Presentation of Public Comments and SACGHS' Final Draft Report on Policy Issues Associated with Undertaking a Large U.S. Population Cohort Project on Genes, Environment, and Disease

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What is an LPS?

- A large population study is one approach to learning more about the relationship(s) among genes, the environment and common disease
- Goals of such studies include:
  - Determining the mechanisms underlying common, complex disease
  - Informing treatment and prevention strategies
  - Improving health

Session Purpose and Goal

- Purpose:
  - Review public comments and the final draft report on:
    - *Policy Issues Associated with Undertaking a Large U.S. Population Cohort Project on Genes, Environment, and Disease*
- Goal:
  - Finalize and approve report for submission to the HHS Secretary by January 2007

Overview of Session

- Summary of major revisions to draft report and recommendations based on public comments and Task Force deliberations
- Discussion:
  - Introduction
  - Scientific Background
  - Policy Issues (four areas)
  - Recommendations
  - Conclusion
  - Readiness of report for submission?

SACGHS Task Force on Large Population Studies

- Hunt Willard (Chair)
- Sylvia Au
- Barbara Burns-McGrath
- Chira Chen
- Kevin FitzGerald
- Julio Licinio
- Joseph Telfair
- Steven Teutsch
- Ellen Fox, DVA
- Sherrie Hans, DVA
- Alan Guttmacher, NIH
- Phyllis Frosst, NIH
- Muin Khoury, CDC
- Katie Kolor, CDC

Key Milestones in Report Development

- June 2003 – NIH requests SACGHS to weigh in on the value of an LPS
- March 2004 – SACGHS priority setting process determines that the issue of a large population cohort project warrants in-depth consideration
- October 2004 – LPS Task Force formed
- March 2005 – Fact-finding session explores scientific approaches to the project and examines scientific, logistical, ethical, legal, and social issues
- June 2005 – SACGHS, with guidance from the NIH Director, focuses the report on policy issues and recommendations for action

Key Milestones in Report Development

- October 2005 – Committee hears in-depth presentations from scientists, ethicists, and public engagement experts
- March 2006 – SACGHS reviews first draft and approves public comment solicitation
- May-July 2006 – Public comment period
- September-October 2006 – Task Force analyzes public comments and discusses changes, leading to a revised report
- Today – SACGHS reviews final draft

Request from NIH Director

- Identify the key policy issues related to a potential LPS in the U.S. that should be addressed **before** undertaking such a project;
- Outline approaches that could be used to address the identified issues (but…do not address the issues themselves);
- Recommend mechanisms that might best address the identified issues.

What SACGHS Was Not Asked To Do

SACGHS was **not** asked to come to a conclusion about whether or not a large population project should move forward in the U.S.

Session Purpose and Goal

- **Review public comments**
- Review final draft report
- Consider approval of final report

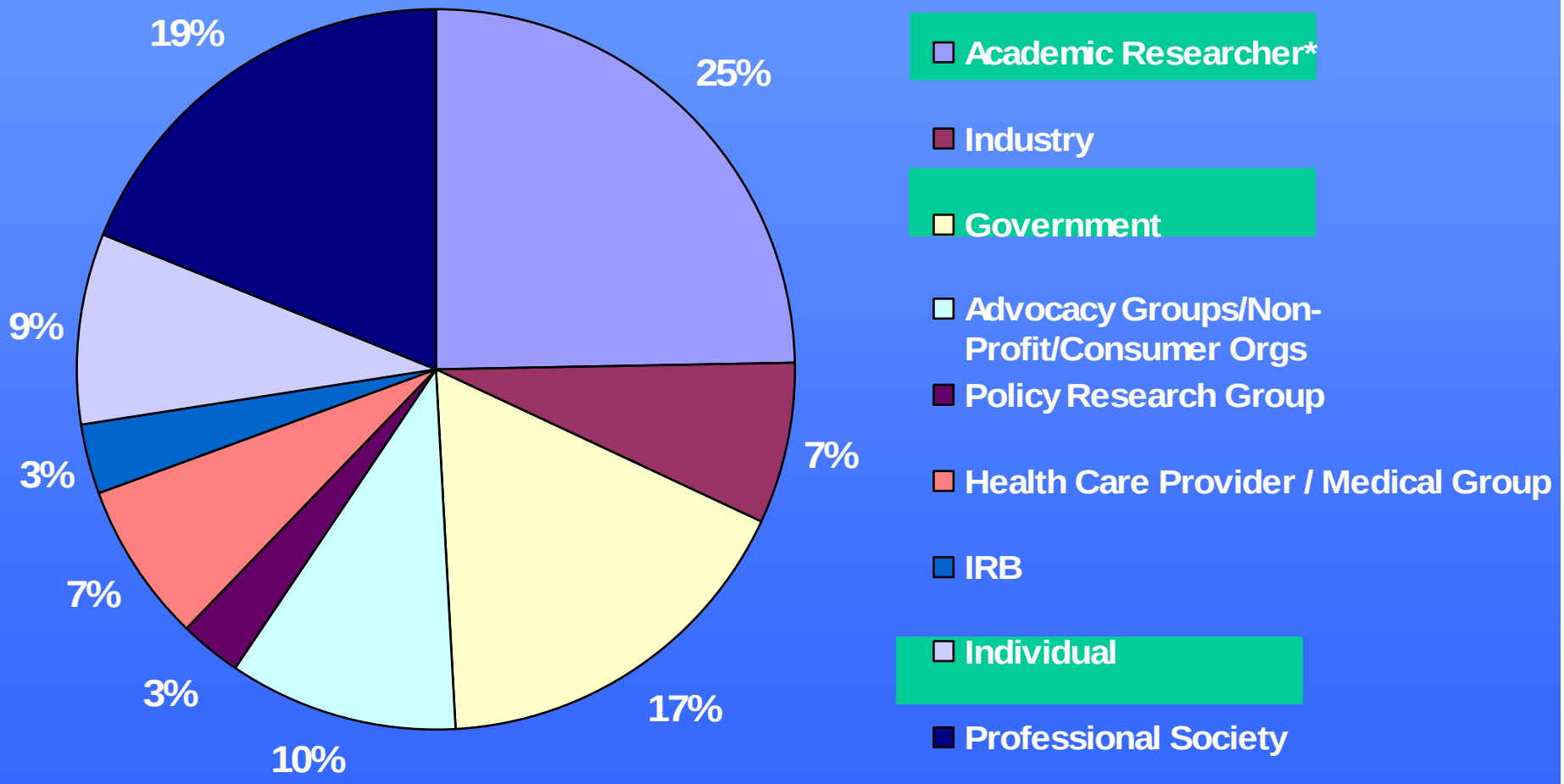
Public Consultation

- Draft report released for a 60-day public comment period May 22 - July 31, 2006
  - Report posted on SACGHS website
  - Targeted email outreach
  - Media outreach via NIH Office of Communication
  - *Federal Register* notice
  - NIH Guide for Grants and Contracts
  - “Dear Colleague” email used for dissemination on listservs
  - Outreach total: 48,000

Public Comments

- 69 sets of comments received
- Summary in Tab 7 of the Briefing Book
- Separate compendium provides full text of comments

Sectors Reflected in Public Comments



Analysis of Public Comments

- Within 69 individual comments, approximately 600 comments were made about specific issues
- Coding system developed to categorize comments by the four major policy issues and public engagement
- Task Force members assigned to review comments in specific areas to identify major themes and decide on comments to be incorporated
- Two meetings of the Task Force held to discuss the comments and the modifications needed in response

Major Themes from Public Comments

- Tone of report not neutral; role of SACGHS not understood
- More information should be included on current cohort studies and interdisciplinary research
- Socioeconomic and cost factors not sufficiently addressed
- Complex ethical, privacy, and confidentiality issues not sufficiently addressed
- Greater ethical oversight needed for such a project
- Public engagement should be discussed in more detail

Session Purpose and Goal

- Review public comments
- **Review final draft report**
- Consider approval of final report

Major Revisions: Organization

- Two sections on public engagement integrated into a single chapter
  - *Improves logical flow of report, eliminates redundancy, and increases emphasis on public engagement issues*

Major Revisions: Tone

- Language more neutral and balanced
  - *Request from NIH Director was to raise issues for exploration, not to endorse or discourage efforts to begin an LPS*
  - *Public comments indicated that statements of enthusiasm for the study were incompatible with purpose of the report*
  - *Language has been altered to present a more neutral perspective throughout (e.g., "such a study would…" replaces "the study will…")*

Major Revisions: Introduction

In response to public comments:

- More background on SACGHS role and charge related to the report
  - Lines 214-242
- More information from the NHGRI *Design Considerations* report
  - Lines 170-212
- Overview of the public comment process and input from stakeholders
  - Lines 244-262

Discussion?

Major Revisions: Scientific Background

- Description of Human Genome Project added
  - Lines 290-308

In response to public comments:

- Expanded section on current cohort studies in the U.S.
  - Lines 466-638

Discussion?

Major Revisions:
Research Policy Issues

- Expanded “Capacity to Conduct Interdisciplinary Science” (Lines 931-996)
  - Incorporated concepts from public comments (lines 970-978)
  - Added Women’s Health Initiative and National Children’s Study as models of interdisciplinary research (lines 980-996)

Major Revisions:
Research Policy Issues

- Expanded Section on “Need for Partnerships” (lines 998 – 1035)
- Expanded Section on “Access to Data and Materials” (Lines 1037-1105)
  - Incorporation of concepts from public comments (lines 1052-1076; lines 1101-1105)

Major Revisions:
Research Policy Issues

- Added section on NIH Genome-Wide Association Studies Initiative (Lines 1114-1136)
- Moved and expanded discussion of "environment" to the text (Lines 1191-1208)
  - Previously a footnote in the introduction
  - Incorporated feedback from public comments to the operational definition of environment

Discussion?

Major Revisions:
Research Logistics Issues

- As in Research Policy, changed definition of "environment" and moved from footnote to the text (Lines 1191-1208)

- Expanded section on "Recruitment and Enrollment"
  - Added material from Dr. Charles Rotimi's presentation to SACGHS (lines 1240-1256)
  - Added section on "Socioeconomic and Lifestyle Factors" (lines 1276-1291)

Major Revisions:
Research Logistics Issues

- Added section on “Multidisciplinary Research Teams”
  - Lines 1340-1353
- Added section on “Coordination Across Multiple Institutions and Healthcare Systems”
  - Lines 1355-1383

Discussion?

Major Revisions:
Regulatory & Ethical Issues

- Expanded the section on “Privacy and Confidentiality” (Lines 1517-1700)
  - Incorporated comments received from the World Privacy Forum, including:
  - “Need for a Privacy Officer” (lines 1647-1659); “Need for a Privacy Impact Assessment” (lines 1661-1670); “Third-Party Use of Project Records” (lines 1672-1688); and “Identifiability” (lines 1690-1700)

Major Revisions:
Regulatory & Ethical Issues

- In response to numerous public comments about the need for ethical oversight, added "Independent Ethics Review Committee" recommendation
  - Text: Lines 1760-1789
  - New: Recommendation 2 (lines 1806-1807)

Discussion?

Major Revisions: Public Health, Social, and Economic Implications

- Public health and social sections integrated
- Added language on potential economic impacts of a large population project (lines 2004-2027) and added "Economic" to section title
- Added a text box indicating SACGHS support of Federal Genetic Nondiscrimination Legislation
  - Reflects public comments stating a need for such legislation prior to embarking on a large population project
  - Page 52 of draft report and lines 1955-1980

Discussion?

Major Revisions:
Public Engagement

- Added section: “Moderated Focus Groups: The National Children’s Study”
  - Lines 2166-2204
- Added section: “NHGRI Public Consultation Initiative”
  - Lines 2206-2243
- Added section: “Recent Survey Data on Public Awareness of Genomics” based on presentation to SACGHS
  - Lines 2072 - 2091

Discussion?

Review of Recommendations

For consensus and for consideration of approval of content

“Options” Are Now “Recommendations”

- Overarching Recommendation: 1
- Research Policy: 5
- Research Logistics: 4
- Regulatory & Ethical: 4
- Public Health, Social, & Economic: 2
- Public Engagement: 2

  – TOTAL RECOMMENDATIONS: 18

Overview of Changes to Recommendations

Overarching	Research Policy	Research Logistics	Regulatory & Ethical	Public Health, Social & Economic Issues	Public Engagement
NEW **p. 20**	#1 Minor Edits	#1 Minor Edits	#1 Minor Edits	**#1** **NEW WORDING** p. 53	#1 Minor Edits
	#2 Minor Edits	#2 Minor Edits	**#2** **NEW (p. 47)**	#2 Minor Edits	#2 Minor Edits
	#3 Minor Edits	#3 Minor Edits	#3 Minor Edits		
	#4 Minor Edits	#4 Minor Edits	#4 Minor Edits		
	#5 Minor Edits				

Policy Issues Associated with a Large Population Cohort Project: Overarching Recommendation

*As part of the process for determining whether to undertake such a large-scale research project – **and prior to a decision being made** – the Secretary should initiate a thorough consideration of the full range of policy issues outlined in this report. The Secretary should consult and engage the full range of potential partners for such a project during this decision-making process, including the public at large, the full scientific community, a wide spectrum of government agencies, and the private sector.*

Lines 717-724

Research Policy Recommendation #1

The HHS Secretary should continue to promote and facilitate ongoing consultation with the public, the international community, and the private sector to explore opportunities for collaboration

Research Policy Recommendation #2

The HHS Secretary, in consultation with relevant HHS agencies and appropriate Congressional committees, should ensure that there is widespread support for sustaining a long-term and stable investment in a large population project.

Research Policy Recommendation #3

Given the trans-disciplinary nature of its scope, the Secretary may wish to establish a highly collaborative model of project leadership and management in multiple HHS and non-HHS agencies and with other stakeholders, including the public and private sectors, biological, behavioral, social, public health, and population-scientific disciplines, and basic biological scientists and epidemiologists.

Research Policy Recommendation #4

The HHS Secretary, in consultation with relevant HHS agencies, should ensure that there are opportunities available to the general scientific community to a) be informed about the potential for such a project; b) present its views about the scientific validity and feasibility of such a project; c) present its views on the commitment of resources to such an effort, including whether there are benefits to leveraging existing efforts; and d) provide input on issues related to fair access by scientists to the project resources and the sharing of data and samples collected within it.

Research Policy Recommendation #5

The Secretary should require that there are clear intellectual property policies in place for discoveries made using the data and samples collected to ensure public benefits.

Research Logistics Recommendation #1

The HHS Secretary should encourage project leadership and the scientific community to develop clear, consistent definitions and parameters for the stratification and classification of the projected sample population to ensure diversity and appropriate representation in the population to be studied.

Research Logistics
Recommendation #2

The HHS Secretary should seek input from the public, as well as researchers and clinicians, on the best approaches to identifying subpopulations for recruitment and on approaching, educating, and enrolling various subpopulations. Project organizers should be encouraged to consult with community-based organizations as part of their recruitment and enrollment strategies.

Research Logistics Recommendation #3

The HHS Secretary, in consultation with related agencies, should refine methods for collecting and analyzing environmental (physical, behavioral, and social) factors influencing health and ensure that resources are devoted to developing new tools to validate existing methods and improve assessments of the environment.

Research Logistics Recommendation #4

The HHS Secretary should encourage project leadership to consult with healthcare providers and organizations to develop uniform and secure approaches for collecting, storing, tracking, and centralizing clinical information to be gathered over the course of the project, including the use of electronic health records (EHRs).

Regulatory & Ethical Considerations Recommendation #1--REVISED

The HHS Secretary should convene a working group of representatives from the Office for Human Research Protections, Food and Drug Administration, the Office for Civil Rights, and other relevant agencies, to address issues and questions raised by the public and to provide technical assistance and guidance to research sites on legal requirements regarding protection of research subjects, health information privacy, and patient safety.

Regulatory & Ethical Considerations Recommendation #2

An independent ethics committee should be established to serve in an advisory capacity to the IRB and project management.

Regulatory & Ethical Considerations Recommendation #3

Project leadership should systematically and regularly seek the input of study subjects regarding their experiences, concerns, and recommendations for enhancing protections to ensure that the appropriate protections are in place and are being consistently implemented.

Regulatory & Ethical Considerations Recommendation #4

Project leadership should develop guidance on the use of data and samples to promote the ethical use of clinical and epidemiological data and specimens. This guidance should be made available to subjects.

Public Health, Social, and Economic Implications Recommendation #1

The HHS Secretary and project leadership should systematically and regularly integrate project findings with other emerging data from other types of studies and regularly disseminate the accumulated knowledge base with clear descriptions of the possible clinical implications of the results and the limitations of the data, their generalizability, and their clinical and public health implications. This information should be tailored to meet the information needs of the public, healthcare providers, and the public health community to use integrated information for the benefit of the population's health. Project resources should be sufficient for the integration, dissemination and translation activities necessary to maximize the public health impact.

Public Health, Social, and Economic Implications Recommendation #2

The HHS Secretary, in consultation with project leadership, should establish an independent standing committee for the duration of the project to periodically assess persistent and emerging social and economic implications of this initiative with special attention to health disparities. The committee could consist of individuals with expertise in the relevant sciences, medicine, law, ethics, and patient and community advocacy. The committee would routinely seek public input on the implications of the project results and report its findings.

Public Engagement Recommendation #1

The public's willingness to participate in a large population project should be assessed before embarking on such an extensive endeavor. Willingness could be assessed through opinion polls, requests for comments posted on agency websites, and other proven methods. Such an assessment should be made in advance of a funding decision.

Public Engagement Recommendation #2

If a decision is made to proceed with the project, it will be important to ensure that public engagement occurs throughout all aspects and stages of the research process, from conceptualization through design, planning, implementation, conduct, and data analysis and reporting. Public engagement also will be important in applying the knowledge gained by the research and in addressing its implications. The Secretary should ensure that sufficient project resources are dedicated to public consultation activities before and throughout the duration of the project.

Regulatory & Ethical Considerations Recommendation #1--REVISED

The HHS Secretary should convene a working group of representatives from the Office for Human Research Protections, Food and Drug Administration, the Office for Civil Rights, and other relevant agencies, to address issues and questions raised by the public and to provide technical assistance and guidance to research sites on legal requirements regarding protection of research subjects, health information privacy, and patient safety.

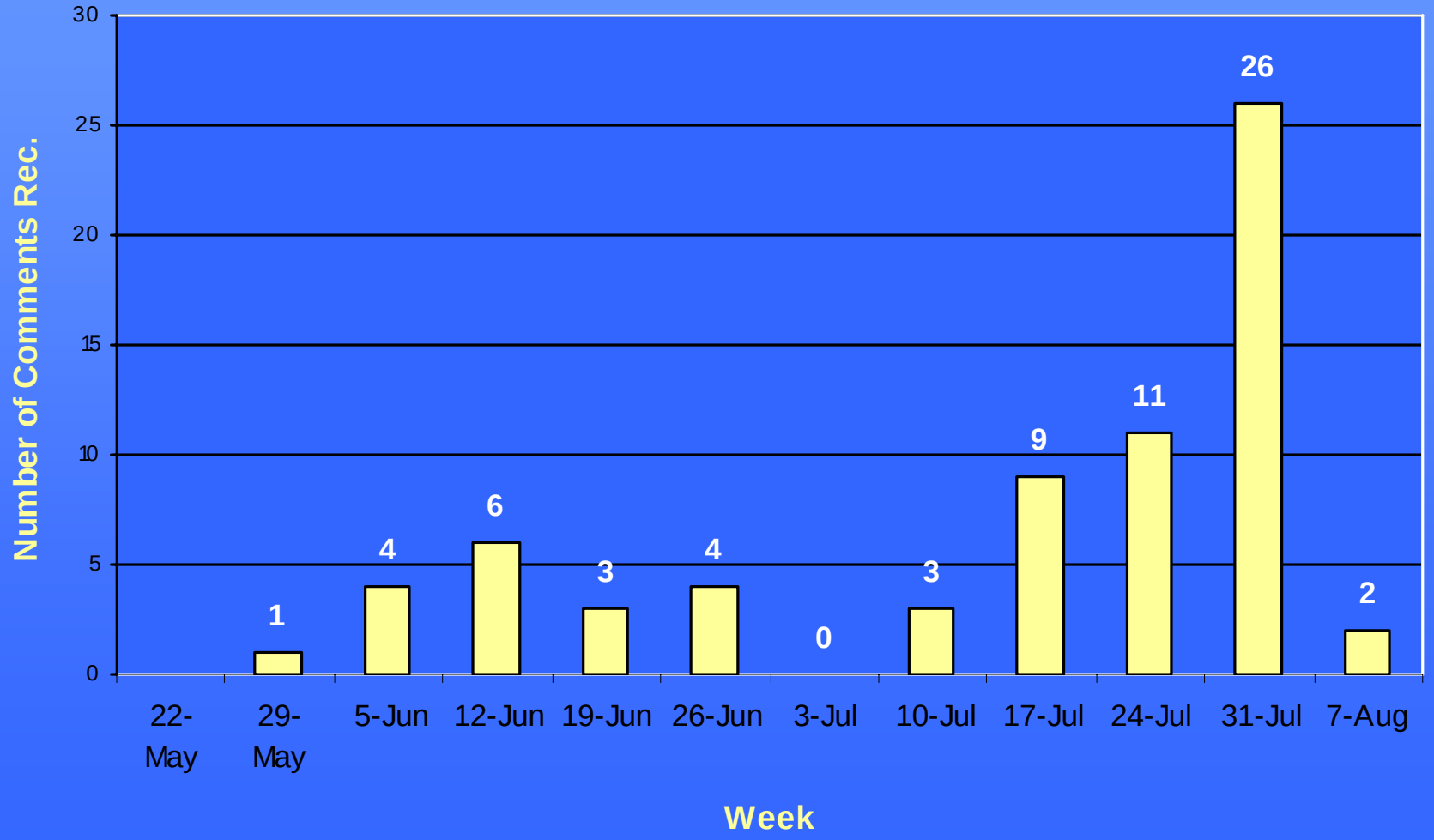
Session Purpose and Goal

- Review public comments
- Review final draft report
- **Consider approval of final report**

Discussion Questions

- Is the introductory material regarding SACGHS and the Task Force's charge appropriate?
- Is the scientific background information sufficient?
- Are the policy issues identified within the five broad policy issue areas complete?
- Do the recommendations adequately address the issues that have been identified?
- Are there any additional areas that need to be addressed?
- What should be emphasized in the conclusion?

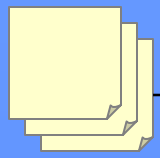
Public Comments Received Per Week
Total # of Comments = 69



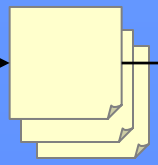
Disciplines Represented in 17 Comments from Academia

Bioethics	3
Neurosciences	3
Academic Biobank	2
Pediatrics	2
Genetics/Medical Genetics	1
Oncology	1
Epidemiology	1
Speech Communication	1
Microbiology & Immunology	1
Genomics & Public Health	1
Unclear	1

Analysis of Public Comments

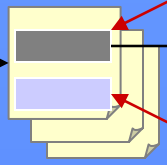


1. Comment Submission



2. ID Assignment

Prefix based on mode of delivery:
- Email - EM
- Fax – FX
- USPS Mail - RM

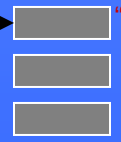


Examples:
Re: Public Engagement: "Mechanisms"

Re: Research Policy: "Intellectual Property"

3. Code Assignment

Comments categorized by policy issue in LPS report



Public Engagement
"Mechanisms"

Research Policy
"Intellectual Property"

4. Code Extraction

Coded comments aggregated into documents (by policy issue)

5. Review Assignments

Each Task Force member assigned one or more sets of coded comments along with full text of all comments

REPORT REVISED

Number of “Options” in First Draft

- Public Engagement: 2 Options
- Research Policy: 5 Options
- Research Logistics: 4 Options
- Regulatory & Ethical: 3 Options
- Public Health: 1 Option
- Social Implications: 1 Option

  – TOTAL OPTIONS: 16