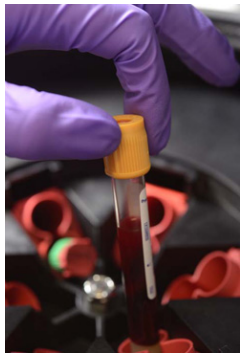
Research Laboratory:



Specimen:
- Collection
- Processing
- Storage/Repository
- Monitoring
- Shipping

Quality Assurance (QA):

- Developing a Quality Assurance Plan
- QA document development
- Quality Control activities
- Source document review
- eCRF and Source Document verification
- Protocol Compliance Monitoring
- Audit Preparation and Mock Audits

Training:

- Documentation Standards
- Compliance (Regulations, GCP)
- Quality Management Plans (QMP)
- Records and Retention

"Our mission is to promote pioneering translational research and discovery."

Contact Us

ID Research Team
Phone: [410.550.9080]
Email: [idresearch@jhmi.edu]]

JOHNS HOPKINS MEDICINE

Johns Hopkins Bayview Medical Center
Division of Infectious Diseases

RESEARCH CONSULTING SERVICES

Johns Hopkins Bayview Medical Center
Division of Infectious Diseases

ID RESEARCH CONSULTING SERVICES

The Infectious Diseases (ID) Research Program at Johns Hopkins Bayview is a team of physicians, nurses, research coordinators, assistants and laboratory personnel from diverse backgrounds and clinical experiences. We have extensive experience in Phase I, II and III clinical research trials, primarily in infectious diseases therapeutics and vaccines. Our program continues its focus on developing robust subject safety and quality assurance processes and procedures.

Government and Industry Experience

We have NIH, CDC, and Industry sponsored clinical trials experience. We have NIH contracts for a large Phase I clinical trials evaluation unit, and a Phase II-III Sexually Transmitted Disease Clinical Trials Unit. We offer extensive knowledge and experience in IRB submissions, NIH/CDC regulatory issues, and FDA oversight procedures, including routine documentation and procedural audit review.

We want to share our experience and expertise to investigators who would like to conduct clinical trials at Johns Hopkins Bayview.

We can be contracted to consult or provide staffing in the following areas:

- **Clinical Trial Implementation**
- **Research Laboratory**
- **Quality Assurance**
- **Training**

Clinical Trial Implementation:

Phase I, II & III (Government & Industry)

- Protocol Review/Feasibility Assessment
- Budget and contract CTA negotiation and development
- IRB/Regulatory Submissions
- Staffing/Operations:
    - Protocol, Source Document, SOP/MOP development
    - Nursing support
    - Phlebotomy/Specimen Collection
    - Subject Recruitment and Remuneration
    - Dosing and Follow-Up
    - Adverse event monitoring and reporting
    - Data entry
    - Bilingual support (Spanish)
- Logistical Planning
- Problem solving on the fly