

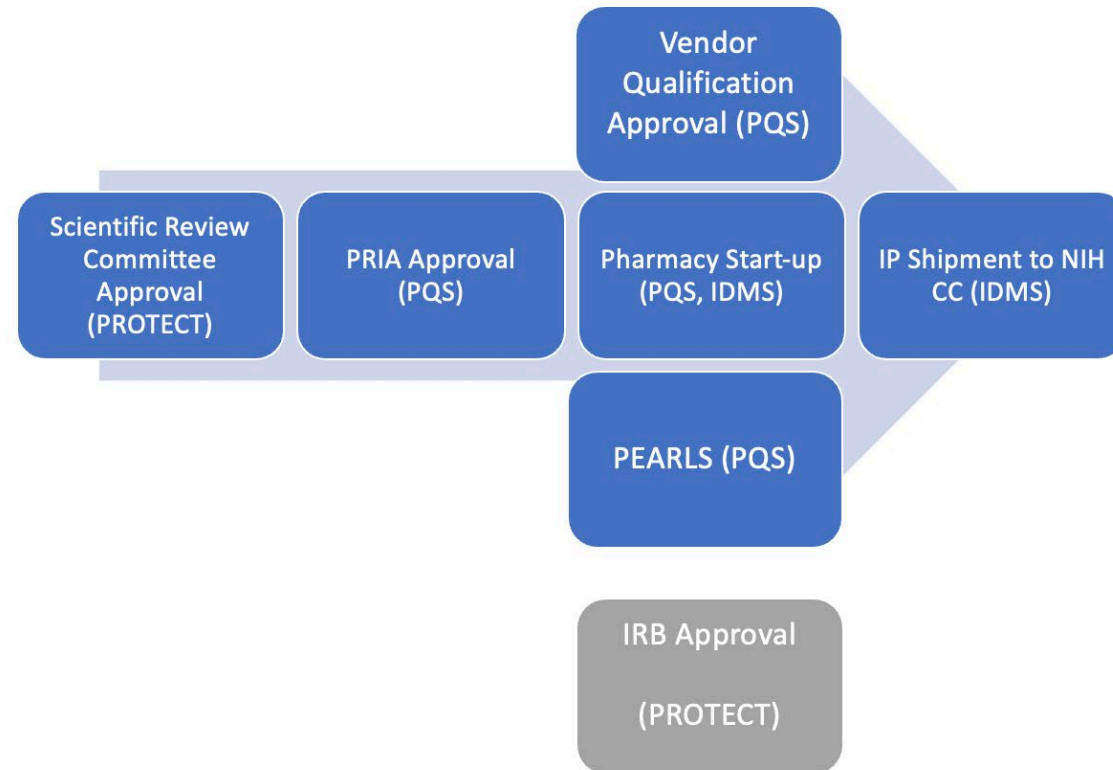
PROTOCOL IMPLEMENTATION AT THE NIH CC SITE

PRIA, PROTRAK QUERY SYSTEM (PQS), PEARLS

TOPICS

- **Overview: study start-up at the NIH CC Site**
- PRIA
- PROTRAK Query System (PQS)
- PRIA Metrics
- PEARLS

OVERVIEW:
PRIA is the first
step for
implementation
at the NIH CC
site



TOPICS

- Overview: study start-up at the NIH CC Site
- **PRIA**
- PROTRAK Query System (PQS)
- PRIA Metrics
- PEARLS

PRIA

PRIA is a targeted, prospective, comprehensive review of the protocol and resource needs conducted in collaboration with the Principal Investigator (PI), key contacts in CC departments, testing and procedure areas, and IC consult services.

PRIAs are managed by three analysts: Anela Kellogg, Dr. M. Schuyler Deming, and Dr. Suma Singh

PRIA review is separate and independent of the IRB review. New IRB-approved protocols may not enroll participants at the NIH CC site until the PRIA is approved by the CEO.

PRIA

Initial Review: All new protocols that will be implemented at the NIH CC site, with the exception of Individual Patient Expanded Access Applications for Emergency Use, must be submitted for PRIA review. A protocol must have PRIA approval to open to enrollment at the NIH CC site.

Amendment: Protocols that previously received PRIA approval but are subsequently amended and/or have operational changes that impact Core Service support must be submitted for PRIA review.

- Change in trial design
- Change in IP or placebo (including change in manufacturer)
- Increase of 20% or more to study accrual
- Addition of new procedures, consults, or specialized testing
- Addition of younger and/or more vulnerable population(s)

PRIA STEPS

1

- PI/ Research Team submits a PRIA action in PQS

2

- Assigned PRIA Analyst reviews submission and submits clarification requests to the PI/Research team as needed

3

- PRIA Analyst distributes PRIA to Core Service Reviewers
- Note: this step may include a round of clarification requests from Core Service Reviewers, facilitated by the assigned PRIA Analyst

4

- PRIA Analyst completes PRIA action and submits to CEO for review/approval
- Note: this step may include another round of clarification requests to the Core Service reviewers and/or the Research Team

5

- PRIA is approved (marked as COMPLETE in PQS)
- PRIA Analyst sends PI a PRIA Approval (or Conditional Approval) letter by email

6

- OPS is authorized to post IRB-approved consent online

PRIORITIZED & EXPEDITED PROTOCOLS

A Clinical Director may request EXPEDITED or PRIORITIZED processing of a PRIA action and/or pharmacy start-up

EXPEDITED = PRIA goes to the top of the queue for all ICs

PRIORITIZED = PRIA goes to the top of the queue for the IC, in the order of prioritization determined by the Clinical Director or designee

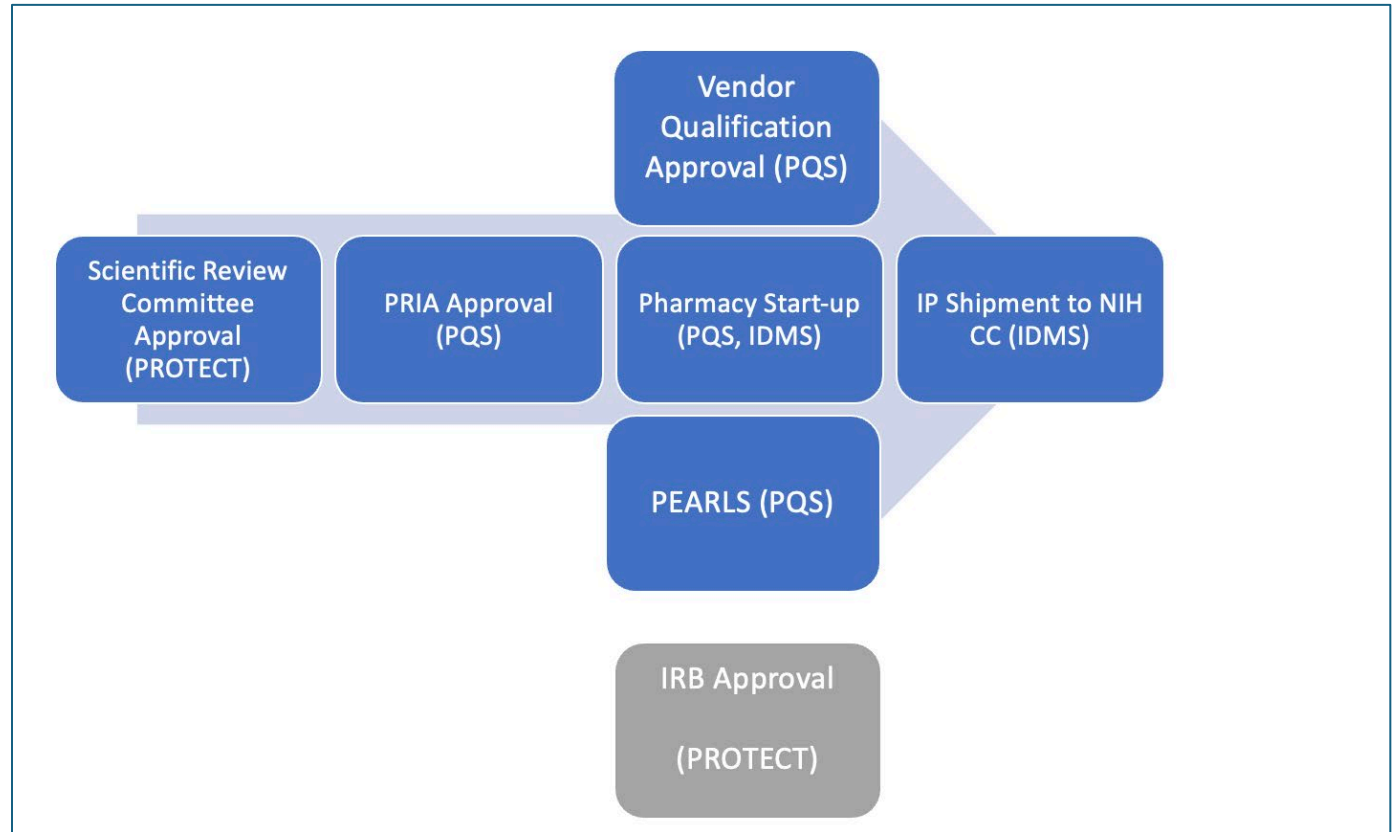
TOPICS

- Overview: study start-up at the NIH CC Site
- PRIA
- **PROTRAK Query System (PQS)**
- PRIA Metrics
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PROTRAK QUERY SYSTEM (PQS)

Initially developed as a repository of study-related information, entered by PIs/study teams, to meet mandatory reporting requirements to federal agencies and to register trials on *clinicaltrials.gov*

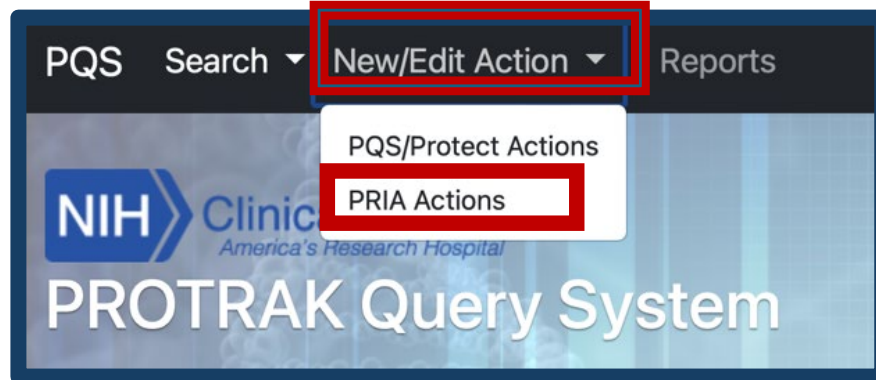
OVERVIEW: STUDY START- UP AT THE NIH CC SITE



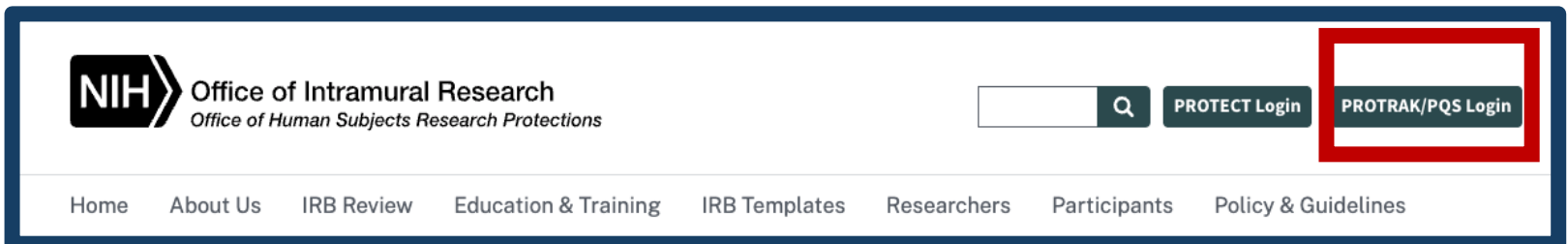
PQS serves as a CC document management platform to support protocol implementation at the CC site.

- PRIA, ORSC Vendor Qualification, and other documentation required for implementation are uploaded to the PRIA record in PQS.
- IDCU Pharmacists, CS Pharmacists, and the ORSC Vendor Qualification teams have unrestricted access to the PRIA record in PQS.

PRIAs are submitted to and approved by the CC in PQS



- Information flows from PROTECT (unidirectional) → PQS
- A new protocol must be established in PROTECT to be able to open a PRIA action in PQS
- PRIA Form permissions in PQS are driven by permissions established in PROTECT



PQS site:
<https://clinweb.cc.nih.gov/pqs>

TOPICS

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PRIA METRICS

	PRIA TURNAROUND IN DAYS	CORE SERVICE REVIEW TURNAROUND IN DAYS
TARGET	60	
2022	172 (MEAN) 141 (MEDIAN)	
2023	111 (MEAN) 100 (MEDIAN)	100 (MEAN) 67 (MEDIAN)
2024	74 (MEAN) 61 (MEDIAN)	35 (MEAN) 29 (MEDIAN)
2025	31 (MEAN) 19 (MEDIAN)	19 (MEAN) 18 (MEDIAN)

2025 Targets

PRIA TURNAROUND (all reviewed actions): 60 days

AMENDMENTS: 45 days

EXPEDITED/PRIORITIZED: 20 days

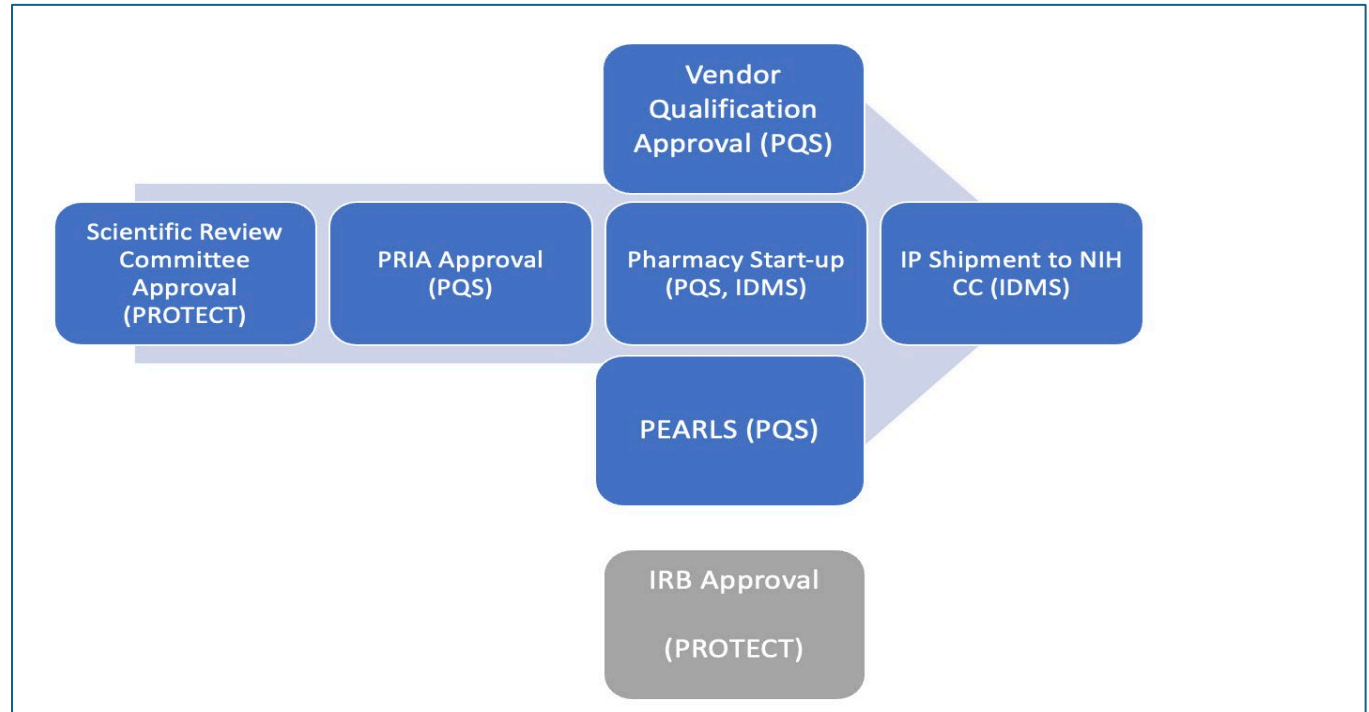
CORE SERVICE DWELL TIME \geq 60 DAYS: 0

EXPEDITED/PRIORITIZED ACTION Core Service Review submitted by due date: 100%

TOPICS

- Overview: study start-up at the NIH CC Site
- PRIA
- PROTRAK Query System (PQS)
- PRIA Metrics
- **PEARLS**

STUDY STARTUP AT THE NIH CC SITE: PEARLS

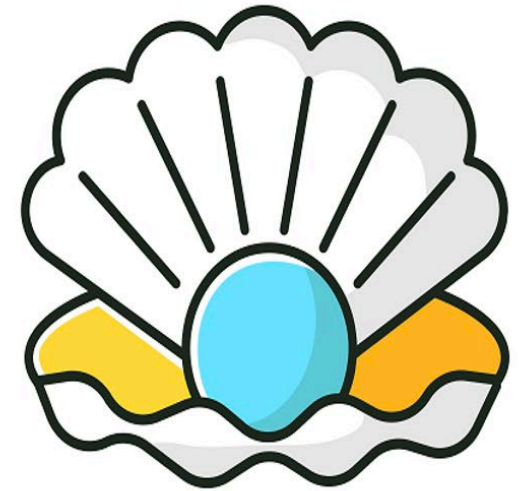


PEARLS Sheets are requested to be prepared by research teams as part of study start up.

- A common conditional approval stipulation by Nursing PRIA reviewers. This is typically required prior to enrollment of first participant on protocol and is an educational tool for CCND protocol-specific in-service.
- A quick tool to help providers at the bedside/in clinic who seek succinct information of a *specific protocol* to provide the best care for a *specific patient* at a moment in time.

PEARLS

Protocol
Expectations (and)
Actions (for)
Real
Life
Scenarios



PEARLS FOCUS: SHARED UNDERSTANDING

Information transfer of important clinical care details relevant to the protocol already known by the research team



Cross-covering clinicians
Medical Consultants
A transferring team
Bedside Nurses
Pharmacists
Respiratory Therapists
Physical Therapist
Occupational Therapist
Dietitians
Radiologists
Outpatient Nurses

And others...

PEARLS

- ✓ A one-page synopsis of the “need to know” information that any provider not familiar with a particular protocol could use at the bedside to best care for the patient
- ✓ A simple PDF form filled out by members of a protocol research team who know the study design best.
- ✓ The finished document uploaded and housed in PQS and accessed quickly through CRIS.
- ✓ A PEARLS sheet is accessible through CRIS banner but remains separate from the IRB documents and is not part of a patient’s medical record
- ✓ PEARLS is a clinical care support tool to improve clinical quality and patient safety.
- ✓ Protocol “study start up” is a great time to generate a PEARLS sheet as it can be a helpful document during in-service and other protocol related trainings.

Protocol Title and ID#

Research Question Contacts

What is being studied



What is happening to the patient

What are likely disease complications





What are likely treatment complications


What to do to manage complications


What NOT to do


 **Protocol Expectations and Actions for Real Life Scenarios** 
Protocol P.E.A.R.L.S Quick Sheet


Title/CC Protocol #: _____


 PI: _____
  Medical AI: _____
 RC: _____
  For patient specific questions contact LIP On Call


 Aim of Study (in 1-2 sentences):

 Protocol Intervention/Treatment (one paragraph):

 Disease Specific Clinical Complications (list up to 3 most important):

 Protocol/Treatment Specific Clinical Complications (list up to 3 most important):

 Complication Management/Interventions (list up to 5 most important):

 Contraindications/Interventions to Avoid with this Protocol/Disease:

Date Effective: _____

Patient questions *On Call Now* 

Date reviewed



Protocol Expectations and Actions for Real Life Scenarios



Protocol P.E.A.R.L.S Quick Sheet



Title/CC Protocol #/PI: SEL 302 in Methylmalonic Acidemia (MMA)/000957 HG/ Venditti

Clinical Contact Person: Dr. Irini Manoli/ Dr. Chuck Venditti/ Carol Van Ryzin, PNP



Aim of Study (in 1-2 sentences):

- Evaluate the safety, tolerability, and pharmacodynamics of SEL-302 (SEL-110 followed by MMA-101) in pediatric subjects with mutant subtype isolated methylmalonic acidemia (MMA).
- First patient will receive only MMA101 with steroid protocol.



Protocol Intervention/Treatment (one paragraph):

- We plan to enroll 6 participants (3-18yr old) with MMA onto this clinical trial of SEL 302.
- SEL 302 consists of 2 drugs, given in sequence.
- SEL-110, is a nanoparticle-encapsulated Sirolimus formulation, given intravenously for immunomodulation, followed by MMA-101, an AAV8 gene vector therapy that targets the liver, also given intravenously.
- SEL-110 will be given again on Day 28 and 56.



Disease Specific Clinical Complications (list up to 3 most important):

- Nausea/vomiting/feeding intolerance (with or without abdominal pain due to pancreatitis). Patients are typically gastrostomy dependent for caloric intake
- Metabolic Acidosis with or without hyperammonemia
- Chronic kidney disease



Protocol/Treatment Specific Clinical Complications (list up to 3 most important):

- Infusion Reactions/Anaphylaxis/Vomiting
- Poor feeding can lead to life-threatening metabolic crisis
- Liver injury, transient and managed by corticosteroids
- Thrombotic microangiopathy that can cause acute kidney injury and require hemodialysis



Complication Management/Interventions (list up to 5 most important):

- STAT Labs: VBG, Acute Care Panel, Ammonia, Lactate, CBC with diff, Mineral, Hepatic Panel, Amylase, Lipase, urinalysis/ketostix, blood/urine cx
- Start D10 + 1/2NS, base replacement
- Start Emergency Meds as indicated: Ammonul/Sodium Benzoate/Carbaglu for hyperammonemia; IV Carnitine, IV antibiotics
- Sick day diet: no or low protein; consider need for TPN/Intralipid

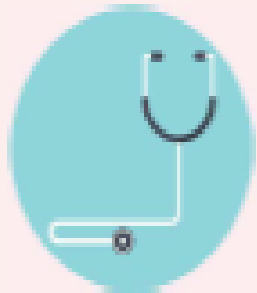


Contraindications/Interventions to Avoid with this Protocol/Disease:

- Don't delay or skip feeds/avoid prolonged NPO times
- Don't give high protein diet
- Avoid nephrotoxic medications, IV contrast
- Call us with any questions

**Date
Reviewed:**

4/13/2023



Complication Management/Interventions (list up to 5 most important):

- STAT Labs: VBG, Acute Care Panel, Ammonia, Lactate, CBC with diff, Mineral, Hepatic Panel, Amylase, Lipase, urinalysis/ketostix, blood/urine cx
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- Don't delay or skip feeds/avoid prolonged NPO times
- Don't give high protein diet
- Avoid nephrotoxic medications, IV contrast
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**Date
Reviewed:**

4/13/2023

PEARLS METRICS

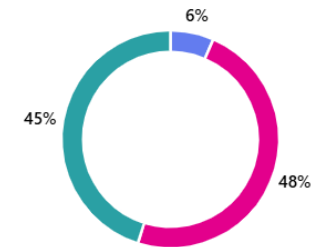
74 PEARLS Sheets submitted to date

2023	9
2024	44
2025	21

31 responses submitted through PEARLS MS TEAMS form (launched late 2024)

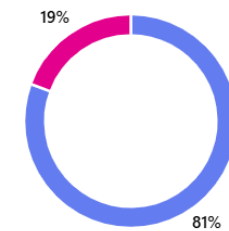
2. Protocol Setting:

Inpatient	2
Outpatient	15
Both inpatient and outpatient	14



3. Is this the initial PEARLS sheet for this protocol?

Yes	25
No, I am updating an existing PEARLS sheet (only complete section(s) which need to be updated)	6



PEARLS by Institute

NCI: 22
NIMH: 17
NINDS: 10
NHLBI: 7
NIAID: 7
NICHD: 4
NIAAA: 3
NHGRI: 1
NINR: 1
NICCIH: 1
NIDCR: 1

Where to find PEARLS

PQS Search ▾ New/Edit Action ▾ Pearls Reports Admin ▾

NIH Clinical Center
America's Research Hospital

PROTRAK Query System

Protocol: 21-C-0012

Modify Protocol Data Download Protocol PQS Submission History **Download Pearl File** Print

A horizontal row of ten icons: a globe, a person with a headset, a red blood drop, a radiation symbol, an envelope with a lock, a person with a gear, a double-headed arrow, a crossed-out 'X', a power button, a stethoscope, and a pearl icon circled in red.

[Welcome to the PEARLS Hub | NIH Clinical Center - America's Research Hospital](#)

PEARLS Quick Sheets for better patient care!

Protocol Expectations and Actions for Real Life Scenarios

Help us get to
100 PEARLS
by the end of 2025!!

Staff can find out more here:
intranet.cc.nih.gov/pearls

The form is titled "Protocol Expectations and Actions for Real Life Scenarios" and "Protocol PEARLS Quick Sheet". It includes the NIH Clinical Center logo and a contact email: "Send completed quicksheet to COODPEARLS@cc.nih.gov". The form has several sections with icons and labels:

- Title/CC Protocol #: _____
- PI: _____
- Research Nurse: _____ Medical AI: _____
- Aim of Study (in 1-2 sentences): _____
- Protocol Intervention/Treatment (one paragraph): _____
- Disease Specific Clinical Complications (list up to 3 most important): _____
- Protocol/Treatment Specific Clinical Complications (list up to 3 most important): _____
- Complication Management/Interventions (list up to 5 most important): _____
- Contraindications/Interventions to Avoid with this Protocol: _____

Icons include a smartphone, a target, a brain, a warning sign, a magnifying glass, a smiley face, and a stop sign.

Over
50
PEARLS sheets
created in
2024!

