

Standard Operating Procedure (SOP)

BRICS System Requirements Specification

Document Information

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Name	Title	Organization	Approval Date
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Peer Reviewers

This Standard Operating Procedure was 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 Standard Operating Procedure impacts the individuals on this Distribution List. The SOP author should notify everyone on this list about changes to this SOP *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

System Requirements Specification (SRS) document provides a high level description of the system including its purpose, scope, business objectives, context, and capabilities. 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 System Requirements Specification (SRS) defines the functional, non-functional, and technical requirements. The purpose of this SRS document is to describe the requirements specification for application and data repository. Developers, project manager, project team, project sponsor, clients, interested end-users, and any stakeholders whose input into the requirements process are the intended audience of this SRS document.

1.3 Scope

This Standard Operating Procedure is applicable to the collection of components that comprise custom software development of the BRICS and its associated systems such as CiSTAR, CASA, and ProFoRMS at NINDS, CIT and CNRM.

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

1.6 Assumptions

This section identifies the statements believed to be true and from which a conclusion was drawn to define this requirements specification.

2. Functional Requirements

This section of the SRS describes the functional requirements that drive the design of the software system. The goal is not to state specific requirements, but rather to provide context to make those requirements easier to understand.

2.1 Users of the System

There are two types of users in CNRM CASA platform:

- a) Study Participants: will enter their information directly into the system.
- b) CNRM Recruitment Core Research Associate: will be responsible for the administration and management of the system.

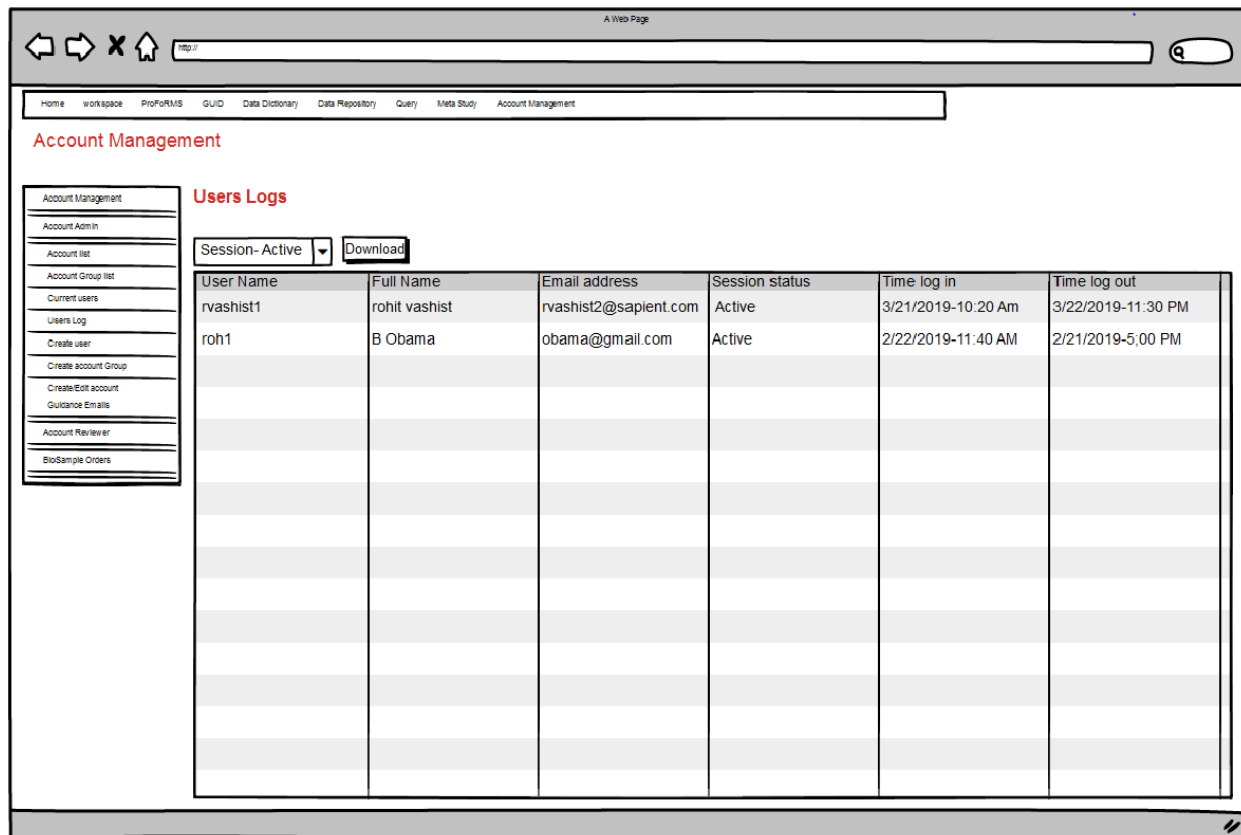
2.2 Data Entry

This section lists the functional requirements for data entry.

- a) Only participants can enter data.
- b) Participants cannot make changes to the data submitted to the Data Repository.
- c) The system should provide unique identifier to each participants.
- d) The system should only allow a single data entry and submission.
- e) If a participant attempts to submit data multiple times, the system should display an error message.
- f) The data entry form shall have the following data elements:

Data Element	Data Type	Control Type
First Name	Text	Text box
Middle Initial	Text	Text box
Last Name	Text	Text box
Address	Alphanumeric	Text box
City	Text	Text box
State	Text	Text box
Zip Code	Numeric	Text box
Phone Number	Alphanumeric	Text box
Alternate Phone Number	Alphanumeric	Text box
Email Address	Alphanumeric	Text box
Age	Number, 18-85	Drop down menu
Injury Year	Number	Drop down menu
TBI Diagnosis	Yes/No	Option
TBI Symptoms	Yes/No	Option
Secondary Diagnosis PTS	Yes/No	Option

Secondary Symptoms PTS	Yes/No	Option
Prior MRI	Yes/No	Option
Sharpnel	Yes/No	Option
DEERS Eligible	Yes/No	Option
Military Status	Active Duty/Reservist/ Guardsmen/Retiree/ Veteran/Unknown	Drop down menu
Study Interest	Observational/Intervention Drug clinical trial/Computer- based, App, or telephone	Drop down menu
Enrolled in other CNRM studies?	Text	Text box
If Yes, Study Name	Text	Text box
How did you hear about us?	Study team/Friend/Website/Social Media/Flyer/Other	Text box
What Symptoms of TBI are most important symptoms to find treatments for?	Headache, sleep disturbances, visual disturbances, memory loss, poor attention/concentration, dizziness/loss of balance, irritability-emotional disturbances, feelings of depression, seizures	Multiple check box




1. On Account management module >under Account Admin (side menu) there will be a new tab as "User Log"
2. System should be able to capture below information in Data table for all the user who have ever interacted with the system.
 1. Username
 2. Full Name

3. E-mail
4. Status
 1. There will be two status for a user in a session
 1. Expired- When user have logged in and logged out of the system (session being expired)
 2. Active- when user have logged in to the system and actively using the system (session being active.)
5. Time log In - (Date (mm/dd/yyyy) and time XX:XX (24 hours format)
6. Time log Out- (Date (mm/dd/yyyy) and time XX:XX (24 hours format)
3. There will be a Date range and search input box on the table
 1. Search input will search from following fields
 1. User Name
 2. Full Name
 3. Email
 2. Date range with input box as start date and End date
 1. It will sort the data in the table based on the inputs

2.4 Form Design

This section lists the functional requirements for form design.

- Subject view of main page on survey site:



CNRM
Uniformed
Services
University

Referral Program Elements

Questions/Help: Please Call
1-855-824-2676

First Name

MI

Last Name

Address

City

State

Zip Code

Phone Number

Alternate Phone Number

Email Address

Age

Injury Year

TBI Diagnosis ☐ Yes ☐ No

TBI Symptoms ☐ Yes ☐ No

Secondary Diagnosis PTS ☐ Yes ☐ No

Secondary Symptoms PTS ☐ Yes ☐ No

Prior MRI ☐ Yes ☐ No

Shrapnel ☐ Yes ☐ No

DEERS Eligible ☐ Yes ☐ No

Enrolled in Other CNRM Studies? ☐ Yes ☐ No

How did you hear about us?

Military Status

Study Interest

What symptoms of TBI are most important symptoms to find treatments for?

Headache	<input type="checkbox"/>	Dizziness/loss of balance	<input type="checkbox"/>
Sleep disturbances	<input type="checkbox"/>	Irritability-emotional disturbances	<input type="checkbox"/>
Visual disturbances	<input type="checkbox"/>	Feelings of depression	<input type="checkbox"/>
Memory loss	<input type="checkbox"/>	Seizures	<input type="checkbox"/>
Poor attention/concentration	<input type="checkbox"/>		

If Yes, Study Name

- [illegible]

A list of user stories can be found at the end of this document in Appendix B.

This section lists the functional requirements for report.

- CNRM Recruitment Core Research Associate should be able to access data via the query tool and the reporting tool.
- CNRM Recruitment Core Research Associate should be able to download data in CSV format.

3. Non-Functional Requirements

Non-functional requirement is a requirement that specifies criteria that can be used to judge the operation of a system, rather than specific behaviors. Quality attributes such as performance, security, usability, compatibility are not a “feature” of the system, but are a required characteristic.

3.1 Design Constraints

This section identifies any limitation that must be taken into consideration prior to the initiation of the project. No design constraints have been identified.

3.2 General System Requirements

The general system requirements are listed as follows:

Req. ID	Requirements	Notes
GSR - 1	The system shall be section 508 compliant.	
GSR - 2	The system shall be accessible with clients running Windows and MAC operating systems.	
GSR - 3	The system shall be accessible on the following web browsers: <ul style="list-style-type: none"> • Internet Explorer • Chrome • Safari • Firefox 	
GSR - 4	The system will be hosted on NINDS/CIT data centers.	

3.3 Security Requirements

The general system security requirements are listed as follows:

- CNRM Recruitment Core Research Associate should access the system using user name and password.

- CNRM Recruitment Core Research Associate should have full access to the system, and can make changes to the data as necessary.
- Data is to be stored within the CNRM data center located within the NINDS data center.

3.4 Accessibility Requirements

The general system accessibility requirements are listed as follows:

- The website link to the data entry form should be accessible on social media and CNRM websites.
- Participants should be able to access the data entry website without user name and password.
- The website link to the data entry form should be accessible via tablets and smart phones.

3.5 Performance Requirements

The general system performance requirements are listed as follows:

Req. ID	Requirements	Notes
GPR - 1	The system shall be available 24 hours a day for 7 days a week, unless there is scheduled maintenance.	No system support after normal work hours

4. Records Management

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

5. Review/Revision History

Date	Author	Description of Change
03/09/2019	Gladys Wang	Document Creation
04/08/2019	Leonie Misquitta	Added Appendix A
04/10/2019	Tsega Gebremichael	Added Appendix B

Appendix A. RTM

The Requirements Traceability Matrix (RTM) in the table below was prepared before a software release.

#	Key	Summary	Linked Test Cases/Comments		
1	PS-4420	Remove/hide the 'Biorepository Subject ID' field and user inputs in ProFoRMS	PS-4477		
2	PS-4378	"See also" - need to increase the size of the field in the database and the text box that displayed in DD	PS-4389		
3	PS-4331	Add to GUID tool Country of Birth	PS-4487	PS-4488	PS-4489
4	PS-4268	As user, system should let me refresh my session in Data Dictionary	PS-4336		
5	PS-4267	As an Operation User, data error report email should be get updated with no of request for archived, deleted data set and requested study.	PS-4327		
6	PS-4266	As a user, system should allow me to change subject label GUID to Subject ID or vice versa in Manage Protocol Section of ProForms	PS-4335		
7	PS-4179	SVN to GIT Migration	Not a Functional Test Item hence NO Test Cases		
8	PS-4135	As a admin user, I need my previous admin noted migrated into the new admin note functionality box.	PS-4308		
9	PS-4031	As cdRNS user, I should able to see cdNRS specific Form Structures	PS-4479		
10	PS-4028	As FITBIR Public site data dictionary - default DE view to Awaiting Publication and Published DEs	PS-4307		

11	PS-4027	As a user, I should know which environment my email came from	PS-4338		
12	PS-4009	As a user, I should know whether my email is for BioSample or BioFind	Duplicate of PS-4027 so was closed		
13	PS-3830	Data Repository - Research Management Table Sort Recommendation	PS-4326	PS-4325	
14	PS-3829	Need to update the primary BRICS public site	Duplicate of CRIT-9102 so was closed		
15	PS-3828	As Account Admin, I should able to approve or rejected privileges individually.	PS-4013		
16	PS-3827	As a Account Admin/Reviewer, I should able to identify user, whose privileges been expired.	PS-4328		
17	PS-3821	As a user, I should see consistent in data set statuses across table	PS-4340	PS-4341	
18	PS-3659	Supporting Documentation The "File" field information appears under the Column Name.	PS-4314	PS-4315	
19	PS-3441	As a user, I want files I'm attempting to upload to be maintained when there is a validation error in related fields when trying to upload the file (PF, Act, DD))	PS-4334		
20	PS-3309	As a user, I should have the Ability to make an optional/recommended question required on the eform level	PS-4343		
21	PS-3226	As an admin or end user, I want the data dictionary search to support special characters *,? and "" in order to increase the likelihood of returning a result the user is searching for.	PS-4483	PS-4484	
22	PS-3214	Implementation of converting byte array to hex is flawed	Not a Functional Test Item hence NO Test Cases		
23	CRIT-10029	Update GUID Manual file	CRIT-10043		

24	CRIT-9903	Data Validation Calculation Rules - an error message should occur if a total score or a subscore is given while one of the needed data inputs is missing	Spreadsheets with datasets attached to the User Story		
25	CRIT-9874	Data validation calculation rules - DHI	Spreadsheets with datasets attached to the User Story		
26	CRIT-9844	Data validation calculation rules - Headache Impact Tool (HIT-6)	Spreadsheets with datasets attached to the User Story		
27	CRIT-9774	Data Validation Calculation Rules - FIM Instrument	Spreadsheets with datasets attached to the User Story		
28	CRIT-9581	As a developer, I should be able to migrate GUID information from one MongoDB instance to another	Not a Functional Test Item hence NO Test Cases		
29	CRIT-9549	As a user, I should be able to generate GUIDs in a batch process	CRIT-9729	CRIT-9730	
30	CRIT-9535	As a user, my PII should be sent to the server as a Hashcode	CRIT-10048		
31	CRIT-9534	As a user, I should be able to interface with the GUID server	CRIT-9767		
32	CRIT-9533	As a user, I should be able to see the interface of the GUID client	CRIT-9721		
33	CRIT-9532	As a user, I should not be able to enter invalid PII	CRIT-8983	CRIT-9787	CRIT-9788
34	CRIT-9531	As a user, I should be able to validate that a GUID exists	CRIT-9785	CRIT-9786	
35	CRIT-9530	As a user, I should be able to convert a pseudoGUID to a GUID	CRIT-9770	CRIT-9771	
36	CRIT-9520	For large result sets in QT, adding to download queue crashes the server	CRIT-9796		
37	CRIT-9511	3.6 Code Merge for NINDS/NIA/GRDR instances + add mongoDB conn info	Not a Functional Test Item hence NO Test Cases		

38	CRIT-9356	NINDS/NIA/GRDR Code Merge	Not a Functional Test Item hence NO Test Cases		
39	CRIT-9259	Data validation-calculation rules - SCAT-3	Spreadsheets with datasets attached to the User Story		
40	CRIT-9223	GUID Javascript Client Design	Not a Functional Test Item hence NO Test Cases		
41	CRIT-8571	Design Basic GUID JS Framework	Not a Functional Test Item hence NO Test Cases		
42	CRIT-7779	As a user, I should be able to access the GUID user guide	CRIT-8990		
43	CRIT-7655	As a user, I should be able to generate a GUID through the new JS Client	CRIT-9768	CRIT-9769	
44	CRIT-7640	As an Admin, I should see all legacy & new GUIDs that have been created by my Entity	CRIT-8993	CRIT-8995	
45	CRIT-7613	As a NINDS user, I should be able to access legacy NINDS GUIDs	CRIT-8993		
46	CRIT-7612	As an NIA user, I should be able to access legacy NIA GUIDs	CRIT-8993		

Appendix B. User Stories

The user stories in the table below was prepared during the requirements gathering and analysis phase.

#	Epic Link	Key	Summary
1	Hulk PS Enhancements	PS-4420	Remove/hide the 'Biorepository Subject ID' field and user inputs in ProFoRMS
2	Hulk PS Enhancements	PS-4378	"See also" - need to increase the size of the field in the database and the text box that displayed in DD
3	Hulk PS Enhancements	PS-4331	Add to GUID tool Country of Birth
4	Hulk PS Enhancements	PS-4268	As user, system should let me refresh my session in Data Dictionary
5	Hulk PS Enhancements	PS-4267	As an Operation User, data error report email should be get updated with no of request for archived, deleted data set and requested study.
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8	Hulk PS Enhancements	PS-4135	As a admin user, I need my previous admin noted migrated into the new admin note functionality box.
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22	Hulk PS Enhancements	PS-3214	Implementation of converting byte array to hex is flawed
23		CRIT-10029	Update GUID Manual file
24	Calculation Rules for Validation Tool & PF	CRIT-9903	Data Validation Calculation Rules - an error message should occur if a total score or a subscore is given while one of the needed data inputs is missing
25	Calculation Rules for Validation Tool & PF	CRIT-9874	Data validation calculation rules - DHI
26	Calculation Rules for Validation Tool & PF	CRIT-9844	Data validation calculation rules - Headache Impact Tool (HIT-6)

27	Calculation Rules for Validation Tool & PF	CRIT-9774	Data Validation Calculation Rules - FIM Instrument
28	Multi-Tenant GUID Migration	CRIT-9581	As a developer, I should be able to migrate GUID information from one MongoDB instance to another
29	GUID Javascript Webstart Refactor	CRIT-9549	As a user, I should be able to generate GUIDs in a batch process
30	GUID Javascript Webstart Refactor	CRIT-9535	As a user, my PII should be sent to the server as a Hashcode
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35	GUID Javascript Webstart Refactor	CRIT-9530	As a user, I should be able to convert a pseudoGUID to a GUID
36	PS Enhancement Backlog	CRIT-9520	For large result sets in QT, adding to download queue crashes the server
37	CI/Jenkins Optimization	CRIT-9511	3.6 Code Merge for NINDS/NIA/GRDR instances + add mongoDB conn info
38	Multi Tenant GUID Solution (PDBP MOU #5)	CRIT-9356	NINDS/NIA/GRDR Code Merge
39	Calculation Rules for Validation Tool & PF	CRIT-9259	Data validation-calculation rules - SCAT-3
40	GUID Javascript Webstart Refactor	CRIT-9223	GUID Javascript Client Design
41	GUID Javascript Webstart Refactor	CRIT-8571	Design Basic GUID JS Framework
42	Multi-Tenant GUID Migration	CRIT-7779	As a user, I should be able to access the GUID user guide

43	GUID Javascript Webstart Refactor	CRIT-7655	As a user, I should be able to generate a GUID through the new JS Client
44	Multi-Tenant GUID Migration	CRIT-7640	As an Admin, I should see all legacy & new GUIDs that have been created by my Entity
45	Multi-Tenant GUID Migration	CRIT-7613	As a NINDS user, I should be able to access legacy NINDS GUIDs
46	Multi-Tenant GUID Migration	CRIT-7612	As an NIA user, I should be able to access legacy NIA GUIDs