## Research and Quality Improvement

There are many activities that are not considered research:

- Quality improvement
- Case Studies (up to 3 clinical cases)
- Program evaluation
- Classroom or coursework
- Oral history
- Public health surveillance activities
- Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes.

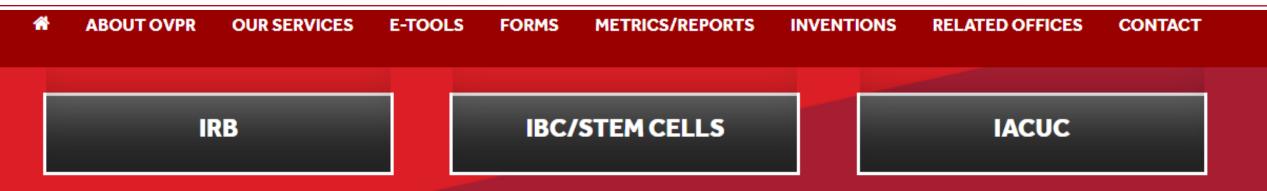




Elements	Research	Quality Improvement
Purpose	Test a formal hypothesis Develop new scientific knowledge	Assess a process, program, or system
Benefits	Knowledge sought may not benefit subjects but may add to the greater good	Knowledge sought directly benefits the process/program/system
Risks	May put subjects at risk	At least as safe as routine care breach of confidentiality is the main risk
Data Collection	Systematic	Systematic
End Point	Answer research question	Improve the program/process/system
Testing/Analysis	Determine validity of hypothesis	Compare the program/process/system to an established set of standards
Intended Result	Share findings with individuals associated with and not associated with the investigation	Share findings only with those individuals associated with the process/program/system. If findings are shared with individuals unassociated with the process/program/system (via publication, conferences,

- Quality Improvement projects are submitted through a Qualtrics "Quality Improvement Survey"
- Confirmation of a short training is required
- An application form describing the Quality Improvement project is required
- Quality Improvement policies and procedures can be found on the webpage at https://www.stonybrook.edu/commcms/researchcompliance/Quality-Improvement/Index.php





#### About myResearch

myResearch is Stony Brook University's single system for researchers, students and staff to manage their proposal submissions and research compliance activities.

myResearch is Stony Brook University's system for certifications under P209: Disclosure of External Interests & Commitments Policy.

#### NetID Username or Password Help

https://it.stonybrook.edu/services/netid or call the Help desk 631-

#### Additional Information

Conflict of Interest

<u>Grants</u>

Agreements\*

IRB Human Subjects

Quality Improvement



## A webpage now exists for improved access to documents: https://www.stonybrook.edu/commcms/research-compliance/

#### Additional Resources



DLAR

Animal Resources



Lab Safety

ENVIRONMENTAL HEALTH & SAFETY



Quality Improvement

INFORMATION



#### Website:

https://www.stonybrook.edu/commcms/researchcompliance/

**Contact Information:** 

Office - 631-632-9036 or 631-632-6541

Email – rebecca.dahl@stonybrook.edu

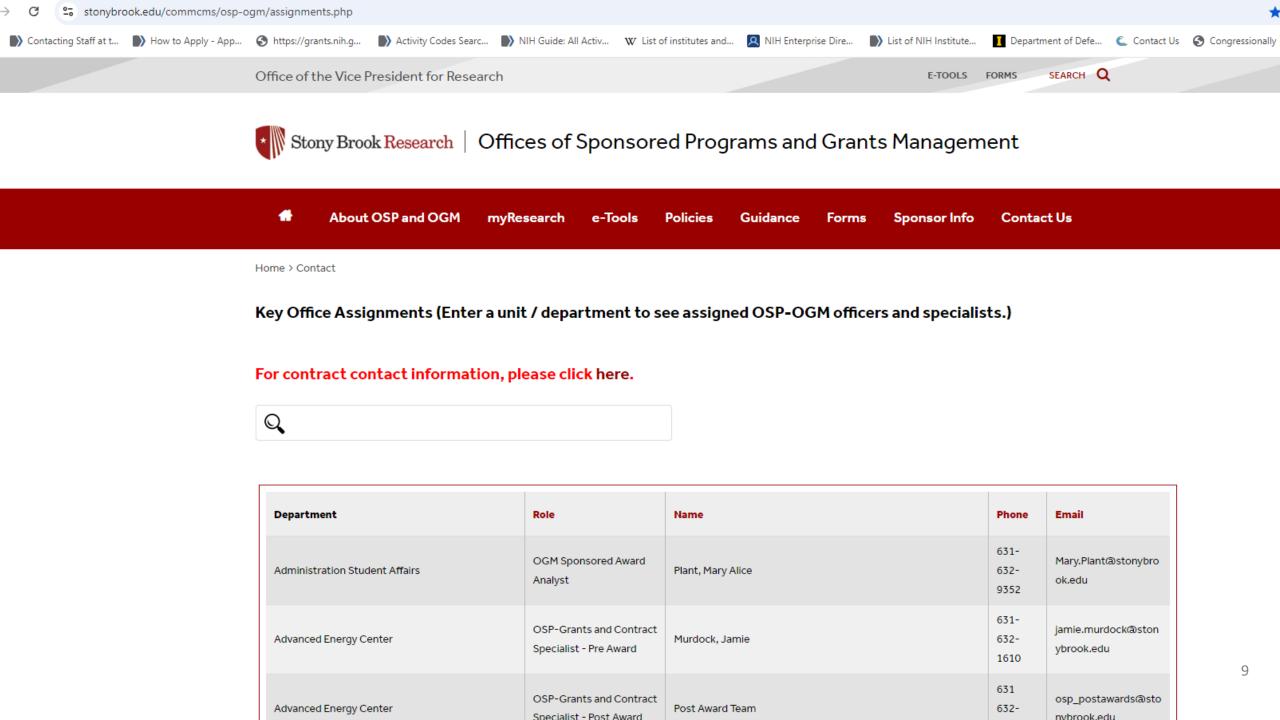
# The Administrative Side of a Proposal and Creating a Budget

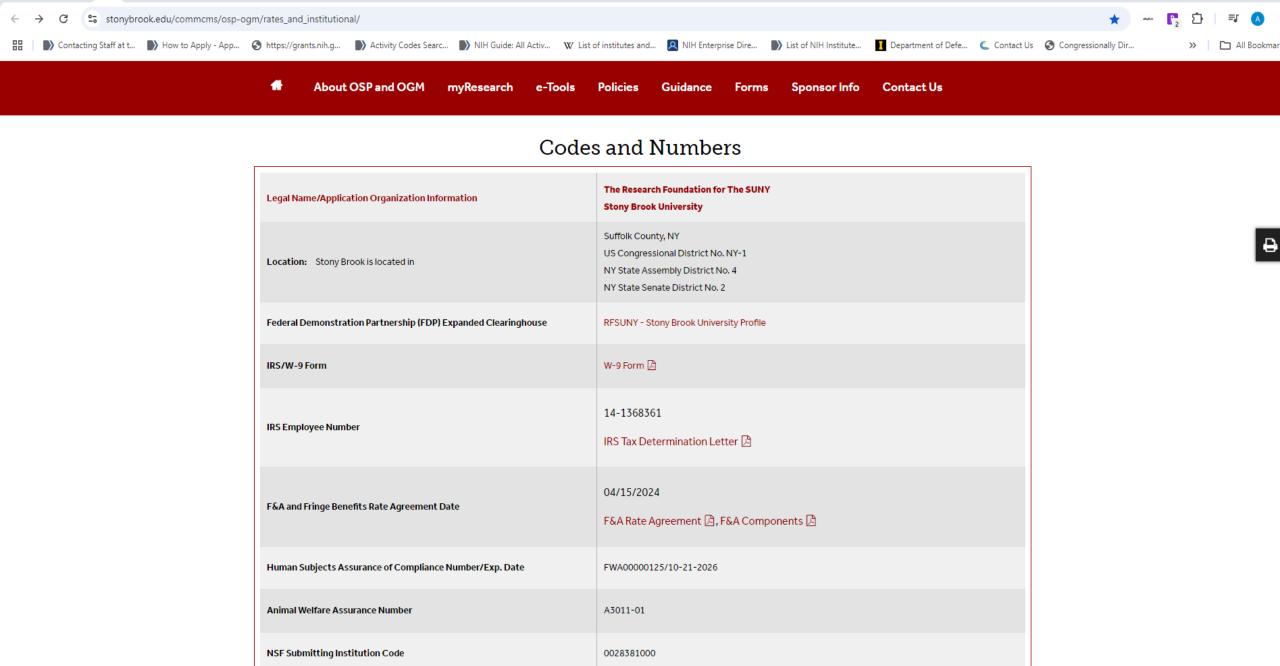
Andria S Adler, Sr. Manager
Office of Clinical Award Administration
Office of Scientific Affairs
631-638-4490
andria.adler@stonybrookmedicine.edu

## **Administrative Components of a Submission**

## Institutional information

- In most cases it is The Research Foundation for the State University of New York
- Administrative Contact is determined by department and type of submission
  - -You can find this information on the Office of Sponsored Programs Website
- Needed Institutional Information including MUI, DUNs and other numbers





804878247

**DUNS Number** 

## **Assistance**

### **University Level**

#### Office of Sponsored Programs (OSP)

- Grants and Contracts Specialist
- Clinical Trial and Contract Specialist
  - Authorized Signing Official

#### Office of Proposal Development

- Large and High-Profile proposals
  - Including Training Grants
- Special Assistance and Programs for Early Investigators

#### School Level

#### School of Medicine

- Office of Clinical Award Administration
  - -Works with all Departments, Centers and Programs in the School Medicine
  - -Will work with the PI and the Project team at their requested level

#### **Health Science Schools**

- School of Health Professions, School of Nursing and School of Social Welfare
- Office of Clinical Award Administration

## **Assistance**

## Check with your department to see if there is a designated resource in your department

Department contacts work with The Office of Clinical Award Administration

## **Budgets**

## **Types**

#### **Direct Cost**

Funding limits only apply to the Direct Cost

#### **Total Cost**

- Funding Limits apply to both Direct and Indirect Cost
  - -Check with Funding Announcement for sponsor requirements
  - -Annual versus All years

## **Rates**

#### **Indirect Cost**

- Also known as F&A
- Set by DHHS or the Funder

#### Fringe

- Benefits that are on top of Salaries
  - -Set by Institution and NYS
  - -By Appointment Type

#### **Tuition**

 Required and set by Graduate School for all Graduate Students



#### Fringe Benefit Rates

#### April 2024 Advisory

#### CURRENT AND RECOMMENDED RESEARCH FRINGE BENEFIT RATES

All Research Foundation accounts will be charged fringe benefits at the rate in effect at the time of expenditure, regardless of the rate at which they were budgeted. No waiver of the fringe benefit rate is permitted.

DATES	EMPLOYEES	POST- DOCTORAL	UNDER- GRADUATE <sup>1</sup>	GRADUATE <sup>2</sup>	SUMMER ONLY <sup>3</sup>	COST SHARING & FACULTY OFFSET <sup>6</sup>
7/1/20	41%	25%	5%	16%	14%	57.71%
7/1/21	39.5%	18%	6%	13%	14.5%	61.85%
7/1/22	40%	23%	6%	13%	14%	63.72%
7/1/23	40%	28%	6%	13%	14%	64.45%
7/1/24	39.5%	31%	5.50%	13%	14%	63.43%
all future years	Use 39.5%	Use 31%	Use 5.50%	Use 13%	Use 14%	Use 63.43%

<sup>&</sup>lt;sup>1</sup> Applies only to full time SUNY undergraduate students who meet the criteria for and are appointed to one of the following titles: Research Aide, Senior Research Aide or Camp



## **Budgets**

### **Components**

#### Personnel Cost

- Salary and Fringe
  - -SOM Personnel can only Cost-Share 5% effort at any given time
  - -Unless otherwise stated all SOM personnel need to show effort (Except for Training grants where they are acting as mentors)

#### Other than Personnel Cost

o Travel, material and supplies, publications, animals, core services, participant cost

#### Subawards

Materials needed from other institutions

#### Consultants

Who can be a Consultant and what is need from them

## INDUSTRY FUNDED CLINICAL TRIALS

Silvia Muniz

Assistant Director for Clinical Trials

Silvia.Muniz@stonybrookmedicine.edu

## OFFICE OF CLINICAL TRIALS (OCT)

## Objectives:

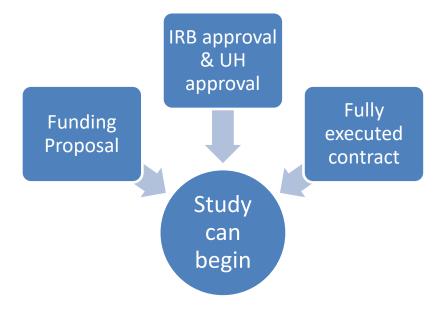
- To streamline process between Industry and SBM
- To match sponsors with Investigators for best overall study outcome
- Assist Investigators with initial process (budget review, payment terms negotiations, financial management)
- Assist Investigators with staff support (Study Coordinators, IRB/Regulatory Coordinator) –
   Fee for service

## Steps:

- Confidential Disclosure Agreement (CDA)
  - Also called: Non-Disclosure Agreement, Secrecy Agreement
  - Negotiated and signed by Office of Technology Licensing (OTLIR)
  - Principal Investigator (PI) signs "Read and Understood"
- Protocol
- Site Survey/Feasibility Questionnaire
- Review/negotiation of study budget
  - RF Overhead (30%); Non-refundable start-up fee; Administrative Institutional fee; IRB fees; Closeout/Archiving fees; Per patient fees; Research vs SOC

## Steps (cont.):

- Submission on myResearch (Grants, IRB, Agreements) and Central IRB, if applicable
- Contract review/negotiation by Office of Sponsored Programs (OSP)



## Helpful Links:

OCT: <a href="https://osa.stonybrookmedicine.edu/octs/welcomelnvestigator">https://osa.stonybrookmedicine.edu/octs/welcomelnvestigator</a>

Clinical Trials Fact Sheet:

https://www.stonybrook.edu/commcms/ospogm/contracts\_negotiation/Types\_Contracts/clinical\_trials/

Office of Sponsored Programs and Office of Grants Management:

https://www.stonybrook.edu/commcms/osp-ogm/about.php

## University Libraries Research Data Services

- Provides assistance with the following:
  - Locating datasets for secondary analysis
  - Identifying repositories for data storage, preservation and sharing
  - Tools and resources for creating data management and sharing plans
  - Review of data management and sharing plans
  - Guidance on data analysis and visualization

## University Libraries Research Data Services

## Dryad Digital Repository

- Institutional digital repository
- Data available for reuse
  - clinical trial data
  - medical imaging datasets
  - epidemiological data

## Dataworks competition

- Win up to \$100k for projects re-using data from Dryad or other generalist repositories—Deadline for proposals October 24th
- For more information: <a href="https://www.herox.com/dataworks">https://www.herox.com/dataworks</a>

## University Libraries Research Data Services

- Contact us:
  - For research data management-related questions:
    - dataservices@stonybrook.edu
  - For other library inquiries:
    - refhsclib@stonybrook.edu

## David G. Cyrille

Chief Research Information Officer
Assistant VP, SBU Information Technology



## Resources Available for QA/QI Activities

- TriNetX: Define cohorts and analyze outcomes using real Stony Brook patient data. (Self-Service with consult support)
- Data Brokerage: Requests for Extracted EMR Data can be broad, can be filtered by SBM location or provider, or can provide MRNs for needed chart review.

 REDCap: A versatile data capture platform that allows users to build data collection projects, including live surveys, and enter and download project data. (Self-Service with consult support)

## Resources Available for QA/QI Activities

 Secure Storage: Individual access-limited electronic storage for projects requiring HIPAA-defined Protected Health Information or limited data sets



Stony Brook Medicine Managed Devices:
 Properly encrypted computing devices are required for use or access to Protected Health Information or limited data sets.



## Requesting Resources for QA/QI Activities

Resource	Request
TriNetX	Request account at stonybrookmedicine.edu/trinetx. Consults with Melanie.Keister@stonybrookmedicine.edu as needed.
Data Brokerage	Request data service via the Health System Reporting link on the Pulse Intranet
REDCap	Access process is described at rci.stonybrook.edu/redcap/access. Consults with <a href="mailto:Tony.Jin@stonybrookmedicine.edu">Tony.Jin@stonybrookmedicine.edu</a> as needed.
Secure storage	Submit an IT Help Request online for Research Computing > Clinical Research Share Drive - https://help.stonybrook.edu/TDClient/653/Portal/Home/
SBM Managed Devices	Ensure use of an SBM-managed desktop or laptop for the project.