SACHRP

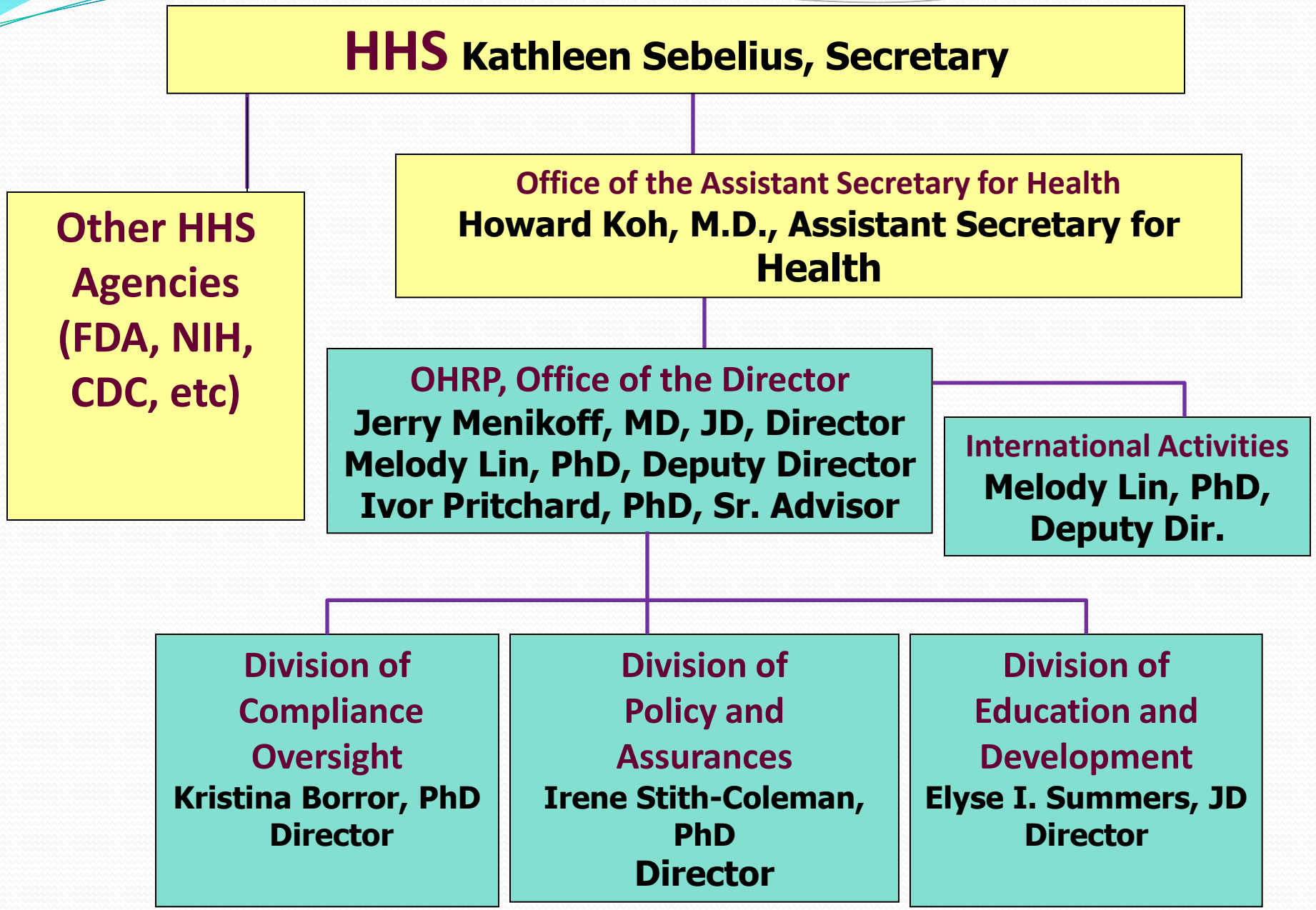
Secretary's Advisory Committee on Human Research Protections

March 12, 2013

SACHRP Background, Impact, and the Guidance and Rulemaking Process

- SACHRP Background
  - *Julia Gorey, J.D., DPA, OHRP*
- Impact of SACHRP on OHRP Policy
  - *Jerry Menikoff, M.D., J.D., Director, OHRP*
- OHRP Guidance Development Process
  - *Irene Stith-Coleman, Ph.D., Director, DPA, OHRP*
- The Rulemaking Process
  - *Laura Odwazny, J.D., OGC*
  - *Andrew Zacker, J.D., OGC*

HHS/OHRP Organizational Structure



History

- OPRR (NIH) becomes OHRP (OS, HHS) – 2000
- National Human Research Protections Advisory Committee (NHRPAC), 2000- 2002
- Secretary's Advisory Committee for Human Research Protections (SACHRP), 2003- ongoing

2012 SACHRP Charge:

Description of Duties

The Committee shall advise, consult with, and make recommendations on matters pertaining to the continuance and improvement of functions within the authority of the Department of Health and Human Services (HHS) directed toward protections for human subjects in research. *Specifically, examples include but are not limited to advice relating to the responsible conduct of research involving human subjects with particular emphasis on:*

Special populations, such as neonates and children, prisoners, and the decisionally impaired; Pregnant women, embryos, and fetuses; Individuals and populations in international studies;

2012 SACHRP Charge:

…Populations in which there are individually identifiable samples, data, or information; and Investigator conflicts of interest.

In addition, the Committee shall be responsible for reviewing selected ongoing work and planned activities of the Office for Human Research Protections (OHRP) and other offices/agencies within HHS responsible for human subjects protection. These evaluations may include but are not limited to a review of assurance systems, the application of minimal research risk standards, the granting of waivers, education programs sponsored by OHRP, and the ongoing monitoring and oversight of IRBs and the institutions that sponsor research.

2012 SACHRP Charge:

Designated Federal Officer

The Director, OHRP will serve as the DFO for the Committee…The DFO will schedule and approve all meetings and any respective subcommittees that are to be held. The DFO will prepare and approve all meeting agendas. Development of the meeting agenda can be done in collaboration with the Committee Chair, and, when it is deemed to be appropriate, the chairs of any respective subcommittees of the Committee can be consulted.

SACHRP Subcommittees

- Subcommittee on Accreditation, 2003-2004
- Subcommittee on Research Involving Prisoners- 2003-2005
- Subcommittee on Research Involving Children- 2003-2006
- Subcommittee for the Inclusion of Individuals with Impaired Decision-making, 2006-2009
- Subcommittee on Federal Policy for the Protection of Human Subjects, 2004-ongoing
- Subcommittee on Harmonization, 2009-ongoing

Process for HHS review of SACHRP recommendations

SACHRP approves recommendation

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OHRP prepares letter for SACHRP Chair signature

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Transmittal memo through the Assistant Secretary for Health to the Secretary

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Secretary acknowledgement and referral to appropriate agency or office for consideration

HHS Consideration of SACHRP Recommendations – Possible Outcomes

- Adopt the recommendation as made
- Adopt the recommendation with modifications
- Defer taking any action regarding the recommendation
- OHRP or other HHS agencies revise existing guidance or develop new guidance

HHS Consideration of SACHRP Recommendations – Possible Outcomes (2)

- Modify existing regulations or implement new regulations
- HHS convenes conference or workshop
- Other

Categories of Recommendations

- Research involving children and subpart D of 45 CFR part 46
- Accreditation of human research protection programs (HRPPs)
- Adverse event reporting
- Research involving pregnant women and subpart B of 45 CFR part 46
- HIPAA Privacy Rule
- Research involving prisoners and subpart C of 45 CFR part 46

Categories of Recommendations (2)

- OHRP/NIH/FDA convene workshop on central IRB review mechanisms
- Subpart A of 45 CFR part 46
- Tribal authority over research involving American Indian or Alaska Native populations
- Research in disaster settings
- Review of the human subjects protection system
- External IRB accountability
- Harmonization of agency regulation and guidance

Categories of Recommendations (3)

- Research involving the Inclusion of Individuals with Impaired Decision-making
- Standards for reporting, disclosure and review of financial conflict of interest
- Initial and continuing training for IRB members, staff, the signatory official and human protections administrator
- FAQs, terms and recommendations on informed consent and research use of biospecimens
- SACHRP comment on *Request for Comments on Human Subject Protections in Scientific Studies*

Categories of Recommendations (4)

- ANPRM: *Human Subjects Research Protections: Enhancing Protections for Research Subjects and Reducing Burden, Delay and Ambiguity for Investigators*
- Component Analysis

Examples of Impacts on HHS agencies

- 407 and 50.54 process guidance
- Adverse Event reporting guidance (FDA and OHRP)
- Subpart C FAQ regarding prisoner rep as expedited reviewer
- 2 sponsored workshops on central IRB review
- ANPRM on IRB accountability
- Conditional IRB approval guidance
- Continuing review guidances (FDA and OHRP)
- Solicited public comment regarding SACHRP's recommendation on expedited review category #7

Examples of Impacts on HHS agencies

- HIPAA/HITECH (OCR)
- OHRP/FDA joint guidance processes
- Archival of local context guidance
- Advice on FDA's IRB review requirements for Single Patient Access
- Input on OHRP work in progress:
  - Revised local context
  - Minor changes in research
  - Transfer of IRB oversight
  - ANPRM

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Secretary's Advisory Committee on Human Research Protections (SACHRP)

SACHRP is governed by the Federal Advisory Committee Act and provides expert advice and recommendations to the Secretary on issues and topics pertaining to the protection of human research subjects. The Committee was created by Secretary Thompson in 2001 after dissolution of the prior National Human Research Protections Advisory Committee (NHRPAC). To date SACHRP has focused its attention on areas such as research involving children, prisoners, and individuals with impaired decision-making capacity; informed consent and the use of biospecimens; harmonization of human subjects regulations and guidance; the reduction of regulatory burden; the HIPAA Privacy Rule; community-engaged research, and accreditation.

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Secretarial Communications

Secretary's Advisory Committee on Human Research Protections (SACHRP)

SACHRP advisory documents are the result of considerable Committee effort, deliberation and consensus building. Once the Committee achieves consensus on an issue, its recommendations are posted on this website and transmitted by the Chair to the Secretary of Health and Human Services, Assistant Secretary for Health, and to the Director of OHRP for their consideration. The content of these documents is advisory and does not represent the official views or policies of OHRP or the Department of Health and Human Services.

19. March 30, 2012 SACHRP Letter to the HHS Secretary
Recommendations from the Subcommittee on Harmonization and Recommendations on Component Analysis [PDF 3617KB]

18. October 13, 2011 SACHRP Letter to the HHS Secretary: SACHRP ANPRM Comments - Final (PDF 494KB)
Attachment - ANPRM Biospecimen Minority Report Final (PDF 47KB)

17. October 13, 2011 SACHRP Letter to the HHS Secretary: Recommendations from SAS & SOH (PDF 84KB)
Attachment A: Approved by SACHRP July 20, 2011 (PDF 94KB)
Guidance on Applying the Regulatory Requirements for Research Consent Forms: What Should and Should Not be Included?
Attachment B: Approved by SACHRP July 20, 2011 (PDF 57KB)
SACHRP Recommendation regarding definition of a minor change in research under 45 CFR 46 and 21 CFR 56
Attachment C: Approved by SACHRP July 20, 2011 (PDF 60KB)
SACHRP Recommendation regarding application of 45 CFR 46 and 21 CFR 56 to early processes in research, such as identifying potential subjects, contacting subjects and recruiting subjects
Attachment D: FAQ 's Terms and Recommendations on Informed Consent and Research Use of Biospecimens (PDF 181KB) The Secretary's Advisory Committee on Human Research Protections (SACHRP) July 20, 2011

16. August 5, 2011 SACHRP Letter to the HHS Secretary (PDF 4KB)
Recommendations on HIPAA/HITECH Notice of Proposed Rulemaking