TRANSLATION TO TRANFORM

Webinar Agenda:
May 19, 2016
10:00 am - 11:30 am ET

Speakers
Jenna Koschnitzky, PhD
Director of Research Programs
Hydrocephalus Association

Yoram Unguru, MD
Pediatric Hematologist/Oncologist
Department of Pediatric Hematology/Oncology
Sinai Hospital of Baltimore

Agenda

10:00-10:05 Introduction (Dr. Jenna Koschnitzky)
Part I:
10:05-10:20 Clinical Trial Basics: Validity, Randomization, Sample Size, Power (Dr. Koschnitzky)
10:20-10:30 Areas for patient input: barriers to entry, patient-centered outcomes (Dr. Koschnitzky)
10:30-10:35 Part I: Q and A

Part II:
10:35-11:20 Clinical Trial Ethics and Key Considerations (Dr. Yoram Unguru)
- Clinical Research vs. Clinical Practice
- Ethics Transgressions (examples/outcomes)
- Clinical Research in vulnerable populations
- Limitations of current US oversight system
- IRB process and goals
- Real-world cases

11:20-11:30 Part II: Discussion/Q and A

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TRANSLATION TO TRANFORM

Workshop
Minneapolis, MN
June 16, 2016
7:30 am – 2:00 pm CT

Speakers
Mike Williams, MD
Director of Adult and Transitional Hydrocephalus and CSF Disorders
University of Washington School of Medicine
University of Washington

Yoram Unguru, MD
Pediatric Hematologist/Oncologist
Department of Pediatric Hematology/Oncology
Sinai Hospital of Baltimore

Jessica Sun, MD
Assistant Professor, Pediatrics
Department of Pediatrics
Duke University School of Medicine

Norman Relkin, MD
Associate Professor, Neurology and Neuroscience
Weill-Cornell Medical School
Cornell University

Abhay Moghekar, MD
Research Director
Cerebral Fluid Center, Department of Neurology
Johns Hopkins University

Agenda

7:30-8:00 *Breakfast*
Introduction & Ethics
8:00-8:10 Introduction/Overview of Day (Dr. Michael Williams)
8:10-8:50 Research Ethics/Framework/Ground Rules (Dr. Yoram Unguru)

Session 1: Prevention/Repair Therapies
11:10-11:30 Clinical Trial Example: Stem Cell Therapy (Dr. Jessica Sun)
11:30-12:10 Structured Group Discussion (Moderator: Dr. Michael Williams):
Risks and Risk Tolerance
Patient-centered outcomes: beneficial/harmful
Clinical Trial Design

Barriers to enrollment
Appropriate intervention/comparators
Appropriate study populations
Responsible stopping points

9:50-10:05 *Break*

Session 2: Non-invasive Treatments

10:10-10:30 Clinical Trial Example: Diamox for NPH (Dr. Norman Relkin)
10:30-11:10 Structured Group Discussion (Moderator: Dr. Michael Williams):

Risks and Risk Tolerance
Patient-centered outcomes: beneficial/harmful
Clinical Trial Design
Barriers to enrollment
Appropriate intervention/comparators
Appropriate study populations
Responsible stopping points

Session 3: Disease Monitoring

8:50-9:10 Clinical Trial Example: Non-invasive ICP measurement (Dr. Abhay Moghekar)
9:10-9:50 Structured Group Discussion (Moderator: Dr. Michael Williams):

Risks and Risk Tolerance
Patient-centered outcomes: beneficial/harmful
Clinical Trial Design
Barriers to enrollment
Appropriate intervention/comparators
Appropriate study populations
Responsible stopping points

12:10-12:55 *Lunch & Discussion*

Session 4: Patient Priorities, Common Themes, and Divisions

1:00-1:30 Review of the Day: Topics for white paper (Dr. Michael Williams)
1:30-1:40 Complete Survey

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