

Coordinator Meeting

April 23, 2007

Welcome.....Margie Brackeen

Margie welcomed everyone and announced that Janet Storment was out of town and would not be attending.

Announcements:

- ❖ Looking for Volunteers for Mom and Me Expo on May 5th. Contact Janet if you would like to volunteer. This is a good chance to advertise your open trials. Be sure to use IRB approved advertisements if you decide to attend.
- ❖ Mock Trial: The Mock Trial is an ACHRI event which will take place on June 18, 2007. The participants were given advertisements to hang in their areas to advertise this event. 4 hours of CNE will be available for the participants who attend.

W9 formsLaura Birdwell

Robyn Graham and Julie Jaekel attended the meeting and answered questions relating to the transmittal of W-9 forms to accounting.

Research Coordinator

NetworkMargie Brackeen

Margie demonstrated the new Research Coordinator Network website

(<http://achri.archildrens.org/guidebook/rcn.html>)

- ❖ Margie asked for any suggestions for this website to be emailed to her as this project evolves.

Foster Children in

ResearchTanda Grisham

Tanda Grisham discussed the use of foster children in research and the new directive from DHHS was given to the participants. (attached)

IRB Training SurveyMargie Brackeen

A survey was presented to the participants asking to rate the current IRB training tool (attached)

STS update.....Janet Storment

Margie announced that the STS system update is still being worked on and that Janet will have updates at the next meeting.

Dangerous Material

Training UpdateJanet Storment

Due to the request for a shorter Dangerous Material Training course, Janet is working with the shipping area to develop a CHEX module which can be used for coordinators who need to ship samples etc. This will be coming online in the next months.

Booth Data Collection Form.....Margie Brackeen

A rough draft of a data collection form for the booth was given to the participants. This will be given to interested parties to collect data for the new database of subjects to be developed soon. The participants were asked to look at this draft and suggest changes to Janet. (attached)

Open Forum..... ALL

No open forum items were discussed.

Meeting was adjourned at 12:00pm

Please complete the following survey concerning the required Institutional Review Board (IRB) training.

For questions 1 through 4 use the following scale

1 = strongly agree 2 = agree 3 = disagree 4 = strongly disagree

1. The subject matter covered on the current IRB training modules and quizzes is applicable to my position at ACH.
1 2 3 4

2. The questions on the current IRB training module quizzes are clear and test on what was presented.
1 2 3 4

3. The content of the current IRB training modules is clear and easy to understand.
1 2 3 4

4. I would like to add a refresher course to this training tool which is shorter and covers current topics in research.
1 2 3 4

Use the following scale for question 5:

1 = excellent 2 = acceptable 3 = needs work

4 = should be replaced

5. Overall I would rate the current IRB Training tool:
1 2 3 4

Comments:

Save the Date!

A Special Grand Rounds Presentation of:

Clinical Research on Trial: A Mock Trial of Current Legal Issues

CJ Craig

Plaintiff, injured patient/research participant

Vs.

Marcus Welby, MD

Defendant, physician/investigator

&

Irby Chair, MD

Defendant, IRB Chair

Mock Trial Demanded

Chairman's Hall, Sturgis Building-- Arkansas Children's Hospital

Monday June, 18, 2007

8:00 am – 2:00 pm

This presentation is a fictional jury trial based on an actual case. It will demonstrate core ethical, legal and regulatory issues in human subjects' research while helping researchers, research staff, research administrators, and residents recognize and address the challenging and sometimes controversial aspects of a clinical trial.

Participants:

- **Robert Steinbuch, Esq** (Assistant Professor of Law; UALR Bowen School of Law) as Judge
- **Attorney Amy Stewart, Esq** (Rose Law Firm) as Plaintiff's attorney
- **Attorney Jason Hendren, Esq** (Friday, Eldredge & Clark) as Defendants' attorney
- **Cassandra Woods** (Human Resources; ACH) as the plaintiff CJ Craig
- **Del Farris M.Div.** (Chaplain; ACH) as Defendant Marcus Welby MD
- **Gary Cameron, MSA RN** (Nursing Education; ACH) as Defendant IRB Chairperson
- **Janet Storment RN CCRC** (Clinical Trials Administrator; ACHRI) as Nurse Clara Barton
- **Lee Smith, CRA** (Research Administrator, ACHRI) as Bailiff

CME/CNE credit will be available

Registration will be required via the ACH Training System

No fee will be charged to ACH/UAMS faculty, staff, residents, IRB members or employees;

Sponsored by:

Arkansas Children's Hospital Research Institute Human Subjects Protections Area

University of Arkansas for Medical Sciences –Department of Pediatrics

For additional information contact **Margie Brackeen** at brackeenmargie@uams.edu or 501-364-3586

This activity has been planned and implemented in accordance with the Essentials and Standards of the Accreditation Council for Continuing Medical Education through the joint sponsorship of University of Arkansas for Medical Sciences (UAMS) College of Medicine and Arkansas Children's Hospital. The UAMS College of Medicine is accredited by the ACCME to sponsor continuing medical education for physicians.

The UAMS College of Medicine designates this educational activity for a maximum of 4.0 AMA PRA Category 1 credit(s)™. Physicians should only claim credit commensurate with the extent of their participation in the activity.

CNE: Arkansas Children's Hospital is an approved provider of continuing nursing education by the Arkansas Nurses Association. The Arkansas Nurses Association is an accredited approver by the American Nurses Association's Credentialing Center's Commission on Accreditation. **This activity provides 4.0 contact hours.**

Speaker Disclosure: Nothing to disclose.

Foster Children in Research:

Foster children are in the custody of The Arkansas Department of Health and Human Services (DHHS) and are considered “wards of the state.” As such, only DHHS may provide consent for their participation in research. Specifically, since foster care is under the Division of Children and Family Services (DCFS), the Director of that division will review all requests for research projects. Foster parents *cannot* provide consent.

If you are considering a research project that specifically targets these children, you will need to contact the DCFS Director before you draft the protocol. There are special considerations that must be addressed and the DCFS staff is ready and willing to assist you in your efforts to protect this special population.

If your research targets a general population and you encounter a child in foster care who would qualify as a study participant, please fax the following to the DCFS Director’s office:

(1) A cover letter describing:

- (a) The nature of the project,
- (b) The Principal Investigator and Research Coordinator’s contact information (telephone numbers and email addresses) and
- (c) The timeframe you need for the consent process to be completed; and

(2) A copy of the consent form.

DCFS contact information is as follows:

Phone: (501) 682-8770

Fax: (501) 682-6968

700 Main Street

P.O. Box 1437, Slot S560

Little Rock, AR 72203-1437

Please check the study opportunity areas that you or a loved one may be interested in. All information is held in strict confidence.

Arkansas Children's
Hospital Research
Institute
501-364-2760

PLEASE PRINT

Name _____
 If minor, parents' name _____
 Street Address _____
 City _____ State _____ Zip _____
 Home (____) _____ Ok to leave message? Y or N
 Work (____) _____ Ok to leave message? Y or N
 Email Address _____
 Birthday ____/____/____
 Male Female

African American Caucasian Hispanic/Latin American
 Native American Oriental/Asian Other : _____

By signing below, I hereby authorize Arkansas Children's Hospital Research Institute to retain this information and to use this information internally solely to assess my eligibility for current/future research studies or to inform me of current/future research studies. I understand and agree that the information I have provided will not be disclosed or sold to any third party.

Signature

Printed Name

Date

- | | | | |
|--|---|--|---|
| <input type="checkbox"/> Acne | <input type="checkbox"/> Cold Sores | <input type="checkbox"/> Headache | <input type="checkbox"/> Ulcers |
| <input type="checkbox"/> ADD/ADHD (circle one) | <input type="checkbox"/> Crohn's Disease | <input type="checkbox"/> Migraine | <input type="checkbox"/> Ulcerative Colitis |
| <input type="checkbox"/> Allergies (Seasonal) | <input type="checkbox"/> Diabetes Type: _____ | <input type="checkbox"/> Tension | <input type="checkbox"/> Urinary Incontinence |
| <input type="checkbox"/> Asthma | <input type="checkbox"/> Tingling/Burning Sensation
in Hands or Feet | <input type="checkbox"/> Healthy | <input type="checkbox"/> Urinary Tract Infections |
| <input type="checkbox"/> Arthritis | <input type="checkbox"/> Kidney Disease Assoc.
w/Diabetes | <input type="checkbox"/> Heartburn | <input type="checkbox"/> Yeast Infections |
| <input type="checkbox"/> Osteoarthritis | <input type="checkbox"/> Eye Disease Assoc.
w/Diabetes | <input type="checkbox"/> High Blood Pressure | <input type="checkbox"/> Other (Please List)

_____ |
| <input type="checkbox"/> Rheumatoid | <input type="checkbox"/> Depression | <input type="checkbox"/> Insomnia | |
| <input type="checkbox"/> Bronchitis | <input type="checkbox"/> Dermatitis Type: _____ | <input type="checkbox"/> Irritable Bowel Syndrome | |
| <input type="checkbox"/> Cancer Type: _____ | <input type="checkbox"/> Dry Eye | <input type="checkbox"/> Psoriasis | |
| <input type="checkbox"/> Canker Sores | <input type="checkbox"/> Endometriosis | <input type="checkbox"/> Seizure Type: _____ | |
| <input type="checkbox"/> Chronic Pain | <input type="checkbox"/> Genital Herpes | <input type="checkbox"/> Sinus Infection | |
| <input type="checkbox"/> Claudication | <input type="checkbox"/> GERD | <input type="checkbox"/> Skin Disorder Type: _____ | |
| <input type="checkbox"/> Constipation | | <input type="checkbox"/> Toe Nail Fungus | |