

Betty Irene Moore Children's Heart Center
Clinical and Translational Research Program (CTRP)

Research Support Services

Biostatistical Support & Data Management

- *Study Design*
- *Proposal Preparation*
- *Database Design*
- *Data Management*
- *Data Cleaning*
- *Data Reports*
- *Data Quality Control*
- *Basic Programming*
- *Statistical Analysis*

Project Development & Oversight

- *Study Consultation*
- *Budget Preparation*
- *CRC Effort Estimation*
- *Feasibility Assessment*
- *Finance Review*
- *Liaise with Contract & Regulatory Offices*
- *Quality and Regulatory Oversight*

Research Staff Management

- *CRC Supervision, Mentorship, & Training*
- *Employee Transitions (i.e. on/off-boarding)*
- *Hiring (i.e. recruiting, screening, interviewing, reference checks)*
- *HR Submissions (i.e. performance reviews, JIFs, business plan, time card approvals)*

Clinical Research Coordinator Services

Study Start-up

- *Budget & Billing Workbook*
- *Case Report Form*
- *Clinical Labs Set-up*
- *Consent Form*
- *CTRU Intake/Initiation*
- *Database Development*
- *Data Use Agreements (OSR/ICO)*
- *Expanded Access/Compassionate Use*
- *IND/IDE Submission Assistance*
- *In-service Staff*
- *Investigator/Site Initiation Meeting*
- *IRB Application*
- *OnCore*
- *Patient Reimbursement Set-up*
- *PFS Study Initiation*
- *Pharmacy Set-up*
- *Recruitment Strategies*

- *Regulatory Binder*
- *RMG Communication*
- *Site Selection/ Site Qualification Visit*
- *Study Supply Set-up*

Study Active

- *Recruitment Effort & Tools*
- *Coordinate/Schedule Visits*
- *Prepare Visit Documents*
- *Patient Screening*
- *Consent Patient*
- *Conduct Study Visit*
- *Screening/Enrollment tracking*
- *Randomization*
- *Administer Questionnaires*
- *Case Report Forms*
- *Pharmacy Coordination*
- *Drug Accountability*

- *Answer Queries*
- *Billing Review*
- *Data Collection/Entry*
- *IRB Submissions (i.e. renewal, modification, comment cycle, reports)*
- *Monitor Visits/e-Monitoring*
- *Patient Reimbursement*
- *Report AEs, SAEs*
- *Specimen Handling & Shipping*
- *Supplies Management*

Study Closeout

- *Final Review of CRFs*
- *Finance Reconciliation*
- *IRB Closeout*
- *Monitor Close-out Visit*
- *Record Archiving*
- *Study supplies Disposition*