Clinical Research Management Software that exemplifies the Objectives of the ICTR Clinical Research Infrastructure System (CRIS);

Features of OnCoRE:

- Allows centralized tracking of a protocol from development through final statistical analysis
- Study setup, budget development and financials management
- Allows electronic storage of all protocol related documents
- Generates subject calendars and planned visits
- Ability to generate source documents based on electronic Case Report Forms (eCRFs)
- Subject safety monitoring
- Reporting capabilities
- Automated notifications
- Study Information Portal
CLINICAL RESEARCH INFRASTRUCTURE SYSTEM (CRIS)
Regulatory Knowledge and Support

The term, “infrastructure” was chosen as it represents the goals of this core in one word. Infrastructure is defined as the collection of components that together form the foundation, and provide support for the development and communication of information\(^1,2\); the basic services needed for the functioning of a community\(^3\). Within clinical research, CRIS is focused on the collection of regulatory components. This includes interaction with many areas that concentrate on regulatory processes, knowledge, and support:

- Health Sciences Institutional Review Boards (IRBs) Office
- Clinical Translational Research Core (CTRC)
- Research Programs, Networks and Community Partnerships
- Clinical practice environments where research is taking place
- Animal Care and Use Committee
- Data and Safety Monitoring Committees
- Office of Clinical Trials
- Office of Research Quality Initiatives

Objectives:

- **Objective 1**: Establish a Clinical Research Infrastructure System (CRIS) to connect, enhance and expand clinical research regulation, preparation, implementation, management, financing, data and safety monitoring, compliance oversight and training
- **Objective 2**: Enhance and expand regulatory processes, services, oversight and quality assurance initiatives by realigning compliance and research integrity efforts throughout the infrastructure
- **Objective 3**: Implement strategies to train and develop research personnel, ICTR community partners and tangential health care professionals through centralized training and ongoing capacity programs

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