



# ORTHOPAEDIC TRAUMA RESEARCH CONSORTIUM



## Investigators Meeting Minutes

October 16, 2008

11:15 am to 12:30 pm

Denver, CO

Thank you everyone for the time and effort you each gave to make the Orthopaedic Trauma Research Consortium Investigators Meeting a priority during the OTA Annual Meeting. The meeting was a success due in large measure to the excellence of the PI's and RC's involved. I thank you and look forward to seeing you in Las Vegas at the 2009 AAOS Annual Meeting.

Below are the meeting action items and minutes. Please review them and send any edits to me by October 31, 2008.

### ACTION ITEMS

- Please confirm that your site is listed under the correct study of interest (Page 4).
- Please send your multicenter study ideas to Paul. A survey with new study ideas will be sent to determine sites interested in participating.
- Please enter all CRF and x-ray data for IMPRESS and SOLVED into the Online Data Capture System.
- Coordinators and/or PI's who have not been trained on the online randomizer or data capture system should notify Mark to set up a training time. User ID's and passwords will be given once a study is approved by your IRB.

### ATTENDANCE

Julie Agel  
Tigist Belaye  
Brett Crist  
Roy Davidovitch  
Robin Driver  
Ken Egol  
Thomas Ellis  
William Ertl  
Eric Farrell  
Darin Friess  
Mike Gardner  
Emily Hui  
Cliff Jones

Phil Kregor  
Mark Lee  
Bob Marburger  
Michael McKee  
Amer Mirza  
Yvonne Murtha  
Sean Nork  
Bill Obremskey  
Robert Ostrum  
Hans-Christoph Pape  
Laura Phieffer  
Claude Sagi  
Emil Schemitsch

Andy Schmidt  
Jodi Siegel  
Deb Sietsema  
Rena Stewart  
Dave Teague  
Paul Tornetta  
Jennifer Vest  
J Tracy Watson  
Ray Wright  
Pat Yoon  
Mary Zadnik  
Mark Zocchi



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**II ONLINE DATA CAPTURE SYSTEM AND RANDOMIZER**

Paul gave a brief overview of the Electronic Data Capture System (EDCS). The system allows users to enter all CRF's and X-rays into a secure, password protected, online database. The database tracks future and past due visits, complete and incomplete CRF's, monitors patient enrollment, etc.

- \* IMPRESS and SOLVED are running on the EDCS (randomization and data entry)
- \* CRFs were shown of The SE Ankle Fracture study:
  - \* Online randomization is available for this study
  - \* Online CRF and x-ray data entry will be available by mid November
- \* The Sacral fracture study is anticipated to be available on the EDCS in 2009

**III STUDIES CURRENTLY ENROLLING**

The status of our current studies was discussed:

- \* 25 Sites have IRB approval for IMPRESS
- \* 21 Sites have IRB approval for SOLVED
- \* 6 Sites have recently begun enrollment in Ankle with 6 more seeking IRB approval
- \* 6 Sites have IRB approval for the Sacral study

IMPRESS, SOLVED, SE Ankle Fractures, and Scapula Fractures are currently enrolling patients. Enrollment has picked up in the IMPRESS and SOLVED studies and started out very strong in the Ankle study.

- \* 25 Subjects randomized into IMPRESS
- \* 35 Subjects randomized into SOLVED
- \* 32 Subjects have been enrolled in the Ankle study within 5 months

All centers were encouraged to keep screening for potential subjects. Sites were reminded that it is especially important to carefully screen out patients unlikely to follow-up. Coordinators can refer to the *Study Retention Guide* now available on the OTRC website for patient enrollment tips.

**IV NEW STUDIES**

New, recently opened studies were discussed:

- \* Study protocols and data forms are available to download on the OTRC website, [www.orthotraumaresearch.com](http://www.orthotraumaresearch.com)
- \* To participate in a study or for submission questions, please contact Mark Zocchi.
- \* **All PI's are encouraged to submit new study ideas to the group.**

1. **Sacral Fractures Study:** A Multicenter Prospective Cohort Study of Sacral Fractures Using Patient Based and Objective Outcomes.

- \* *Study Overview:* 1) Prospective cohort trial 2) Radiographic and clinical outcomes 3) Look for the grey areas 4) Outcome versus displacement 5) Decision making, etc.
- \* *Inclusion criteria:* Adults 18 – 80 with unilateral sacral fractures.
- \* *Exclusion criteria:* Patients unable to comply with outcome measures, prisoners, pregnant women, those with APC injuries, Zone 3 sacral fractures, and those unable to comply with follow-up.



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2. **rhBMP-2 Study** (Critical Size Tibia Defect): rhBMP-2 vs. Autograft for Critical Size Tibial Defects: A Multicenter Randomized Trial.
  - \* *Study Overview:* 1) rhBMP-2 vs. Autograft 2) IDE approval from FDA 3) 50 patients 4) Per-patient funding through OTA 5) Randomization with envelopes
  - \* *Inclusion criteria:* Adults 18 – 65, able to consent, uninfected, open fracture with critical defect treated with a tibial nail.
  - \* *Exclusion criteria:* Pregnancy, transient, prisoner, bone metabolic defect, nursing mothers, liver or kidney disease, autoimmune disease, immune deficiency, prior tumor in the extremity, elevated CRP, intraoperative (+) gram stain or appearance of infection

### V GRANT SUBMISSIONS AND AWARDS

Paul reviewed all submitted and awarded grant money:

<i>Agency</i>	<i>Study</i>	<i>Amount Awarded</i>
OTA	IMPRESS	\$80,000 (\$500/pt for 1-year follow-up)
OTA	SOLVED	\$80,000 (\$500/pt for 1-year follow-up)
OTA	rhBMP-2	\$63,000 (\$1,000/pt for 1-year follow-up)
FOT	Sacral fractures	\$30,000 (for database development)
OTC/AIOD	Ankle fractures	submitted

### VI NEXT MEETING

The next proposed OTRC Investigator’s Meeting will be scheduled during the 2009 AAOS Annual Meeting in Las Vegas.



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### VII CO-INVESTIGATOR SITES

Please confirm that your site is listed under the correct study of interest.

- \* If not listed under a study you would like to participate in contact Mark or Paul.
- \* If incorrectly listed under a study contact Mark or Paul.

	IMPRESS	SOLVED	ANKLE	SCAPULA	SACRAL	rhBMP
Barnes-Jewish Hospital	X	X	X	X	X	
Boston Medical Center	X	X	X	X	X	X
Brown University	X	X				
Campbell Clinic	X	X			X	
Carolinas Medical Center		X		X		X
Cooper University Hospital	X	X			X	
Duke University Medical Center	X	X				
Halifax, Nova Scotia			X			
Hamilton General Hospital		X			X	
Harborview Medical Center	X				X	
Hennepin County Medical Center	X	X	X	X	X	
Indiana University	X	X	X	X	X	X
John Peter Smith Hospital	X	X				
Mayo Clinic Rochester	X	X			X	
New York University	X	X	X			
Ohio State University	X	X	X		X	
Oregon Health & Science University				X	X	
Ortho. Assoc. - Fort Worth	X	X	X	X	X	X
Ortho. Assoc. - Grand Rapids	X	X	X	X	X	
Ortho. Assoc. - North Texas						X
Sydney Ortho. Trauma Recon. Surg.			X			
St. Louis University	X	X			X	X
St. Michaels, Toronto	X				X	
Tampa General Hospital	X	X				X
UC Davis		X	X		X	
UC San Francisco						X
UMASS Medical Center	X	X				
University of Alabama Birmingham	X					X
University of Maryland Baltimore	X	X				
University of Michigan	X	X	X		X	
University of Minnesota					X	
University of Missouri						X
University of Oklahoma	X	X	X	X	X	X
University of Pittsburgh	X	X			X	
University of Rochester	X	X				
Vanderbilt University		X				X
Victoria Hospital	X					
Wake Forest University						X