Who is the VPR-CTO?

• Serve Under the Vice President for Research

• Part of the Research Administration

• We work closely with:
  
  - Regulatory Affairs and Compliance
  - OIRB
  - OCR
  - OSP
  - UT Medicine
  - University Hospital – Research Department

MOST IMPORTANTLY
We work with Research Teams!
Clinical Trials Office Staff:

- Jason Bates, MBA – Director, Clinical Trials Office
- Patricia R. Miranda, BBA – Budget Analyst – Senior
- Mysti M. Trainer, MSA – Budget Analyst - Associate
- Lynda Schrack, BA – Clinical Trials Specialist
- Cristina Morales, BSBA – Clinical Trials Specialist
What is Velos eResearch?

Velos eResearch is a web-based, clinical trial management system (CTMS)

• Clinical Research Simplified
  - Efficient Study Management and Administration
  - Patient Management
  - Reporting Functionality
What is Velos eResearch?

• Study Management
  
   Document Study Demographics for quick reference
  
   Ability to track a study from start to finish
  
   Set user roles and permissions
What is Velos eResearch?

• Patient Management (Required when a study presents a Billing Risk)
  ❖ Patient calendars to help you track patient procedures
  ❖ Streamline Patient registry, scheduling, and follow-ups
  ❖ Record visits, get timely notifications, reduce deviations
What is Velos eResearch?

• Reporting Functionality
  - Ability to run ad-hoc queries
  - Improve Metrics tracking
  - Ability to share reports
Velos eResearch – CTMS

CTO’s Role

• Builds Study Framework in eResearch
• Provides hands on training for user access
• Manages Functional Use of eResearch
  ❖ Assists with User Access
  ❖ Provides Functional Support
Research Team Expectations

• Study Management Activities
  ❖ Maintain Study Enrollment Status – Ensure study is in an Open Enrollment Status to allow Patients to be associated to a study
  ❖ Making sure to add Study Team Members to your study
Research Team Expectations (cont.)

- Patient Management Activities
  - Adding Patients to the system within 24-72 hours after first study visit
  - Maintaining Patient Study Status
  - Associate Study Patients to a Study Calendar

- Keeping CTO updated on any Amendments to the study
Have you taken Velos Training?

- Complete required training
  - Velos eResearch Training: Study Overview and Patient Management
  - Velos eResearch: CTRC General Overview Session
Velos eResearch – Training

Sign-up in Knowledge Center Today!

Computer Classroom Training Course will cover:

- Hands on Training in the Test Environment
- How to navigate in Velos eResearch
- Patient Search and Registration
- Learn how to log Patient visits
Velos eResearch – CTMS

Version 10 Upgrade

• Currently in testing phase

• Go live is expected at the end of Summer 2017

• Classroom Training is currently being updated to feature Version 10 enhancements
Billing Risk Review

Lynda Schrack - Clinical Trials Specialist
What is a Billing Risk?

A research billing risk occurs when study-related services are provided in a clinic setting and have the potential to be billed to the research subject or their insurance.
Why do we conduct Billing Risk reviews?

Billing clinical services:

- Paid for by a funding sponsor
- Promised to patients for free in the study consent
- Performed for research purposes only
- Billed to Medicare, or other third party payer, that do not meet specific criteria based on the CMS Clinical Trial Policy
- It’s REQUIRED in order to obtain institutional approval
The following documents are required to complete the Research Billing Risk review:
The following documents are required to complete the Research Billing Risk review:

- Research Protocol
- Institutional Step 1 and Step 2 forms
- Informed Consent Form
- Funding Agreement (CTA, Notice of Grant Award, or other Funding agreement)
- Itemized Budget
- Investigational Device Exemption (IDE) number, 510K approval
The Evolution of Billing Risk
What’s Changed?

• Preliminary Billing Risk Review
What’s Changed?

• Full Billing Risk Review
Coverage Analysis

YES or NO?

If your study has a **Billing Risk** or a **Limited Billing Risk**

it needs a COVERAGE ANALYSIS
Coverage Analysis
## Study Specific Information

- **Sponsor Name:** DeepPocket Pharma
- **NCT Number:** 8675309
- **Protocol Number:** 12345
- **IND/IDE Number:** N/A
- **Protocol Version:** vMay18-2017
- **Principal Investigator:** Dr. McDreamy
- **Coverage Analysis Prepared By:** Lynda Schrack

## Coverage Analysis

<table>
<thead>
<tr>
<th>Event/Procedure Name</th>
<th>CODE/CP T</th>
<th>Coverage Determination</th>
<th>Site of Service</th>
<th>Total Quantity</th>
<th>Screening</th>
</tr>
</thead>
<tbody>
<tr>
<td>Consent</td>
<td></td>
<td>R - Research</td>
<td>UTHSCSA</td>
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<td>1</td>
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<tr>
<td>Demographics and Med Hx</td>
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<td>R - Research</td>
<td>UTHSCSA</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>MRI</td>
<td></td>
<td>R - Research</td>
<td>RII - Research Imaging Institute</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Physical Examination</td>
<td>99211-99215</td>
<td>SOC - Standard of Care</td>
<td>University Health System</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Questionnaire</td>
<td></td>
<td>NB - Non-Billable</td>
<td>FORU - First Outpatient Research Unit</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>Labs - Comprehensive Metabolic Panel</td>
<td>83880</td>
<td>Inv-R - Invoice Research</td>
<td>UTHSCSA</td>
<td>2</td>
<td>1</td>
</tr>
</tbody>
</table>

**Visit 1**

- **Day 1:**
  - **Week 1:**
  - **Day 60:**
- **Day 7:**
- **Day 14:**

**Visit 102**

- **Week 1:**
- **Week 2:**

**Visit 103**

- **Week 1:**
- **Week 2:**

**EOT (Day 60)**

- **Day 60:**
What’s Changed?

- Phasing Out of the Research Activity Billing Trigger (RABT)
What’s Changing?
What’s Changing?

Standardization of Tools:
- Coverage
- Notification of Billing Risk result

Coordinating Efforts:
- Emails
What remains the same?

Our commitment to support Research Teams with the shared goal of making your Clinical Trials a success!
Management of Research Participant Payments

Cristina A. Morales – Clinical Trials Specialist
Overview

- What are Participant Payments?
- HOP 7.7.2 Requirements
- Approved Payment Methods
- Management Process
What is a Participant Payment

- Incentive for research participation
- Debit Cards, Petty Cash, Check or Gifts
- Method and Amount – approved by Institutional Review Board (IRB) and Clinical Trials Office (CTO)
HOP 7.7.2 Overview

- Identify approved payment methods
- Safeguard payment inventory
- Separation of duties
- Documentation for all transactions
- Reconcile payments and/or inventories
Approved Payment Methods

- HSC Debit Card – Preferred
- Local State Voucher
- Petty Cash
- Gifts
- Sponsor Provided Payments
The research team initiates the Participant Payment review by indicating participants will be paid.

<table>
<thead>
<tr>
<th>Item 9</th>
<th>Question</th>
<th>Option 1</th>
<th>Option 2</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>Will you be interacting or intervening with living individuals?</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>If Yes</td>
<td>What is the age range?</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Approximately how many subjects do you plan to screen for eligibility?</td>
<td>Provide number:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>N/A this is a HUD or expanded access protocol (not research)</td>
<td>Skip to 10</td>
<td></td>
</tr>
<tr>
<td></td>
<td>What is your planned target enrollment number for completers?</td>
<td>Provide number:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Is this a multi-center study and the sponsor has authorized competitive enrollment?</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td></td>
<td>Do you plan to pay subjects?</td>
<td>No</td>
<td>Yes - Submit <a href="#">Participant Payment Form</a></td>
</tr>
</tbody>
</table>
**Participant Payment Documents**

**Institutional B**
- Submitted to the IRB by the Research Team
- Identifies payment type, frequency, and additional reimbursements.

**Participant Payment Workbook**
- Completed after Inst B is approved by CTO.
- Used for recording, tracking & managing payment inventory.
- Assigns members of study team to payment roles, establishes payment milestones, & identifies the value of the payment & type of payment.
Participant Payment Roles

Principal Investigator (PI) responsibilities:
- Conduct of the research project
- Manage Research Participant Payments
- Designates Employees to Participant Payment Roles

<table>
<thead>
<tr>
<th>Payment Method</th>
<th>Authorized Signatory</th>
<th>Department Representative</th>
<th>Custodian</th>
<th>Payor</th>
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<tbody>
<tr>
<td>Local State Voucher</td>
<td>Required</td>
<td>Suggested</td>
<td>Required</td>
<td>Suggested</td>
</tr>
<tr>
<td>Cash</td>
<td>Required</td>
<td>Required</td>
<td>Required</td>
<td>Suggested</td>
</tr>
<tr>
<td>Gift</td>
<td>Required</td>
<td>Required</td>
<td>Required</td>
<td>Suggested</td>
</tr>
<tr>
<td>HSC-Debit Card</td>
<td>Required</td>
<td>Required</td>
<td>Required</td>
<td>Required</td>
</tr>
<tr>
<td>Sponsor Provided Gift Card</td>
<td>N/A</td>
<td>Required</td>
<td>Required</td>
<td>Suggested</td>
</tr>
</tbody>
</table>
Participant Payment Workbook - Change Request

- Types of changes:
  - PID
  - Staffing
  - Method / Frequency of Payment
  - Amount of compensation

Please notify the CTO of any necessary changes and allow more than 24 hour turnaround time.
Research Navigator

Patricia Miranda – Budget Analyst - Senior
Research Navigator

Main Goals

• Match PI’s with Sponsor Studies
• Increase Number of trials
• Decrease time to Study Activation

Objectives

• Feasibility and Site Selection Process
• Negotiate Budget and Contracts Needed
• Coordinate IRB Submissions
• Utilized Velos eResearch for Study Metrics
How can you contribute?

Welcome to the Vice President for Research (VPR) Clinical Investigator Registry.

What is this registry? The VPR Office uses this registry to match HSC researchers with outside Pharmaceutical Sponsors/CROs or our Network contacts looking to place their studies at the Health Science Center.

How do I register the first time? Please complete this form to provide information on your experience, expertise and interest in conducting clinical research trials.

How do I update my information? Periodically the VPR Office will send you an email invitation to return to this form and update your information. Your previous answers will display on the form, please update applicable sections and upload a revised version of your CV (if needed). You may return to this registry in the future to modify your responses by navigating to the registry URL and entering the return code provided upon completion.
Research Navigator Role – *Group Based*

Jason Bates - Director, Clinical Trials Office

Deborah Mote - FIRST Program Coordinator

Cristina Morales - Clinical Trials Specialist

Patricia Miranda - Budget Analyst - Senior
How to contact the CTO

Email: VPRCTO@uthscsa.edu
Webpage: http://research.uthscsa.edu/cto/

Clinical Trials Office

We are committed to the success of your trials!