

# Clinical Research Informatics: An Ever Changing Journey to Support the Creation of Evidence



Patricia P. Sengstack DNP, RN-BC, CPHIMS

# Objectives

- ▶ Describe 3 strategies where informatics can support clinical research
- ▶ Identify 3 strategies where informatics professionals can use research/evidence to enhance patient care
- ▶ Discuss a leadership career pathway in the field of clinical research informatics



# Agenda

- ▶ Clinical Research
- ▶ Supporting the creation of evidence with informatics
- ▶ Supporting the use of evidence with informatics
- ▶ Leadership – My journey in supporting all of the above
- ▶ Looking to the future

# National Institutes of Health



NIH Clinical Center



# The Challenge

- Research at the NIH Clinical Center is our focus and mission
- Clinical care is important, but secondary
- We've needed to take a vendor developed system and make it work in a clinical research setting



# Types of Clinical Research

EUN  
2009

- ▶ Prevention
- ▶ Screening
- ▶ Diagnostic
- ▶ Treatment
- ▶ Quality of Life
- ▶ Compassionate Use



# Phases of Clinical Research Trials

- **Phase 1** - small group, first time
- **Phase 2** - larger group, to test effectiveness and to further evaluate its safety
- **Phase 3** - large groups, to confirm effectiveness, monitor side effects, compare it to commonly used treatments, and collect safety information
- **Phase 4** - after the drug or treatment has been marketed to gather information on the drug's effect in various populations and any side effects associated with long-term use



# Before Clinical Trials

- ▶ FDA - Rigorous process for both new medications and new medical devices
- ▶ Lengthy drug approval process
- ▶ Animal studies (short term)
- ▶ Animal studies (long term)
- ▶ Institutional Review Board
- ▶ Without rigorous testing ....

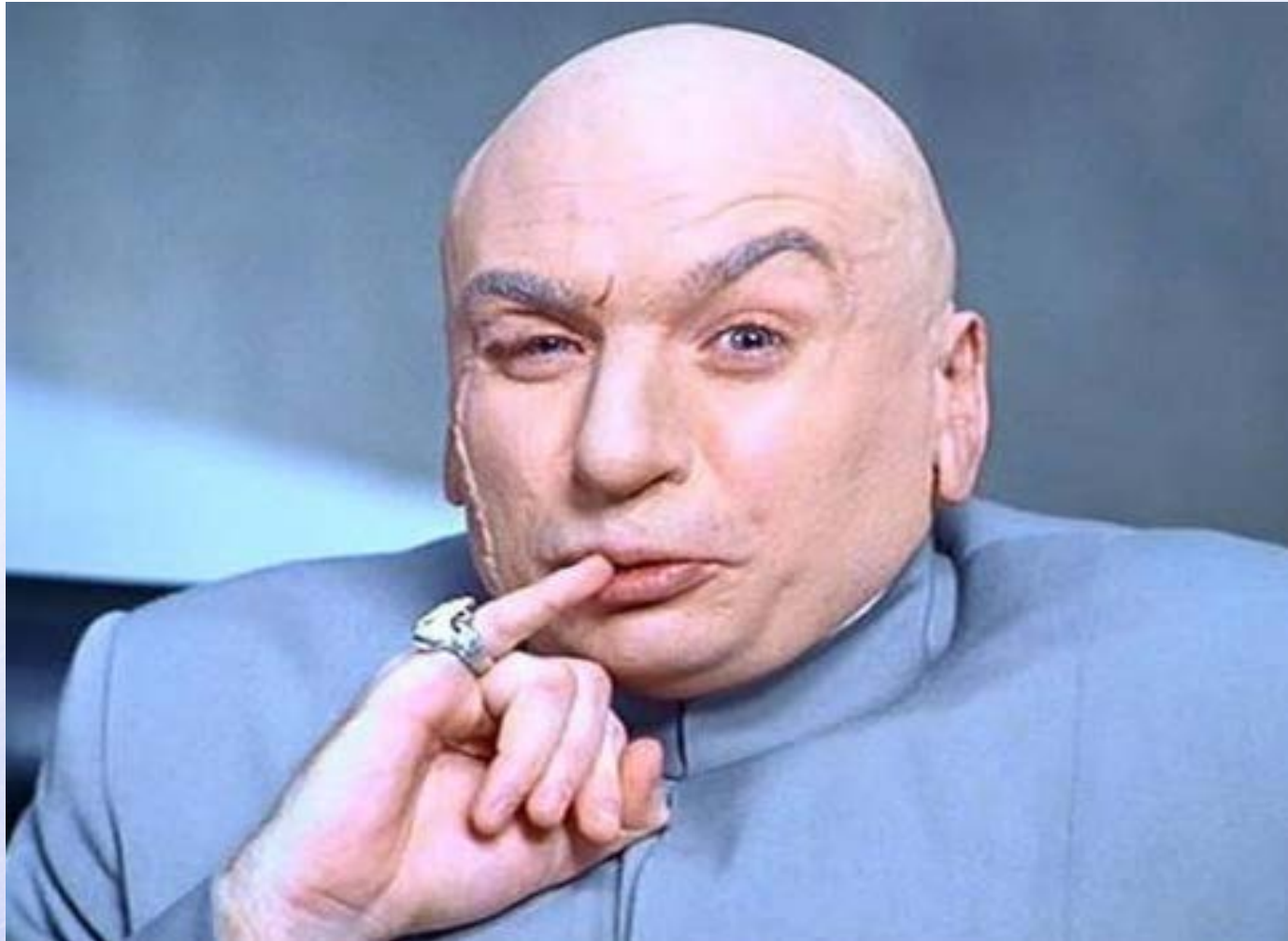


EUN  
2009





EUN  
2009



# NIH Clinical Center

- ▶ Inpatient clinical trials ~1,500 active
- ▶ Patients do not pay
- ▶ Study participants recruited worldwide
- ▶ 240 acute care beds
- ▶ 15 Outpatient clinics
- ▶ 82 day hospital beds
- ▶ Integration with 14 NIH Institute systems
  - NCI, NHLBI, NIMH, NIAID, NICHD, et.al.



# NIH Clinical Center

- 6,000 inpatient admissions a year
- 10,000 new patients a year
- 95,000 outpatient visits a year
- 1,200 credentialed physicians, dentists, and Ph.D. researchers
- 620 nurses
- 450 allied health-care professionals, such as pharmacists, dietitians, medical technologists, imaging technologists, therapists, medical records and medical supply staff.



# Department of Clinical Research Informatics - DCRI

- ▶ 96 staff members
- ▶ Both technical and clinical
- ▶ 15 Nurses – 10 graduated from U of MD NI Masters program
  - Clinical documentation configuration
  - CRIS Training
  - CRIS End User Support
  - CRIS application security
  - Bar code management
  - Orders and order set development
  - Web site management
  - Project Management



# Clinical Research Information System - CRIS

- ▶ EHR– HIMSS Analytics – level 5
- ▶ CPOE
- ▶ Result retrieval – lab, radiology, ECG
- ▶ Clinical Documentation
- ▶ Bar coding
  - Specimen collection
  - Blood product administration
- ▶ Clinical Decision Support
  - Alerts
  - Access to knowledge
  - Protocol order sets



# Clinical Research



- Patients are “research volunteers”
- <http://www.clinicaltrials.gov>
- All patients are on a research protocol
- Care is protocol based
- Protocol
  - a precise study plan for executing the clinical trial
  - to assure safety and health of the trial subjects
  - to provide an exact template for trial conduct by investigators at multiple locations




# Protocols









- Once the protocol is approved by NIH's IRB, they are 'named'
- Standard naming convention for protocols
  - Year-Institute-sequence number
  - NIDA's - Effects of Smoked Marijuana on Risk Taking and Decision Making Tasks
  - 2009-DA-0131
- Currently 1,500 active protocols



# Protocol Listing – Health Issues

- Visit Reason – this visit's primary protocol
- Protocol – other protocols for patient



	Type	Code	Health Issue	Status
	Visit Reason	00-CC-0165	2000-CC-0165	Active
	Protocol	02-CH-0195	2002-CH-0195	Confirmed
	Protocol	02-C-0052	2002-C-0052	Confirmed
	Protocol	05-CC-0175	2005-CC-0175	Confirmed
	Protocol	05-C-0010	2005-C-0010	Confirmed
	Protocol	00-C-0018	2000-C-0018	Confirmed
	Protocol	00-CC-0165	2000-CC-0165	Unconfirm
	Protocol	05-AR-0014	2005-AR-0014	Unconfirm
	Protocol	01-M-0152	2001-M-0152	Unconfirm
	Protocol	01-M-0185	2001-M-0185	Unconfirm
	Protocol	02-AT-0172	2002-AT-0172	Unconfirm
	Protocol	99-DK-0042	1999-DK-0042	Unconfirm
	Protocol	00-CH-0093	2000-CH-0093	Unconfirm



# Protocols

TEST, PATIENT LAB INPATIENT 1 - Sunrise Acute Care

File Registration Edit View GoTo Actions Preferences Tools Help

TEST, PATIENT LAB INPATIENT 1 10-00-00-7 / 050911054422 74y (07/18/1935)  
 CADRE-CC Prot: 00-CC-0165 DOB:1935Jul18

*On Isolation* Chief Complaint: TEST RUN Allergies: acetaminophen, Fortaz, Other, Alcohol, Wine

Patient List Orders Results Patient Info Summary Documents Flowsheets Clinical Summary Signout Report Appointments Protocol Info EBP InfoBot CustomTabSample

Current List: \*Lincoln Select All Patients 8 Visit(s) Save Selected Patients...

Patient Name	Patient ID / Visit Number	Birthdate	Current Location	Visit Status	Admit Date	Admit Time	Provider	Admitting Protocol
NIHCCTEST, PATIENT M...	40-63-99-5/050718136689	09/13/1961	CADRE-CC	DSC	09/30/2005	00:00		00-CC-0165
TEST, PATIENT LAB INP...	10-00-00-7/050911054422	07/18/1935	CADRE-CC	DSC	09/11/2005	00:00		00-CC-0165
TEST, PATIENT TEST	32-17-31-0/050903006833	01/01/1980	CADRE-CC	DSC	09/03/2005	00:00		05-CC-0027
NIHCCTEST, PATIENTBJ...	34-48-41-1/051005079030	01/01/1970	CC-CADRE	DSC	10/05/2005	00:00		00-CC-0165
NIHCCTEST, PATIENTBL...	34-48-42-3/050325075621	01/01/1960	CC-CADRE	DSC	03/25/2005	00:00		00-CC-0165
NIHTESTCC, PATIENTBP...	39-81-76-9/060120116107	07/18/1935	CC-CADRE	DSC	01/20/2006	00:00		00-CH-0093
TEST, PATIENT GE DRD	36-23-81-6/060120101023	08/01/1975	CC-CADRE	DSC	01/20/2006	00:00		00-CH-0093
TEST, PATIENT LAB OU...	21-09-37-2/050329004353	01/01/1956	CC-CADRE	DSC	03/29/2005	00:00		05-CC-0033



**Change Protocol Assignment - NIHCCTEST, PATIENTBP MIS**

Order: Change Protocol Assignment Order ID: 001326KQM

Requested By: Farnum, Lincoln S Template Name:

Messages: Use to add or remove a Protocol, or change a patient's Visit Reason Protocol. Changes must be approved in advance by the Principal Investigator and must be discussed in advance with the patient. Call the MRD for any questions (301) 496-2292.

Actions Requested: Please use the checkboxes provided below to identify the specific protocol changes you wish to make. Select all that apply.

Protocol Institute Instructions: Select the Institute which corresponds to the Protocols that are to be assigned to the patient. The dropdown list of protocols for that specific Institute will appear below once another field is selected.

Protocol Institute: CC

Remove From Protocol Instructions: You may also use the information in the "Add Patient To Protocol" items that follow removal to enter a patient onto another protocol directly from within this order.

Remove Patient From Protocol:  Effective Date of Removal: 08/31/2009 Reason For Removal: Completion of Protocol

CC: 1991-CC-0117 : H

- 1991-CC-0117 : HCV IN BLOOD DONORS (91-CC) : PI: Harvey J. Alter, M.D.
- 1992-CC-0141 : ENDOTOXIN IN NORMAL HUMANS : PI: Anthony F. Suffredini, M.D.
- 1993-CC-0094 : METHOD DEVELOPMENT/PT SAMPLE : PI: Thomas A. Fleisher, M.D.
- 1995-CC-0123 : EVAL OF NMDP MARROW DONORS : PI: Susan F. Leitman, M.D.
- 1998-CC-0019 : NORMAL VOL SCANNING ON MR : PI: John A. Butman, M.D.
- 1998-CC-0090 : EVALHEMATOLOGICPTSNOTRSCH : PI: Jay N. Lozier, M.D.
- 1999-CC-0163 : MR AT 3.0 AND 1.5 TESLA : PI: Joseph A. Frank, M.D.
- 1999-CC-0168 : COLLECT BLOOD/RESEARCH USE : PI: Susan F. Leitman, M.D.
- 2000-CC-0165 : PBSC DONATION BY NMDP DONORS : PI: Susan F. Leitman, M.D.
- 2000-CC-0205 : EMERGENT CARE NIH GUEST EMPL. : PI: Henry Masur, M.D.

Add Protocol Instructions: To place a patient on a protocol, you must have completed the protocol consent prior to entering this order. By entering this order you will be certifying that the consent process has been completed for the protocol specified in the order.

Add Patient to Protocol:  Effective Date of Addition: 08/31/2009 Reason For Addition: New Accrual

CC: 1995-CC-0123 : E

Item Info Repeat View Document OK Cancel



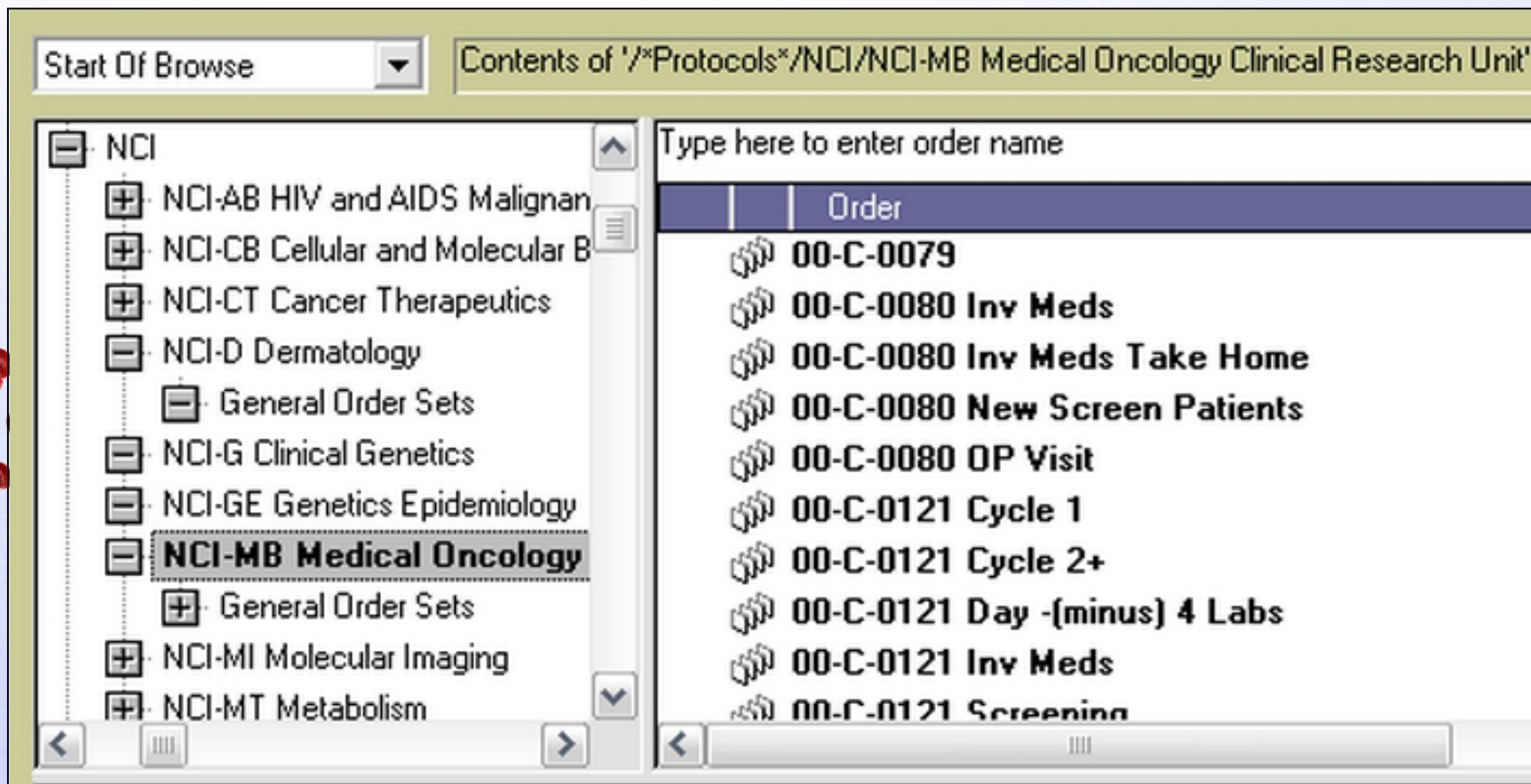
# Protocol Order Sets

- Over 2,600 Order Sets have been built
- When possible - default values are pre-entered to reduce the need for manual entry and possibility of error
- Investigational medications contained within these order sets are configured to allow only those physicians identified to place these types of orders



# Protocol Order Sets

Start Of Browse Contents of '/\*Protocols\*/NCI/NCI-MB Medical Oncology Clinical Research Unit'



Order
00-C-0079
00-C-0080 Inv Meds
00-C-0080 Inv Meds Take Home
00-C-0080 New Screen Patients
00-C-0080 OP Visit
00-C-0121 Cycle 1
00-C-0121 Cycle 2+
00-C-0121 Day -(minus) 4 Labs
00-C-0121 Inv Meds
00-C-0121 Screening

# Clinical Documentation

- ▶ Challenge: Capture the clinical care of the patient and key elements of the research process
- ▶ Embedded into multiple structured notes and flowsheets
  - Structured Notes – 143
  - Flowsheets – 39
  - Free text for direct entry – 73
  - Free text from interface – 94
- ▶ All care delivered is considered research related – or is it?
- ▶ Goal is to capture research treatment and outcomes

EUN  
2009



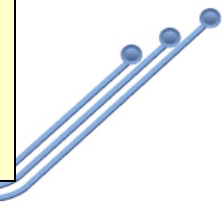
# Documentation of Protocol Consent

## Eligibility

- All baseline/screening studies have been completed and reviewed
- This patient meets all inclusion criteria
- This patient has no exclusionary criteria present

## Consent Process

- A copy of the consent was given to the patient to review prior to signing
- The protocol was discussed with the patient in a private setting
- Treatment options, adverse events, expectations of involvement while on the study and protocol schedule were discussed
- Contraception was discussed with the patient
- The patient's general responsibilities were discussed
- All patient and/or family questions were answered in full
- The patient verbalized understanding of the consent
- A copy of the consent signed by the investigator and the patient was given to the patient



# Consent Monitoring Note

Introduction		
Protocol Number	<input type="text"/>	
Conducted By	<input type="text"/>	
Attended By	<input type="text"/>	
Clinical Research Advocate Contact Information Provided	<input type="radio"/> Yes	<input type="radio"/> No
Consent Elements Discussed		
Voluntary Nature of Research	<input type="radio"/> Yes	<input type="radio"/> No
Purpose of Research	<input type="radio"/> Yes	<input type="radio"/> No
Study Design	<input type="radio"/> Yes	<input type="radio"/> No
Protocol Procedures	<input type="radio"/> Yes	<input type="radio"/> No
Risks	<input type="radio"/> Yes	<input type="radio"/> No
Benefits	<input type="radio"/> Yes	<input type="radio"/> No
Alternatives to Research	<input type="radio"/> Yes	<input type="radio"/> No

# Supporting the use of evidence





# Protocol Information Custom Tab

- The Challenge: Researchers needed easy access to information about specific patient protocols
- Information was decentralized with associated fragmented processes
- Creation of custom tab pulled together key pieces of protocol information including:
  - Access to [clinicaltrials.gov](http://clinicaltrials.gov)
  - Link to consent form - signed
  - Link to associated research via PubMed



# Protocol Info Tab

energies, aspirin, NSAIDs, Ozonol, warfarin, Citrus, Egg, Soy

- Patient List
- Orders
- Results
- Patient Info
- Documents
- Flowsheets
- Clinical Summary
- Signout Report
- Appointments
- Protocol Info
- EBP InfoBot
- Image Viewer
- Meds View
- ICD9
- CDV
- Analyst

NHCCTEST, INNA NMN      Born 06/12/1966 (46y)      Gender Female      MRN 99-99-7

Protocol Filter  Active Protocols  Inactive Protocols  All Protocols

Protocols						
Protocol Name	Type	Status	PI	Onset Date	Recruitment	Protocol Status
Description						
04-AA-0058	Protocol	Unconfirm	PI: Hibbeln	1/1/1900	Active Followup	No longer recruiting/follow-up only
<b>Positron Emission Tomography Imaging of Incorporation of Docosahexaenoic Acid (DHA) from Plasma into Human Brain</b>						
04-AR-0205	Protocol	Prot Inst Chnge	PI: Ward	11/27/2006	Active Accrual	Participants currently recruited/enrolled
<b>Progression of Spinal Fusion in Ankylosing Spondylitis</b>						
05-C-0186	Protocol	Prot Inst Chnge	PI: Kumar	5/17/2008	Active Accrual	Participants currently recruited/enrolled
<b>A Pilot Trial of Oral Topotecan for the Treatment of Refractory Advanced Solid Neoplasms Expressing HIF-1 Alpha</b>						
07-E-0023	Protocol	Unconfirm	PI: Fessler	1/1/1900	Active Accrual	Participants currently recruited/enrolled
<b>Innate Immunity Signal Transduction in Human Leukocytes</b>						
09-C-0224	Protocol	Confirmed	PI: Hardy	8/1/2009	Active Accrual	Participants currently recruited/enrolled
<b>Pilot Study of Radiation-Enhanced Allogeneic Cell Therapy for Progressive Hematologic Malignancy After Allogeneic Hematopoietic Stem Cell Transplantation</b>						
12-AA-9990	Protocol	Active	PI: Henderson	1/20/2013		
<b>Treatment IND</b>						
12-AR-8001	Protocol	Active	PI: Goldbach-Mansky	12/12/2012		
<b>Compassionate Use Treatment Protocol I4V-MC-JAGA; Treatment of Autoinflammatory Syndromes Expected to Benefit from JAK Inhibition</b>						
12-AR-9990	Protocol	Active	PI: Henderson	12/17/2012		
<b>Treatment IND</b>						
12-C-0004	Protocol	Active	PI: Kreisel	1/20/2013		

## Associated References

- Protocol Details
- PubMed
- PubMed
- PubMed

# ClinicalTrials.gov

***ClinicalTrials.gov***

A service of the U.S. National Institutes of Health

[Home](#)

[Search](#)

[Study Topics](#)

[Glossary](#)

Search

ClinicalTrials.gov is a registry of federally and privately supported clinical trials conducted in the United States and around the world. ClinicalTrials.gov gives you information about a trial's purpose, who may participate, locations, and phone numbers for more details. This information should be used in conjunction with advice from health care professionals. [Read more...](#)

## ► [Search for Clinical Trials](#)

Find trials for a specific medical condition or other criteria in the ClinicalTrials.gov registry. ClinicalTrials.gov currently has **78,675 trials** with locations in **171 countries**.

## ► [Investigator Instructions](#)

Get instructions for clinical trial investigators/sponsors about how to register trials in ClinicalTrials.gov. Learn about

## Resources:

[Understanding Clinical Trials](#)

[What's New](#)

[Glossary](#)

## Study Topics:

[List studies by Condition](#)

[List studies by Drug Intervention](#)

[List studies by Sponsor](#)

[List studies by Location](#)



This site complies to the HON standard

# Signed Consents

<b>MEDICAL RECORD</b>	<b>MINOR PATIENT'S ASSENT TO PARTICIPATE IN A CLINICAL RESEARCH STUDY</b> • Attach to NIH-2514-2, Consent to Participate in a Clinical Research Study
-----------------------	--

INSTITUTE: National Heart, Lung, and Blood Institute

STUDY NUMBER: 04-H-0012 PRINCIPAL INVESTIGATOR: Richard W. Childs, M.D.

STUDY TITLE: Collection of Blood, Bone Marrow, Urine and/or Tissue Samples from Patients with Solid Tumors, Hematological Malignancies or Nonmalignant Hematologic Disorders or HLA-Compatible Family Members

Continuing Review Approved by the IRB on 2/17/09

Date Posted to Web: 7/22/09

Amendment Approved by the IRB on 6/30/09 (R)

Minor

This form is written in a way so that even our youngest patients might better understand why this study is being done and what tests will be performed. No matter what your age, we will also give to you your own copy of the longer and more detailed consent form that your parents or guardians need to read and sign. If you are interested and able to do so, you are invited to read that longer more detailed consent form. We will also talk to you about what is in that form and explain it to you. If you have any questions about any of the way we collect samples, we are eager to answer them, so please ask questions at any time.

#### WHY ARE YOU BEING ASKED TO PARTICIPATE?

You have been diagnosed with a blood condition. We want to learn more about your blood condition, and to learn why some treatments work better than others, to discover new treatments, and to study methods of disease prevention.

#### WHAT WILL YOU HAVE TO DO?

During your treatment for your blood condition, your blood or bone marrow have been sampled. We would like to ask your permission to test some of that sample in our research laboratories.

- We may ask for a small amount of blood that was collected as part of your medical care.
- We may ask for a stool or urine sample
- We may ask you to swab the inside of your cheek
- We may ask for a small amount of the bone marrow that was collected as part of your medical care
- We may ask for a small amount of tissue that was collected as part of your medical care

#### HOW WILL I FEEL WHEN SAMPLES ARE COLLECTED?

The samples will be collected at the same time as samples for your medical care, so there will be no additional discomfort.

I have had this study explained to me in a way that I understand, and I have had the chance to ask questions. I agree to take part in this study.

Signature of Minor Patient: \_\_\_\_\_ Date: 1/08/09

Signature of Investigator: *Richard W. Childs* Date: 8/17/09

#### PATIENT IDENTIFICATION

\_\_\_\_\_

#### MINOR PATIENT'S ASSENT TO PARTICIPATE IN A CLINICAL RESEARCH STUDY

NIH-2514-2 (4-97)

P.A.: 09-25-0099

FAX TO: (301) 480-3126

File in Section 4: Protocol Consent (3)

Reviewed by: MRI

Confidential Patient Information. Unauthorized disclosure is prohibited by the Federal Privacy Act of 1974.

# EBP InfoBot

## Evidence Based Practice (EBP) InfoBot

### More Resources

- » CINAHL
- » ClinicalTrials.gov
- » Cochrane Reviews
- » Drug Information
- » Drug Search by Description
- » MedlinePlus
- » Micromedex
- » Mosbys Nursing Skills
- » Pillbox Drug Identifier
- » PubMed
- » Scopus
- » Turning Research Into Practice
- » UpToDate

### CRIS Data

46y Male Chief Complaint: [DIVERTICULOSIS](#)

### Medications

acetaminophen  
aspirin  
cyclobenzaprine  
diphenhydramine  
enoxaparin

### Pill Box images

cyclobenzaprine  
fluconazole  
moxifloxacin

### Protocol(s)

[12-C-0175](#)

[99-C-0128](#)

### Procedures and Standards of Practice

### MedlinePlus

[DIVERTICULOSIS](#)

## Evidence Based Practice Search Results

DIVERTICULOSIS

Search Clear

check spelling  has abstract  English  Human  Subsets  Preference

[Meckel diverticulum: ten-year experience in adults.](#) *South Med J* 2004

more ...

[Large diverticulum and volvulus of the small bowel in adults.](#) *World J Surg* 2005

more ...

[\[Prevalence of diverticulosis and colon tumors among adult population of Moscow with constipation and symptoms of anxiety \(according to population-based study MUSA\)\].](#) *Eksp Klin Gastroenterol* 2011

more ...

[\[Prevalence of diverticulosis and colon tumors among adult population of Moscow with constipation and symptoms of anxiety \(according to population-based study MUSA\)\].](#) *Eksp Klin Gastroenterol* 2011



[Evaluate the InfoBot](#)



### Not Searched

These resources require a login or are not included in the search.

#### Administrative

Abbreviations  
Admissions, Travel and Vouchers  
Med Admin Series Policies  
Occurrence Reporting System  
Protocol Consent

#### Biomedical Information

DXplain  
LiverTox  
NIH Library Research Tools

#### Drugs and Chemicals

Chemical MSDS  
Pharmacy Department

#### Laboratory

Dept of Laboratory Medicine  
Dept of Transfusion Medicine Pathology  
NCI CCR Laboratory of Pathology

#### Nursing

Mosby's Nursing Skills  
Nursing Intranet

#### Patient Education

CRC Patient Education

#### Patient Tracking

StatCom  
TM ECGVue

#### People

102 Pager Website  
Medical Staff Directory  
NED

### Searched

Keywords were placed directly into the search box of each resource and return the number of records. The retrieval depended on the capabilities, functionalities and limitations of the resource. To refine or improve the search, go directly to each resource.

#### Administrative

Medical Administration Series Policies - 0

#### Biomedical Information

AccessMedicine Books - 4  
Harrison's Online - 4  
MDConsult Books - 197  
PubMed @ NIH - 8,297  
UpToDate - 11

#### Clinical Trials

ClinicalTrials.gov - 2  
Search the Studies - 0

#### Drugs and Chemicals

Drug Information Portal - 5  
Formulary - 0  
Goodman & Gilman's - 2  
Micromedex 2 - 8  
Pharmaceutical MSDS - 0

#### Evidence-Based Medicine

ACP Journal Club - 0  
Cochrane Reviews - 0  
TRIP - 59

#### Laboratory

DLM Master Test Guide  
Quick Search - 0  
Test Code Search - 0  
Tube Code - 0


#### Nursing

CINAHL - 20

#### Patient Education

Micromedex CareNotes - 0

# Meds View Tab



Navigation tabs: Patient List, Orders, Results, Patient Info, Documents, Flowsheets, Clinical Summary


View Level: - + [Color Selection] \*ACTIVE Filter\* Filters Details Comments ? Allergies: No Known All

Med Summary - Past Orders Filter Date >= 04/28/2013

<b>acetaminophen</b>	(Current 1, Past 0)
<b>albuterol</b>	(Current 0, Past 1)
<b>albuterol-ipratropium</b>	(Current 0, Past 1)
<b>ampicillin-sulbactam</b>	(Current 0, Past 1)
<b>aspirin</b>	(Current 1, Past 0)
<b>calcium gluconate</b>	(Current 0, Past 5)
<b>cyclobenzaprine</b>	(Current 1, Past 0)
<b>diphenhydramine</b>	(Current 1, Past 1)
<b>enoxaparin</b>	(Current 1, Past 1)
<b>fluconazole</b>	(Current 1, Past 1)
<b>furosemide</b>	(Current 0, Past 7)
<b>hydromorphone</b>	(Current 0, Past 3)
<b>ibuprofen</b>	(Current 0, Past 1)
<b>iohexol</b>	(Current 1, Past 1)
<b>linezolid</b>	(Current 1, Past 0)
<b>loperamide</b>	(Current 1, Past 1)
<b>micafungin</b>	(Current 0, Past 1)
<b>moxifloxacin</b>	(Current 1, Past 0)
<b>Naloxone Inj</b>	(Current 2, Past 8)
<b>oxycodone</b>	(Current 1, Past 0)
<b>phenol topical</b>	(Current 1, Past 0)
<b>potassium chloride</b>	(Current 0, Past 14)
<b>Sodium Chloride, Injectable</b>	(Current 0, Past 4)

Context menu for **albuterol-ipratropium**:

- Refresh Meds List
- MicroMedex
- Medline Plus
- PubMed - Medline
- Clinicaltrials.gov for Med
- Clinicaltrials.gov for Protocol
- Copy Order ID to Clipboard





# Leadership in Clinical Research Informatics

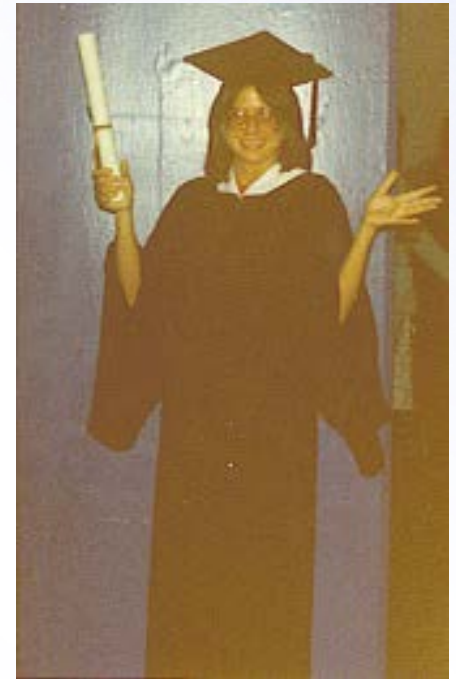


## The Journey



# The Journey

- ▶ BSN, University of Maryland – 1982
- ▶ Go Terps!







# The Journey

- ▶ Masters in Nursing/Healthcare Administration, U of MD - 1988
- ▶ Post Master's Nursing Informatics, U of MD – 2002
  - Transitioned from Clin Spec to IT department at Adventist Healthcare
  - 2003 hired by CSC to work on CRIS project at NIH
  - 2007 hired by NIH as Deputy CIO, Clinical Center



# The Journey

- ▶ DNP, Vanderbilt – 2010
- ▶ ANIA President, May 2013



# Steps to Successful Leadership

- ▶ Lifelong learning – continue to educate yourself
- ▶ Knowledge is power – or at least it gives you a step up in most cases
- ▶ Stay neutral – consider all opinions and options before making decisions (data!)
- ▶ Listen
- ▶ Learn to write well and publish
- ▶ Volunteer on organization-wide committees
- ▶ Volunteer to give presentations

# Steps to Successful Leadership

- ▶ Learn to negotiate
  - Deputy CIO, Chief of Clinical Informatics at the NIH Clinical Center
    - Title
    - Salary
    - Benefits
- ▶ Provide ongoing positive feedback
- ▶ Laugh at yourself



# Words of Wisdom

- ▶ Pass the feather
- ▶ Hire people smarter than you and give them the resources they need to do great work
- ▶ Don't take yourself too seriously
- ▶ Keep a pair of sneakers under your desk
- ▶ “Hey Dad, if you're not the lead duck, you're looking at butts!” (Dr. Kevin Fickenscher's 7 year old daughter)





# Little Things Count

- ▶ Be on time
  - To meetings
  - Deliverables
- ▶ Put your cell phone away at meetings
- ▶ Sit up straight and listen!
- ▶ Don't interrupt
- ▶ Proof read all emails before hitting send
- ▶ Close the loop on communication



# Looking to the Future

- ▶ Pharmacogenomics
- ▶ Mobile devices
- ▶ Patient engagement
- ▶ Big Data
- ▶ Sequestrations impact on research

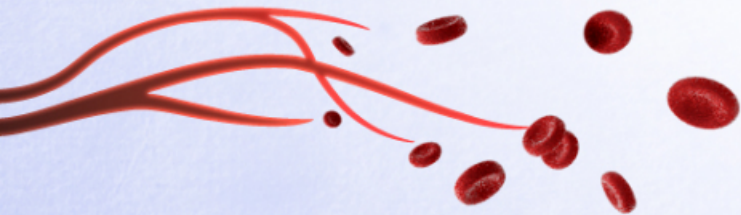


# Looking to the Future

- ▶ Demographic changes
- ▶ Chronic illnesses
- ▶ Medical home/ACOs
- ▶ Mobile electronic scooters



# Questions?



Thank you!

Patty Sengstack  
psengstack@cc.nih.gov