BRICS User Guidelines

Document Information

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The SOP approval/distribution process is as follows:

1. The SOP author sends the SOP SharePoint link to their peers/subject matter experts (SMEs) for review.
2. After editing, the SOP author decides whether the SOP is ready for approval. If the SOP is ready, the author adds the SOP to the ITBP Manager meeting agenda.
3. At the ITBP Managers meeting or via email, NINDS Management formally approves/disapproves the SOP.
4. The SOP Author sends the SOP link to all people on the Distribution List.

NINDS Approval

This User Guidelines (UG) is approved for distribution and implementation as of the Director ITBP approval date listed below. NINDS ITBP management is authorized to conduct periodic audits to ensure compliance with this procedure. Requests for corrections or changes to any part of this procedure must be submitted to the Document Owner to review. Exceptions to any procedure must be approved by the ITBP Management and documented.

Approved By:

Name	Title	Organization	Approval Date
Yang Fann	IT Director	NINDS DIR ITBP	03/28/19
Matthew McAuliffe	BIRSS Chief	CIT OIR ISL BIRSS	03/28/19
Dominic Nathan	Informatics Core Director	CNRM	03/28/19
Mark Edwards	IT Manager	NINDS DIR ITBP	03/28/19

Name	Title	Organization	Approval Date
Willy Calderon	ISSO	NINDS DIR ITBP	03/28/19

Peer Reviewers

This User Guidelines were reviewed by the peers (i.e., subject matter experts) listed below. The procedure will be reviewed by the peer reviewers at least annually.

Reviewed By:

Name	Title	Organization	Date
Tsega Gabremichael	Team Lead	CIT OIR ISL BIRSS	03/27/19
Leonie Misquitta	Sr Scientific Advisor	CIT OIR ISL BIRSS	03/27/19
Dominic Nathan	Informatics Core Director	CNRM	03/27/19

Distribution List

This User Guidelines impact the individuals on this Distribution List. The UG author should notify everyone on this list about changes to this UG *within one week* of NINDS approval.

Distributed To:

Name / Department / Group / Team
Yang Fann
Matthew McAuliffe
Dominic Nathan
Willy Calderon

1. Introduction

1.1 Overview

BRICS is a collaborative and extensible web-based system to support the collection of research studies and clinical trials, using a set of modular components that cover all stages of the research life cycle. It is challenging and difficult to capture all information in a document. This User Guidelines (UG) are created to provide the first-stop source of information on getting users started with BRIC platform and guide them in choosing the modules based on their unique needs. The intended audience for this procedure includes the groups/individuals listed below:

- NINDS DIR Clinical Informatics Development Team
- CIT OIR ISL BIRSS Development Team
- Business stakeholders and partners

1.2 Purpose

The purpose of the User Guidelines is aimed to help the users to plan and conduct their research studies. This document includes information on the main steps and stages in sequence of designing a clinical protocol so they can perform their roles effectively and efficiently while experiencing various BRICS modules.

1.3 Scope

This procedure guidelines are based on the current policies and system structures of the BRICS and its associated systems such as CiSTAR, CASA, and ProFoRMS at NINDS, CIT and CNRM. It is important to know that appropriate review will be essential as a number of changes are anticipated as the system continues to evolve.

1.4 Roles and Responsibilities

The following personnel are primarily responsible for performing the procedures:

Name	Title	Responsibility
Clinical Trial Unit	NINDS DIR CTU	NINDS Governance committee for approvals
Steering Committee	Informatics Core	CNRM Governance committee for approvals
Yang Fann	BRICS Co-Director NINDS IT Director	Authorizing Official to operate Approve requirements

Name	Title	Responsibility
Matthew McAuliffe	BRICS Co-Director CIT BIRSS Chief	Approve requirements
Dominic Nathan	Informatics Core Director	Manage the project
Leonie Misquitta	Sr Scientific Advisor	Provide scientific consulting
Tsega Gebremichael	Sr Software Engineer	Provide technical guidance
Change Control Board	Subject Matter Experts	Manage and approve change requests and system enhancements
Business, Product owner, Instance Program Manager	Key Stakeholders	Review and validate requirements and work products
NINDS/CIT Clinical Informatics Development team	Software Engineer	Responsible for understanding and following the scrum development processes outlined in this document.

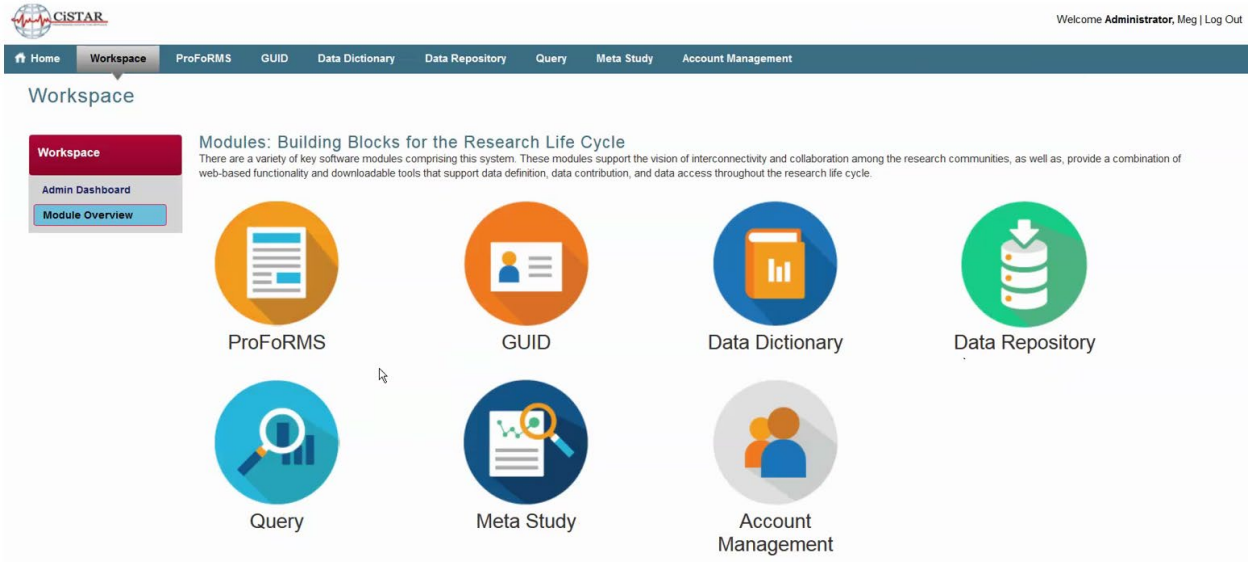
1.5 Key Words

The following key terms are used in this SOP.

- BRICS – Biomedical Research Informatics Computing System
- CiSTAR – Clinical Informatics System for Trials and Research
- CASA – Collection Access Sharing Analytics Platform
- CNRM – Center for Neuroscience and Regenerative Medicine
- SRS – System Requirements Specification

2. Guidelines

This set of user guidelines provides a combination of web-based functionality and downloadable tools that support data definition, data contribution, and data access throughout the research life cycle. This document preseumes a coordinated function providing users across different software components on BRICS platform. The screen shot below represents one of such systems.



2.1 ProFoRMS: Protocol Management and Data Capture

The researchers can define electronic case report forms, schedule and collect clinical data, and then export, analyze, and report on the data. The user guide for the clinical trial and research module is available online at: ProFoRMS User Manual.

2.2 GUID

The GUID is a Global Unique Identifer for each study participant that allows researchers to aggregate and share a participant's data without exposing Personally Idenfiable Information (PII). The user guide for the GUID module is available online at: GUID User Manual.

2.3 Data Dictionary: Define and Validate Data

The Data Dictionary provides functionality for creating, managing, and searching data dictionary components as well as services for validating research data against the standardized common data elemtns (CDEs). The user guide for the Data Dictionary module is available online at: Data Dictionary User Manual.

2.4 Data Repository

The Data Repository is the central hub of the BRICS system, providing functionality for defining and managing study information, and for contributing, uploading, and storing the research data associated with each study. The user guide for the Data Repository module is available online at: Data Repository User Manual.

2.5 Query

The Query tool provides a powerful means to sift through volumes of aggregated research data across studies. The user guide for the Query module is available online at: Query Tool User Manual.

2.6 Meta Study

A Meta Study contains findings from other studies that can be aggregated by researchers to conduct additional analysis. The information within the Meta Stud can be referenced in publications. The user guide for the Meta Study module is available online at: Meta Study User Manual.

2.7 Account Management

The Account Management provides a control center for creating, approving, and managing user accounts, including management of access controls, roles, permissions groups, and authorization to other BRICS modules. The user guide for the Account Management module is available online at: Account Management User Manual.

2.8 Data Mapping Tool

The Data Mapping Tool allow users to map their data to the BRICS data dictionary's common data elements. In addition, it builds a BRICS compliant file that can be validated and uploaded into BRICS based repository. The user guide for the Data Mapping Tool module is available online at: Data Mapping Tool User Manual.

2.9 MIPAV Imaging Data Submission Tool

The MIPAV (Medical Image Processing, Analysis, and Visualization) application enables quantitative analysis and viewing of medical images, such as PET, MRI, CT, or microscopy. A MIPAV plugin is used to package and submit image data of many formats (i.e. DICOM, NIFTI, Analyze, AFNI and many others) into BRICS. The user guide for the MIPAV Imaging Data Submission Tool module is available online at: MIPAV Imaging Data Submission Tool User Manual.

3. Records Management

All data and/or records generated during this procedure are stored in the NINDS SharePoint-based Document Library.

4. Review/Revision History

Date	Author	Description of Change
03/09/2019	Gladys Wang	Document Creation