Human Subjects Research at UB

Orientation/Guide

May 2024

The Players

Who’s who

Non-HIPAA Covered Entities

- The University at Buffalo (UB)
  - **All research is conducted under the University at Buffalo.**

- The Research Foundation for The State University of New York (RF)
  - RF is a non-profit education corporation that assists the University in the identification of opportunities, procurement, use and disposition of funds from the federal, state, and municipal government and other sources to support all research and sponsored programs at the University.

- **ALL research agreements (e.g., CTA, NDA, DUA, etc.) are signed by The Research Foundation on behalf of The State University of New York at Buffalo.**

Some HIPAA Covered Entities/UB Affiliates

- **Any research that involves the use of Personal Health Information (PHI) requires an IRB approved HIPAA mechanism to release that PHI from the Covered Entity to UB.**
- Any resources used from an affiliate for research requires a **Facilities Agreements**
  - signed by The Research Foundation on behalf of The State University of New York at Buffalo
  - Signed by the Affiliate

UB|MD Physicians' Group

ECMC

Kaleida Health

Catholic Health

ROSWELL PARK Comprehensive Cancer Center

general physician pc

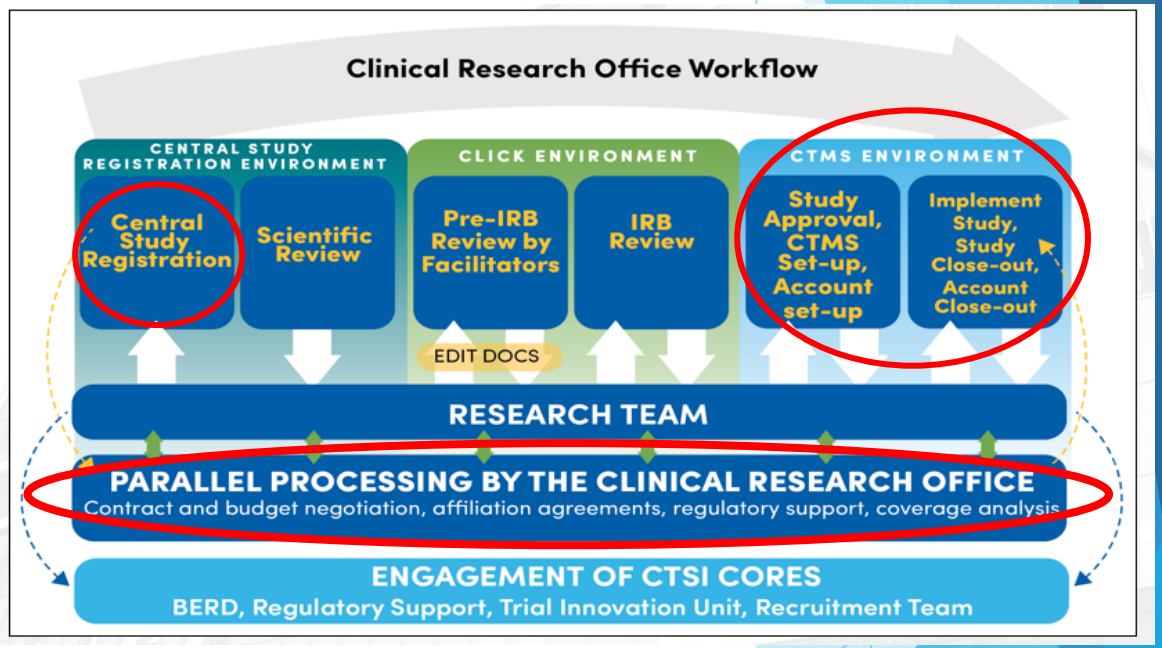
VA | U.S. Department of Veterans Affairs

UB Research Support

Clinical Research Office (CRO)

https://www.buffalo.edu/research/about-us/units/cro.html

- A centralized office charged with **administrative and financial oversight** for all clinical research activities of the university's faculty members
- All human subjects research passes through the CRO to ensure compliant, meaningful research.
- Part of the Clinical and Translational Science Institute (CTSI)
- CRO Services



Contract negotiation | Budget development | Protocol development | Pharmacy services | Regulatory Assistance

Sponsored Projects Services (SPS)

https://www.buffalo.edu/research/about-us/units/sps.html

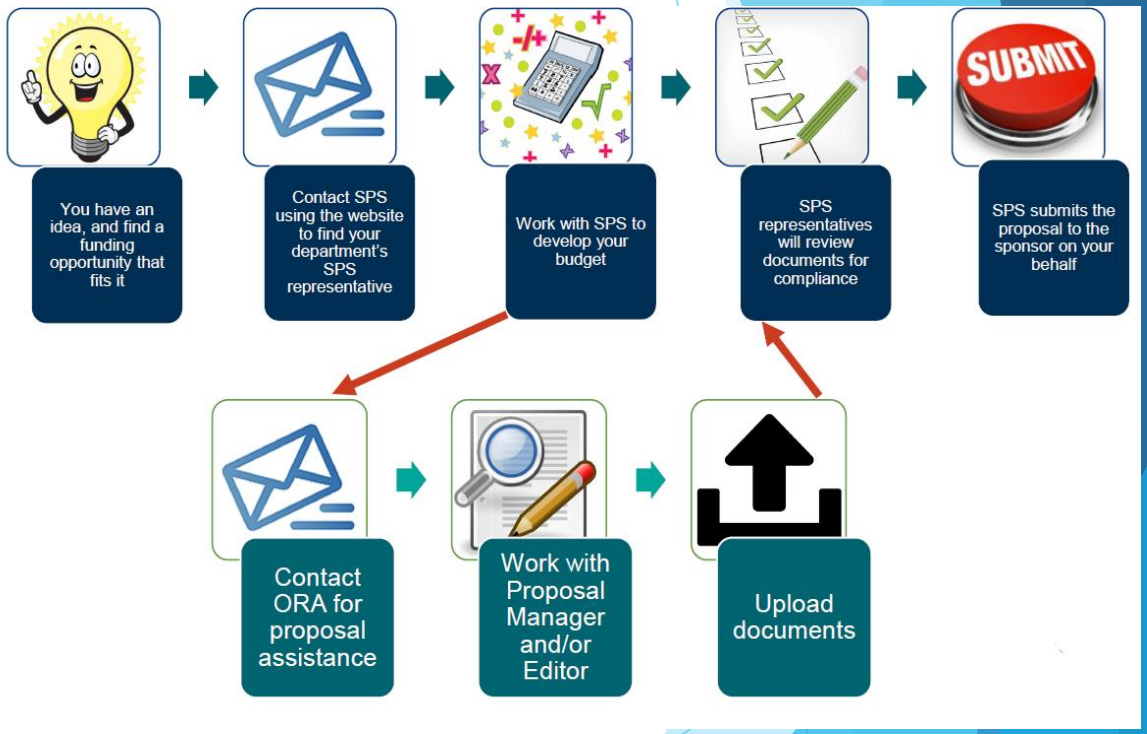
- First office to contact when developing a funding proposal
- Official unit to prepare, review, and submit proposals for sponsored funding
- Provides stewardship of awarded funds to ensure compliance with applicable regulations and policies.
- Required for Federal and Federal Flow-Through funds

- **Contact a Grant Expert:** https://www.buffalo.edu/research/about-us/staff-directory/contact-grant-expert.html

Office of Research Advancement (ORA)

https://www.buffalo.edu/research/about-us/units/ora.html

- ORA supports the university's research and scholarly community in the pursuit of external grant and research funding.
- Comprehensive administrative and technical support are available to researchers as they:
  - form their research teams
  - identify collaborators
  - refine their projects and
  - develop their proposals
- Provides help with proposal development
- Offers programs to enhance faculty grantsmanship
- Assists with networking with funding agency program managers
- Email: ubgrants@buffalo.edu



Clinical and Translational Science Institute (CTSI)

- UB's CTSI is one of more than 60 academic health centers in the US currently receiving Clinical and Translational Science Award (CTSA) Program funding from the National Institutes of Health (NIH) National Center for Advancing Translational Sciences (NCATS).

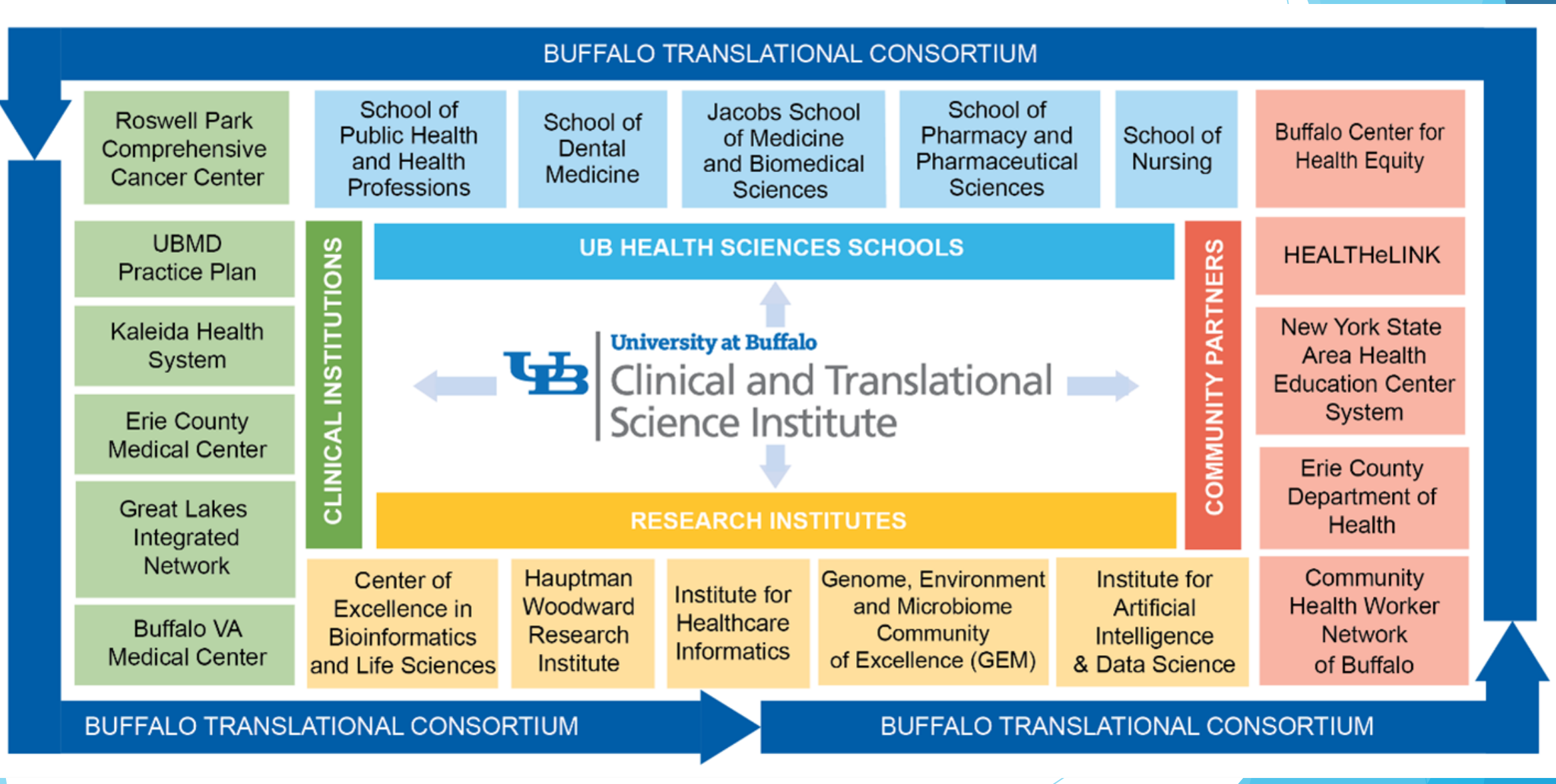
University at Buffalo
Clinical and Translational Science Institute

- **All publications that result from the use of UB CTSA resources are required by the NIH to cite the CTSA.**
  - *Language provided at https://www.buffalo.edu/ctsi/cite-the-ctsa.html*

- The CTSI has the following cores that provide faculty and trainees with comprehensive, broad-based support for clinical and translational research projects.
  - BERD (Biostatistics, Epidemiology and Research Design)
  - Clinical Research Office
  - Community Engagement
  - Drug Development
  - Imaging
  - Informatics
  - Pilot Studies
  - Recruitment and Special Populations
  - Team Science
  - Workforce Development

- More information
  - https://www.buffalo.edu/ctsi.html
  - https://www.buffalo.edu/ctsi/cite-the-ctsa.html
- Service Request
  - https://www.research.buffalo.edu/portal/ctsa/#/loginsignup

Buffalo Translational Consortium



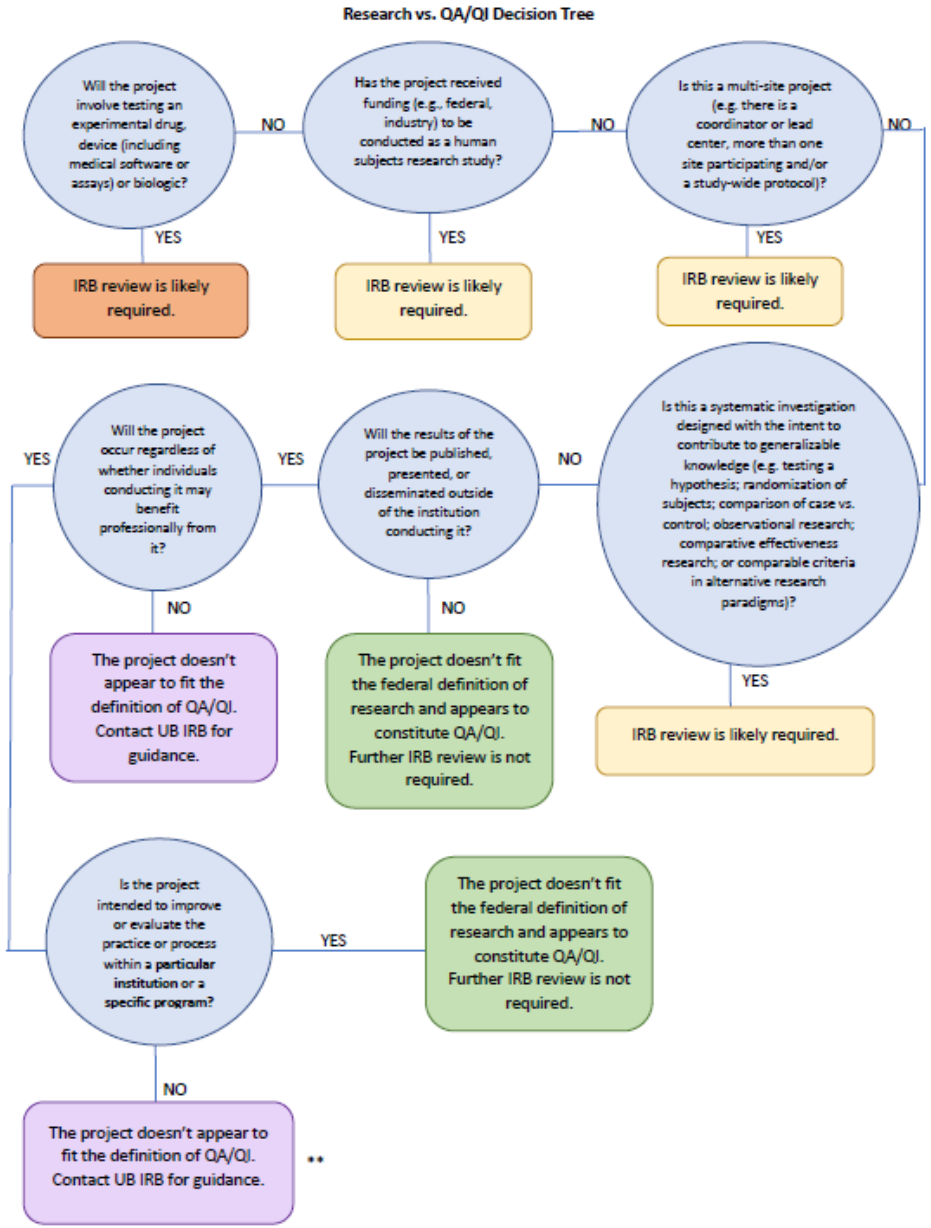
The Platforms

What's what

UB Research Platforms

	QA/QI	ALL PROTOCOLS				FUNDED PROTOCOLS				SPENDING		Other
	QA/QI Self-Cert	CSR	Click IRB	Click COI	OnCore	Click Agreements	Click Grants	RF Report Center	CRMS	ShopBlue	Concur	Click Safety
NOT RESEARCH – QA/QI	X											For studies needing to complete safety committee applications for: · Biosafety · Radiation safety · Chemical safety · Stem cell research oversight
RESEARCH												
○ Not Human Subjects			X	X		X	X	X		X	X	
○ Human Subjects												
● Exempt			X	X		X	X	X		X	X	
● Non-Exempt												
○ Humanitarian use		X	CRO creates	X		X	X	X	X	X	X	
○ Retrospective		X	CRO creates	X		X	X	X		X	X	
○ Prospective												
● Non-Interventional		X	CRO creates	X	X	X	X	X		X	X	
● Interventional												
○ Drug/Device		X	CRO creates	X	X	CRO uploads	X	X	X	X	X	
○ Behavioral												
● NIH/NSF/Foun-dation/Industry		X	CRO creates	X	X	X	X	X	X	X	X	
● Other/Unfunded		X	CRO creates									

QA/QI Self-Cert	This tool is to be used to assist in determining whether a project may be deemed quality assurance (QA)/quality improvement (QI) and therefore not require IRB review or approval. Go to: https://redcap.link/UB-QI-determination
CSR	Central Study Registration - This is the first place to enter your study. From the information provided, the CRO will create (but NOT submit) your IRB submission in Click IRB.
Click IRB	Part of the CLICK Compliance Suite, Click IRB is the module used for submitting studies to the UBIRB.
Click COI	.This is the Click module where researchers disclose any research-related conflicts of interest either annually or if there is a change.
OnCore	The Clinical Trial Management System (CTMS) is used to track subject enrollment & financials. Sponsors are invoiced based on data entered in OnCore.
Click Agreements	All contracts and agreements must be signed by one of UB/RF's designated individuals**. PIs cannot sign any contracts on UB/RF's behalf.**
Click Grants	The CRO will enter and submit your funding proposal for industry sponsored account establishment. SPS will facilitate completion for Federal awards.
RF Report Center	The RF Report Center helps investigators stay current on the fiscal status of their sponsored awards.
CRMS	This is a billing compliance system, which is used to track standard of care (SOC) v. research expenditures.
ShopBlue	ShopBlue is a fully integrated eProcurement system allowing authorized UB faculty and staff to place orders for necessary goods and services.
Concur	This is the travel & expense reimbursement system used to book business travel and submit business travel and non-travel expenses for reimbursement.



QA/QI Self Certification

- Determine whether a project may be deemed quality assurance (QA)/quality improvement (QI) and therefore not require IRB review or approval.
- Can print a self-certification form for your records
- Assessment tool:
  - https://redcap.link/UB-QI-determination

UB Research Platforms

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○ Drug/Device		X	CRO creates	X	X	CRO uploads	X	X	X	X	X	
○ Behavioral												
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Concur	This is the travel & expense reimbursement system used to book business travel and submit business travel and non-travel expenses for reimbursement.
Click Safety	The Click Safety module incorporates forms for biosafety, radiation safety, chemical safety and stem cell research oversight.

Additional Research Platforms

	ALL PROTOCOLS		DATA COLLECTION/RECRUITMENT							FUNDED PROTOCOLS	USE OF MENTAL HEALTH RECORDS FROM OMH PROVIDER
	CITI	ClinicalTrials.gov	REDCap	TriNetX	Buffalo Research Registry	Research Match	Participate in Research	Affiliate EMR	Affiliate Data Request	US Bank (Prepaid Debit Cards for Research Participants)	Kline IRB
NOT RESEARCH - QA/QI											
RESEARCH											
○ Not Human Subjects											
○ Human Subjects											
● Exempt	X										
● Non-Exempt											
○ Humanitarian use	X			X			X	X	X	X	
○ Retrospective	X		X	X			X	X	X	X	X
○ Prospective											
● Non-Interventional	X		X	X	X	X	X	X	X	X	
● Interventional											
○ Drug/Device	X	X		X	X	X	X	X	X	X	
○ Behavioral											
● NIH/NSF/Foundation/Industry	X	X	X	X	X	X	X	X	X	X	
● Other/Unfunded	X	X	X	X	X	X	X	X	X		

CITI	The Collaborative Institutional Training Initiative (CITI Program) includes required training for ALL research staff at UB.
ClinicalTrials.gov	ClinicalTrials.gov is a website and online database of clinical research studies and information about their results.
REDCap	REDCap is a secure web platform for building and managing online databases and surveys. REDCap can only be used for Investigator initiated studies.
TriNetX	TriNetX is a de-identified clinical patient database that include inpatient, outpatient, and claims data.
Buffalo Research Registry	Buffalo Research Registry is a list of local people, ages 18 and up, who are interested in participating in research.
Research Match	ResearchMatch is a free and secure tool that helps match willing volunteers with eligible researchers.
Participate in Research	Searchable list of studies at UB (https://www.research.buffalo.edu/portal/clinicaltrial/).
Affiliate EMR	Use of an affiliate EMR requires appropriate credentialing at that affiliate.
Affiliate Data Request	Use of affiliate data requires appropriate submission request (e.g., http://kaleidascope/decisionsupport/requestform.aspx)
US Bank	The Prepaid Debit Card program has been developed to allow researchers to pay their participants using a prepaid visa card. Choose from 3 options.
Kline IRB	A determination from Kline IRB is needed for studies using records that originate from a facility that appears on the Office of Mental Health (OMH) directory of providers (e.g., ECMC).

A Note About Affiliates

Working with UB Affiliates

Investigator

- **ALL CLINICAL STUDIES:**
  - **Submits Application for Permission to Conduct Clinical Research at ECMC,** Protocol, ICF, and IRB approval (when available)
- **FUNDED STUDIES:**
  - Identifies use of hospital resources, such as pharmacy, laboratory, radiology or nursing
  - Submits Coverage analysis to CRO.

ECMC

- **ALL CLINICAL STUDIES:**
  - Determines if other agreements are needed (if you are accessing ECMC electronic medical records)
  - Determines if **Research Associate Application** is needed
- **FUNDED STUDIES:**
  - Submission reviewed by Departmental Directors and Fiscal Department
  - Determine rates and billing process

Approval granted

- Letter sent from the Office of Medical Director.

Kaleida Health

Investigator

- **FUNDED STUDIES:**
  - Identifies use of hospital resources, such as pharmacy, laboratory, radiology or nursing
  - Submits Coverage analysis to CRO.

Kaleida Health

- ALL CLINICAL STUDIES:
  - Determines if data request needs to be submitted through Kaleidascope
  - Determines if Research Associate Application is needed
- **FUNDED STUDIES:**
  - Works with CRO to ensure fair market pricing and compliant billing practices

This process takes time.

Submit Early!

FUNDED

FUNDED STUDIES: Coverage Analysis(CA)

- Investigator and CRO review clinical events specified in the protocol to decide:
  - which can be reimbursed by Medicare/Medicaid or insurance
  - which should be covered by the research sponsor
- For example:
  - a CT scan as part of SOC → billed to insurance
  - a CT scan for research only → billed to study

- More information:
  - https://www.buffalo.edu/research/research-services/clinical-and-behavioral-research/set-up-study/coverage-analysis.html
- Forms at:
  - https://www.buffalo.edu/research/research-services/clinical-and-behavioral-research/forms-and-templates.html
- Email: careview@buffalo.edu

First steps

CITI Training

- Required Courses:
  - Conflict of Interest (COI)
  - Biomedical/Clinical Research
    - *Human Research Curriculum, Biomedical Research Investigators Basic* or *Refresher Course* completed within the past 3 years.
    - *CITI Good Clinical Practice Course Basic* or *Refresher Course* completed within the past 3 years.
  - Social/Behavioral/Educational
    - *Human Research Curriculum, Social & Behavioral Research Investigators Basic* or *Refresher Course* completed within the past 3 years.
    - *Social and Behavioral Responsible Conduct of Research Course Basic* or *Refresher Course* completed within the past 3 years.

- If you have a **CITI** account with another institution, you can log into that account and then add an affiliation with *SUNY-Buffalo (University at Buffalo)*

- More information:
  - https://medicine.buffalo.edu/orientation/checklist/citi-training.html
  - https://www.buffalo.edu/research/research-services/training/compliance-training.html

- Log in at:
  - http://www.citiprogram.org

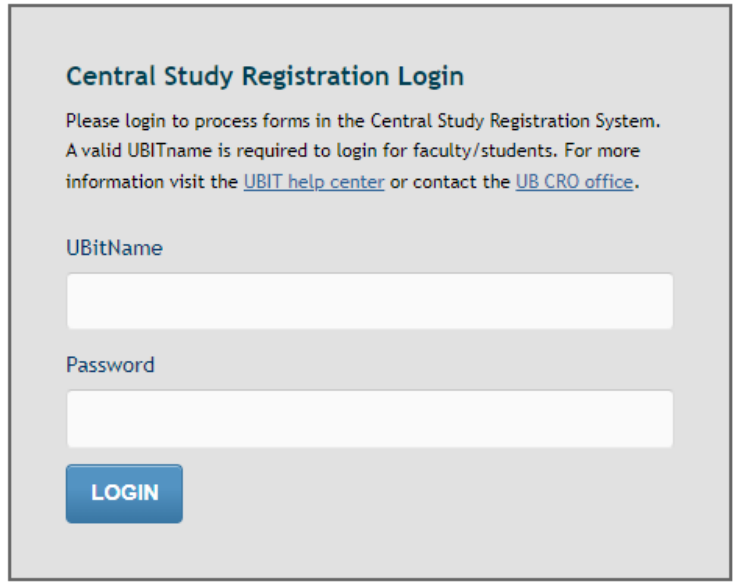
CITI PROGRAM

Central Study Registration (CSR)

- This is where you first enter your study:
  - If your home department is within one of the health sciences schools. (School of Medicine & Biological Sciences, School of Nursing, School of Pharmacy & Pharmaceutical Sciences, School of Dental Medicine, School of Public Health and Health Professions)
  - You are within one of the mandated schools and doing a chart review
  - If your study meets the NIH definition of a Clinical Trial, irrespective of School

- *Registration of your study is Not required when:*
  - *You are seeking a determination of Not Human Subjects Research*
  - *You are seeking an exempt status for your study*
  - *You are within a Non-Mandated School and you are not conducting a clinical trial by NIH definition*

- From the information provided, the CRO will create (but NOT submit) your IRB submission in Click IRB and upload your CTA into Click Agreements (if applicable).
- Request support from the CRO
- Designate PI Proxies



- More information at: https://www.buffalo.edu/ctsi/cores/clinical-research-office/educational-modules/introduction-to-central-study-registration.html
- Login at: https://www.research.buffalo.edu/studyregistration/main/login

Click

Remember to CLICK submit

Click Portal

- The Click Compliance Suite integrates all aspects of grants management into a single system using the following modules:
  - Click IRB
  - Click IACUC
  - Click Grants
  - Click Conflicts of Interest (COI)
  - Click Agreements
  - Click Safety

- To create a Click account:
  - Go to http://www.buffalo.edu/click/registration and
  - Fill out the **Request Account** section.
  - *Please be sure to have all UB browsers closed when you request your account (e.g. UB Learns, Email, Course scheduling, etc.)*

Click Portal – COI

- An electronic system for management of research-related conflict of interest disclosures.
- Each researcher is required to complete an Annual Financial Disclosure form
  - at the time of applying for funded research or prior to the release of grant funds, whichever occurs first,
  - annually thereafter (November),
  - and within 30 days of discovering or acquiring a new significant financial interest.

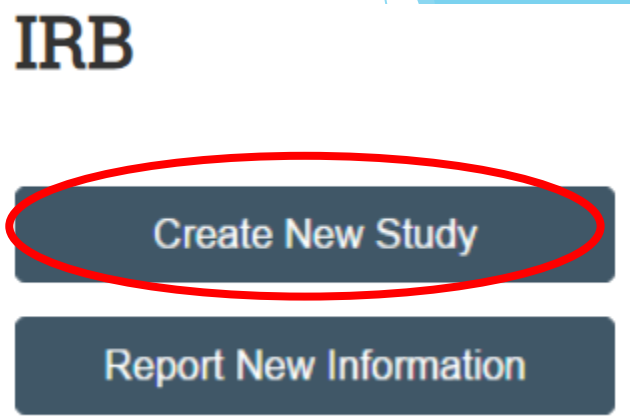
- More information at:
  - https://www.buffalo.edu/research/research-services/training/training-workshop/COI-module.html

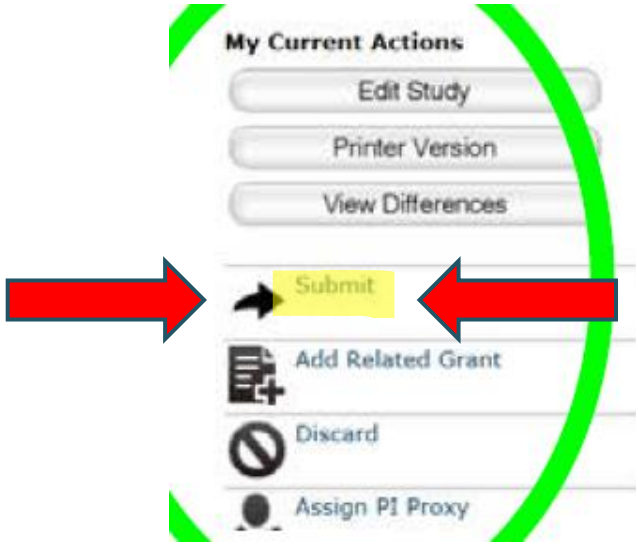
- **Training Materials**
  - Click COI Module(2.3 MB)
  - Guidance for Completing a COI(962 KB)
  - Click COI Module - Sample Disclosure(320 KB)
  - Click COI Guide(1.7 MB)
  - Click COI - Edt and Submit a Certification(413 KB)

Click Portal - IRB

- Investigators enter submissions directly into Click IRB for:
  - Not Human Subjects Research
  - Exempt Research

- Enter comment into CLICK IRB seeking determination



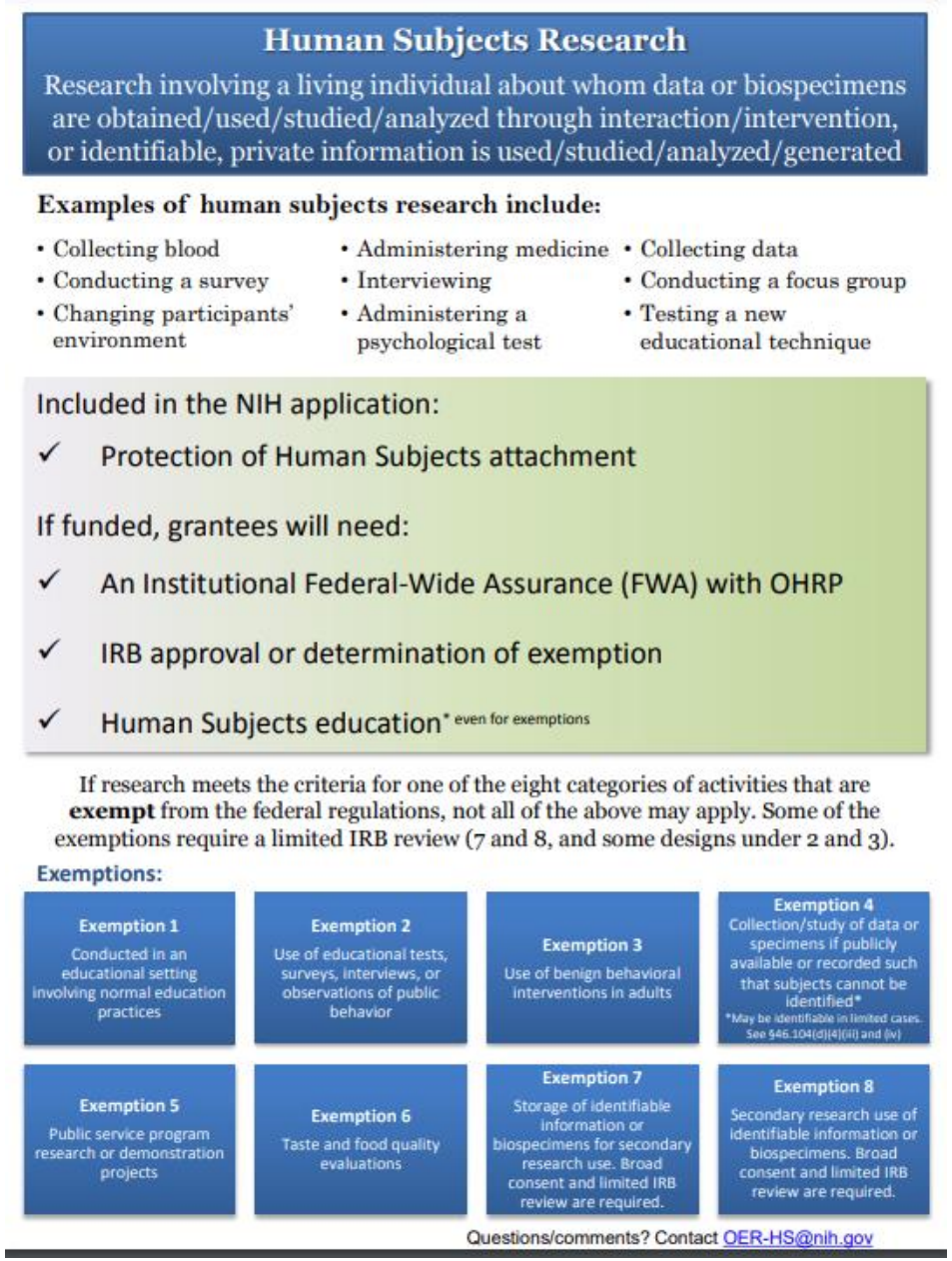


- The CRO creates the IRB submission for ALL other Human Subjects Research.
  - The CRO will NOT submit the submission.
  - Site staff are responsible for uploading all required documents and **submitting** to the IRB.

Human Subjects Research defined

Link at: https://grants.nih.gov/sites/default/files/human-subjects-research-infographic.pdf

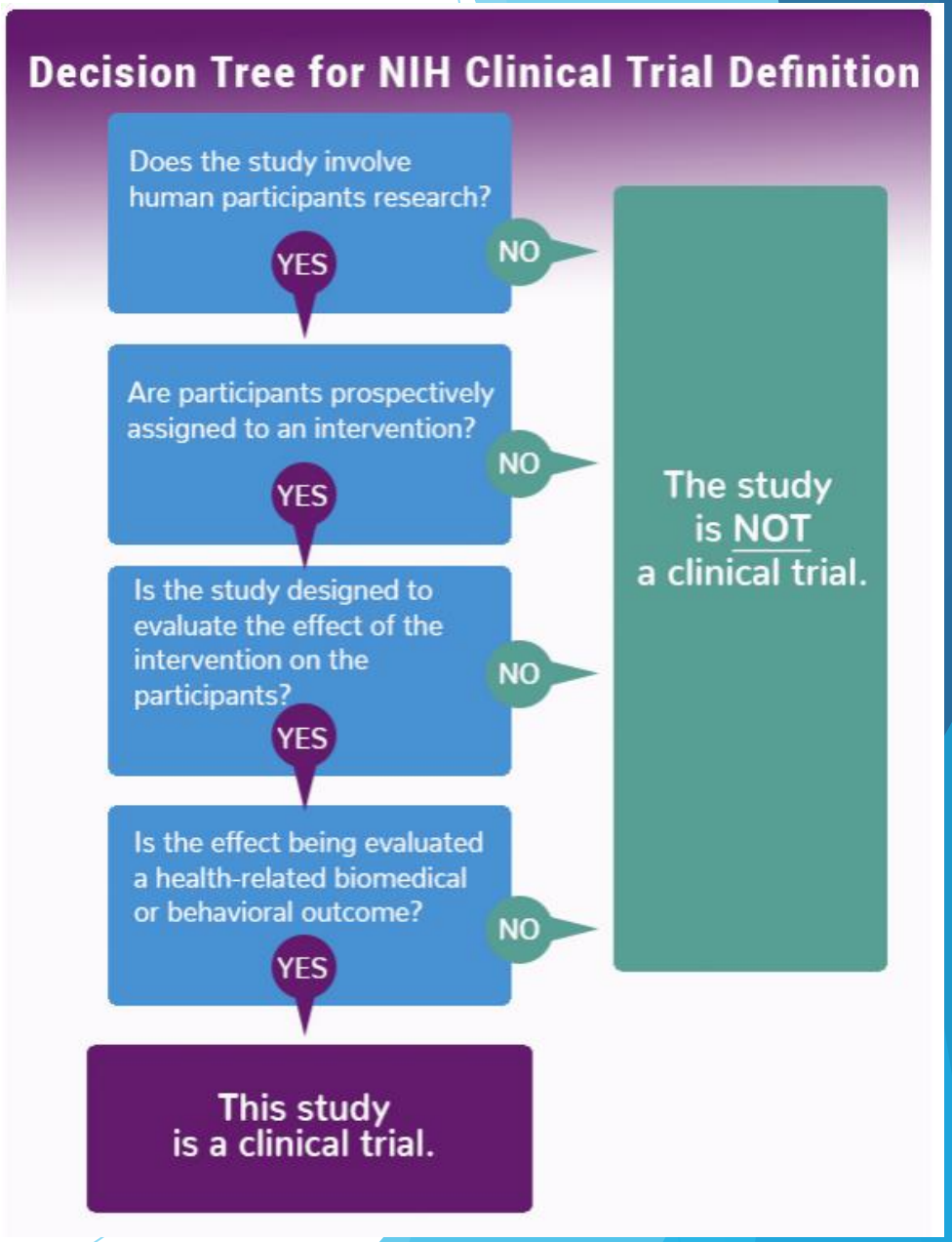
Decision tool at: https://grants.nih.gov/policy/humansubjects/research.htm



NIH Clinical Trial defined

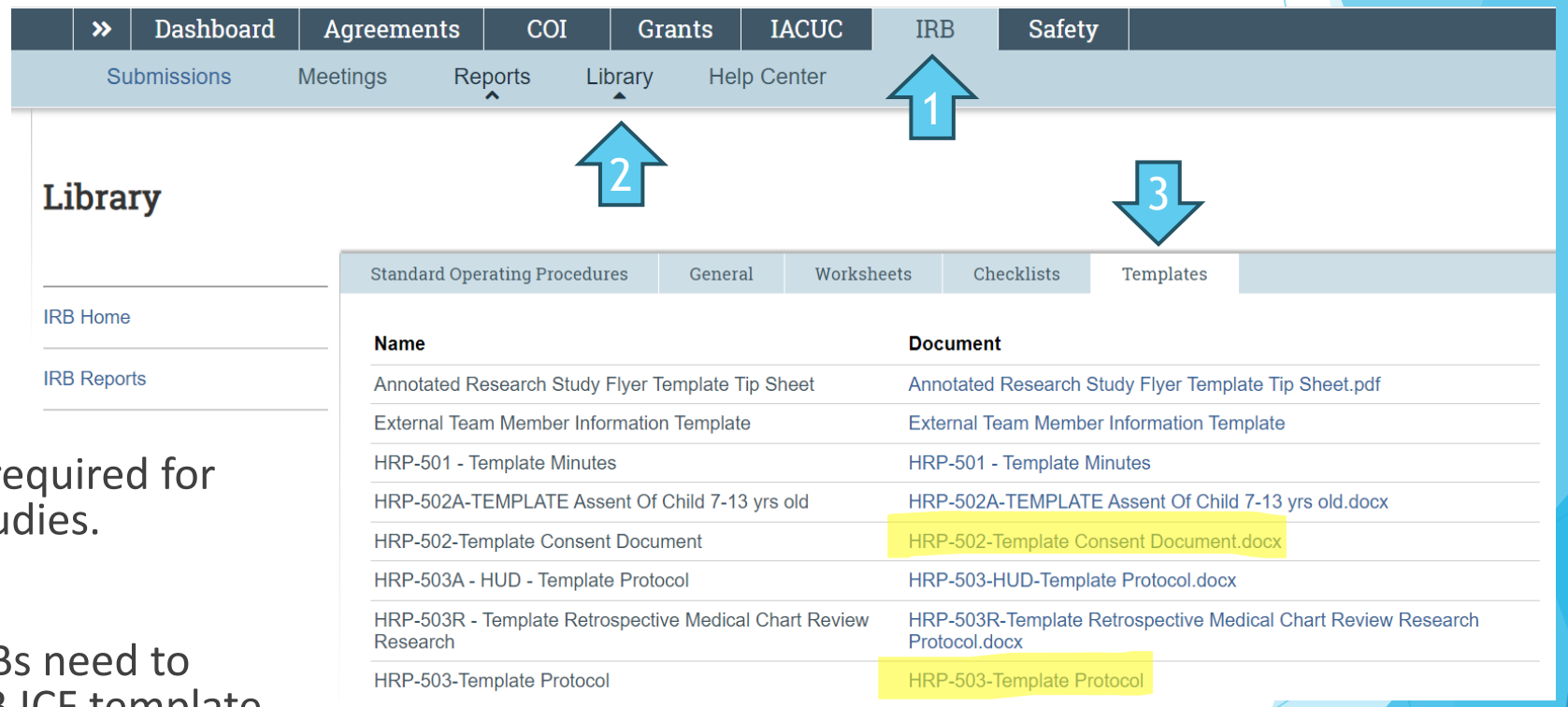
Link at: https://grants.nih.gov/policy/clinical-trials/CT-decision-tree.pdf

Decision tool at: https://grants.nih.gov/policy/clinical-trials/definition.htm



Click Portal - IRB

- UB IRB templates can be found in the Click IRB module within the Library.



- URB IRB templates are required for investigator-initiated studies.

- Studies using central IRBs need to incorporate required UB ICF template language (e.g., research related injuries, HIPAA) into external ICFs.

Click Portal - IRB

- More information at:
  - https://www.buffalo.edu/research/research-services/training/training-workshop/irb-module.html
  - https://www.buffalo.edu/research/research-services/click-implementation/modules/irb.html

- Log in at:

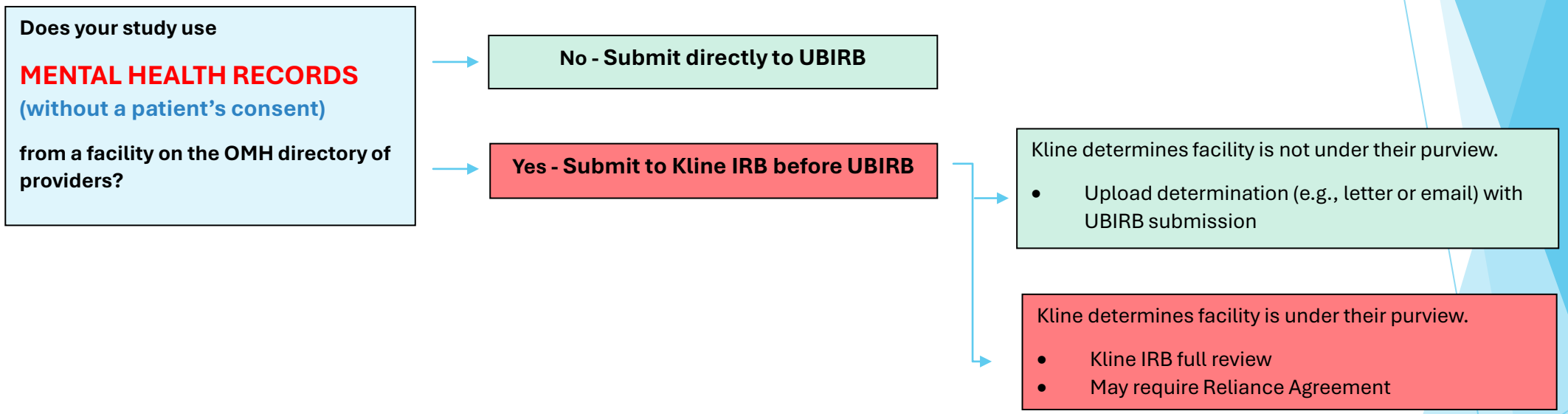
  https://shibboleth.buffalo.edu/idp/profile/SAML2/Redirect/SSO?execution=e1s2

- **Course Materials**
  - Click IRB Module - Introduction(2 MB)
  - Click IRB Module - Sample Study(303 KB)
  - Click IRB Module - Training Setup(337 KB)
  - Click IRB Study Submission Guide(1.8 MB)
- **Work Instructions**
  - Click IRB - Create and Submit a New Study(425 KB)
  - Click IRB - Create and Submit a Modification or Continuing Review(374 KB)
  - Click IRB - Clarifications Modifications and Deferral Process(223 KB)
  - Click IRB - Reportable New Information(369 KB)
- **Quick Reference Guides**
  - Create a New Study Download pdf(306 KB)
  - Clarification Requested and/or Modifications Required Download pdf(327 KB)
  - Reportable New Information (RNI) Download pdf(317 KB)

Research Using Mental Health Records from OMH Provider

Kline BEFORE Click

New York State Mental Hygiene Law Section 33.13



- The Mental Health Program Directory provides information on all programs in New York State that are **operated, licensed, or funded** by the State Office of Mental Health (OMH).
- The directory can be found here: https://my.omh.ny.gov/bi/pd/saw.dll?PortalPages&PortalPath=/shared/Mental%20Health%20Program%20Directory/_portal/Mental%20Health%20Program%20Directory&page=Full%20Directory&Action=Navigate

Click Portal - Agreements

- Provides an electronic system for management of research-related contracts and agreements. It includes:
  - Sponsored Research Agreements
  - Clinical Trial Agreements (CTA)
  - Non-Disclosure Agreements (NDA or CDA)
  - Material Transfer Agreements (MTA)
    - Any material moving to or from UB needs an MTA
  - Data Use Agreements (DUA)
    - Any data moving to or from UB needs a DUA
- Agreements are signed by RF on behalf of SUNY
- PIs cannot sign ANY agreements on RF's behalf
- More information at:
  - https://www.buffalo.edu/research/research-services/training/training-workshop/agreements-module.html

- **Course Materials**
  - Click Agreements Module(7.8 MB)
- **Work Instructions**
  - Click Agreements - Agreements Workflow(219 KB)
  - Click Agreements - Create and Submit an Agreement(355 KB)
  - Click Agreements - Respond to Clarifications Requested(323 KB)
  - Click Agreements - Create and Submit an Amendment(255 KB)
  - Click Agreements - PI quick Reference(304 KB)
  - Click Agreements - Reviewer quick reference(889 KB)

Click Portal – Grants

(Funded Studies)

- The internal routing proposal for all sponsored funding submissions
- Helps estimate the resources, time and effort needed for a research project

- CRO submits for industry sponsored studies
- SPS will facilitate completion for Federal awards

- **Creates an account** and assigns a **Project-Task-Award (PTA) number**, which you need in managing your award.

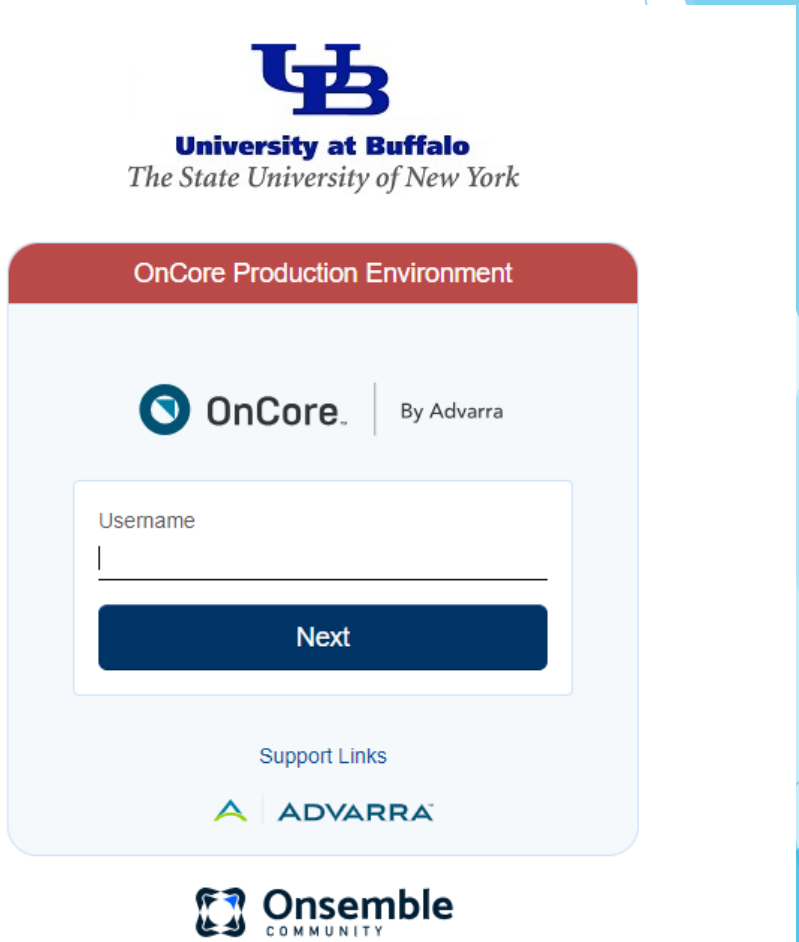
- More information at:
  - https://www.buffalo.edu/research/research-services/prepare-and-submit-your-grant-proposal/approval--submission-and-tracking/click-grants-module.html
  - https://www.buffalo.edu/research/research-services/training/training-workshop/grants-module.html

- **Training**
  - Budget Frequent Errors.pdf(434 KB)
  - Create a Funding Proposal(3 MB)
  - Credit Distribution.pdf(827 KB)
  - Funding Proposal Frequent Errors.pdf(258 KB)
  - Routing.pdf(1.4 MB)
  - CIP Code Description(480 KB)
  - HERD Code Description(618 KB)
  - How Click Grants Unit Data Impacts Reporting and Oracle Access(194 KB)
- **Training Materials**
- **For Principal Investigators and Co-Investigators**
  - Create a Non-System-to-System Approval Form(3 MB)
  - Guidelines for Reviewers (Co-PIs, Chairs, and Deans)(1.4 MB)
  - Updating the Credit Distribution(827 KB)
  - Click Grants Module - Frequent Errors(154 KB)
  - NSF Codes - Detailed Examples(567 KB)
  - Frequent Errors - Approval Form(258 KB)
  - Frequent Errors - Budget(434 KB)
- **For Deans and Department Chairs**
  - Guidelines for Reviewers (Co-PIs, Chairs, and Deans)(1.4 MB)

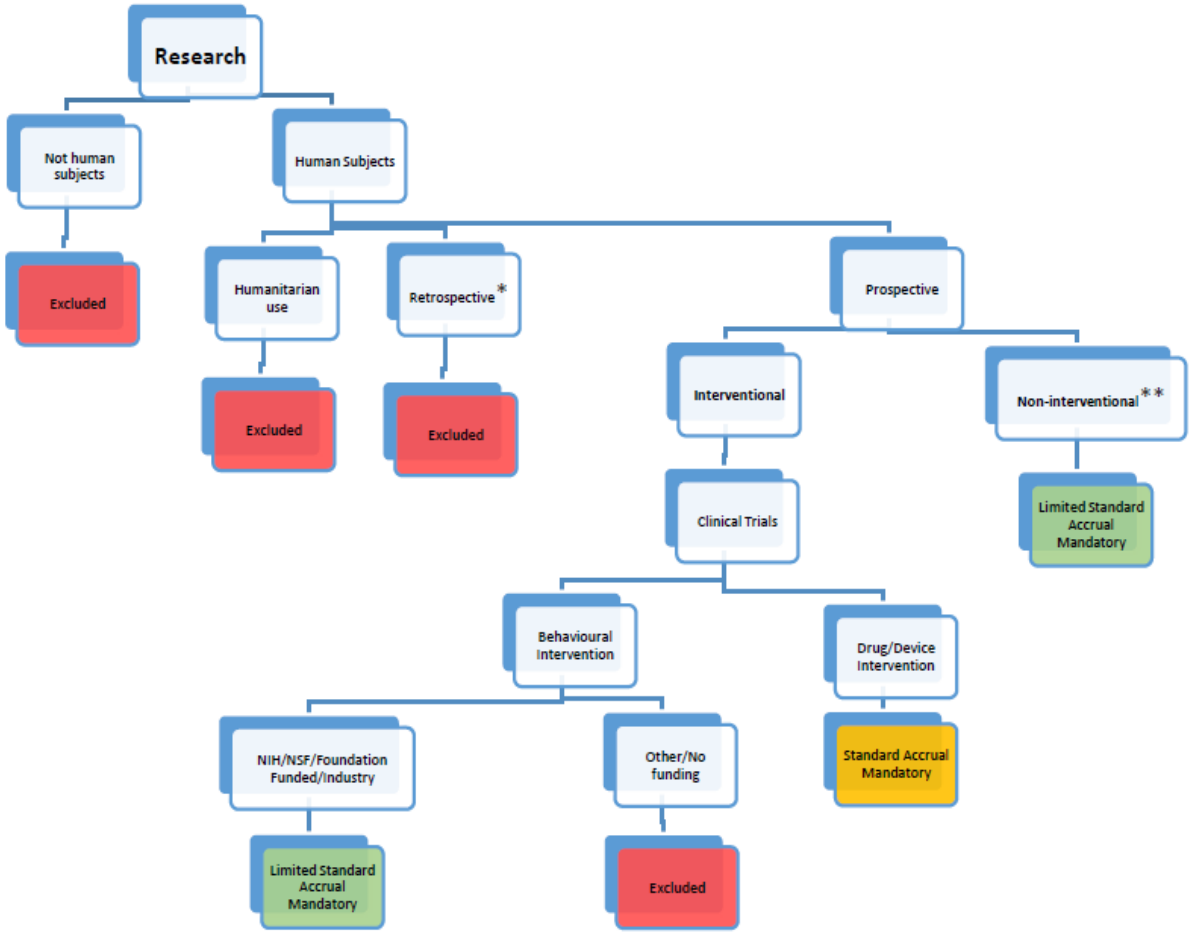
Compliance & Billing

OnCore

- Clinical Trial Management System (CTMS)
- Tracks subject enrollment and financials
- Sponsors are invoiced based on data entered in OnCore.
- Required for:
  - Non-interventional studies
  - Drug/Device intervention studies
  - Funded behavioral intervention studies



Studies and Level of Data Collection Required in OnCore CTMS System for Clinical Research



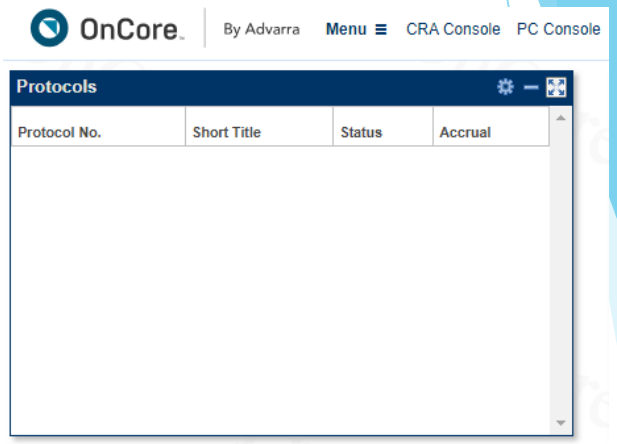
- **Standard Accrual:** Per patient entry and all study activities details required.
- **Limited Standard Accrual:** Per patient entry of the following data:
  - a. Date enrolled
  - b. Gender
  - c. Age Group
  - d. Ethnicity
  - e. Race
  - f. Zipcode
  - g. Insurance Type (optional but strongly encouraged)

- * No consent signed, includes chart reviews, previously collected biological samples (unless industry-sponsored/funded)
- ** Includes registries, surveys, observational studies and industry-sponsored chart review.
- **In limited circumstances aggregate enrollment data is permissible – Contact OnCore Coordinator for more information/direction.
- **Excluded:** Study will not be entered into OnCore – No data required

- Email: ctms@buffalo.edu

OnCore Training Materials

- **Policy Statement**
  - Required use of University Clinical Trial Management System (OnCore CTMS)(570 KB)
- More information at:
  - https://www.buffalo.edu/research/research-services/oncore-implementation.html
  - https://www.buffalo.edu/content/www/research/research-services/training/training-workshop/oncore-intro-pw.html
  - https://www.buffalo.edu/content/www/research/research-services/training/training-workshop/oncore-submit-admin-pw.html
- Log in at:
  - https://ctms.buffalo.edu/forte-platform-web/login
- Email: ctms@buffalo.edu



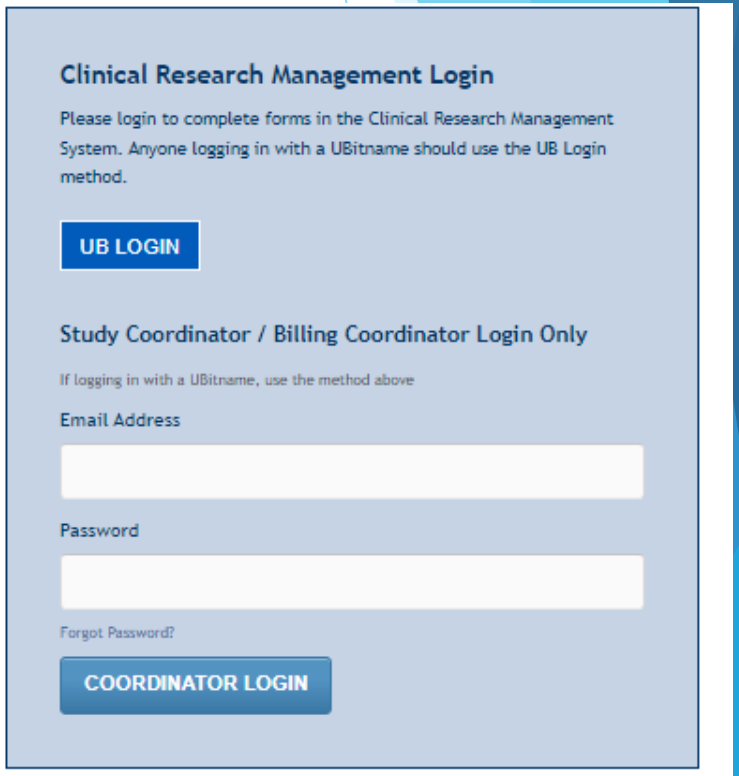
- **Training Materials**
  - OnCore Training.pdf(6.7 MB)
  - Important Tasks in OnCore for Coordinators.pdf(139 KB)
  - OnCore training manual(20.7 MB)
- You will need to log in with your UBIT to view training materials.

FUNDED

Clinical Research Management System (CRMS)

(Funded studies)

- This is a billing compliance system, which is used to track standard of care (SOC) v. research expenditures as determined by the **coverage analysis**.
- This is necessary to ensure proper billing for research procedures done at one of our affiliate partners.
- Most often used by the study coordinator
- Login at:
  - https://www.buffalo.edu/research/about-us/units/cro.html



Award Management

FUNDED

Award Management

(Funded Studies)

- Grant payments
  - Funding received upfront and/or on grant defined schedule

RESEARCH & RELATED BUDGET - Cumulative Budget

	Totals ($)
Section A, Senior/Key Person	
Section B, Other Personnel	
Total Number Other Personnel	
Total Salary, Wages and Fringe Benefits (A+B)	
Section C, Equipment	
Section D, Travel	
1. Domestic	
2. Foreign	
Section E, Participant/Trainee Support Costs	
1. Tuition/Fees/Health Insurance	
2. Stipends	
3. Travel	
4. Subsistence	
5. Other	
6. Number of Participants/Trainees	
Section F, Other Direct Costs	
1. Materials and Supplies	
2. Publication Costs	
3. Consultant Services	
4. ADP/Computer Services	
5. Subawards/Consortium/Contractual Costs	
6. Equipment or Facility Rental/User Fees	
7. Alterations and Renovations	
8. Other 1	
9. Other 2	
10. Other 3	
Section G, Direct Costs (A thru F)	
Section H, Indirect Costs	
Section I, Total Direct and Indirect Costs (G + H)	
Section J, Fee	
Section K, Total Costs and Fee (I + J)	

- Industry Sponsored Clinical Trial Payments
  - Fee for service
  - Often broken down to a per patient per visit cost

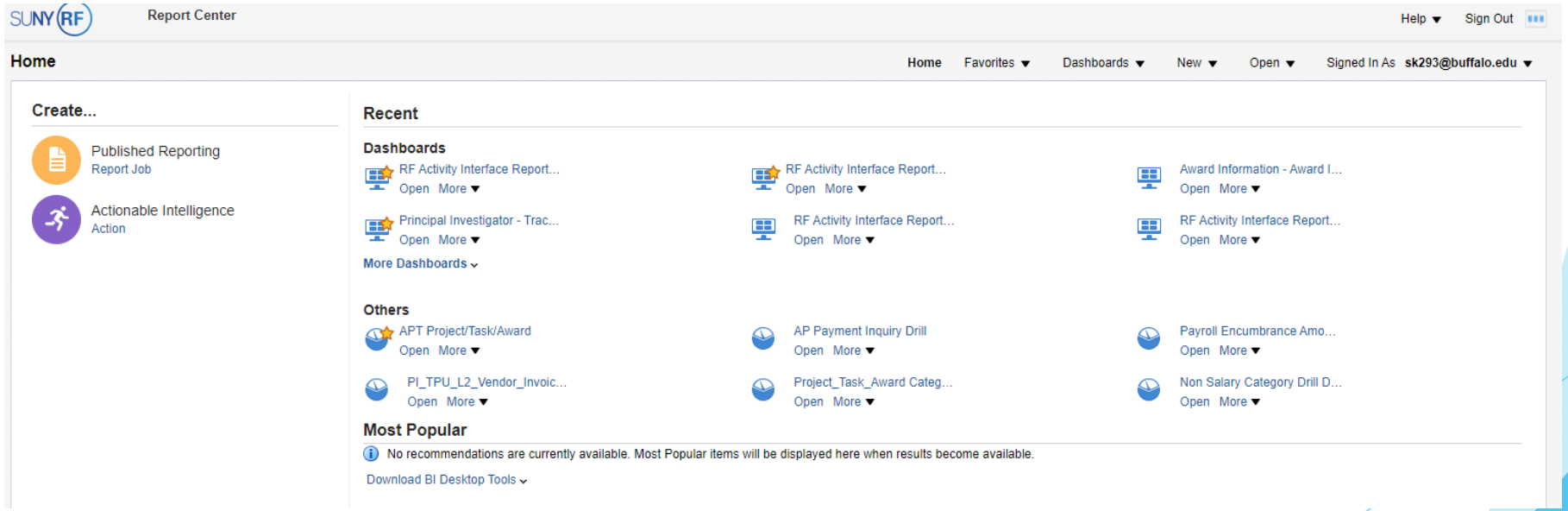
Assessments	Cost	Visit 1	Visit 2	Visit 3	TOTAL
Informed Consent	$XX.xx	X			$XX.xx
Inclusion/Exclusion Criteria	$XX.xx	X			$XX.xx
Vital Signs	$XX.xx	X	X	X	$XX.xx
ECG	$XX.xx	X	X	X	$XX.xx
Physical Exam	$XX.xx	X	X	X	$XX.xx
Per Patient Activity Totals:		$XX.xx	$XX.xx	$XX.xx	$XX.xx

FUNDED

Award Management

(Funded Studies)

- SPS takes the first step by establishing an account in the Research Foundation business system.
- This account will be assigned a **Project-Task-Award (PTA) number**, which you need in managing your award.
- Award details can be viewed in RF Report Center.



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RF Report Center

(Funded studies)

- Helps investigators stay current on the fiscal status of their sponsored awards.
- Answer Questions like:
  - How much money is left on award xxx?
  - How much money has been spent on award xxx?
  - How can I determine when a vendor payment was made?
  - Where can I see payroll charges to balance accounts for a portfolio?

- More information at:
  - https://www.buffalo.edu/research/research-services/rf-report-center.html
  - https://www.rfsuny.org/Information-For/Online-Tools-/RF-Report-Center/

- Log in at:
  - https://www.rfsuny.org/Information-For/Online-Tools-/RF-Report-Center/Report-Center-Login/

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Award Management (SPS)

(Funded Studies)

- Setting up Your Award
- https://www.buffalo.edu/research/research-services/administering-your-award-set-up-to-closeout/setting-up-your-award.html

- Managing Your Award
- https://www.buffalo.edu/research/research-services/administering-your-award-set-up-to-closeout/managing-your-award.html

- Closing Your Award
- https://www.buffalo.edu/research/research-services/administering-your-award-set-up-to-closeout/closing-your-award.html

Things to Keep in Mind

- Expenditures
  - Income Fund Reimbursable
  - Payroll
  - Tuition
  - Subcontracts
  - Independent Contractors/Consultants
  - Supplies, Equipment and Services
  - Subject Payments and Advances
  - Cost Share
- Grant Management
  - Cost Transfers
  - Signing Authority
  - Electronic Payroll Review
  - No Cost Extensions
  - Reporting Requirements
  - Report Center Access
  - Discovery, Intellectual Property and Invention
  - Confidential Information or Material Transfer
  - Residual Balances

FUNDED

Concur (Travel & Expense System)

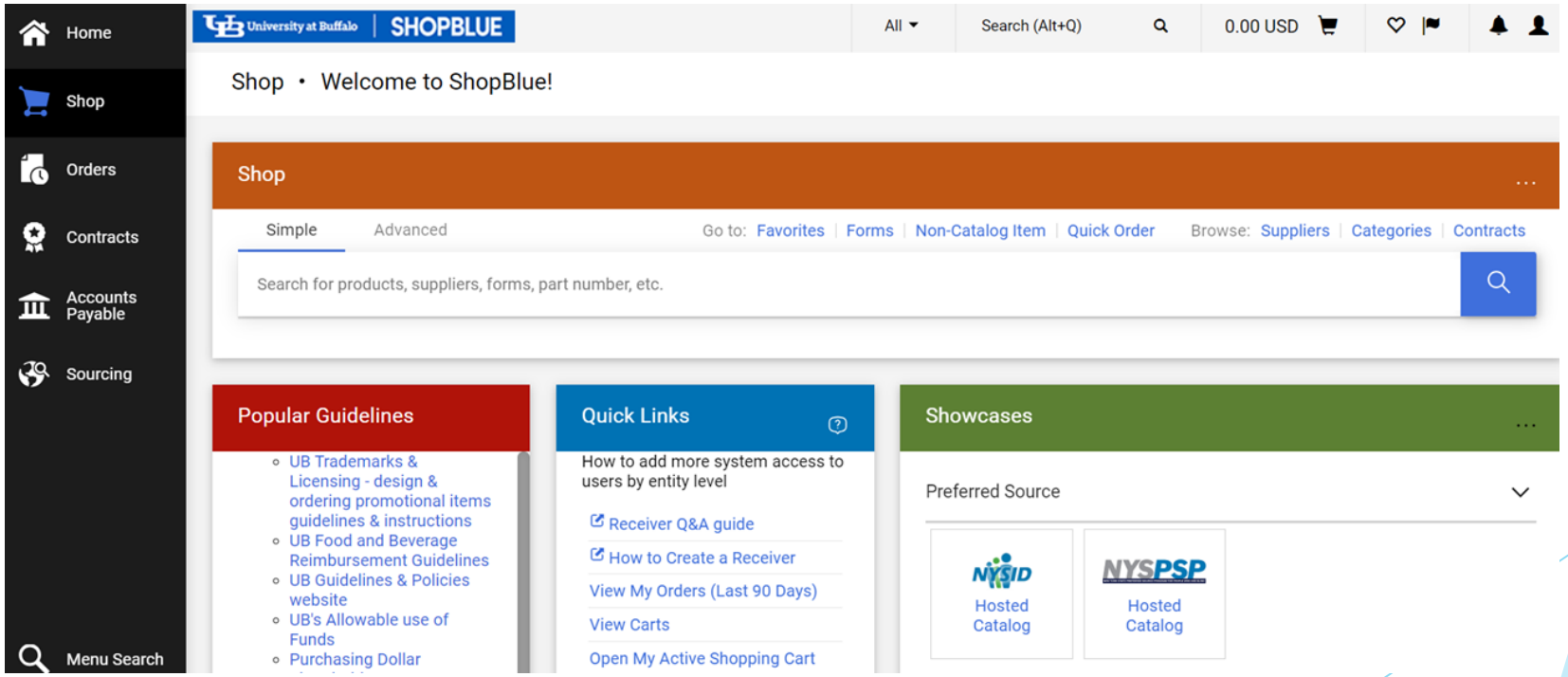
- Authorized UB faculty and staff can:
  - book business travel
  - submit business travel expenses for reimbursement
  - submit non-travel expenses for reimbursement.

- More information & log in at:
  - https://www.buffalo.edu/administrative-services/business-travel/travel-expense-reimbursement-system.html

FUNDED

SHOPBLUE

- ShopBlue is a fully integrated eProcurement system allowing authorized UB faculty and staff to place orders for necessary goods and services.



FUNDED

SHOPBLUE

Common Expenditures

- Scientific equipment
- Equipment calibration
- Scientific supplies
- Clinical tests for research purposes
- Advertising
- Salaries/Fringe benefits
  - Reimburse Employer
    - UBMD Practice Plan
    - Affiliate (e.g., Kaleida, ECMC, GPPC)
- 3rd Party space fee
  - UBMD Practice Plan
  - Affiliate (e.g., Kaleida, ECMC)
- PI Oversight (see 05Dec2023 policy)

FUNDED

SHOPBLUE

- More information at:
  - https://www.buffalo.edu/administrative-services/managing-procurement/shopblue-system.html

Using ShopBlue

Find step-by-step instructions on how to complete tasks in ShopBlue by user role.

- For Approvers
- For Requesters
- Profile Management
- ShopBlue Forms
- Business Purpose

- GUIDES
  - Download the ShopBlue Perfect Shopping Experience Guide(454 KB)
  - Download the ShopBlue Receiver Questions Guide(454 KB)
- NAVIGATION MAP AND ICONS
  - Download the ShopBlue Navigation Map and Icons(368 KB)
  - Download the ShopBlue Approver Dashboard Navigation Map and Icons(336 KB)
- EMAIL: UBS-SHOPBLUE-SUPPORT@BUFFALO.EDU

FUNDED

Interdepartmental Invoice (IDI) Form

- **NOT a UB web platform**
- A way to pay for goods or services by another UB department
- Excel templates for
  - Multiple IDIs
  - Individual IDIs

- **Instructions**
  1. Enter requested information into the form.
  2. Print the form.
  3. Get required signatures.
  4. Scan a copy of the signed form for your records.
  5. Send a copy of the signed form to the appropriate email addresses.

- More information at:
  - https://www.buffalo.edu/administrative-services/forms-catalog/finances/idi-form.html

FUNDED

US Bank

(Prepaid Debit Cards for Research Participants)

(Funded Studies)

- Pay participants using a prepaid visa card.
  - Reloadable Card
  - One-Time Digital Reward
  - One-Time Plastic Reward Card
- Before Completing the Application Have the Following Ready
  1. IRB Approval
  2. Account Number
  3. US Bank Advance Request Form
  4. Study Payment Schedule
- More information at:
  - https://www.buffalo.edu/administrative-services/managing-procurement/card-programs/rf-study-card-program.html
- On-line application at:
  - https://www.buffalo.edu/administrative-services/forms-catalog/procurement/prepaid-debit-human-subject-app-rf.html

Human Subject Compensation Matrix - Research Foundation Sponsored Awards - Sponsored Projects Services (SPS)

	Direct Payment	Cash Advance	Cash Advance for Gift Card Purchase	US Bank Cards	Gift Card Purchase through eReq System	Checking Account
Benefits	* Participation compensation is mailed directly to the participant. * No reconciliation is needed. * Any IRB approved denomination can be paid to subjects. * Reduced administrative burden and risk of loss/theft compared to other payment methods because cash, card or check are not stored on hand.	* Immediate compensation to the study participant. * Any IRB approved denomination can be paid to subjects.	* Immediate compensation to the study participant. * Flexibility to obtain Gift Cards from area merchants of your choice. * Any IRB approved denomination can be paid to subjects.	* Gain financial transparency and control. * Increased patient engagement. * Three card type options (Reloadable Focus Blue Card, One-Time Digital Reward Card, One-Time Plastic Reward Card) * One-Time Plastic Reward and One-Time Digital Reward card Card do not require identifying information from subjects. * Low card cost, varies from $0 - $1.50. * US Bank system offers a report that can be used to create the reconciliation with minimal updating to the report needed. * Reloadable card can be used for multiple payments. * US Bank card eliminates cash handling for PIs, staff, and subjects. * US Bank system offers a report that can be run to determine which subjects were paid $600 or more within a calendar year for tax purposes.	* PIs do not need to use their own funds to purchase gift cards. Gift cards can be ordered through OmniCard. This is a Procurement process and PIs must work with Procurement. * Multiple vendors participate in the OmniCard system. A wide variety of gift card options are available. * There are no restrictions on the value of the gift card. Physical gift cards or e-gift cards can be ordered. * A slight discount is offered when ordering gift cards in bulk. * E-gift cards are delivered to subject's email address. OmniCard will provide a report to show that each subject recieved his/her gift card(s). Physical gift cards can be mailed to project staff for disbursement.	* Checks can be distributed to human subjects. * Bank Statements are available. * Cash does not need to be stored on hand due to the fact that the funds are held in the checking account. * Key Bank offers Fraud Protection upon request. * Any IRB approved denomination can be paid to subjects.
Guidelines & Restrictions	* Project staff completes a Subject Payment Request Form and submits the form to SPS. * Once the form is processed by SPS staff, the subject will receive a check from RF Central in typically 5 - 7 business days to the address listed on the form. * Tax reporting required for any individual receiving $600 or more in a calendar year (W-9 must be kept at the department level).	* Can be used for compensation for study participation ONLY. * Department initiates the request for a cash advance by completing and submitting a Request for Cash Advance form to SPS. * Payee must have a relationship with the award, typically the PI, Co-I, or project manager. If the check is issued to the PI then a higher level signature is required on the request. * Payee will receive a check that they will need to cash to obtain the funds to disburse as compensation to study participants. Cash cannot be deposited into a personal bank account. * PI assumes financial responsibility for the funds upon cashing the check. * Cash must be kept in a locked receptacle or safe. * Monthly Cash Reconciliation should be provided to the SPS Award Analyst via email. This must be provided prior to requesting additional funds. * Project staff must maintain signed and dated receipts from the participant that received compensation for their participation in the study. * Unused funds must be returned to the SPS analyst by submitting a personal check issued to The Research Foundation for SUNY. * Tax reporting required for any individual receiving $600 or more in a calendar year (W-9 must be kept at the department level).	* Can be used for compensation for study participation ONLY. * Department initiates the request for a cash advance by completing and submitting a Request for Cash Advance form to SPS. * PI will receive a check mailed to the address that is listed on the cash advance request. The individual will then cash the check to facilitate the purchase of gift cards to disburse as compensation to study participants. Cash cannot be deposited into a personal bank account. * The gift cards must be kept in a locked receptacle or safe. * Monthly Gift Card Reconciliation should be provided to the SPS analyst via email. This must be provided prior to requesting additional funds. * The project staff must maintain signed and dated receipts from the participant that received the compensation for their participation in the study. * Unused gift cards cannot be returned. If there are gift cards that were not distributed to study participants then the PI will need to issue a check to The Research Foundation for SUNY and mail this to SPS to reimburse the cost of the unused gift cards to the project. * Gift cards issued in the amount of $100 or more require a W-9, per UB's Allowable Use of Funds policy. * Tax reporting required for any individual receiving $600 or more in a calendar year (W-9 must be kept at the department level).	* Can be used for compensation for study participation ONLY. * An online application should be submitted via UB's administrative gateway and is reviewed by UB's Study Card group before it is forwarded to SPS. * Along with the online application, a US Bank Advance Form is used to advance the funds to US Bank. * Once the form is completed, SPS issues an advance to US Bank. * UB's Study Card group provides a training for the PI/department and coordinates disbursement of cards to the PI/department. * Once funds are in the US Bank account, they can be used for subject payments. Note that some accounts are shared within a department or school though. *PIs need to provide the SPS Award Analyst with a monthly reconcilation to monitor the funds in the account that are related to their specific project(s). * Questions in regards to requesting to use US Bank cards for subject payments should be directed to rfstudycardprogram@buffalo.edu. * Project staff must maintain records showing that the subjects received payment. * Tax reporting required for any individual receiving $600 or more in a calendar year.	* Contact Procurement for the OmniCard representative contact information in order to set up a user account with OmniCard. You can also add to an already existing UB account. * Be prepared to supply the OmniCard representative with the amount of gift cards needed along with the associated dollar amount, per gift card. * Separate eReqs must be created for physical gift cards verse e-gift cards. * Gift cards issued in the amount of $100 or more require a W-9, per UB's Allowable Use of Funds policy. * OmniCard will provide an invoice for the gift cards. With this invoice, the department will create an eReq for an advance payment with the invoice attached. Please note that eReqs go through multiple approvals through the system. When ordering gift cards, time for these approvals must be taken into account. * After the eReq routes through all the approval levels, accounts payable will make the payment, per the invoice. Once OmniCard receives the payment the gift cards will be sent via email or through the mail for physical gift cards. * SPS can only provide guidance on allowability and sponsored award information. For questions in regards to OmniCard, departments will need to contact Procurement. * Tax reporting required for any individual receiving $600 or more in a calendar year (W-9 must be kept at the department level).	* Can be used for compensation for study participation ONLY. * Bank Account Request form must be used to establish an account. This request is submitted to the SPS analyst by the department. * To properly segregate duties, cash/check funding, disbursement, and account reconciliation processes should be assigned to different personnel. * Bank account must be balanced regularly at the department level. Monthly reconiliations & bank statements must be emailed to the SPS analyst by the 15th of the following month. * Reconciliation can be submitted using the reconciliation template available on the SPS website, a similar departmental template, or using Quicken if the program is available (please note, there may be a cost associated with the Quicken program). * Requests for additional funds must be received by SPS at least seven business days prior to needing the funds in order to avoid an overdraft. The department can submit these requests via email to their designated SPS analyst. The last four digits of the checking account number as well as the PTA should be included in the request. The PI should either be making the request or reply all with her/his approval. * When reconciling, departments must investigate & resolve checks that have been oustanding for more than 120 days. * Departments must submit a request to close the bank account in a timely manner to their designated SPS award analyst and follow the Due Diligence process as listed in the RF policy on Establishing and Maintaining Campus Bank Accounts and Petty Cash Funds. A zero dollar statement should accompany the closeout request. * RF Central conducts a checking account audit on a yearly basis. * Tax reporting required for any individual receiving $600 or more in a calendar year (W-9 must be kept at the department level).
Forms\ Links	W-9 Form Subject Payment Request Form	Cash Advance Request Form Cash Advance Reconciliation Template	Cash Advance Request Form Allowable Use of Funds Policy	US Bank Card Application for Subject Payments US Bank Card Advance Request Form Prepaid Debit Cards for Human Subjects Website	OmniCard Website Allowable Use of Funds Policy	Campus Bank Account Request Change Form Establishing and Maintaining Campus Bank Accounts and Petty Cash Funds Checking Account Reconciliation Template

* Per Procurement, P-card cannot be used for human subject payments. Please contact the P-card office at UBS-RFPcard@buffalo.edu with questions in regards to this.

Matrix link: https://www.buffalo.edu/content/dam/www/research/pdf/sps/Human%20Subject%20Compensation%20Matrix.xlsx

Recruitment and Data Collection

Recruitment Resources

https://www.buffalo.edu/ctsi/cores/community/brr.html

https://www.buffalo.edu/ctsi/cores/clinical-research-office/educational-modules/i2b2-and-trinetx--an-introduction.html

https://www.researchmatch.org/

https://trialinnovationnetwork.org/

https://redcap.buffalo.edu/redcap/

- Buffalo Research Registry is a list of local people, ages 18 and up, who are interested in participating in research.
- TriNetX is a de-identified clinical patient database that includes inpatient, outpatient, and claims data.
- ResearchMatch is a free and secure tool that helps match willing participants with eligible researchers and their studies at institutions across the country.
- Trial Innovation Network is a collaborative initiative within the CTSA Program and is composed of three key partners – the CTSA Program Hubs, the Trial Innovation Centers (TICs), and the Recruitment Innovation Center (RIC).
- REDCap can be used as a tool to screen potential eligible volunteers for study participation.
- CTSI Recruitment Resources Toolkit is a collection of recruitment-related resources for UB research teams. For more information, contact: ctsiresearch@buffalo.edu

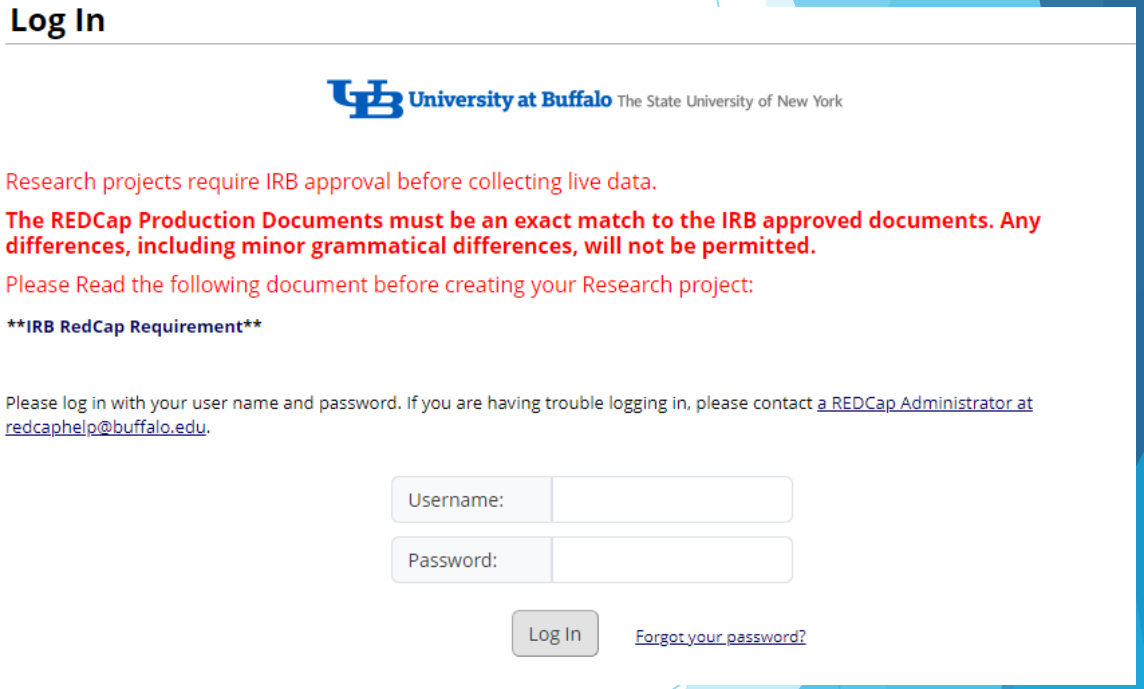
REDCap®

- REDCap is a secure web platform for building and managing online databases and surveys.
- For investigator-initiated studies only

- More information at:
  - https://www.buffalo.edu/research/research-services/project-support/redcap.html

- Login at:
  - https://redcap.buffalo.edu/redcap/

- Email: redcaphelp@buffalo.edu



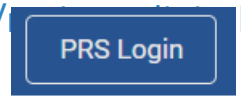
- ClinicalTrials.gov

ClinicalTrials.gov

- Registering your study with ClinicalTrials.gov is a necessary step for investigators to be compliant with regulations.
- Sponsors typically register multi-site trials.
- Investigators typically register investigator-initiated studies.

- More information:
  - https://www.buffalo.edu/ctsi/cores/clinical-research-office/educational-modules/clinicaltrials-gov--how-to-register-your-trial.html
  - https://www.clinicalTrials.gov/about-site/about-ctg

  - Log in at:
    - https://[redacted]lTrials.gov/



- To see if your study needs to be listed go to:
  - https://prsinfo.clinicalTrials.gov/ACT_Checklist.pdf

Question	Yes	No
1. Is the study interventional (a clinical trial)? *Study Type* data element is "Interventional"	☐	☐
2. Do ANY of the following apply (is the answer "Yes" to at least one of the following sub-questions: 2a, 2b, OR 2c)? a. Is at least one study facility located in the United States or a U.S. territory? *Facility Location – Country* data element is "United States," "American Samoa," "Guam," "Northern Mariana Islands," "Puerto Rico," "U.S. Virgin Islands," or other U.S. territory. b. Is the study conducted under a U.S. FDA Investigational New Drug application (IND) or Investigational Device Exemption (IDE)? *U.S. Food and Drug Administration IND or IDE Number* data element is "Yes." c. Does the study involve a drug, biological, or device product that is manufactured in and exported from the U.S. (or a U.S. territory) for study in another country? *Product Manufactured in and Exported from the U.S.* data element is "Yes."	☐	☐
3. Does the study evaluate at least one drug, biological, or device product regulated by the United States Food and Drug Administration (U.S. FDA)? *Studies a U.S. FDA-regulated Device Product* data element is "Yes" and/or *Studies a U.S. FDA-regulated Drug Product* data element is "Yes."	☐	☐
4. Is the study other than a Phase 1 trial of a drug and/or biological product or is the study other than a device feasibility study? For drug product trials, *Study Phase* data element is NOT "Phase 1" and for device product trials, *Primary Purpose* is NOT "Device Feasibility."	☐	☐

If "Yes" is answered to all 4 questions, and the study was initiated on or after January 18, 2017, the trial would meet the definition of an ACT that is required to be registered under 42 CFR 11.22.

- Contact:
  - Lynn Jagodzinski, UB CTSI Clinical Research Regulatory Administrator, at lynnjago@buffalo.edu
  - Urmo Jaanimägi, UB CTSI Quality Assurance Specialist, at uj@buffalo.edu.

Additional Resources

- Research Flow at UB:
  - https://www.buffalo.edu/ctsi/cores/clinical-research-office/research-flow-at-ub.html
- Educational Modules:
  - https://www.buffalo.edu/ctsi/cores/clinical-research-office/educational-modules.html
- CTSI YouTube:
  - https://www.youtube.com/@ubuffaloctsi/videos

SUNY Buffalo CRO Industry Sponsor Quick Reference

- ***Office Address***
  SUNY Buffalo Clinical Research Office
  875 Ellicott St., Suite 6040, Buffalo, NY 14203

- ***Medical Director***
  Sanjay Sethi MD, FACP
  Professor of Medicine
  Assistant Vice President for Health Sciences
  Director, Clinical Research Office
  Deputy Director, CTSI
  Division Chief, Pulmonary/Critical Care/Sleep Medicine
  (716) 888-4864; ssethi@buffalo.edu

- ***Associate Operational Directors***
  Pamela Anderson RN, BSN
  (716) 888-4841; pka2@buffalo.edu

  Kimberly Brunton RN, MSN
  (716) 888-4840; kbrunton@buffalo.edu

- ***Budgets***
  Rosanne Johnson
  Clinical Research Budget & Coverage Analyst
  (716) 888-4844 ; rosannej@buffalo.edu

- ***Payments and Invoicing***
  Mary Beth Gareis
  Clinical Research Finance Manager
  (716) 878-3319; mgareis@buffalo.edu

- ***OnCore***
  Mariya Cherneva, MA
  CTMS Specialist: OnCore Coordinator
  (716) 888-4768; mchernwa@buffalo.edu

- ***Questions***
  Sevie Kandefer, MS
  Clinical Research Associate
  (716) 829-6019; sk293@buffalo.edu

- **What is SUNY?**
  - The State University of New York (SUNY) is the largest public comprehensive university system in the United States. Our impact in New York State and across the globe begins with our 64 institutions, including research universities, academic medical centers, liberal arts colleges, community colleges, colleges of technology and an online learning network. The SUNY system has 5 medical campuses that provide innovative care to diverse patient populations in Brooklyn, Buffalo, Manhattan, Syracuse and Stony Brook, NY.

- **What is the University at Buffalo?**
  - SUNY at Buffalo (UB) is a premier, research-intensive public university and a member of the Association of American Universities. It is the largest, most comprehensive institution in the 64-campus SUNY system.

- **What is the UB Clinical Research Office?**
  - The UB Clinical Research Office is a centralized office charged with administrative oversight for all clinical research activities of the UB faculty members.

- **What is the Research Foundation?**
  - The Research Foundation for The State University of New York (RF) is the largest comprehensive university-connected research foundation in the country. It exists to serve SUNY by providing essential administrative services that enable SUNY faculty to focus their efforts on education and research. The RF is a private non-profit tax-exempt education corporation. UB recognizes the RF as the only approved entity for the fiscal administration of industry-sponsored clinical research. Funds received for clinical research directed by UB faculty and staff as part of their university work must be deposited with and administered by the RF.

- **Who does the Investigator work for?**
  - Clinical research conducted by UB is done by UB faculty members within the scope of their employment with UB. UB does not own a teaching hospital and does not provide “care” to patients in the scope of its research activities. Depending on the study, clinical research is either done on-campus or at one of the sites of our unique consortium of affiliated teaching hospitals and health care systems in the Buffalo area.