Subcommittee on Harmonization (SOH) Update

Mark Barnes
David Forster

July 10, 2013

Membership

- **Albert Allen M.D.**
- **Susan Alpert, Ph.D, M.D.**
- **Mark Barnes, J.D., LL.M. - Co-Chair**
- **Gary Chadwick, Pharm.D., CIP**
- **David Forster, J.D., MA, CIP – Co-Chair**
- **Dean Gallant, A.B.**
- **Karen N. Hale, RPh, MPH, CIP**
- **Justin P. McCarthy, J.D.**
- **Marjorie A. Speers, Ph.D.**
- **Susan Stayn, J.D.**

Meetings

- Convened meetings:
  - April 15-16, 2010
  - September 21-22, 2010
  - February 8-9, 2011
  - June 29-30, 2011
  - September 12-13, 2011 (joint meeting with SAS)
  - September 20-21, 2012
  - February 20-21, 2013 (joint meeting with SAS)
  - June 27-28, 2013 (joint meeting with SAS)
- Monthly teleconferences

Completed Activity – HHS Conflict of Interest Policies

- Recommendation regarding adoption of a single conflict of interest standard across DHHS entities.
- Approved by SACHRP at July 21, 2010 meeting.

Completed Activity – Commentary on NPRM on HITECH

- Recommendation approved by SACHRP at October 19, 2010 meeting.
- Five topics:
  - Compound Authorizations
  - Future/Secondary Research
  - Minimum Necessary
  - Business Associates
  - Restriction on Sale of PHI

Completed Activity – Definition of Non-Scientist

- Recommendation approved by SACHRP at October 19, 2010 meeting.

Completed Activity – Addition of FDA Considerations to SAS FAQs on Biospecimens

- Recommendation approved by SACHRP at July 20, 2011 meeting.

Completed Activity – Definition of a Minor Change in Research

- Recommendation approved by SACHRP at July 20, 2011 meeting.

Completed Activity – Early Processes in Research

- Application of 45 CFR 46 and 21 CFR 56 to early processes in research, such as identifying potential subjects, contacting subjects, and recruiting subjects.
- Recommendation approved by SACHRP at July 20, 2011 meeting.

Completed Activities

- Recommendation regarding applicability of FDA regulations.
- Recommendation regarding protocol deviations.
- Recommendation regarding individual patient treatment use protocols.
- Recommendation regarding OHRP, ORI, and FDA overlapping jurisdiction of research misconduct and research non-compliance.
- All four recommendations approved by SACHRP at February 28-29, 2011 meeting.

Completed Activities

- SOH recommendation on IRB knowledge of local context.
- Commentary on the OHRP and FDA draft guidance documents on transfer of research to new IRBs and institutions.
- Both approved by SACHRP at October 9, 2012 meeting.

Today's Topics

- SACHRP comment regarding the June 4, 2013 FDA Request for Comment relating to the Availability of Masked and De-identified Non-summary Safety and Efficacy Data
  - Comments due by August 5, 2013
- Cluster Randomized Trials – Panel today
- Certificates of Confidentiality – Panel today

Future Topics

- Always more to come.