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# **2012 Autumn Conference**

## **International Society for CNS Clinical Trials and Methodology**

**1-3 October 2012**

**Marina del Rey, California**

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# Mission Statement

**The International Society for CNS Clinical Trials and Methodology (ISCTM) is a multi-disciplinary independent organization, devoted to promoting advances that address strategic clinical, regulatory, methodological and policy challenges that arise in the development and use of CNS therapeutic agents. This work is accomplished through partnership with persons in academia, industry, government, policy-making, and the public.**

# PRINCIPLES

- **Improving the lives of our patients through excellent science**
- **Many stakeholders**
  - **Patients, Clinicians, Investigators, Statisticians, Regulators, Policy-makers, Public**
- **International**
- **Non-commercial, non-promotional**
- **Mutually critical**
- **Mutually respectful**
- **Pre-competitive and/or collaborative**

# PRINCIPLES

- **Active participation is strongly encouraged**
  - Questions and solutions provided by audience are key to promotion of better methodologies
  - Ample time for discussion, when problems can get solved collaboratively
  - Not debate for its own sake; we have serious work to do, problems to solve and patients who suffer
- **Approaches utilized at this meeting**
  - Plenary sessions
  - Workshops/Working Groups
  - Poster Session
  - Efforts to increase publications resulting from meeting (*Innovations in Clinical Neuroscience*)

# Activities of the Society

- **ISCTM Comments on following guidances:**
  - NAPA's Scientific Agenda for a National Initiative on Alzheimer's Disease (March 2012; Ereshefsky, Chair)
  - EMA Guideline on Clinical Investigation of Medicinal Products in the Treatment of Depression (March 2012; Pikalov, Chair)
  - FDA Schizophrenia Data Standards Draft (August 2012; Pikalov, Chair)
  - FDA Guidance on Suicide Ideation and Behavior (Stewart and Butler, Chairs)
- **Working Groups:**
  - **Development of Autumn Workshops**
  - **Adaptive Design Group**
    - Continuing Work on Manuscript (target completion – Dec 2012)
  - **Suicidal Ideation and Behavior**
    - Manuscript completed
    - Poster presented at NCDEU 2012
  - **Initial work toward formation of *Stimulant Dependence* Working Group and *Cognitive Assessment* Working Group**

# Activities of the Society

- **Other Publications in the ‘pipeline’**

- Large Registries Workshop Overview ready for publication (Feb Innovations)
- Clinically Meaningful Effect from Feb 2012 Meeting

- **Development of expanded Autumn (and Feb) meetings**

	<b>Autumn 2011</b>	<b>Autumn 2012</b>
– General Session	3	4
– Workshops	5	8
– Speakers/Chairs	31	42

- **Membership Demographic Survey**

- **Outreach to academic leaders, neurologists, statisticians**

- **Ongoing collaboration with other societies: AAIC, ACNP, CNS Summit, NCDEU**

- **All supported by the organizational skills and ninja cajoling techniques of Carlotta McKee and Mary Bea Harding and IT wizardry of Joe Cocchini!**

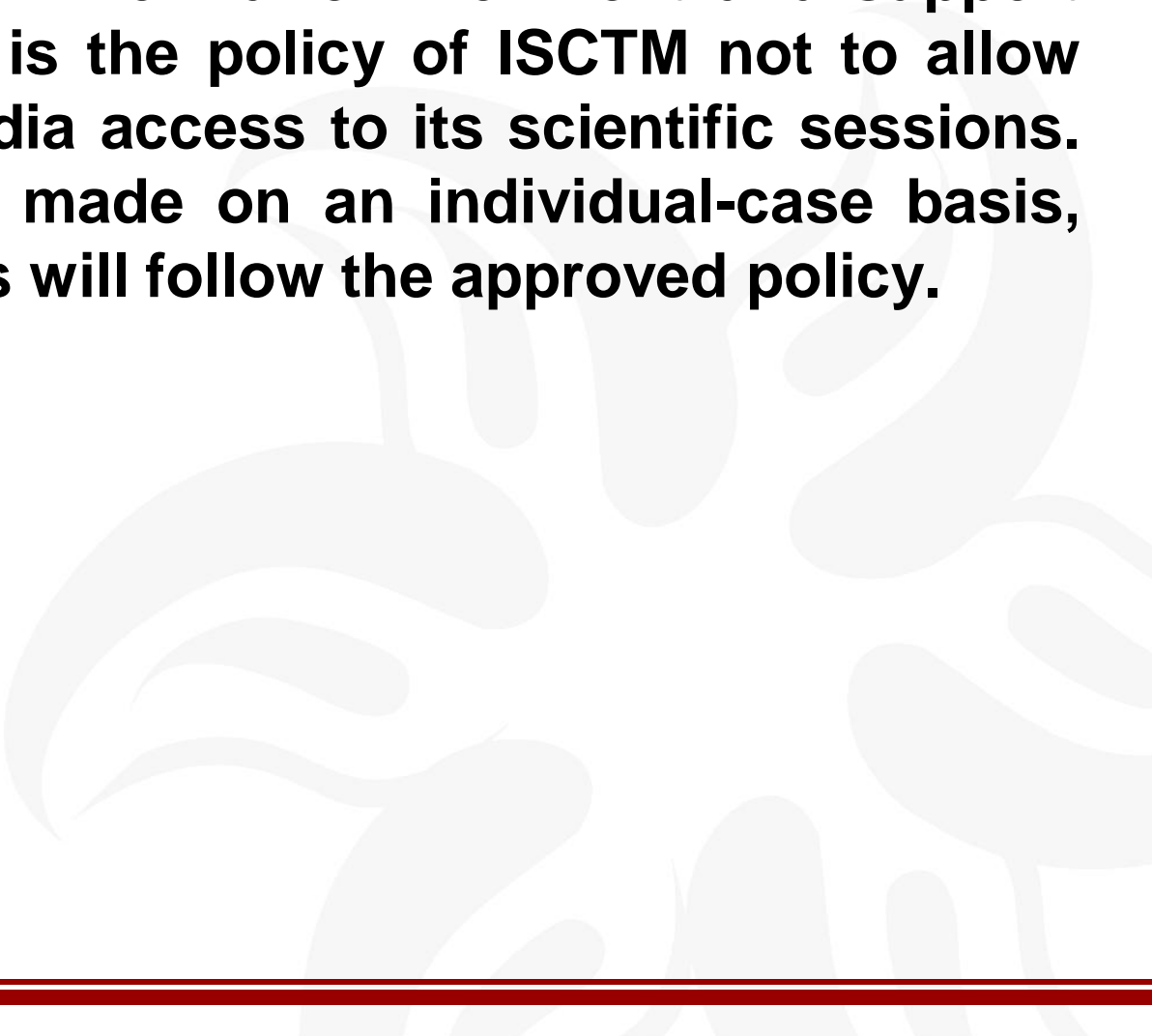
# Program Booklet

- QR code format
- Best barcode scanner for iPhone
- Direct links also available from email sent yesterday
- Slides will be available to registrants

## **Policy on Press – Approved by Executive Committee, April 2012**

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**In order to foster an informal environment and support open discussion, it is the policy of ISCTM not to allow members of the media access to its scientific sessions. Exceptions may be made on an individual-case basis, and such exceptions will follow the approved policy.**



# The Current Exception

- Plan approved 10-2 by Executive Committee
- I have communicated to the Chairs of each session that Benedict Carey, science writer from the New York Times may be in attendance. Chairs must obtain approval from all speakers in their session before Ben is allowed access to their session, which has happened.
- I will announce his presence in my overview statement:
  - This exception follows the Media Policy Guidelines
  - There were two previous minor exceptions prior to the development of the Media Guideline Policy but this one is potentially more visible with greater effect on participant interaction
  - ISCTM meetings are private but open
  - Ben has volunteered not to quote anyone or to report on the meeting; he is here to gather background information on clinical trials: “why all the negative trials?”
  - One of the original missions of ISCTM is the dissemination of information to the public, and that this will be an opportunity for us to help fulfill that mission. It is also a statement on the growth of the society that there is interest in the good work we are doing
  - We will initiate a fuller discussion among the membership on this issue for future meetings.
  - Since this is the first time we have enacted the Media Policy Exception, we will be monitoring its effect; if it has negative consequences we will want to hear about them and weigh them against the potential positives.
- The Media Policy is that media should make requests for interviews through the Executive Director who will then arrange for the interview. Ben will not conduct an on-the-record conversation with anyone without the permission of the President and the Executive Director

# MEETING AGENDA

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## October 1

### Workshops

## October 2

**8:15 – 3:00 Statistical, Clinical, Payor and Regulatory Perspectives on Dimensions that Define the Spectrum of Efficacy and Effectiveness Trials (Alphs, Schooler, Haynes)**

**3:30 – 5:30 Neurocognition and Social Cognition as Endpoints for Clinical Trials (Green, Marder)**

**6:00 – 8:00 Poster session**

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## October 3

### **8:00 – 12:00 Parallel Sessions**

- **Clinical Trials in Autism Spectrum Disorders: Methods, Measurements, Designs, and Outcomes (Feltner, Horrigan)**
- **Stratified Medicine and Targeted Clinical Trials for Alzheimer's Disease Drug Development in Light of Recent Phase III Trial Results: Example ApoE Genotype (Schneider, Goldberg, Ereshefsky)**