

Children as Stem Cell Donors in Research

When is it ethical? When is it approvable?

Friday, March 13, 2015

AGENDA

WELCOME AND INTRODUCTIONS

8:00 Nirali N. Shah, MD, MHS, Dave Wendler, PhD

SESSION I: REGULATIONS GOVERNING PEDIATRIC RESEARCH

8:00-8:30 **Review of Regulations Governing Pediatric Research**

Jerry Menikoff, PhD
Director, Office for Human Research Protections

8:30-9:00 **Applying the Regulations to Minor Donors**

Dave Wendler, PhD
Head, Unit on Vulnerable Populations, Department of Bioethics, NIH

9:00-9:30 **Discussion; Q&A**

9:30-9:45 Break

SESSION II: RISKS & BENEFITS TO DONORS AND NOVEL USES AND INDICATIONS

10:30-10:50 **Medical Risks and Benefits for a Minor Donor**

Michael Pulsipher, MD
Chair, Pediatric Blood and Marrow Transplant Consortium

10:50-11:10 **Psychosocial Risks and Benefits for a Minor Donor**

Galen Switzer, PhD
Co-Chief, Measurement Core, VA Center for Health Equity Research and Promotion

11:10-11:30 **Novel Uses for Donor Products**

Terry Fry, MD
Head, Hematologic Malignancies, Pediatric Oncology Branch, National Cancer Institute

11:30-12:00 **Discussion; Q&A**

12:00-1:00 Lunch

SESSION III: CURRENT STRATEGIES ADDRESSING DONORS IN RESEARCH

1:00-1:45

NMDP Approach to Adult Donors on Research Protocols

Roberta King, MPH

Vice-President, Center for International Blood and Marrow Transplant Research

Proposed Algorithm for Minor Donors on Research

Nirali N. Shah, MD, MHS

Clinical Investigator, Pediatric Oncology Branch, National Cancer Institute

SESSION IV: WORKING GROUPS

1:30-3:00

Working Groups

- Risk Analysis

Co-Chairs: Michael Pulsipher, MD & Galen Switzer, PhD

Goals: In the growing era of novel uses for donor products and increasing indications for cellular therapy and transplantation, the goals for this group are to help define what procurement procedures and therapies currently fall within a well-established standard of care. Identifying current standard practices and associated risks will help to serve as a metric against which donor risk assessment for future studies can be measured.

- Subpart D, 405 (Direct Benefit) and 406 (Subject's Condition)

Steven Joffe, MD,

Goals: Due to the intense debate over whether healthy related minor donors are recipients of direct benefit, the goals of this group are to revisit the concept of direct benefit. In addition, the 406 statute of "subject's condition" may possibly be applicable to healthy donors, and the goals for this group are to address this as a possibility.

- Streamlining 407 and Guidance for "Healthy Donor" Research

Co-Chairs: Robert "Skip" Nelson, MD, PhD; Jerry Menikoff, MD & Dave Wendler, PhD

Goals: The Federal regulations governing pediatric research currently do not incorporate a well-established mechanism for addressing the role of healthy donors on research protocols. The goals for this group are to brainstorm innovative approaches to either streamlining the 407 processes, considering a waiver for healthy donor research, or consider updating the federal regulations to incorporate guidelines for healthy donors.

3:00 -3:15

Break

SESSION V: WORKING GROUPS PRESENTATIONS

3:15-4:30

Working Group Presentations

4:30

Next Steps