

# Sustainability Considerations for Clinical and Translational Research Informatics Infrastructure

Dear [first\_name] [last\_name],

Please complete the survey below by 5/20/2017.

If this is not your name above, then you have been forwarded a personalized link that was sent to someone else. Please contact one of us to (re-)send you your personal invitation.

Thank you!

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## Instructions

The working group's efforts were focused on two aims:

1. Enumerate, define, and categorize the various informatics resources.
2. Elicit comments from domain experts on sustainability considerations for each category of resources.

Note: We have organized the various resources that came up into Categories and those in turn into Major Headings.

[Click here to view the spreadsheet on google drive.](#)

The distinct categories from the spreadsheet are shown in this survey. For further information on these individual resource types, their definitions, examples, references, or sustainability considerations, please refer to the spreadsheet.

Locus of Control Definitions:

Informatics: The informatics core, service, center or institute (including a CRIO) that gets some funding from the CTSA for any Informatics activity.

Research Office: Office of Research and Sponsored Programs, Clinical Research Office, VP for Research Office.

IT or CIO: Information Systems, Information Technology Department under the CIO either at the Health system or hospital system, or university or college.

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## 1. Application and Support of Clinical and Translational Research - Research / Regulatory Compliance

Research/Regulatory Compliance

Examples include (see spreadsheet above for definitions)

- \* Conflict of interest management system
- \* Electronic IRB management system
- \* Consent
- \* CT.gov registration process
- \* Public access policy compliance tracking

Locus of control or ownership

- Informatics
- Research office
- IT Department / CIO
- Other

Locus of control general notes

Sustainability options

- 
- Institutional infrastructure
  - Fees for service model
  - Sustained grant support
  - Other

Sustainability general notes

Any general comments on the structure and definition of this category?

This can include

- \* Additions of missing items within this category
- \* Removal of superfluous or inappropriate items
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## 2. Application and Support of Clinical and Translational Research - Service Request / Fullfillment

Service Request / Fullfillment

Examples include (see spreadsheet above for definitions)

- \* Service request system
- \* Resource navigation and inventory
- \* Service fullfillment system

Locus of control or ownership

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### 3. Application and Support of Clinical and Translational Research - Program Evaluation

Program Evaluation

Examples include (see spreadsheet above for definitions)

- \* Citation Capture and Service
- \* Fulfillment Attribution

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Locus of control general notes

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#### 4. Application and Support of Clinical and Translational Research - Grants and Contracts Systems

Grants and Contracts Systems

Examples include (see spreadsheet above for definitions)

- \* Electronic Grants and Contracts System
- \* CTSA and other pilot grants

Locus of control or ownership

- Informatics
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Locus of control general notes

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#### 5. Application and Support of Clinical and Translational Research - CTMS Components

CTMS Components

Examples include (see spreadsheet above for definitions)

- \* Clinical Research Budgeting
- \* Participant Payment Model
- \* Billing compliance
- \* Adverse events reporting

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Locus of control general notes

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## 6. Application and Support of Clinical and Translational Research - Electronic Data Capture

Electronic Data Capture

Examples include (see spreadsheet above for definitions)

- \* Investigator Initiated Studies
- \* Multicenter studies
- \* Large studies
- \* 21CFR11 support
- \* Patient Reported Outcomes (PRO)
- \* Mobile app support

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Locus of control general notes

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## 7. Application and Support of Clinical and Translational Research - Biobanking Systems

Biobanking Systems

Examples include (see spreadsheet above for definitions)

- \* Biobank or biorepository management systems

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Locus of control general notes

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**8. Application and Support of Clinical and Translational Research - Data Repositories and EHR Data**

Data Repositories and EHR Data

Examples include (see spreadsheet above for definitions)

- \* Cohort exploration tools (self-service)
- \* IDR navigation/honest broker services
- \* Analytics services
- \* Study specific integrated data
- \* Big data storage
- \* Big data interfaces
- \* Analysis tools
- \* Visualization tools
- \* Molecular Data Set
- \* Imaging Data Set
- \* Public Health Data Set
- \* Environmental Data Set

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Locus of control general notes

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## 9. Application and Support of Clinical and Translational Research - Clinical Medical Information Systems (EHR Systems Research Interface)

Clinical Medical Information Systems (EHR Systems Research Interface)

Examples include (see spreadsheet above for definitions)

- \* Research Related Decision Support
- \* Recruitment
- \* Research that utilizes the EMR
- \* Interfaces with EHR

Locus of control or ownership

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Locus of control general notes

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## 10. Application and Support of Clinical and Translational Research - Communication

Communication

Examples include (see spreadsheet above for definitions)

- \* Content collaboration
- \* Project management
- \* Information/Service Portal
- \* Research Networking
- \* Data publishing and data sharing plans

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## 11. Research Collaboration - Extramural data collaborations

Extramural data collaborations

Examples include (see spreadsheet above for definitions)

- \* Resources for participating in large networked collaborations
- \* Back-end
- \* Front-end provider facing
- \* Front-end patient facing

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## 12. Cyber Infrastructure - Security

Security

Examples include (see spreadsheet above for definitions)

- \* People/documentation/Training
- \* Protecting privacy
- \* Server security
- \* FISMA compliance

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Locus of control general notes

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### 13. Cyber Infrastructure - IT Infrastructure

IT Infrastructure

Examples include (see spreadsheet above for definitions)

- \* Servers
- \* Software licenses
- \* Networks

Locus of control or ownership

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Locus of control general notes

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### 14. Oversight and Governance - Governance

Governance

Examples include (see spreadsheet above for definitions)

- \* Standing IT governance committees or steering committees
- \* Regulatory operational support

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## 15. Training and Support - Education

Education

Examples include (see spreadsheet above for definitions)

- \* Seminars (Top Down)
- \* Courses
- \* In-app video training
- \* Regulatory training
- \* One on one (Bottom up)

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**16. Methodological Research and Innovation - Informatics innovation**

Informatics innovation

Examples include (see spreadsheet above for definitions)

- \* Faculty
- \* Student pipeline
- \* Software engineers/professional staff
- \* Support for rapid prototyping and implementation.

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