

# Institutional Research Center of Excellence

Optimize Your Research Administration, Compliance, and Operations

Develop, implement, and uphold research compliance and administrative practices in alignment with federal regulations, state and local law, and industry best practices.

Advarra's Institutional Research Center of Excellence (CoE) empowers the research community to achieve excellence by:



Facilitating shared responsibility for compliant research ethical conduct



Supporting institutions, investigators, and research teams through process improvement, innovative technologies, and education



Propagating best operational practices to maximize research activity efficiencies

#### Solutions & Services

### **Research Compliance:**

Ensure regulatory compliance within clinical research programs

- Human Research Protection Program (HRPP)
- Institutional Review Board (IRB)
- Institutional Animal Care and Use Committee (IACUC)
- Institutional Biosafety Committee (IBC)
- Conflict of Interest (COI)
- 21 CFR Part 11 and computer system validation
- Export control/research security
- Research misconduct investigations
- Health Insurance Portability and Accountability Act (HIPAA) privacy and security rules

# **Research Administration:**

Streamline and fortify research architectures

- Data privacy practices management
- Data sharing and material transfer management
- Protocol and informed consent form (ICF) development
- Research administration revitalization
- Research technologies evaluation and implementation
- Policy/standard operating procedure (SOP) gap analysis and development

#### **Research Operations:**

Site-level assistance with clinical trial operations

- Feasibility review
- Scientific review
- Regulatory assessment/assistance with investigational new drug (IND) and investigational device exemption (IDE) applications
- Standard operating procedure development
- Monitoring/auditing
- Study startup
- Study closeout

# **HRPP Support:**

Implement and guide compliant human research protection programs with industry experts

- Research staffing solutions
- HRPP assessment
- Accreditation application support
- Policy standard operating procedures gap analysis and development
- Training for investigators and other research staff
- Audit prep and communications with federal authorities
- Completely managed local IRB service

