

SACGHS Session on Genomic Data Sharing

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Secretary's Advisory Committee on Genetics, Health, and Society

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SACGHS Steps Taken to Date

- Oct. 2009: A SACGHS steering group was formed and a session on genomic data sharing organized for the February meeting.
- Feb. 2010: The session explored five models of genomic data sharing and existing policies.
- June 2010: A Task Force was formed and charged with focusing on group harms, with a secondary focus on the international context for genomic data sharing.
- July – Sep. 2010: The Task Force provided input for development of a session for the October meeting.

SACGHS Genomic Data Sharing Task Force

SACGHS Members

Charmaine Royal (Chair)

David Dale

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Kevin Fitzgerald

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Session Goals

- Explore issues related to the involvement of indigenous, racial, and ethnic groups in genomic research and broad sharing of data for secondary research purposes.
- Explore best practices in the U.S. and other countries to address risks of group harm.
- Determine whether there are policy gaps that should be addressed.
- Come to consensus regarding specific policy issues that should be addressed relating to group harms in genomic data sharing.

Background

- Need for diverse study populations in genomic research
- Importance of genomic data sharing
- Risks and potential benefits to specific populations
- Current policies addressing the participation of groups in genomic research and data sharing

Session Presentations

To provide perspectives about participation in genomic research and broad sharing of data for secondary research purposes relating to:

- Indigenous Groups
- Racial and Ethnic Groups
- U.S. Policies that Address the Participation of Groups
- Canadian Policies that Address the Participation of Groups

Central Questions

- Why is it important for indigenous, racial, and ethnic groups to participate in genomic research?
- How might groups benefit from genomic data sharing?
- What constitutes “group harm”?
- What are the risks of genomic data sharing to groups?
- How are researchers, research institutions, and IRBs addressing risks to groups?

Central Questions

- In what, if any, settings are decisions about research participation and genomic data sharing made at the group level?
 - How are the wishes of the group and the autonomy of the individual members of the group both respected?
- Are existing U.S. policies adequate for addressing the research participation of groups or group interests?
- Are other countries' policies applicable in the U.S. environment?

Next Steps

- What specific policy issues are the most critical to address relating to groups' participation in genomic research and data sharing?
- What type of advice or recommendations should SACGHS transmit to the Secretary in this area?
 - Identification of policy gaps?
 - Prioritization of policy needs relating to groups' participation in genomic research and data sharing?
 - Recommendations of appropriate venues for further policy deliberations relating to groups' participation in genomic research and data sharing (i.e., other Federal advisory committees or departments)?

Issues for Committee Consideration

- Adequacy of current knowledge about the perspectives of groups on genomic data sharing
 - Is more research needed among specific groups not traditionally surveyed about their attitudes and experiences?
 - Has attitudinal research that has been conducted among indigenous, racial, and ethnic groups in the U.S. been incorporated sufficiently into policy?

Issues for Committee Consideration

- Importance of considering cultural perspectives in the design of genomic research studies
 - Is community engagement an effective mechanism for researchers to learn about cultural perspectives?
 - How can we achieve balance between cultural perspectives and the aims of research, e.g., estimation of ancestry?

Issues for Committee Consideration

- Role of the IRBs in addressing potential group harms and ensuring that they are carefully considered in the design and implementation of genomic data sharing projects
 - Do local IRBs and other oversight bodies need additional guidance regarding the potential for group harms in genomic research and data sharing?
 - Can policies be developed that are flexible enough to address heterogeneity within groups?
 - How can we more effectively inform research participants about secondary uses of their genomic data and potential implications for their group?

Issues for Committee Consideration

- Adequacy and effectiveness of U.S. policies to protect groups in genomic research and data sharing
 - Should consideration be given to expanding the scope of existing OHRP/human research protection policies to include group concerns, and risks and benefits to groups?
 - Are additional policies needed relating to the involvement of groups in genomic research and broad sharing of data?

Issues for Committee Consideration

- Policies of other countries and whether they may be models for application in the U.S.
 - Should genomic research policies developed in other countries for indigenous groups be extended to comparable tribal members living in the U.S.?
 - Do country-specific regulatory frameworks preclude the applicability of policies from other countries to policy development in the U.S.?