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# THE MFMU NETWORKER

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## Study Updates

**BEAM:** Data forms for the infant follow-up were pilot tested at a successful two day training session for twelve pediatric examiners at the Johns Hopkins Kennedy-Krieger Institute, May 18-19. Revised forms and manual for the follow-up exams were sent to centers June 3. Another five examiners were trained June 11-12. The examiners will return in a year for more training and meanwhile are required to submit one videotaped exam to Dr. Peter Blasco for review.

**Terbutaline:** The final data forms, manual and certification materials were mailed to centers on June 3. A final training conference call was held with coordinators on June 12 and pharmacists on June 16. Study drugs are being prepared by EMINENT Company and are being sent to the centers in mid June. Centers can begin the study as soon as they are certified.

**Progesterone:** All centers are certified; about six are actively screening patients. As of June 10, 35 patients have been randomized.

**Asthma Studies:** Only one patient from the Asthma Observational study has been enrolled in the ancillary study to collect maternal and cord vein blood. Enrollment for the Observational Study is nearing the end; only 40 more are needed for the moderate severe group. An announcement to stop recruiting should be forthcoming early this fall.

## DSMC Recommends New Eligibility Restriction for Asthma RCT

The Asthma subcommittee has approved the Data and Safety Monitoring Committee's recommendation, from their April 16 conference call, that only patients who regularly take asthma medications may be randomized to the moderate group of the RCT. It is expected that this new criteria will decrease the current rate of enrollment by 40%. Network PI's must approve this eligibility change.

The DSMC will discuss the TV and Fetal Fibronectin Trials during a June 30 conference call. All current ongoing Network trials will be reviewed at a DSMC meeting on October 6.

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## August 20 is SMFM Deadline for Abstracts

The Publications Committee held a conference call on June 17 to prioritize all the ideas proposed for abstracts to be presented at the next Society of Maternal Fetal Medicine's annual meeting (previously known as SPO). Fewer abstracts will be submitted by the MFMU Network this year in order to allow BCC staff and investigators to devote more time towards bringing new studies on board. The subcommittee hopes that the abstract for the primary outcome of the BV trial will be selected for a plenary session. All abstracts must be received by SMFM by August 20, which is an earlier date than usual. A conference call to review the final abstracts will be held during the second week in August.

**Important Reminder:** Instead of the usual July Steering Committee meeting, the Coordinators' conference call will be July 13 and the Principal Investigators' conference call will be July 14. The next Steering Committee meeting is October 22-23.

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## Two New Studies in the Works

Efforts to get two new studies up and running in the MFMU Network have intensified. Data forms are well underway and the manual of operations is being written for the C Section Registry. Dr. Mark Landon and Francee Johnson will be meeting with the BCC in July to go over more details. Sharon Leindecker, following her successful completion of her master's degree, has been appointed as the project statistician. Molly Fischer and Liz Thom are also actively involved in study preparations. This study is anticipated to be online by early fall.

BCC staff is working with Co-PI's, Drs. Wapner and Dudley on finalizing protocol details and a draft of data forms for the Safety and Efficacy of Repeated Steroids trial. Study drug is being provided by Schering Pharmaceuticals; however, the placebo injection drug will most likely have to be specially manufactured for this trial. Hopeful plans are to have this trial underway by the end of the year.

*On the Light Side*

## People in the News

◆ Congratulations to **Sharon Leindecker**, BCC research assistant, who received her masters degree in statistics from GWU in May. Sharon, who also has a MBA, has been named as the project statistician for the C Section Registry.

◆ **Rachel Copper**, MFMU Network nurse coordinator at UAB, has been promoted to be Assistant to the Director for the Center for Research in Women's Health at UAB. We will miss her input to Network research, but expect that UAB research efforts will remain at high standards under her direction. Congratulations and thanks, Rachel, for all your contributions to the Network. Best wishes for success in your new job.

◆ **Anita Das** is undertaking her second annual AIDS Ride June 17-21. After being bused to Raleigh, North Carolina, more than 1900 people will cycle 350 miles to Washington, DC. Thanks, Anita, for all your efforts (including other volunteer work) for people with AIDS.

◆ **John Hauth**, MD, has been named the new Vice Chairman for Research and Director, Center of Women's Research at the University of Alabama. Congratulations, John!!

◆ It was reported that **Ron Wapner**, MD, received a ticket for jay walking in Los Angeles at a recent conference! The policeman wasn't sure he had the correct identification, however, because he couldn't read Dr. Wapner's signature. Ah, why is it so hard to read doctors' handwriting?

## NICHD MFMU Network Documents Posted on the Web Sites

To remain current with NICHD MFMU Network action items, Steering Committee meeting minutes, dates, latest versions of protocols, manuals and data forms, etc. remember to check the MFMU Network web sites. To get your center specific userid and password for the BCC web site containing study specific material, call or email Lucy Leuchtenburg at the BCC (you can directly access her email address from the web site). Please refer to the handout from the April Steering Committee meeting for a summary of the two web sites.

- NICHD MFMU Network Web Site: <http://www.mfmnetwork.org>
- MFMU Network Biostatistical Coordinating Center (BCC) Web Site: <http://www.bsc.gwu.edu/~mfmweb>

