Penn Medicine

Clinical Research

Ambulatory Practice Manager On Boarding Basics for Clinical Research

Amanda Brock and Laura Fluharty

2024

Introductions

- Laura Fluharty, MPH, CCRC

- Amanda Brock, MSN, MBE, RN

Learning Objectives

- Explain importance of Clinical Research at Penn and definition of clinical trials
- Connection to the Penn Medicine Strategic Plan
- Phases of Clinical Trials
- Informed Consent
- Who's Who on the Research Team
- Epic Functionality

Importance of Clinical Trials

Through clinical trials:

- Combinations of medical, surgical and radiation therapy are improving treatment effectiveness and enhancing outcomes
- Diagnosing diseases has become more precise
- Medications are more successful
- Medical and surgical techniques have advanced
- Strategies to address the late effects of disease and its treatment are improving quality of life

Penn Medicine Clinical Research Enterprise

CR: $412m

CT: $73.5m

297,836 patients

3,042 Studies in CRMS

2,320 studies in PennChart

29

FDA Approvals

2,003

PIs

~1,200

Clinical Research Professionals

Historic Milestones at Penn

- Uterine Transplant
- Over 250,000 participants in the biobank
- Nobel Prize winning work on mRNA vaccine technology
- Future risk of disease and risk monitoring
- CAR-T Cell trials at Penn led to FDA approval of the first engineered cell products

Phases of Clinical Trials

Phase 1

- Find a safe dose
- Determine how the new treatment is given (oral, IV etc)
- To see how the new treatment affects the body and fights cancer
- **15-30 subjects**

Phase 2

- Determine what affect the new treatment has on a specific type of cancer
- To see how the treatment affects the body and the cancer
- **<100 subjects**

Phases of Clinical Trials

Phase 3

- To compare the new treatment (or new use of a treatment) with the current standard treatment.
- **100-several thousand patients**

Phase 4

- Drug is now approved for use in the general population
- Post-marketing surveillance
- Assess how the drug works in real-life scenarios
- Study long term risks AND benefits
- Learn what rare side effects are

Informed Consent

- **Informed Consent** - is a written statement of the study, accompanied by a verbal explanation
- **Without exception, the language of the consent must be in the everyday language of the subject**
- At HUP, the consenting of a study is done by the Investigator. Pennsylvania Law recently changed to allows for qualified practitioner or member of the study team as delegated and trained by the Investigator.
- The participant must be given adequate time to consider the explanation, with no rushing or coercion.

2023-2028: Serving a Changing World

Make breathtaking discoveries and put them to work

- *Discovery propels us, improving and differentiating our service to patients, students, and the world. We will invest in opportunities we can see now and invest in an environment that creates and captures opportunities not yet seen.*

Check our our new website!

Our Mission | Penn Medicine Clinical Research | Perelman School of Medicine at the University of Pennsylvania (upenn.edu)

New Penn Medicine Clinical Research Website

https://www.med.upenn.edu/clinicalresearch/

Penn Medicine BioBank (PMBB)

- Single institutional research program
- Any University of Pennsylvania Health System patient is eligible
- Pre-COVID: recruitment from a variety of outpatient sites in the course of routine clinical care (disease agnostic)
- Post-COVID: electronic consenting (targeted and universal consent)
- Collection of blood with centralized processing
- Storage of DNA, plasma, serum, and residual tissues (including CSF)
- Access to clinical data via EHR
- Permission for re-contact and call-back studies

Biobank Consent

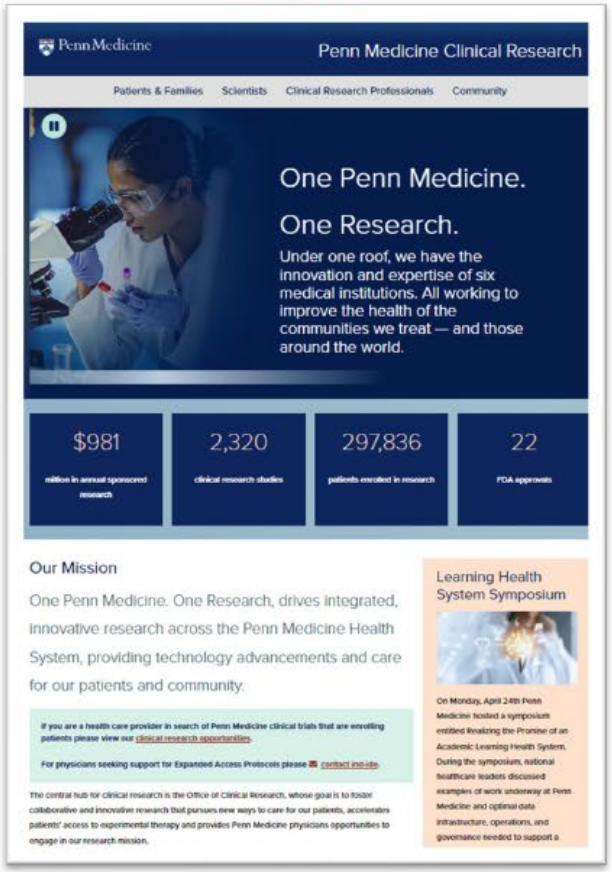
- Broad consent form that is integrated into the front desk check in process
- My Penn Medicine can also be used for patients to sign up to participate
  - There is also an opt out process in My Penn Medicine for patients that do not wish to be contacted for research studies.
- For more information please visit the PMBB website → https://pmbb.med.upenn.edu/

Penn Medicine - One Research

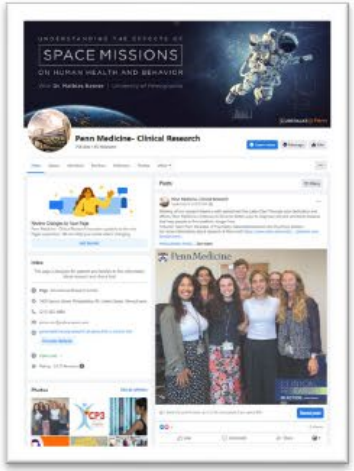
- Foster collaboration & innovation across the system
- Provide access to experimental therapies to all UPHS patients
- Provide providers research opportunities & support creation of networks
- Eliminate redundancy and duplication
  - One IRB protocol with one contract and one budget serving all locations
  - Integrated technology support across all locations
  - Apply in common data model to all clinical data
  - Provision central access to data and resources
  - One portal of entry via new Penn Medicine One Research Website
- Facilitate Penn-CHOP collaboration

Penn Medicine Clinical Research Community Outreach

Website



Social Media



Outreach Resources

Learning Health System

- Data Governance Structure
  - Establish data standards
  - Secure enclave environment
  - Articulate unambiguous use cases across health system
  - Create user groups of SMEs
  - Establish process to provision and oversee data access
- LHS projects and grant funding inventory
- Provide resource navigation – digital storefront
- Establish community

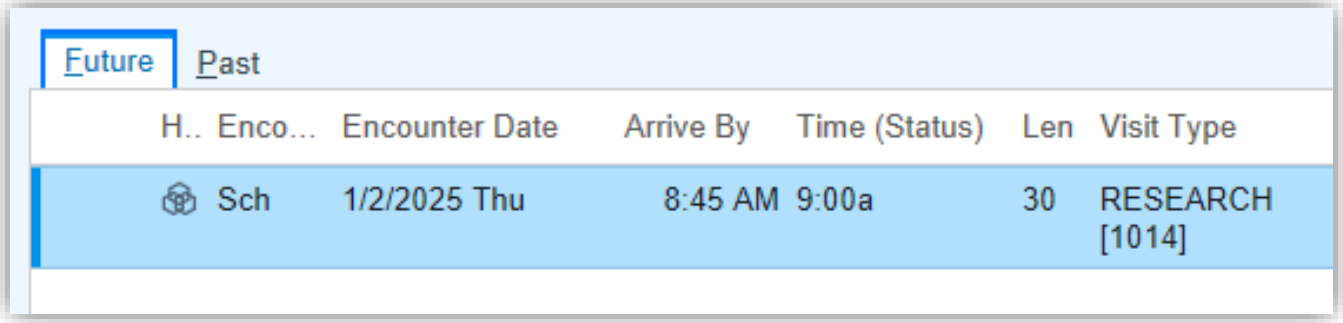
Clinical Study Team Roles

- 1) **Attending Physician (investigator or PI)** trained on the protocol and will make treatment decisions
- 2) **A nurse (Clinical Research Nurse)** knowledgeable about all aspects of protocol. Their role is to consult the investigator to support any decisions related to the patient's treatment and execution of protocol related requirements.
- 3) **A Clinical Research Coordinator (CRC):** They are a resource for protocol logistics, such as allowable dates and any study required labs that are sent to non-Penn processing centers.
- 4) **Lab staff:** Research samples are often processed and shipped externally, they are handled by teams outside the clinical labs.
- **5) Research Quality and Regulatory Professionals:** Assist study teams with audits, IRB and FDA submissions.
- **6) External Monitors or Internal Monitors:** They may request access to Penn Chart to monitor data for the study.

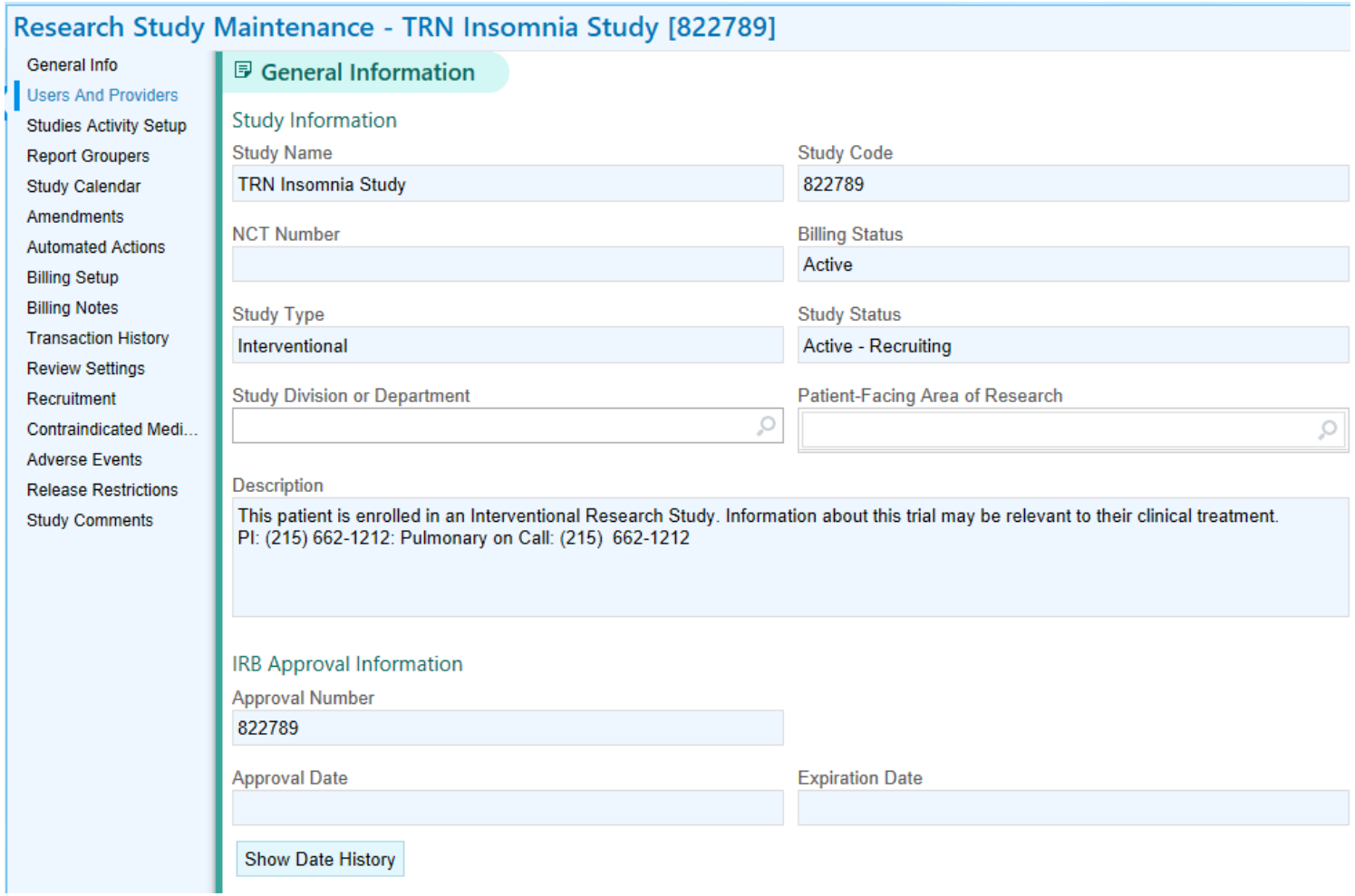
Research Indicators in the EMR

- Research Participant Banner in Storyboard

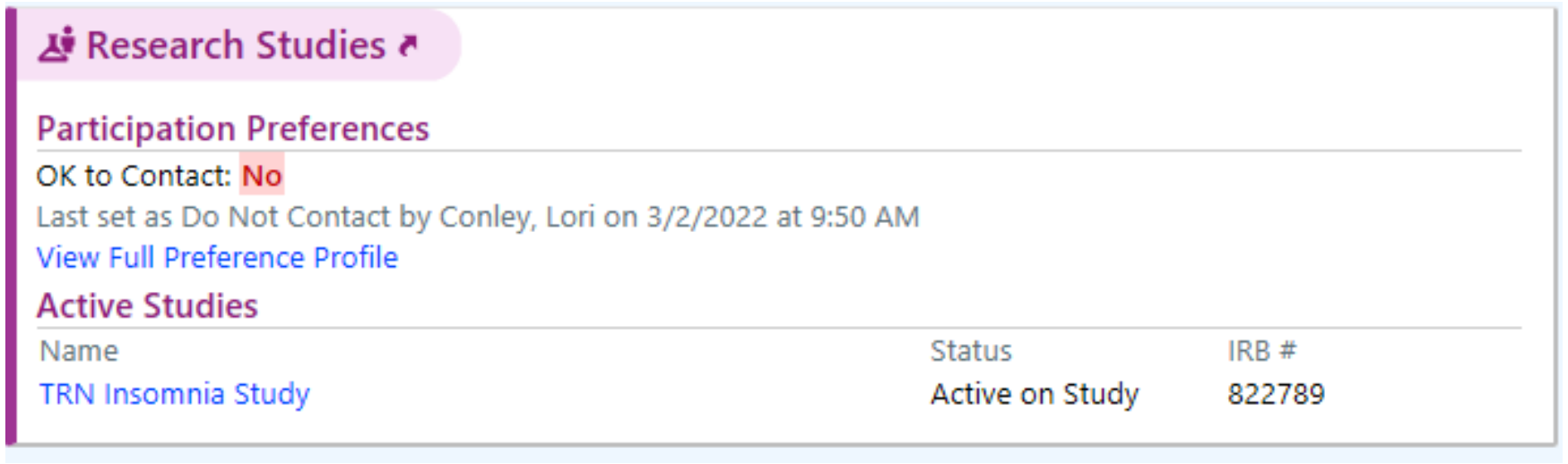
- Research Indicator on Patient Appt.



Basic EMR Research Record



Research Opt Outs



Electronic Patient Data Collection

Function	Smart Documentation	Adverse Events	Investigational Products	Consents
	• SmartForms • SmartPhrases • SmartText • Flowsheets	• Attributions • Coding Dictionaries • PI review and attestation	• Investigational Medications • Electronic Ordering • Dispensation and Administration	• Electronic signature • Remote consent • Consent Storage

Electronic Patient Data Collection
- MPM surveys / questions
- MPM messaging
- Direct patient secure access to complete
- More real time and ongoing data collection

eSource Documentation & Subject Communication PennChart/EMR

Benefits				
	• Discrete Documentation • Audit trail and reporting • Multisite standardization	• Reduced redundant documentation • Clear attestation and attribution	• Clarified ordering and administration • Verification for allergies or contraindications	• Low contact consent • Versioning

Clinical and Research Service Line Integrations

- Clinical Research Staff EMR Training
  - Ambulatory MA Training
  - Clinical Research Workflows
  - Clinical Research Biller Training
  - SchedReg (for those scheduling or new patients coming to Penn for research)
- Research and Clinical Coordination Recommendations
  - Research representative attend weekly clinic schedule review meetings
  - Research representative attend Service Line Operations Meeting
  - Space Issues
    - Scheduling email listservs for transparency around room requests and troubleshooting room/ scheduling issues per protocol

Questions about Clinical Research at Penn??

- Please contact us directly!
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