

# **Study Activation Team**

# **Study Activation Team (SAT)**

The Study Activation Team (SAT) provides regulatory, budgetary and workflow expertise that translates into efficient study activation timelines. Open your study sooner! SAT services include:

## **Regulatory Services**

- IRB Submission
- Application completion and submission of institutional committee and ancillary service approvals, including:

### **Institutional Committees or Approvals:**

- · Scientific Review
- Coverage Analysis
- Institutional Biosafety Committee (IBC)
- ESCRO
- DSMB
- MRSC
- CIRC
- Value Analysis Committee (VAC)

### **Ancillary Services:**

- Centralized Pathology Research Services (CPRS)
- Radiology Research Services
- Investigational Pharmacy Services
- Clinical & Translational Research Services (CTRC)
- Jules Stein Opthalmology Services
- · Clinical Engineering
- · Regulatory Binder development

#### **Budget and Contract Management**

- Contract Office (CTC-SR, TDG, or OCGA) document submission
- Budget Development
- Budget Negotiation

## ResearchConnect, OnCore, CareConnect Activation

- OnCore sign-offs for activation
- careConnect activation
- · careConnect content build review



## **Study Activation Team**

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## **Study Document Development**

- e-CRF Development
- Consent Form Development
- Source Document Template Development

## FDA Submissions (IND/IDE)

• Preparation/Submission of complete FDA submissions for IND or IDE applications. Consultation provided in conjunction with Office of Clinical Research FDA Affairs.

Contact us to meet with one of our team members to discuss your project needs.

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