

FAQ When Completing Feasibility Questionnaires:

Can the PI sign the CDA/NDA? (Confidentiality Agreement/Non-Disclosure Agreement)

No. **PI's do not have signatory authority to sign any contract on behalf of the University.**

If the CDA/NDA is sent electronically (often times included at the end of the feasibility questionnaire), the PI can request a word document from the sponsor/CRO (Contract Research Organization – ie: Medpace, PPD, IQVIA etc) and upload it to Click Agreements. All CDA/NDAs are to be uploaded into Click Agreements by the PI or study team member for **institutional signature.**

Name of Institution: Research Foundation of SUNY on behalf of University at Buffalo

Is parallel processing possible? (i.e. budget/contract negotiation while IRB in process):

Yes

Can a Central IRB be used?: Yes. A reliance agreement will need to be signed by UB IRB and the central IRB. This process is started in CSR – our central registration system

Is there a preference for Central IRB?: No

Local IRB fee when Central IRB is used: \$2640 one time fee

For Local IRB: UB Federalwide Assurance ID#: FWA00008824

The UB IRB meets weekly

The official review of a completed proposal takes about 6-8 weeks

Local IRB review fee: \$3960 initial review; \$1,320 each continuing review

Will monitors be given access to EMR (Electronic Medical Record)?:

Currently no, certified copy or over the shoulder access – this may change when EPIC EMR is fully implemented through affiliates and UBMD practices (full implementation planned for Fall 2026). **EMR is 21 CFR compliant**

Remote and onsite monitoring is permissible.

Are there any other review committees for studies?:

ECMC: For studies conducted at or through Erie County Medical Center there is a research review committee that studies must go through for approval. This requires a [research application](#) to be completed and submitted to The Office of Clinical Research Coordination . Contact person: Cindy Ersing – cersing@ecmc.edu.

Kaleida Health: There is currently no additional committee that studies must go through at any of the Kaleida facilities. Kaleida facilities include: Buffalo General Medical Center, Golisano Children's Hospital, Millard Fillmore Suburban, Millard Fillmore Ambulatory Surgery Center, Southtowns Surgery Center, Spindrift Infusion Clinic, any GPPC practices and Visiting Nurses Association of WNY.

UB: University has internal site activation steps (i.e. Clinical Research Office sign off)

Contact Information for Budget and Contract:

This will always be the coordinator or the person that will enter the study into Central Study Registration. A study team member will upload the contract and budget into UB's Central Study Registration (CSR) and the documents will be routed to a Contract Specialist and Budget Specialist.

A template contract from the sponsor is preferred.

Contract timeline for completion is 6-10 weeks

Budget timeline for completion is approximately 6 weeks

Start-up process time from receipt of ALL start up documents (IRB/CTA / Budget, pharmacy manual, imaging manual, lab manual) to SIV date?

4-6 months

Has the site been inspected by any regulatory agencies?: Many 'not for cause' FDA inspections with no 483 issued.

Fees- standard

University overhead/indirect costs rate is 32% Total Direct costs (TDC)

Start-up Fee: \$25,000 All interventional studies; \$10,000 non interventional

Affiliate Review Fee for studies done through Kaleida Health or Erie County Medical Center locations - depending on hospital being used for research procedures, this fee may vary.

Close Out Fee: \$3500

Complete Fee Schedule will be sent at start of budget negotiation

Site Facilities/Resources:**CRC-** Clinical Research Center

Clinical Research Center Unit located above GVI 875 Ellicott street Suite 6040 Buffalo, NY 14203 .

- Dedicated 24 hour temperature monitored medication room
- Part time research Pharmacist
- Lab with ambient and refrigerated centrifuge
- Dry Ice
- Minus 80 and 30 freezer with 24 hour lab alert monitoring
- Equipment calibrated annually
- 6 patient rooms with access to B/P, pulse ox, temperature monitoring and EKG
- Phlebotomy services
- Monitoring space for onsite monitor visits

Outpatient lab facilities for Local testing (CLIA certificates available upon request)

Radiology services including PET scan (Depending on site)

Contact Pam Anderson (pka2@buffalo.edu) for more information.