

**External Laboratory Safety Workgroup (ELSW)
Meeting Summary
Monday, April 21, 2015
8:00 A.M. – 9:00 A.M.**

Attendance	
Joseph Kanabrocki, PhD, CBSP – <i>Co-Chair</i>	√
Kenneth Berns, MD, PhD – <i>Co-Chair</i>	√
Debra L. Hunt, DrPH, CBSP	
Thomas V. Inglesby, MD	√
Patricia Olinger, RBP	
Michael Pentella, PhD, D(ABMM)	√
David Relman, MD, PhD	
Heather J. Sheeley, BA, MS, CBiol, MSB, CMIOSH, FISTR	
Fred Sparling, MD	
Jill Taylor, PhD	
Domenica (Dee) Zimmerman	√
Sarah Wiley, MPH, <i>Designated Federal Officer, CDC</i>	√
Matthew Amann, CSP, <i>Safety and Occupational Health Manager, FDA</i>	√
Jeffrey DeGrasse, PhD, <i>Regulatory Counsel, FDA</i>	√
Kristine Leiphart, PhD, <i>Deputy Chief Operating Officer, FDA</i>	√
√ In attendance	

Meeting Summary

Roll Call and Call to Order

Sarah Wiley, Designated Federal Officer (DFO) and ELSW Members

Plans for Food and Drug Administration (FDA) Site Visit

FDA Representatives Kristine Lephart, Jeffrey DeGrasse, Matthew Amann, and ELSW Members

During this session, FDA representatives engaged in a discussion with ELSW members regarding the upcoming site visit scheduled for May 11 – 13, 2015.

- **Laboratory Safety Practices and Policies Workgroup (LSPPW)**
 - ELSW members will have the opportunity to meet the members of the LSPPW. This committee has representation from all FDA centers and is a consensus-driven workgroup that engages on all matters related to biosafety and biosecurity.
- **Staff Engagement**
 - The ELSW will meet with the Senior Program Manager from FDA’s Employee Safety and Environmental Management (ESEM) staff, who will review the laboratory safety training program.
 - Members will meet with Principal Investigators (PIs) from the Center for Biologics Evaluation and Research (CBER).
 - Dr. Stephen Ostroff, FDA’s Acting Commissioner, will begin the second day with a presentation pertaining to his vision and priorities for the agency in terms of laboratory-related activities.
 - ELSW members will also engage with FDA’s Director of Security Operations Policy & Planning. He will review FDA’s security operations, including surveillance and how badges are used to access laboratory areas.
 - During the second day of the visit, members will meet with the Co-Chairs of the FDA’s Institutional Biosafety Committee.
- **Laboratory Visits**
 - Members will conduct a visit to the vivarium and laboratories at the White Oak Campus and tour one of the larger off-campus laboratories in College Park.

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Discussion Points

ELSW Members, FDA Representatives, and Sarah Wiley

Follow-up questions from ELSW members.

- Members asked if they would engage with individuals involved in occupational health.
 - Members will meet with representatives from the Occupational Medicine Program.
 - FDA completes an annual HHS-driven report in which the FDA rates the agency on multiple assessment factors. The ELSW will be provided with this self-assessment report.
- With regard to the smallpox issue, FDA submitted a formal response to HHS on August 24, 2015. Due to the incident, FDA authored a draft staff manual guide with input from each of the centers.
 - Although in draft form, FDA will share with ELSW members.
 - This Staff Manual Guide addresses a variety of issues (e.g., inventories, what levels, who has the responsibility, where accountability lies, type of training, etc.).
- ELSW members will also receive information regarding FDA's risk assessment and staff competency processes.

Advisory Committee to the Director (ACD) Presentation

ELSW Members and Sarah Wiley

Dr. Kanabrocki reminded everyone that he and Dr. Berns would be presenting the ELSW's observations / proposals resulting from the NIH site visit to the ACD on April 23, 2015. In addition, a set of ELSW's meeting minutes dating from November through March 9, 2015 will be presented for approval by the ACD and entered into the record.

- During the January 2015 ACD meeting, the ACD voted to accept the first set of ELSW meeting summaries through October 2014.

Administrative Matters and Adjournment

Sarah Wiley and Dr. Joseph Kanabrocki

- The ELSW teleconference scheduled for May 4, 2015, is cancelled.
- CDC will plan to host the ELSW for another in-person meeting in the late summer or early fall for an updated perspective and to meet with the new Associate Director for Laboratory Science and Safety (ADLSS).
- Future ELSW meeting topics that need to be revisited include:
 - Re-administration of the staff survey, which was conducted last year as an activity of the workgroup.
 - A refresher presentation regarding the Conflict of Interest requirements of a workgroup.