study with IRB
Confirm no further data analysis is required. Formally Close the study.
Study publication
Assist with preparing manuscript for publication.