



Arkansas Children's Hospital Research Institute

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November 19, 2007

Present: Janet Storment, Rita Brown, Mark McGhee, Kara Smith, Harper Grubbs, Margie Brackeen, Kim Bobrosky, Laura M. Rule, Hope Mullins, Alex Reading-Meyer, D'Ann Pierce, Glenda Hefley, Billy Furgerson, Cindy Moreau, Tara Hubbart, Anne Hiegel, Pat Brady, Dana Simshauser, Suzanne Carlisle, Nancy Chambers

1. Clinical Trial Web-Site- Mr. Grubbs introduced the clinical trial web site that will be available on the ARCHILDRENS.ORG web site. There several comments and recommendations that will be taken into consideration as the development proceeds. The expected go live date is November 21, 2007.
2. Mark McGhee handed out a form to be used when requesting a trial is listed on the web site. The coordinator should submit this form as well as the letter from the IRB stating approval when requesting that a trial be listed. The web-site and data base will be managed by Mark McGhee. This form will be available on the Coordinator Network web site located on the ACHRI web site.
3. Research in the clinics was discussed and Laura M. Rule was a guest today to discuss a few of the recent issues. Communication with the clinic staff and the appropriate director would be a big help. It was requested that the coordinators notify the directors and the clinic staff of a pending study noting the expected start and stop dates of the project if known. It was also requested that the clinic staff be notified of upcoming study visits and what the staff responsibilities will be. The current list of clinic directors will be added to the Coordinator Web-Site.
4. Margie Brackeen- Reviewed the ACHRI Top 10 Audit Findings in David Letterman fashion.
5. Margie Brackeen- Demonstrated the Coordinator web-site and all the information that can be found at this site.
6. Other Business:
PCRU: The unit is getting busier and with all the people in the unit it can get quite loud. It has been asked that each coordinator do their part in trying to keep the noise level at a minimum as to not bother the others that are also conducting research in the unit.
CFR 21 Part 11 Consultants: ACHRI had a group of consultants evaluate our institution in regards to our compliance to the FDA regulation. We are expecting a

list of needed SOP's that will need to be developed as a result of the evaluation. Please be thinking of needed SOP's for your area. Kim Bobrosky mentioned that ACHRI will be looking to have available SOP template for everyone to use when developing their SOP's.

Next Meeting will be February 2008 – Date to be sent out in January.

Prepared by Janet Storment, RN, CCRC
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