

UAMS

UNIVERSITY OF ARKANSAS
FOR MEDICAL SCIENCES



Research Support Information Network (RESIN)

Presented by: Office of the Vice Chancellor for Research

Date: May 7, 2013



Agenda

■ Updates & Timely Information from Research Support:

- ⊕ Office of the VCR
- ⊕ RSC
- ⊕ IRB
- IACUC
- HIPAA
- UAMS Library
- BioVentures
- Cost/Grants Accounting
- COI
- ORSP
- ORC
- DLAM
- OGSP
- CCTR/Core Facilities
- ⊕ Office of Compliance
- ⊕ IT- Research



External IRBs

Jennifer Sharp, IRB Director

- **IRB / Institutional Review**
 - Allowed (with some caveats)
 - AAHRPP
 - Sponsor Required
 - Consortium Agreements



Student Research Day 2013

Lessons Learned Diana Barr, RSC

- **Student Research Day - By the Numbers**
 - Total # of Posters = 104
 - # of Graduate Students = 55
 - # of Professional Students = 28
 - # of Postdocs/House staff/Fellows = 21



Student Research Day 2013

Lessons Learned

Diana Barr, RSC

■ Judges

- Total # of Judges = 68 potential judges
 - Identified from abstract submissions as mentors/sponsors by participants
 - # of judges who were on travel or had clinical responsibilities = 22 after initial email
 - 46 judges on Monday before SRD
 - 10 judges cancelled 24-48 hrs. prior
- 36 judges available morning of SRD 2013



Student Research Day 2013

Lessons Learned Diana Barr, RSC

■ Judging Needs for SRD 2014

- Judges needed for ~105-127 abstracts = 42 judges needed for all types of research (3 posters each)
 - At least 20 additional judges needed for non-bench type research (2-3 posters each)

■ Overall Types of Judges

- **Bench** research judges
- **Non-bench** research judges
- **“On-deck”** - week prior to SRD assigned/notified
- **Emergency** – called when judges don’t show up for morning or afternoon sessions



Student Research Day 2013

Lessons Learned Diana Barr, RSC

■ Poster Awards

- 1st place = \$125
- 2nd place = \$75
- 3rd place = \$50
- Best Overall = \$250

■ Two Judges Assigned/Poster

- If a poster does not receive 2 judges' scores, the participant is disqualified and cannot receive an award

■ Judges Needed

- Contact Linda Williams, ldwilliams@uams.edu or Diana Barr, dlbarr@uams.edu



CLARA Update: IRB Module

Jennifer Sharp, IRB Director

- **CLARA Updates**
 - Usernames/Passwords
 - Migration/Archive Documents
 - Modifications to Update System
- **Questions?**



CLARA Update: Budget and Coverage Module

Julia Washam, Assistant Director, RSC

■ Billing Questions

BUDGET-1.

Does your protocol involve any tests or procedures that will potentially be billed to a UAMS patient or a third party payer?

Yes No



CLARA Update: Budget and Coverage Module

Julia Washam, Assistant Director, RSC

■ Budget Requirement Determination

Budget Requirement Determination

BUDGET-11.

Based on the answers of the questions in this section, is a budget required?

Yes, you need to create a budget for this study. [Click here to open the budget builder in a new window](#)



- If you have any questions, please contact (501)526-6808 or send your request to CLARABudgetHelp@uams.edu



CLARA Update: Budget and Coverage Module

Julia Washam, Assistant Director, RSC

■ Creating a Budget Matrix

New budget

How would you like to enter the budget for this study?

Basic Budget is for visit-only budgets.

Complex Budget enables all options, including adding arms, phases, cycles and visits.

Basic Budget

Complex Budget

Load from saved template...



CLARA Update: Budget and Coverage Module

Julia Washam, Assistant Director, RSC

■ **Contacts**

Budget Questions

Julia Washam	686-8572
Cynthia Spinks	526-4619
Sharon Sandria	686-8567
Lisa Richardson	686-8539
Karen Duvall	686-8713

Medicare Questions

Barbara Adams	686-8187
Mtonya Hunter-Lewis	686-8184



Human Research Studies:

Entry into Epic Angie Smith, LCSW, CCRP Research Operational Lead

- **What is Epic?**
 - Electronic Medical Records (EMR) System
 - Inpatient EMR
 - Outpatient EMR
 - Integrated Access and Revenue Systems
 - Registration/ADT & Hospital Billing
 - Practice Management



Human Research Studies: Entry into Epic

Angie Smith, LCSW,
CCRP Research Operational Lead

■ Systems Replaced by Epic

<u>System</u>	<u>Replaced by</u>
Soft Lab	Epic Beaker
RadNet	Epic Radiant
PAT(CPA)/iPath(CPM)	Epic OpTime
Centricity (EMR)	EpicCare Ambulatory
Sunrise (EMR)	EpicCare Inpatient
HBOC	Epic Prelude/ADT
Inhouse Kiosk System	Epic Welcome
Inhouse Patient Tracker	EpicCare Ambulatory (custom dashboards)
PHS	Epic Cadence
Pharmacy RX 3000	Epic Willow Ambulatory
RQI	Epic Cadence/Prelude
SMS	Epic Resolute
Star Pharmacy	Epic Willow Inpatient
TeleTracking	Epic Prelude/ADT (BedTime)



Human Research Studies:

Entry into Epic Angie Smith, LCSW, CCRP Research Operational Lead

■ Epic & Clinical Research

- Improve clinical research efficiency AND good clinical care for patients involved in research trial
 - Integrate clinical/research activities to provide seamless experience for patient and greater efficiency for the research clinicians
 - Integrate clinical and research information for comprehensive picture of a patient's medical profile
- Improve operational efficiency and compliance related to clinical trials
 - Use Epic features to accelerate recruitment
 - Provide support for research billing compliance



Human Research Studies:

Entry into Epic

Angie Smith, LCSW,
CCRP Research Operational Lead

- **Creating a Study Record in Epic**
 - Only applicable for research studies requiring a CLARA budget
 - Study 'shell' pushed from CLARA to Epic upon IRB approval (automated process)
 - Study 'shell' consists of:
 - IRB #
 - Study Title or UConnect (Epic) study title
 - Study Description



Human Research Studies: Entry into Epic

Angie Smith, LCSW,
CCRP Research Operational Lead

■ Epic Field in CLARA: Study Title

The screenshot shows the CLARA web application interface. At the top, there is a navigation bar with 'CLARA Protocols - Contracts - Help' and a user login 'Logged in as SmithAngelaA'. The main content area displays 'IRB #200101: Test' and 'New Submission: Epic'. A 'Back' button is on the left, and a 'Next' button is on the right. The 'UConnect (Epic) title' field is highlighted with a yellow 'REQUIRED' icon. Below the field is a help box with a question mark icon and the following text: 'This information appears in the chart of any patient who is linked to the study and can be as informative as is appropriate for the study. The study title will auto-populate in this field; however, studies with sensitive information may only wish to enter IRB# or a study identifier in this field.' and '200 character limit'. On the right side, there is a 'SUBJECTS' list with items like HIPAA, Consent, Risks, Data and Safety Monitoring, Miscellaneous, Drugs and Devices, Funding Sources, Budget and Coverage, and Contract. A 'Skip to Documents..' button is at the bottom right of the subjects list.



Human Research Studies: Entry into Epic

Angie Smith, LCSW,
CCRP Research Operational Lead

■ Epic Field in CLARA: Study Description

The screenshot shows the CLARA web application interface. At the top, there is a navigation bar with 'CLARA Protocols - Contracts - Help' and a user login for 'SmithAngelaA'. The main content area displays 'IRB #200101: Test' and 'New Submission: Epic'. A 'Back' button is on the left, and a 'Next' button is on the right. The 'UConnect (Epic) description' field is highlighted with a yellow 'REQUIRED' icon. Below the field is a checkbox for 'N/A: Not Applicable'. A help box contains two bullet points: 'This information appears in the chart of any patient who is linked to the study and can be as informative as is appropriate for the study.' and 'This field is often used to list contact information in case a physician has concerns about patient care that might be related to the patient's participation in a study.' On the right side, there is a 'SUBJECTS' sidebar with a list of categories: HIPAA, Consent, Risks, Data and Safety Monitoring, Miscellaneous, Drugs and Devices, Funding Sources, Budget and Coverage, and Contract. Below this list is an 'Epic' section with a 'Skip to Documents..' button. The bottom of the page shows a status bar with 'Trusted sites | Protected Mode: Off' and a zoom level of '100%'.



Human Research Studies: Entry into Epic

Angie Smith, LCSW,
CCRP Research Operational Lead

■ Study Description in Epic

Hyperspace - EHS RESEARCH SUPPORT - Current Model Playground - RESEARCH I.

Epic Review Pt Research Studies Patient Station Patient Lists Appts Rsch Admin Telephone Call Print Log Out EpicCare

Blue, Becky

Blue, Becky Female, 37 y.o. DOB: 04/21/1975 SSN: xxx-xx-8599 Research: Active Allergies Unknown: Not on File MRN: 201436

Research Studies

Add a new study to list [+ Add](#) Show: Inactive Pre-enrollment Deleted

Enrolled

[MODEL RESEARCH STUDY-INSOMNIA](#) [Report INTEGRATED, RESEARCH ...](#)

Study Code: 100 Principal Investigator: Physician Neurology, MD

Study Description

This is the description from the RSH record for the insomnia study.

For potential patient care concerns, please contact the study at:
24/7 pager: 608-123-4567
Study Coordinator, Robin Bird: 608-888-9999
Study PI, Ned Nuerology: 608-999-9999

Patient Timeline and Associated Encounters

Display Options: By Patient Timeline By Encounter Date [+ Add to Timeline](#)

No encounters have been associated with the study.



Human Research Studies:

Entry into Epic Angie Smith, LCSW, CCRP Research Operational Lead

■ Linking Research Billing Definition to Study Record

Epic Workbench: NIH12505 - ASTHMA CONTROL AND TREATMENT EFFICACY [9100353] - View Only - Protocol Builder

Protocol - Expected Research Charges - 0 lines configured

Asthma Protocol - Perform: 1 time. Length: 10 weeks.

Visit 1: Screening - Perform 1 time on day 1 of the cycle. Day length: 1 day. Research tolerance: -0/+6 days.

Expected Research Charges - 7 lines configured

List study-related charges in the grid below. In the process of redirecting study charges, those found in the grid below without Research Billing Modifier Type set will file to the study account to bill to the study budget. Charges with Research Billing Modifier Type specified will file to the patient account in order to bill to insurance.

Study Charges	Type	Record	Billing Modifier Type
1	Component	OFFICE VISITS (PX) [20]	
2	Procedure	COMPLETE CBC & AUTO DIFF WBC [85025]	Routine
3	Component	CHEST XRAYS [9100036]	
4	Procedure	BASIC METABOLIC PANEL [80049]	
5	Procedure	LIPID PANEL [80061]	
6	Procedure	PULMONARY STRESS TESTING,SIMPLE [94620]	Routine

Pull Charges from Orders

Accept Cancel

Component - OFFICE VISITS (PX) [20]
 Procedure - COMPLETE CBC & AUTO DIFF WBC [85025], Billing Modifier Type: Routine
 Component - CHEST XRAYS [9100036]
 Procedure - BASIC METABOLIC PANEL [80049]
 Procedure - LIPID PANEL [80061]
 Procedure - PULMONARY STRESS TESTING,SIMPLE [94620], Billing Modifier Type: Routine
 Procedure - SPUTUM SPECIMEN COLLECTION [89220]

ROBIN BIRD | Research Eligibility | 11:05 AM



Human Research Studies:

Entry into Epic Angie Smith, LCSW,
CCRP Research Operational Lead

■ Associating Patients with Research Studies

- How to associate a patient with a research study?
 - Manually
 - Interface with C3PR
- C3PR
 - Subject registration application within UAMS Comprehensive Research Informatics Suite (CRIS)
 - Enables efficient & streamlined registration of study participants into clinical trials
 - Interface with Epic (C3PR registration pushed to Epic eliminating dual registration process)



Human Research Studies: Entry into Epic

Angie Smith, LCSW,
CCRP Research Operational Lead

■ Associating Patients with Research Studies

The screenshot shows the Epic Hyperspace interface for a patient named Blue, Becky. The patient's status is 'Research: Active', which is highlighted with a red box. The 'Enrolled' status in the Research Studies section is also highlighted with a red box. The research study details for 'MODEL RESEARCH STUDY-INSOMNIA' are displayed, including the study code (100), principal investigator (Physician Neurology, MD), and contact information for the study coordinator and PI.

Research: Active

Enrolled

MODEL RESEARCH STUDY-INSOMNIA

Study Code: 100 Principal Investigator: Physician Neurology, MD

Study Description
This is the description from the RSH record for the insomnia study.

For potential patient care concerns, please contact the study at:
24/7 pager: 608-123-4567
Study Coordinator, Robin Bird: 608-888-9999
Study PI, Ned Nuerology: 608-999-9999

Patient Timeline and Associated Encounters
Display Options: By Patient Timeline By Encounter Date

No encounters have been associated with the study.



Human Research Studies:

Entry into Epic Angie Smith, LCSW, CCRP Research Operational Lead

■ Creating a Patient-Study Timeline

■ What is it?

- A listing of the date windows that each study visit is expected to occur for the patient

■ Why use it?

- Provides high-level reference regarding where a patient is on the study
- Allows you to associate encounters to a specific point on patient's timeline
- Impacts charge routing - enables the system to use logic to direct research charges



Human Research Studies: Entry into Epic

Angie Smith, LCSW,
CCRP Research Operational Lead

■ Patient-Study Timeline

Hyperspace - EHS RESEARCH SUPPORT - Current Model Playground - RESEARCH.I

Epic Review Pt Research Studies Patient Station Patient Lists Appts Rsch Admin Telephone Call Print Log Out

Blue,Becky

Blue, Becky
Female, 37 y.o. DOB: 04/21/1975 SSN: xxx-xx-8599 MRN: 201436 Research: Active Allergies Unknown: Not on File

Research Studies ? Resize Close

Add a new study to list + Add Show: Inactive Pre-enrollment Deleted

Enrolled

MODEL RESEARCH STUDY-INSOMNIA Report INTEGRATED, RESEARCH ...

Study Code: 100 Principal Investigator: Physician Neurology, MD

Study Description
This is the description from the RSH record for the insomnia study.
For potential patient care concerns, please contact the study at:
24/7 pager: 608-123-4567
Study Corodinator, Robin Bird: 608-888-8888
Study PI, Ned Neurology: 608-999-9999

Patient Timeline and Associated Encounters

Display Options: By Patient Timeline By Encounter Date + Add to Timeline

(RSH-100) INSOMNIA RESEARCH BILLING CALENDAR (Ver. 1) 🔍 ✕

- ➡ Week One (08/31/2012 to 09/06/2012)
- Week Three (09/14/2012 to 09/20/2012)
- Week Five (09/28/2012 to 10/04/2012)



Human Research Studies:

Entry into Epic Angie Smith, LCSW, CCRP Research Operational Lead

■ Linking Encounters & Orders

■ Why?

- Helps more easily identify research-related encounters
 - Encounter tracking
 - HIM/ROI usage
- Enables “mixed” visits to be handled within one encounter
- Better supports Epic research billing



Human Research Studies:

Entry into Epic

Angie Smith, LCSW,
CCRP Research Operational Lead

■ Linking Encounters to Study

Chart Review Last refresh: 6:22:09 PM

Filters Text Search Preview Refresh Select All Deselect All Review Selected Side-by-Side Master Report Round

Encounters Labs Micro Imaging Procedures ECG Other Orders Meds Episodes Letters Notes Referrals Media Misc Reports

18 records match filters, more records to load Default filter Clear All

Filtered: Default filter

R	Date	Type	Department	Specialty	Provider	Description
	03/23/2011	Office Visit	EMC FM	Fam Med	Family Medicine, Phy...	
	11/03/2010	Office Visit	EMC FM	Fam Med	Family Medicine, Phy...	Essential Hypertension ...
	09/29/2010	Procedure visit	EMC PULM	Pulmonology	Pulmonary, Physicia...	
	11/05/2009	Office Visit	EMC FM	Fam Med	Family Medicine, Phy...	Acute Bronchitis (Prima...
	10/27/2009	Orders Only	EMC FM	Fam Med	Family Medicine, Phy...	Hemoptysis (Primary Dx)
	10/22/2009	Office Visit	EMC FM	Fam Med	Family Medicine, Phy...	Acute Bronchitis (Prima...
	10/03/2009	Office Visit	EMC DERM	Derm	Dermatology, Physici...	Nevus, Non-Neoplastic (...)
	09/14/2009	Office Visit	EMC FM	Fam Med	Family Medicine, Phy...	Back Strain (Primary Dx)



Human Research Studies: Entry into Epic

Angie Smith, LCSW,
CCRP Research Operational Lead

■ Associate Orders to Study: Within Order Entry

The screenshot displays the Epic EHR interface for a patient named Blue, Becky. The top navigation bar includes 'Epic', 'Review', 'Pt Research Studies', 'Patient Station', 'Patient Lists', 'Apts', 'Rsch Admin', 'Telephone Call', and 'Encounter'. The patient's information is shown as 'Blue, Becky', Female, 37 y.o., with DOB: 04/21/1975, MRN: 201436, and SSN: xxx-xx-8599. The status is 'Research: Active' and 'Allergies: Unknown: Not on File'. The main area is titled 'Place orders (Enc Date: 8/31/2012) - Wt: (Not entered for this visit) Ht: (Not entered for this visit)'. A red box highlights the 'Research Association' button in the top toolbar. Below the toolbar, there is a search bar for 'New order:' and a list of orders and prescriptions. The list includes 'General sleep study', 'X-ray chest 4 + view', and 'CBC and differential'. The bottom right corner shows 'F7- Prev Order F8- Next Order'.



Human Research Studies: Entry into Epic

Angie Smith, LCSW,
CCRP Research Operational Lead

■ Associate Orders to Study: Within Order Entry

The screenshot shows the Epic Hyperspace interface for a patient named Blue, Becky. The patient's information includes DOB: 04/21/1975, MRN: 201436, and SSN: xxx-xx-8599. The patient is currently in a research study, indicated by the 'Research: Active' status. The 'Allergies' section shows 'Unknown: Not on File'. The 'Place orders' screen is displayed, showing a list of orders and prescriptions procedures. The 'Orders and Prescriptions Procedures (3 Orders)' section is highlighted, and a red box is drawn around the 'General sleep study' order, which is a routine, ancillary performed procedure. Other orders include 'X-ray chest 4 + view' and 'CBC and differential'. The interface also shows a search bar for new orders and various navigation options.



Human Research Studies:

Entry into Epic Angie Smith, LCSW, CCRP Research Operational Lead

■ Summary

- Explicitly associate patients to specific studies
- Track patient statuses on studies & run study-specific reports
- Access to activity/information controlled by security
- Facilitates more efficient association of visits to studies in Epic
- Improve clinical research efficiency AND good clinical care for patients involved in research trials
- Improve operational efficiency and billing compliance related to clinical trials



Human Research Studies:

Entry into Epic Angie Smith, LCSW,
CCRP Research Operational Lead

Questions?

- More to Come: **Research-Specific Epic Training**
 - June & July 2013 (TBD)
 - Watch for announcements!



Controlled Substances and Animal Research

Darri Scalzo, Research Compliance Officer

- **Controlled Substances Used in Animal Research Regulated by:**
 - DEA – 21 CFR Chapter II Parts 1300-1321
 - AR Department of Health Pharmacy Services
 - UAMS Admin Guide Policy 16.1.13
 - http://www.uams.edu/AdminGuide/PDFs/Section%2016/16_1_13_Non_Human_Research_Use_of_DEA_Controlled_Substances_2012.pdf



Controlled Substances and Animal Research

Darri Scalzo, Research Compliance Officer

- **DEA Regulations on Biannual Inventories**
 - 21 CFR § 1304.11
 - Inventory of all stocks of controlled substances on hand shall be taken at least every 2 years.
 - This will be a finding in a DEA audit if not done.



Controlled Substances and Animal Research

Darri Scalzo, Research Compliance Officer

- **UAMS Admin Guide Policy 16.1.13**
 - Also requires the biannual inventory
 - Office of Research Compliance will:
 - Create an inventory form to be used
 - Send to all researchers using controlled substances in animal research



RESIN on Summer Break

■ Next RESIN

- **August 6, 2013 @ 12:00 p.m.**
- Location - **Walton Auditorium**, Winthrop P. Rockefeller Cancer Institute, 10th floor
- All RESIN presentations archived on the UAMS Research website
 - http://www.uams.edu/research/RESIN_Achive.asp