STONY BROOK MEDICINE | LINCATS STANDARD OPERATING PROCEDURE RUBRIC FOR QUARTERLY DATA COLLECTION

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Approval

Chief Operating Officer, Rodrigo Valles Jr., Ph.D.

Director of Educational Effectiveness, Catherine Scott

Director, Center for Excellence in Learning and Teaching (CELT), Rose Tirotta-Esposito, Ed.D.

Assistant Professor of Practice, Graduate Program Director, Brenda L. Hoffman, Ph.D.

Clinical Research Associate, Neurology, Sandra Skinner, Ph.D.

Senior Education Specialist, School of Medicine, Wei-Hsin Lu, Ph.D.

Responsibility

Responsibility for review and maintenance of this policy is assigned to:

Chief Operating Officer, Rodrigo Valles Jr., Ph.D.

Author and/or Designee:

Chief Operating Officer, Rodrigo Valles Jr., Ph.D.

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1 Purpose

This policy functions as an instruction manual and a guide for quarterly LINCATS data collection. The first quarter will be from July 2022 to September 2022.

2 Policy Statement

This SOP is reflective of the guidelines set forth by HIPAA and IRB to protect patient privacy while advancing research to improve the quality of health for our community.

3 Responsible Personnel

- a. Chief Operating Officer, LINCATS
- b. Evaluation Team, LINCATS

4 Definitions

Evaluation Team: a team of individuals who evaluate, collect, clean and analyze data across activities supported by LINCATS

Principal Investigator (PI): the individual responsible for a clinical trial or scientific research grant.

SPARCRequest: a web-based research management system providing a central portal to researchers and study teams.

5 Procedure

The Evaluation Team will collect quarterly data, from LINCATS providers, associated with the Milestones and Metrics for each Module. The Evaluation Team will ensure data is complete, cleaned and stored in a centralized location.

<u>Table 1</u> lists all common data fields to be collected. The left side of the table corresponds to our collection spreadsheet headings. The notes in the center column provide context for the Evaluation Team. The inclusion status in the right column states the relative importance of each field, namely:

- Service data without <u>Mandatory</u> fields (Name, Service Type, and Date) will not be accepted.
- Preferred data should be added by Evaluation Team if at all possible or available.
- <u>Ideal</u> data is good to have, but the expectation is that it may not always be present or available.

Table 1: Common Data, Notes and Inclusion Status

Common Data Fields	Definition/Notes	Inclusion Status
Program Service		Mandatory*
PI Last Name		Mandatory*
PI First Name		Mandatory*
PI Middle Initial		Ideal
PI Title	PI title at time of service	Preferred
PI Institution		Preferred
PI Department		Preferred
PI Division		Preferred
PI Career Status		Preferred
LINCATS Service	Choose all that apply	Mandatory*
Dependent on other Service?	Is a different Service a prerequisite or	Preferred
	preceding step	
Notes	Include any existing notes. OK if text	Ideal
	uses up a lot of space. OK if no notes.	
Date of Inquiry or Request	Must be prior to Service	Mandatory if collected
Date of Service	Must fall after Inquiry.	Mandatory*
Project Title	Project title at time of service	Preferred
Protocol Number	This should be IRB# if applicable	Ideal
Hours Spent on request	May only apply to consults. Estimates	Mandatory if collected
(Estimate)	OK, actual is ideal. Include person hours	
	vs total time if possible	
Publications Accepted	Yes/No/Do Not Have	Preferred
Grants Awarded	Yes/No/Do Not Have	Preferred
IP	Yes/No/Do Not Have	Ideal

a. Demographics: *PI Title, PI Institution, PI Department, PI Division, PI Career Status*We will capture this manually if it is a service that was not requested through SPARCRequest. Please note that this should be **PI Title at the time the service was completed.** "Institution" can also be a proxy for Community Organization or other Affiliations.

b. LINCATS Service:

The following LINCATS Services and Activities are required to provide quarterly, or upon request, data on their services. <u>Table 2</u> represents all LINCATS Services or Activities teams responsible for collecting and providing their data to LINCATS leadership with and serves as a tracking tool for their associated Evaluation Team member for the completeness of the provided data. This data completeness will be assessed by the Evaluation Team Member after each round of data collection.

<u>Table 2</u>. LINCATS Services and Activities Data Completeness Tracking Evaluation Team member (7/31/22)

Module activity or Service	Eval Team 2022	Eval Team 2023	Program Service	Depdnt on other Service	PI Name/ Title/ Demog	Project Name/ Title	Dept/ Div	Service	Notes	Date of Inq	Date of Serv	Hrs	Pubs Grants IP
C1	S. Skinne r												
PROPEL													
LINCATS Connect													
LINCATS Crowd													
C2	B. Hoffm an												
Community Ambassadors													
CAB													
Town Hall													
Summer Research Institute													
D1	W. Lu												
BERD													
RKS													
PAR													
BTA													
CfB													
Informatics Consultation													
Community Consultation													
Inpatient Unit													
D2	R. Tirotta , C. Scott												
Pilots													

Research Concierge							
D3	R.						
	Valles						
RDW							
Bootcamp							
Courses							
K12	R.						
	Valles						
Scholars							

- **c. Program Services:** (These are the five meta-categories that map to the LINCATS Logic Model. The Evaluation Team will select all the Service/Activity categories that apply)
 - Infrastructure
 - Workforce Development
 - Community and Stakeholder Engagement
 - Pilot Funding
 - Resources and Services
 - Informatics

The following Service and Activity lists have been created to help define and assign Service Types.

<u>Infrastructure</u>

- Steering Committees
- Advisory Boards

Workforce Development

- K12
- PROPEL
- LINCATS Connect
- LINCATS Crowd
- Informatics Bootcamps
- Informatics Courses

Community and Stakeholder Engagement

- Community Consultation
- Community Ambassadors
- CAB
- Town Hall
- Summer Research Institute

Pilot Funding

- Pilot Award
- Proposal Audit and Review (PAR)

Resources and Services

- Biostatistics and Research Design (BERD)
- Regulatory Knowledge and Support (RKS)
- Proposal Audit and Review (PAR)
- Biobanking Tissue Acquisition and Analysis (BTA)
- Center for Biotechnology (CfB)
- Informatics Consultation
- Community Consultation
- Inpatient Unit

Informatics

- Research Data Warehouse
- Informatics Consultation

d. Program Service Type:

Service type is structured as

Program Service Type "Choose all that apply"

- Letter of Support
- Grant Development
- Publication Development
- Study Design
- Budgeting
- Consulting re: best practices (with a single Protocol and/or PI)
- Networking (with a group e.g. Community Linkage, Inter-Institutional, Inter-Disciplinary)
- Data Consult
- Data Analysis
- Data Management
- Training (Non-credit)
- Training/Funding (K12)
- Event
- Pilot Award
- Studio
- Other

e. Notes

Evaluation Team, please include any relevant notes for all data collected.

f. Dates: Date of Inquiry/Request vs. Date of Service

The Date of Inquiry or Request must always fall prior to the Date of Service. **Please note that the "Year of Service" is the most important for our aggregation purposes.** After an Inquiry/Request a LINCATS service could move to one of three states:

- 1) Yes. (Completed. Very short consult. Could also be referred elsewhere.)
- 2) Yes. (Needs more consultative services TBD)
- 3) No. (PI just asking about but not receiving services, or the request is not approved)

If the request is not approved, please either opt to not include the data or make the status clear in the notes section.

Table 3. "Date of Service" for all Programs

Programs	Date of Service "Own Language"
PROPEL	Date of Service Own Language Date service requested in SPARCRequest, Date PROPEL starts.
LINCATS Connect	Applicants: date submitted resume for specific job. Pls: 1) created job in Connect or
LINCATS Connect	2) accepted applicant for role.
	2) accepted applicant for fole.
LINCATS Crowd	Date request/question submitted to LINCATS Crowd.
Community	NA NA
Ambassadors	
CAB	NA NA
Town Hall	Date of event.
Summer Research	Date of event.
Institute	
BERD	Date service requested in SPARCRequest, Date service approved and date of delivery
	by service provider.
RKS	Date service requested in SPARCRequest, Date service approved and date completed
	by service provider.
PAR	Date service requested in SPARCRequest, Date service approved by committees.
BTA	Date service requested in iLab, Date service approved by provider.
CfB	Date consult requested in iLab, Date service approved/referred by provider.
Informatics	Date consult requested in SPARCRequest, Date service approved by service provider.
Consultation	
Informatics Courses	Date service requested in SPARCRequest, Date course starts.
Community	Date consult requested in SPARCRequest, Date service approved by service provider.
Consultation	
Inpatient Unit	Date service requested in SPARCRequest, Date service approved by committees.
Pilots	Date application submitted in Submittable, Date application is accepted as complete,
	Date application is reviewed by reviewers, Date reviews are reviewed by
	Management Committee.
Research Concierge	Date service requested in SPARCRequest, Date service approved by committees.
RDW	Date service requested in SPARCRequest, Date service approved by committees.
Informatics	Date service requested in SPARCRequest, Date bootcamp starts.
Bootcamp	

g. **Project Data:** Project Title, Protocol Number

Project Titles will evolve over time as Researchers refine their work. Whenever possible the Evaluation Team should try to capture the working titles at the date of service. If there is an IRB # associated with the project, this data should be collected.

h. Hours Spent

Where possible record consultative hours and/or time to fulfillment. SPARCRequest will collect this information for some services.

i. Outcomes: *Publications, Grants, IP*Collect Outcomes with a Yes/No/Do not Have. Include numbers for the quarter being collected.

6 References

None

7 History and Updates

Version		
Number Date		Summary of Revisions Made:
1.0	8/2/22	NA
2.0	10/14/22	Added Evaluation Team member assignments
3.0	10/17/22	Edited data collection terminology

8 Appendix and Attachments

APPX A.

<u>Title and Seniority Level to Calculate Junior vs. Senior Status</u>

Junior Investigator

- Assistant Professor
- Clinical Assistant Professor
- Instructor
- Postdoctoral Associate
- Postdoctoral Fellow
- Medical Fellow
- Fellow
- Research Associate

Senior Researcher

- Associate Professor
- Full Professor
- Program Director/Associate Program Director
- Senior Research Scientist

APPX B. Workshops, seminars and courses fall under the umbrella of "trainings" whereas "events" should be separately listed.

Definitions

- Event— one time only, registration encouraged (not required), large number of participants, not expected to claim any outcomes
- Workshop one time only or series, registration required, limited number of participants, participants working on something with instruction and has an end to it, may claim outcomes
- Seminar one time or series, registration encouraged (not required), limited number of participants, not interactive, not expected to claim any outcomes
- Course series, registration required, limited number of participants, connected to larger curriculum structure, count outcomes

Classification System for Events vs Trainings

	One time vs.	Prior Registration	Large vs. small	Project	Outcomes
	series				
Event	One time	Maybe	Large	No	No
Workshop	One time	Definitely	Small	Yes	Maybe
Seminar	Either	Maybe	Small	No	No
Course	Series	Definitely	Small	Maybe	Yes
Bootcamp					

9 Attestation Letter

An electronic signature or electronic process may be used, as long as approved by the SBMIT Chief Research Information Officer.