

ILSI Health and Environmental Sciences Institute (HESI)

E.I. Subcommittee on State of the Science: Evaluating Epigenetic Changes

January 2009

Co-Chairs: Dr. Jay Goodman, Michigan State University
Dr. Karen Augustine, BMS
Staff: Cyril Pettit



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Mission and Goal

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MISSION:

- To design and execute a **public workshop** focused on enhancing the scientific knowledge base regarding epigenetics and the possible relationship between epigenetic changes and transgenerational effects.

GOAL: .

- The **goal** of the workshop is to gain an understanding of what we need to know prior to thinking about incorporating an “epigenetic evaluation” into safety assessments.



Project Progress Timeline

- **August 2007:** Selected by EISC to be pursued as a workshop, facilitated by SOT's Contemporary Concepts in Toxicology (CCT)
- **Sept 2007:** Steering team formulated
- **Dec 2007:** HESI submits proposal for CCT sponsorship of Hemangiosarcoma workshop
- **Oct '07 – Feb '08:** Workshop agenda, overview document, budget (w/SOT staff input), and submission letter prepared per available SOT CCT guidance
- **February '08-** HESI Hemangiosarcoma Workshop accepted for CCT sponsorship
- **March '08 –** Epigenetics Workshop materials submitted to SOT.



Project Progress Timeline

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- **April '08– Sept '08** – SOT promise of feedback on submission 'soon', indications that CCT process undergoing revision/formalization, mixed messages about viability of 2 HESI CCTs in one year.
- **Oct '08:** CCT committee asks HESI to resubmit under new guidelines, offers no timelines for decision process, suggests HESI proposal may be disadvantaged.
- **Oct '08:** HESI EISC authorizes Subcommittee to proceed with workshop plans but **WITHOUT** pursuing CCT sponsorship
- **Dec '08:** HESI-SOT CCT Hemangiosarcoma Workshop Held



Project Progress Timeline

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- Nov '08 to Present:
 - Steering Team informed of revised charter
 - Agenda re-examined and speakers specified
 - Outreach for potential venues/co-sponsors completed
 - NIEHS in RTP
 - Georgetown U
- Program and site selection to be finalized in 1Q '09 and workshop anticipated by end of '09.



Steering Team

Dr. Chunhua Qin – Merck

Dr. Herman Autrup - U. Aarhus

Dr. Adriana Doi- BASF

Dr. Klaus Olejniczak - EISC Sci Advisor to Committee - Fed.
Institute for Drugs and Medical Devices

John Rogers - EPA

Randy Jirtle - Duke University

Michael Bolger – FDA

Ammie Bachman - ExxonMobil

Jerry Heindel- NIEHS

Jay Goodman- MSU (Co-Chair)

Karen Augustine - BMS (Co-Chair)

Rick Storer - Merck



Excerpted Agenda

I. State of the science of epigenetics

A. Where is the field? Why this workshop?

B. Epigenetics 101

C. Epigenetics in Development – background information

II. What constitutes Epigenetic changes?

I. Normal variability and adaptive changes

II. Transgenerational changes

III. Adverse effects

III. Research in Epigenetics

I. Development

II. Disease

III. Application to safety assessment

IV. Measuring Epigenetic Changes (techniques and interpretations)

V. Panel Discussion



Anticipated Outcomes

- **White paper to be generated to summarize workshop presentations and discussions, and the consensus reached regarding the goals of the workshop**
- **Recommendations from workshop could be circled back to EISC for consideration as potential new topics**