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

Jeffrey R Botkin, MD, MPH
Professor of Pediatrics
Chief, Division of Medical Ethics and Humanties
Associate Vice President for Research
10/1/14

SACHRP

ASH > OHRP Home > Advisory Committee (SACHRP)

- **OHRP Home**
- **About OHRP**
- **Regulations**
- **Policy & Guidance**
- **IRBs & Assurances**
- **International**
- **Compliance Oversight**
- **Education**
- **Advisory Committee (SACHRP)**
  - Charter
  - Members
  - Meetings
  - Secretarial Communications
  - Contact SACHRP
  - Subcommittees
- **News Room**
- **Archived Materials**
- **Contact OHRP**

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.

SACHRP Members July 10-11, 2013
From left to right front: Pilar Ossorio, Lainie Freedman Ross, Suzanne Rivera, Susan Krivacic, Jeffrey Botkin (Chair) and Jerry Menikoff (OHRP Director)

From left to right back: Assistant Secretary for Health Howard Koh, Albert Allen, James Anderson, Stephen Rosenfeld, Thomas Eissenberg, Owen Garrick and Gary Chadwick.

HHS/OHRP Organizational Structure

HHS Sylvia M. Berwell, Secretary

Other HHS Agencies (FDA, NIH, CDC, etc)

Office of the Assistant Secretary for Health
Wanda K Jones Dr.Ph, Acting Assistant Secretary for Health

OHRP, Office of the Director
Jerry Menikoff, MD, JD, Director
Ivor Pritchard, PhD, Dep Dir

International Activities
Ed Bartlett
Deputy Dir.

Division of Compliance Oversight
Kristina Borror
Director

Division of Policy and Assurances
Irene Stith-Coleman, PhD
Director

Division of Education and Development
Yvonne Lau
Director

Current Members

- **Albert J. Allen, M.D., Ph.D.**

Eli Lilly & Co

- **James Anderson, Ph.D.**

University of Nebraska Medical Center

- **Jeffrey Botkin, M.D., M.P.H.**

University of Utah

- **Gary L. Chadwick, Pharm.D., M.P.H., C.I.P.**

University of Rochester

- **Thomas Eissenberg, Ph.D.**

Virginia Commonwealth University

- **Owen Garrick, M.D., M.B.A.**

Bridge Clinical Research

- **Reed E. Pyeritz, MD, PhD**

University of Pennsylvania

- **Diana Chingos, MS, MFA**

Noreen Fraser Foundation

- **Pilar Nicole Ossorio, Ph.D., J.D.**

University of Wisconsin Law School

- **Stephen Rosenfeld, M.D., M.B.A.** Quorum Review IRB
- **Holly Fernandez-Lynch, JD, M.Bioethics**

Harvard Law School

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

My Involvement

- Member, Subcommittee on Research with Children 2003 – 2006
- Member, SACHRP, 2006 – 2009
- Member, Subcommittee on Individuals with Impaired Decision-making Capacity, 2007 – 2009
- Chair, SACHRP, 2012 -

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

↓

OHRP prepares letter for SACHRP Chair signature

↓

Transmittal memo through the Assistant Secretary for Health to the Secretary

↓

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

Organizational Challenges

- Collaborative relationship with OHRP
  - Committee agenda is jointly developed by SACHRP and OHRP
  - Good: SACHRP addresses issues that are likely to be welcomed by OHRP/DHHS
    - Don't waste our time on recommendations that will be dead on arrival
  - Not So Good: We lack independence from OHRP to provide recommendations that may not be welcome by OHRP/DHHS
    - Not an independent voice from the research or human subjects communities

Organizational Challenges

- Examples:
  - Compensation for research injury
    - Long-standing problem
    - Of significant interest to a number of SACHRP members
    - Was the subject of a report by the President's Bioethics Commission
      - They recommended attention by SACHRP to the issues
    - Waiting action at the White House before SACHRP can address the issue
  - Controversial OHRP findings
    - Public Citizen has recommended twice that SACHRP review decisions by OHRP
    - SACHRP not intended to serve as an oversight body for OHRP

Limited Successes

- No changes in the human subjects regulations to date
- Extensive comments on the ANPRM from SACHRP but SACHRP not involved in ANPRM
- Primary focus has been at the level of guidance.

Recent Work

- Considerations and Recommendations Concerning Internet Research and Human Subjects Research Regulations
- Expedited Review Categories
- Cluster Randomized Trials
- Certificates of Confidentiality
- The definition of Engagement

Work in Progress

- Return of Results
  - General results
  - Participant results
  - Incidental findings
- Research using “big data”
- Informed consent
  - Minimal risk studies
  - Greater than minimal risk studies

Website

- About OHRP
- Regulations
- Policy & Guidance
- IRBs & Assurances
- International
- Compliance Oversight
- Education
- Advisory Committee (SACHRP)
  - Charter
  - Members
  - Meetings
  - SACHRP Recommendations by Date
  - SACHRP Recommendations by Topic
  - Contact SACHRP
  - Subcommittees
- News Room
- Archived Materials
- Contact OHRP

SACHRP Recommendations by Date

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.

23. July 3, 2014 SACHRP Letter to the HHS Secretary
    Attachment A: Recommendations on Assurances and Engagement
    Attachment B: Recommendations on Certificates of Confidentiality
    Attachment C: Recommendations on Regulatory Issues in Cluster Studies

22. December 4, 2013 SACHRP Letter to the HHS Secretary (PDF - 169 KB)
    Attachment A: SACHRP comment regarding the June 4, 2013 FDA Request for the for Comment relating to the
    availability of masked and de-identified non-summary safety and efficacy data (PDF - 179KB)

21. May 20, 2013 SACHRP Letter to the HHS Secretary (PDF - 172KB)
    Attachment A: Recommendation on Changes to Expedited Review Applicability and Categories (PDF - 182KB)
    Attachment B: Considerations and Recommendations concerning Internet Research and Human Subjects Research
    Regulations, with Revisions (PDF - 409KB)

20. January 20, 2013 SACHRP Letter to the HHS Secretary (PDF - 104KB)
    Attachment A: Consideration of Local Context with Respect to Increasing Use of Single IRB Review (PDF - 62KB)
    Attachment B: Comments on OHRP and FDA Draft Guidance Documents Regarding IRB Transfers (PDF - 72KB)
    Attachment C: Investigator Responsibilities (PDF - 56KB)