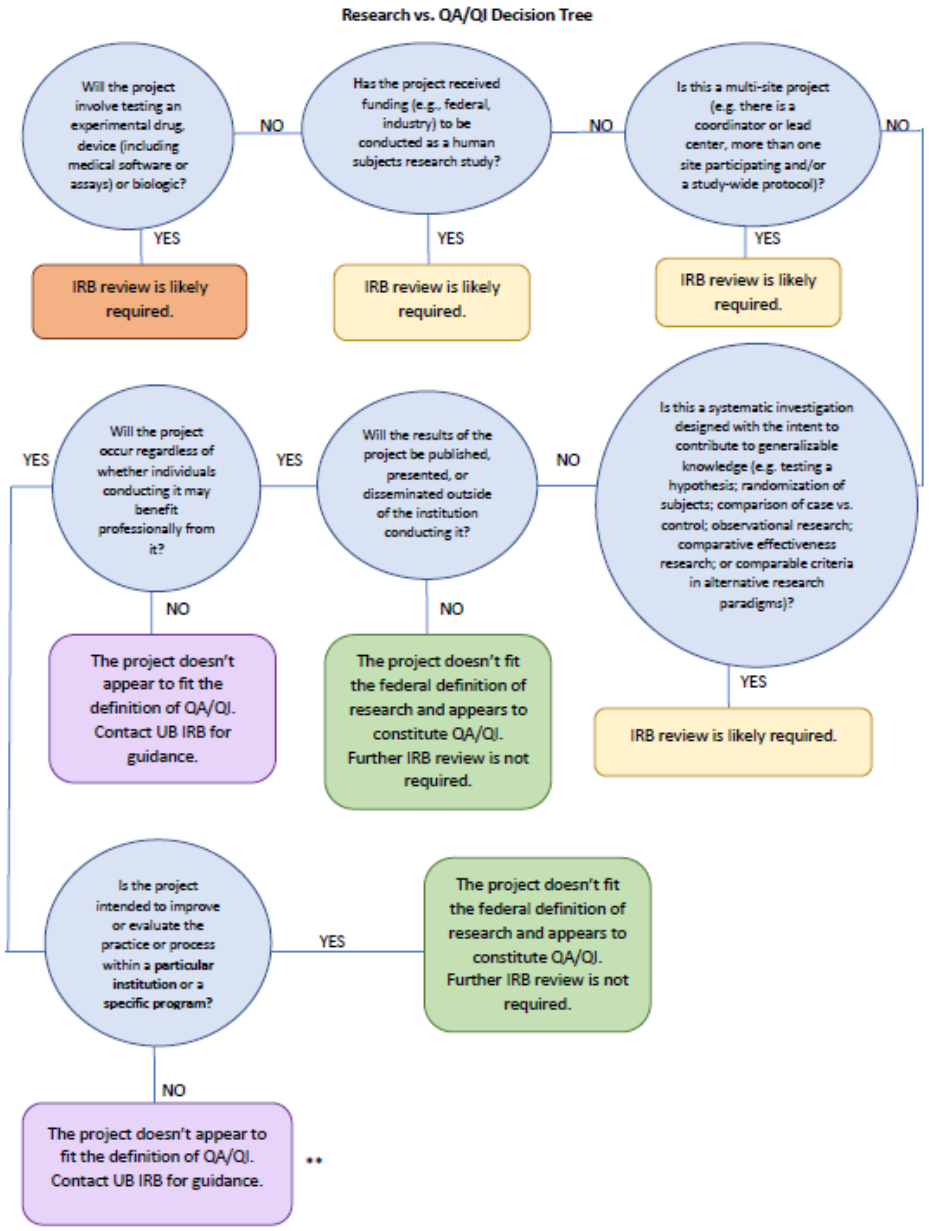
Clinical Research Facilitation

Sanjay Sethi MD

Director, Clinical Research Office

Deputy Director, Clinical and Translational Science Institute



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.buffalo.edu/redcap/surveys/?s=8LYE9T733M4W99YP

NIH Definition of Clinical Research

- Patient-oriented research. Research conducted with human subjects (or on material of human origin such as tissues, specimens and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects. Excluded from this definition are *in vitro* studies that utilize human tissues that cannot be linked to a living individual. Patient-oriented research includes:

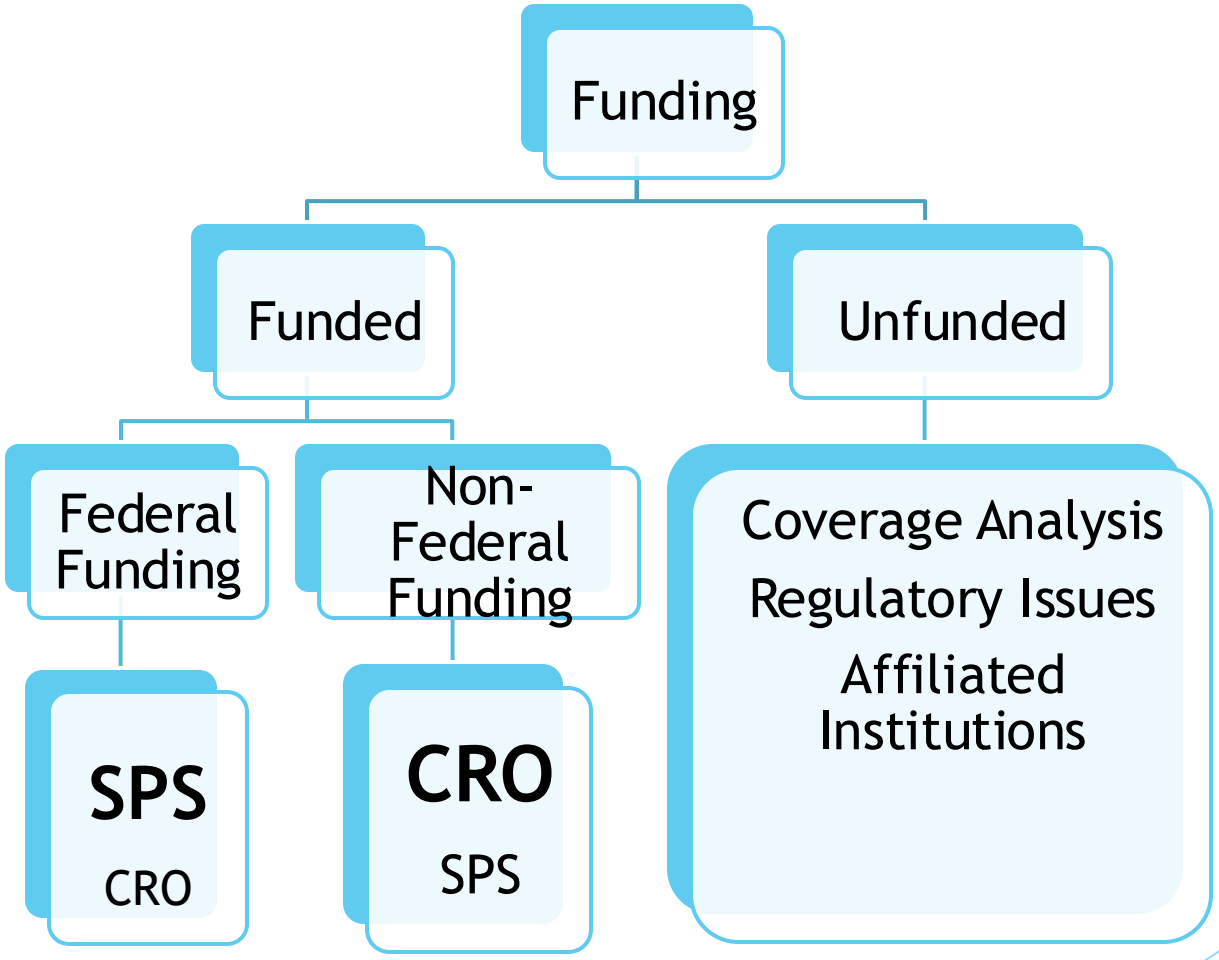
  a. Mechanisms of human disease,
  b. Therapeutic interventions,
  c. Clinical trials, or
  d. Development of new technologies.

- Epidemiologic and behavioral studies
- Outcomes research and health services research

NIH definition of Clinical trials

- A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.

Clinical Research Categories by Sponsor



IRB Concerns

- Human subject protection (Risk benefit ratio has been minimized)
- Consent forms
- Conflict of Interest
- Recruitment Strategies
- Protected Health Information
- Adequate training of Investigator and Staff
- Continuing Review
- All Clinical Research has to be blessed by the IRB
  - Full board
  - Expedited
  - Exempt

CRO Concerns

- Pre- Award
  - Representation and Protection of University interests (Agreements)
  - Is it possible? (Feasibility)
  - Is the funding appropriate? (Budget)
  - Who is paying for what? (Coverage Analysis)
  - Regulatory issues (IND, IDE, Clinicaltrial.gov)
  - Are the affiliated institutions informed and compensated?
  - Study Design
- Award
  - Clinical Trial Management (CTMS, OnCore)
  - Invoicing and Accounting (AR/AP)
  - Study Personnel (Coordinators)
  - Study space (CRC)
- Post-Award
  - Study Closure
  - Residual Funds

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.
- Closely work with the Clinical and Translational Science Institute (CTSI)

CRO Services

Contract negotiation

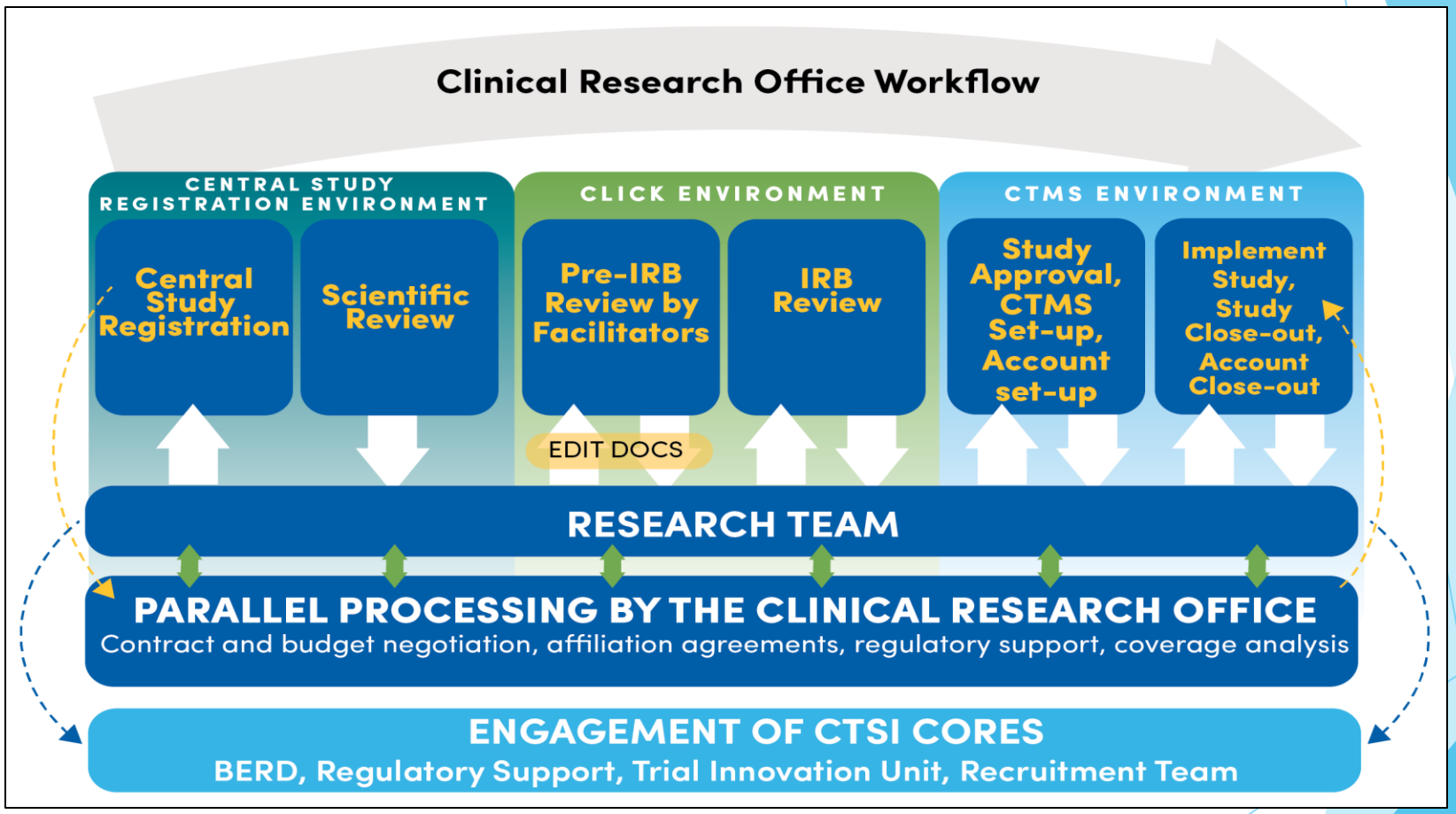
Budget development

Protocol development

Pharmacy services

Regulatory Assistance

Clinical Research Workflow



CRO/CTSI Staff

CRO Associate Directors

Kim Brunton

Pam Anderson

CTSI

- Marchelle Brooks (Clinical Research Facilitator)
- Alexis O'Brien (Clinical Research Facilitator)
- Lynn Jagodzinski (Regulatory Knowledge and Support)
- Ashley Regling (Recruitment Coordinator)
- Urmo Jaanimagi (QA/QC Coordinator)

CRO Support

- Allison Brashear (VPHS, Dean, JSMBS)
- Venu Govindaraju (VPRED)

Device research

Sevie Kendefer

Budget/Coverage Analysis

Roseanne Johnson

TBH

CDA, Contracts

Conor Flynn

Ryan Mcnany

CTMS implementation

Laura Holtz

Mariya Cherneva

Billing/Accounts

Mary Beth Gareis

Kathleen Abromowski

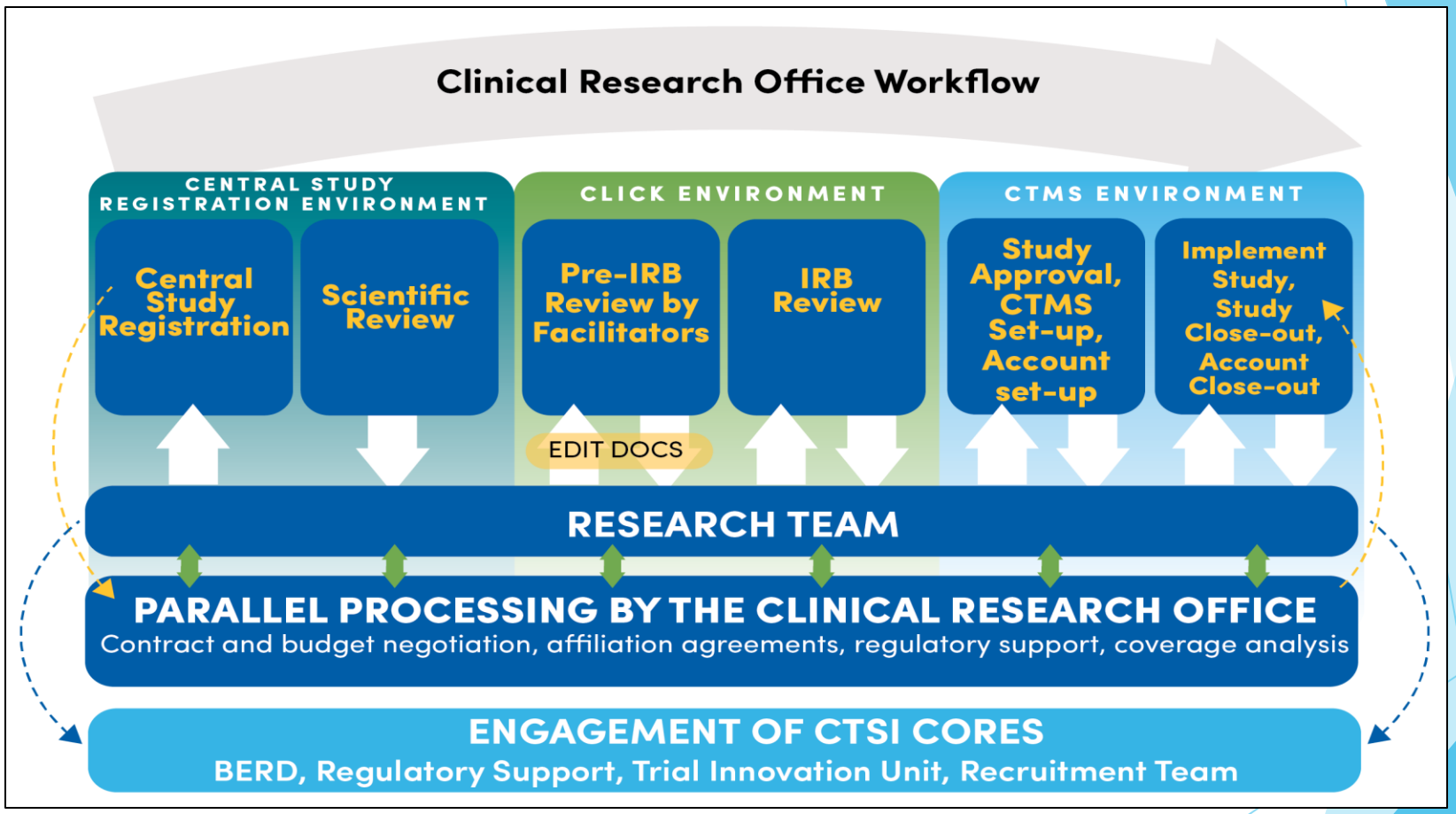
Study Coordination

Catherine Wrona

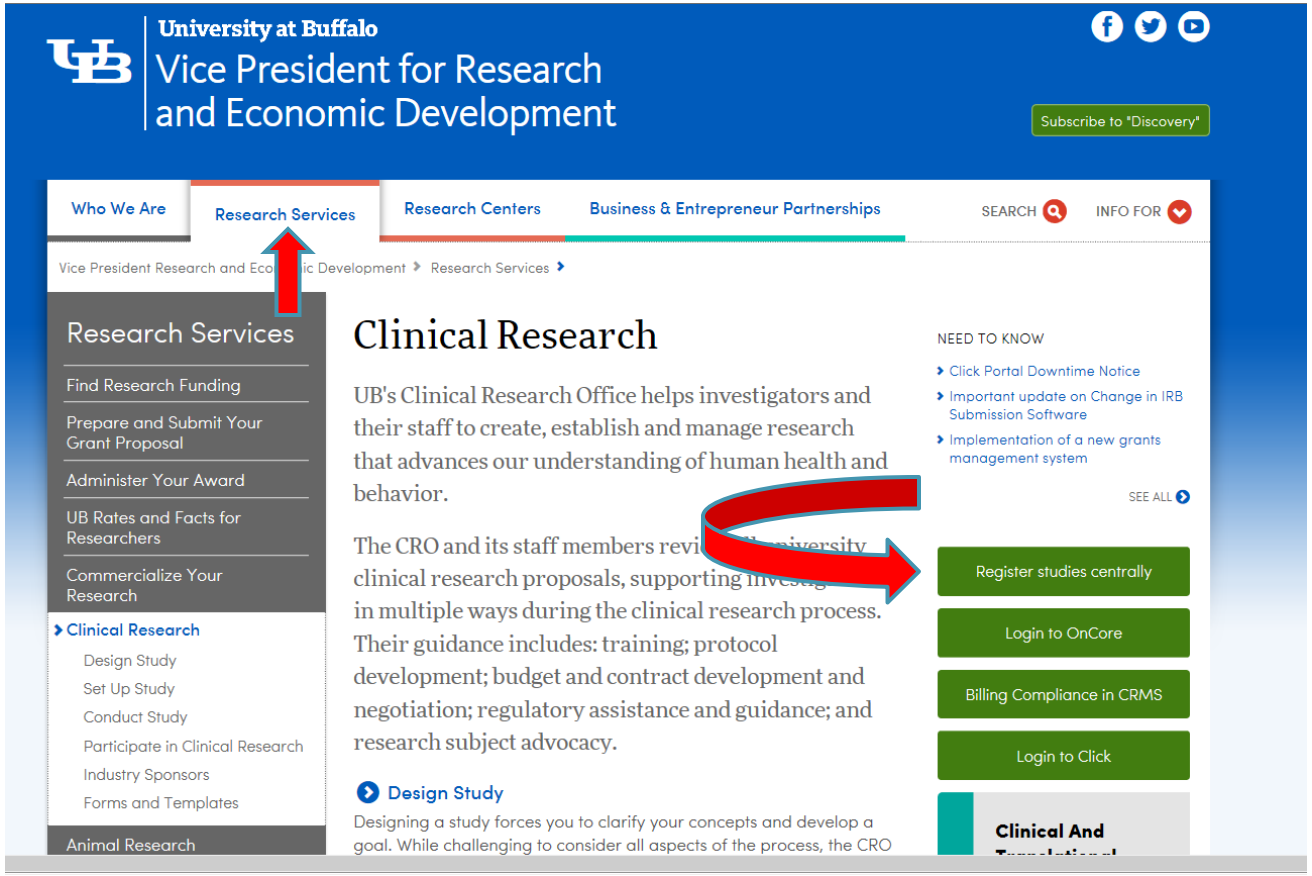
Maja Tonkaska

Chelsea Cowan

Clinical Research Workflow



Clinical Research Office



http://www.buffalo.edu/research/research-services/clinical-and-behavioral-research.html

Resource Assistance

Can We Help?

PLEASE CHECK ANYTHING BELOW YOU NEED ADDITIONAL INFORMATION OR ASSISTANCE WITH. YOU CAN CONTACT OUR RESEARCH FACILITATORS FOR ADDITIONAL ASSISTANCE FOR THINGS YOU DON'T SEE HERE.

TRAINING

- ☐ Blood Borne Pathogen Training
- ☐ CITI (IRB Human Subjects required Training)
- ☐ CLICK
- ☐ Conflict Of Interest Training
- ☐ Good Clinical Practice
- ☐ Lab safety
- ☐ ONCORE
- ☐ Radiation Safety Training
- ☐ Shipment of dangerous goods (blood/lab shipment)
- ☐ Social and Behavorial Human Research Education/Presentations
- ☐ Study Budget Development

BIOSTATS

- ☐ Data management
- ☐ Post-study Analysis
- ☐ Pre-study Consultation
- ☐ Randomization
- ☐ Statistical analysis of results
- ☐ Statistical analysis plan creation
- ☐ Study design/Sample size calculation

PHARMACY SERVICES

- ☐ Compounding
- ☐ Dispensing
- ☐ Drug Destruction
- ☐ Drug supply/ordering
- ☐ Packaging drug doses
- ☐ Patient counseling
- ☐ Pharmacy budgeting
- ☐ Placebo preparation

INVESTIGATOR SERVICES

- ☐ Community Engagement
- ☐ Feasibility
- ☐ NIH Certificate of Confidentiality
- ☐ Protocol Development
- ☐ REDCAP
- ☐ Recruitment
- ☐ UB's Research Imaging capabilities

SAVE PROGRESS Optional. Full save on the bottom of the page.

Summary Email

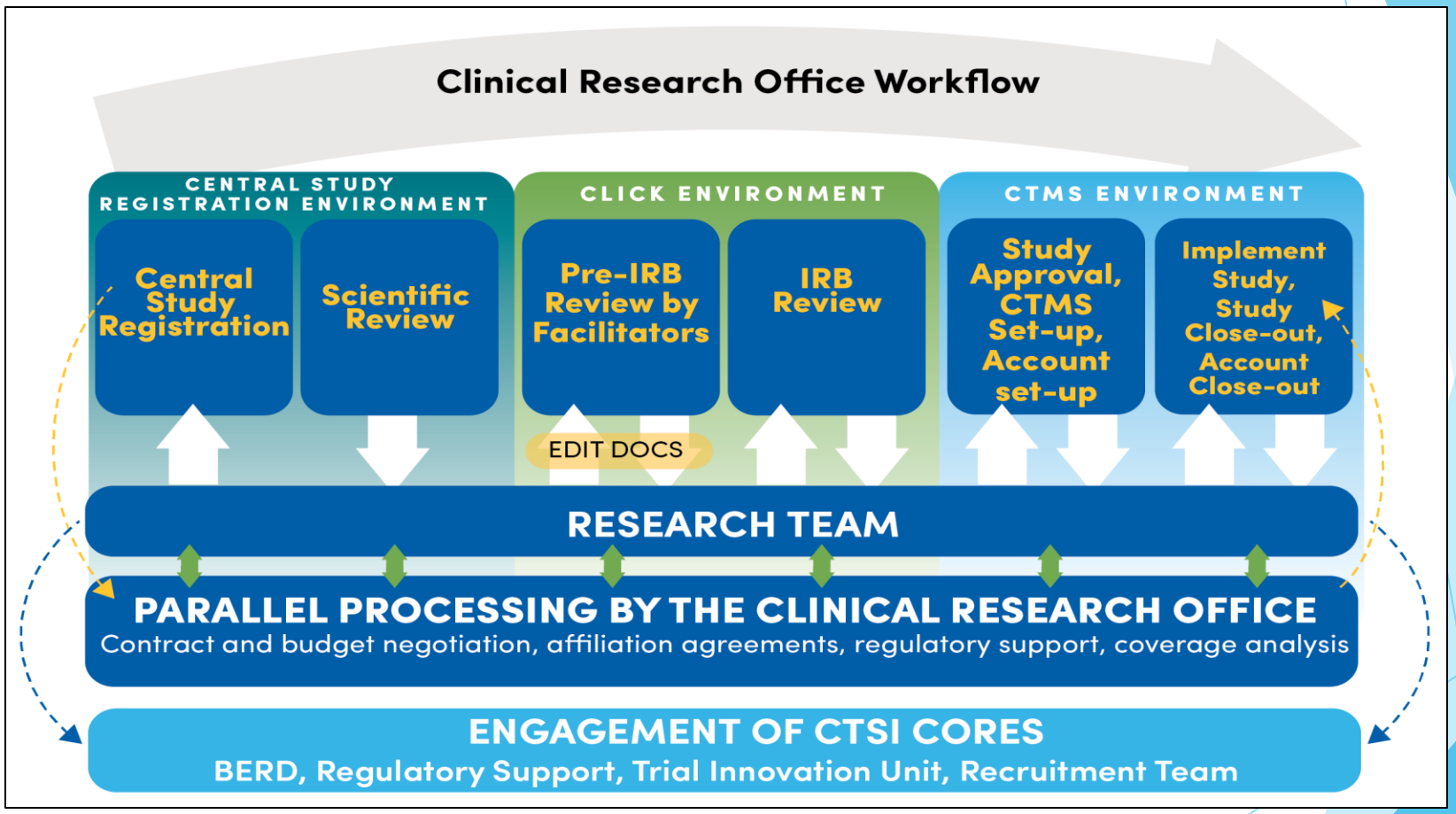
You require assistance with Submission to ClinicalTrials.gov (NCT)
All clinical trials occurring at the University at Buffalo should be registered in the system to make the public aware of ongoing research and available results. Additionally, many professional journals require NCT registration and results reporting in order to accept a manuscript related to the study for publication. **Failure to register your study may result in the inability to publish the results of the trial** in an **ICMJE-associated journal**. (ICMJE - International Committee of Medical Journal Editors). Those who are uncertain whether their trial meets the expanded ICMJE definition should err on the side of registration if they wish to seek publication in an ICMJE journal. You can request submission assistance by contacting our regulatory knowledge and services coordinator, **Lynn Jagdozinski**. Additional information may be found by contacting one of the Clinical Research Navigators through the **Buffalo CTSA Request Portal**. Create an account or sign in to the menu and choose 'Clinical Research Navigators' to access a full list of available services.

You are using an Investigational New Drug
Please be aware that there may be charges for the storage, dispensing and accountability of study medications when developing your study budget. Contact the Clinical Research Office (**ubcro@buffalo.edu**).
The UB School of Pharmacy provides many services that may be useful to Investigators requiring advanced pharmacy services. A complete list of the support they can provide is available **here**.

You require assistance filing for an IND
The Clinical Research Office has personnel to assist you to assess your need for an IND or to file for your IND. Beginning mid 2018, the FDA will require applications to be submitted electronically through an encrypted FDA software system. The CRO has this software and will assist with your submission. The Regulatory Specialist in the CRO is **Lynn Jagodzinski**. You can request information about assistance for an IND by contacting one of the Clinical Research Navigators through the **Buffalo CTSA Request Portal**. Create an account or sign in to the menu and choose "Clinical Research Navigators" to access a full list of available services, Regulatory documents review for IND, IDE and HDE. Additional information regarding IND may be found on the **FDA Website**.

The study will be conducted at one of the Kaleida Health affiliate locations
Any study personnel that are not directly employed by Kaleida Health (KH) (ie. Research Foundation, UBMD Practice Plan, UB Foundation, Investigator) and will require access to Kaleida's electronic medical record (EMR) for purposes of chart review, recruitment or follow up activities; or will be conducting study related procedures within KH must complete an **APPOINTMENT PACKAGE** and submit to Kaleida's Office of Research and Sponsored Projects, **Kelly Gleason**. For information regarding conducting research at any of the Kaleida Health locations please refer to the **Kaleida Health Research Associate Orientation Manual**.

Clinical Research Workflow



Pre-review by Clinical Research Facilitators

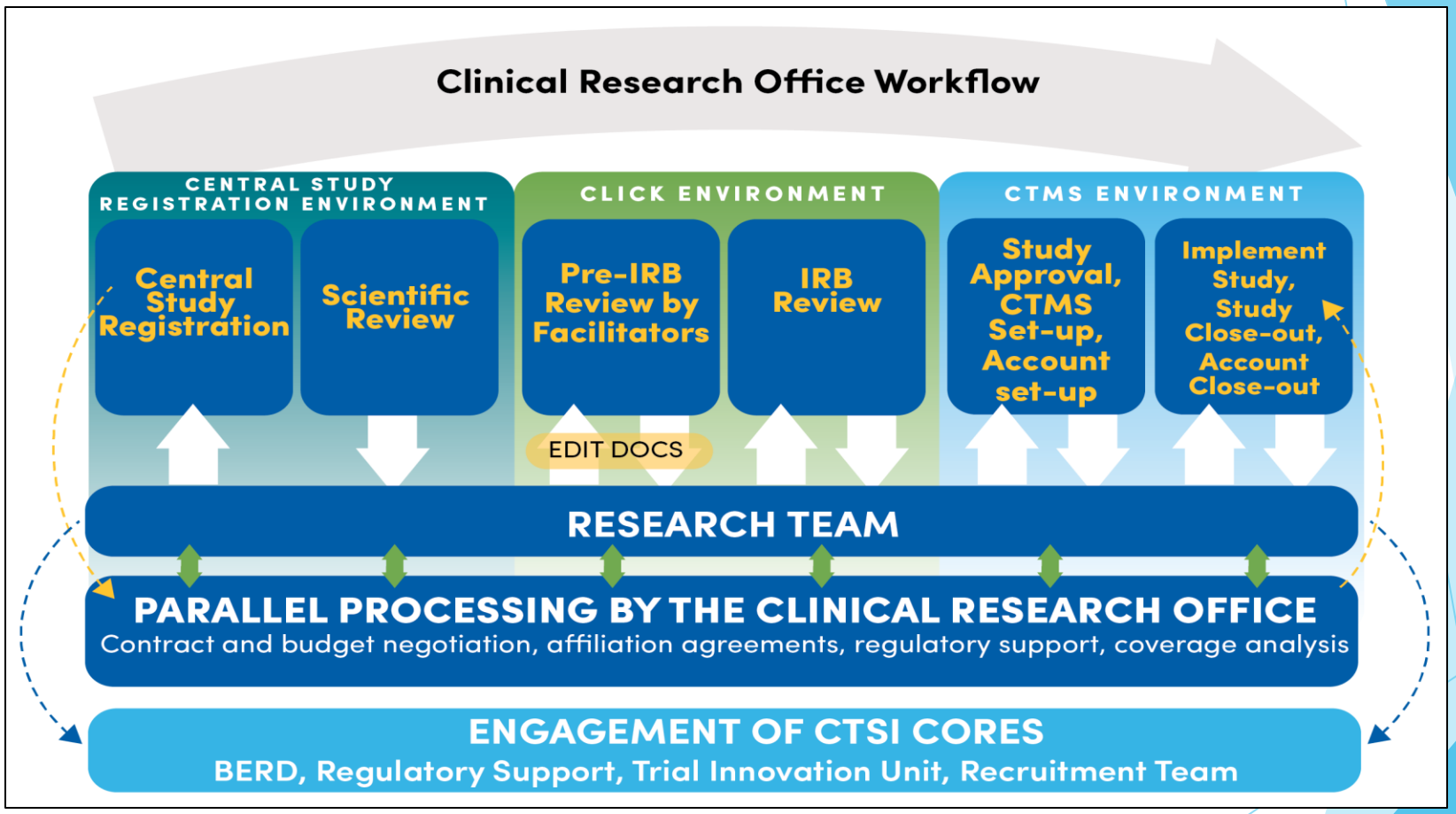
- Prevent delays in IRB review
  - Address clarifications based on common feedback given by the IRB during determination review
  - Identify documents that are missing from the IRB submission
  - Identify inconsistencies/contradictions between submitted documents

Pre-Review

The CRF will:

- Review all submitted documents, sometimes providing detailed notes on protocols and consent documents
- CRF pays particular attention to readability of forward-facing documents, consistency between procedures listed in the protocol and described in the consent, and that privacy and confidentiality issues are addressed.
- CRF emails a zip file containing any documents that need edits to the Principal Investigator, PI Proxy, and Primary Contact

Clinical Research Workflow



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!

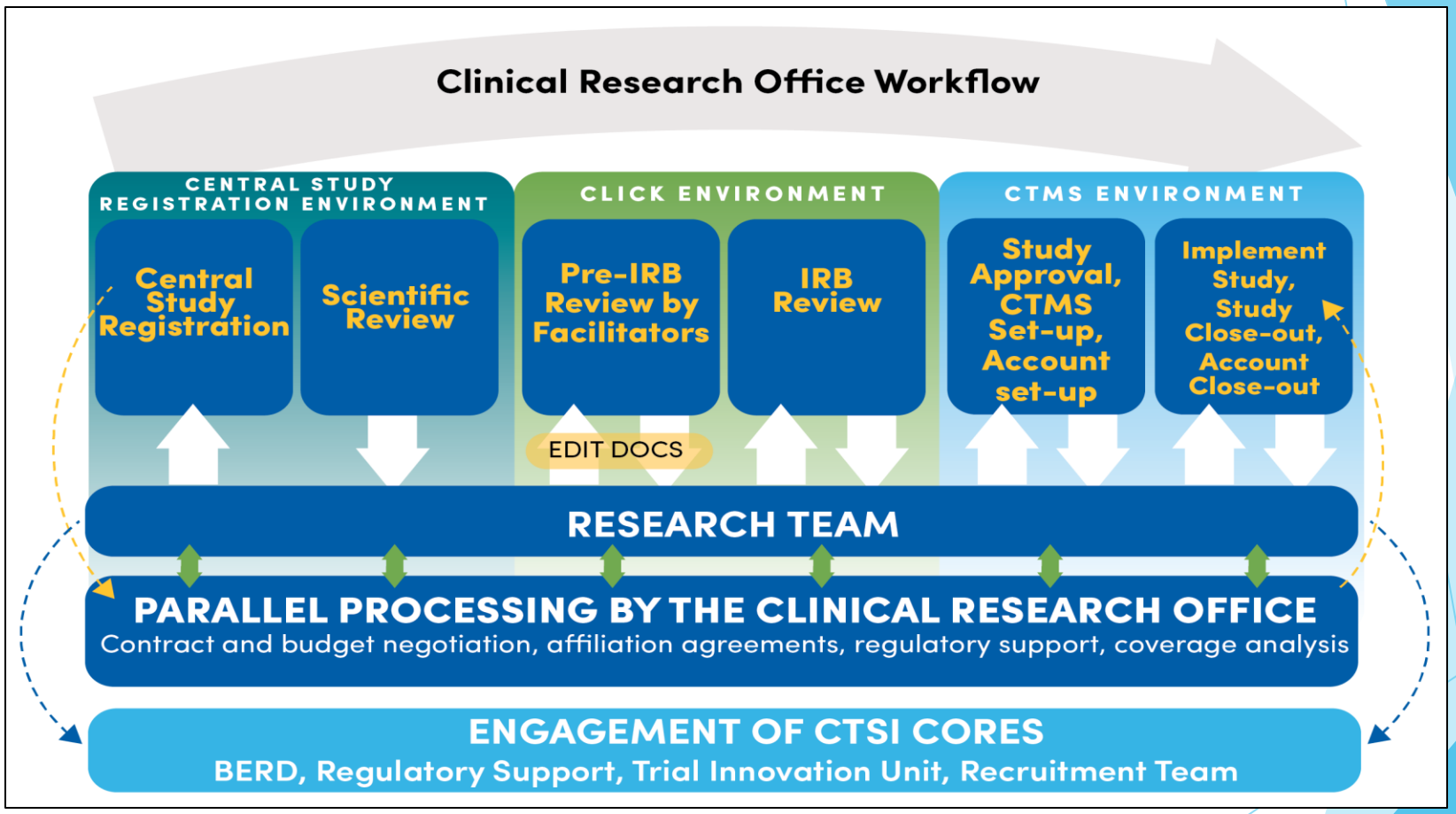
FUNDED

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

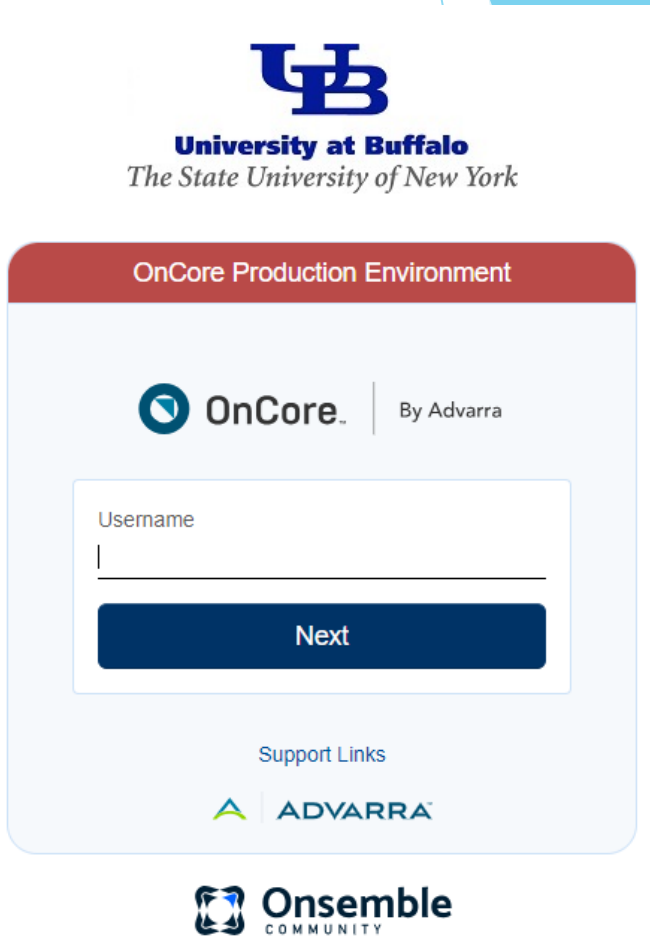
- More information:
  - https://www.buffalo.edu/research/research-services/clinical-and-behavioral-research/set-up-study/coverage-analysis.html
- Forms at:
  - https://www.buffalo.edu/research/research-services/clinical-and-behavioral-research/forms-and-templates.html
- Email: careview@buffalo.edu

Clinical Research Workflow



Oncore

- Clinical Trial Management System (CTMS)
- Tracks subject enrollment and financials
- Sponsors are invoiced based on data entered in Oncore.
- 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

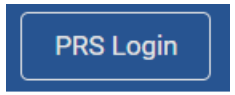


Clinicaltrials.gov

- 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/module_5.html
  - https://www.clinicaltrials.gov/about-site/about-ctg

  - Log in at:
    - https://register.clinicaltrials.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.

Clinical Research at UB Educational Videos