The Secretary's Advisory Committee on Human Research Protections (SACHRP): Recommendations Regarding the Newborn Screening Reauthorization Act of 2014

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SACHRP

- Reports to the Secretary of Health and Human Services
  - Reports through the Office of the Assistant Secretary of Health
  - Staffed through Office of Human Research Protections (OHRP)
    - Julia Gorey, JD, Executive Director

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

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- **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

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;

SACHRP Recommendations regarding Public Law 113-240

- SACHRP recommends that OHRP rapidly disseminate guidance to the research community regarding the implementation of this law.

SACHRP Recommendations

- SACHRP recommends OHRP guidance reinforce that institutions should continue to assess proposed activities to determine whether or not they represent research.
  - Concern that the law may negatively impact quality assurance activities

SACHRP Recommendations

- SACHRP recommends that guidance make clear that the requirements of subsection (a) of the law only apply to research that is funded by HHS and does not impact research with other types of data or specimens. Any related OHRP-enforcement actions will be limited to HHS-funded research.

SACHRP Recommendations

- SACHRP recommends that OHRP's existing 2008 Guidance on Engagement of Institutions in Human Subjects Research be revised to include scenarios for the collection of newborn dried blood spots.
  - Limit the extent to which birthing centers are considered "engaged" in research by virtue of NBS bloodspot collection

SACHRP Recommendations

- SACHRP recommends that OHRP guidance encourages that blood spots used for research be de-identified unless there is a clear justification otherwise.

SACHRP Recommendations

- SACHRP recommends that OHRP guidance note that the expedited review categories may be used for HHS-funded research with newborn dried blood spots.

SACHRP Recommendations

- SACHRP recommends that OHRP guidance emphasize that the consent process for research use of residual newborn dried blood spots would be simplified if one-time permission is sought for broad future research use.

SACHRP Recommendations

- SACHRP recommends that OHRP consider developing an example document for broad consent to research use of newborn dried blood spots as part of its guidance.

SACHRP Recommendations

- SACHRP further recommends that the guidance emphasizes the ability of IRBs to grant waivers of documentation of consent under §46.117(c)(2).

SACHRP Recommendations

- Exempt Research
  - Exempt category 4 (§46.101(b)(4)) covers "[r]esearch involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects."
  - The law does not preclude exemption
  - Given the law's deliberate elimination of waivers or alteration of informed consent, SACHRP would advise caution in the application of exempt category 4 to research involving these specimens.

SACHRP Recommendations

- Full statement available at:

http://www.hhs.gov/ohrp/sachrp/commsec/researchusesofnewborndriedbloodspots&thenewbornscreening.html