

Policies and Procedures for the Advisory Committee on Heritable Disorders and Genetic Diseases in Newborns and Children

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ACHDGDNC Policies and Procedures

- For membership qualifications/expertise
- For liaison representatives
- For voting
- Meeting description
 - Public comment
 - Establishing agendas
- For the establishment of subcommittees and workgroups

ACHDGDNC Policies and Procedures

(continued)

- For the development of recommendations for evaluating tests/technologies/disorders
 - Nomination process
 - Review process
- For Committee policy analysis and recommendations
- For publication of recommendations
- For implementation and evaluation of recommendations

Membership

- Consideration of Nomination
 - Expertise required (legislation)
 - Financial conflicts of interest
 - Federal law prohibitions
 - Waivers
 - Representatives versus members
 - Solicitation process
 - Selection process

Member Responsibilities

- Voting
- Meetings and Attendance
- Financial Conflicts
- Media Interaction

Subcommittees

- Subcommittees
 - Charge established by the Committee
 - Membership
 1. must include two or more ACHDGDNC members,
 2. must include HRSA staff members, and
 3. may include *ex officio* members and, as consultants, liaison representatives.

Workgroups/Subgroups

- To review research data, published literature and expert opinion and develop options for presentation to the full Committee
- Committee appoints working group members and these members need not be Committee members.
 - Manufacturers may make presentations

Developing Recommendations: Technical Aspects

- Workgroup formation for reviewing research data
 - Develop options (recommendations) for Committee's deliberation
- Process of developing recommendations includes
 - a review of the scientific literature;
 - evaluation of equity in access to the screening technology, test or process and responsible management of public funds

Developing Recommendations: Technical Aspects (continued)

- a review of the associated morbidity and mortality associated a review of the recommendations of other groups; and
- a consideration of the feasibility of the screening technology, test or process in existing newborn and child screening programs.
- ACHDGDNC recommendations may be issued jointly with nongovernmental professional organizations or other PHS advisory committees

Policy Analysis

- Many of the issues addressed by the Committee are not technical but policy issues.
- Formal policy analysis may be requested and/or performed by the ACHDGDNC

Heritable Disorders Grant Program

- Committee charged to make recommendations about the Heritable Disorders Program (HDP)
- ACHDGDNC recommendations for the HDP are developed and voted upon in a separate process, distinct from ACHDGDNC recommendations.
- Process based upon the unique statutory authority for the HDP established by Title XI, Section 1110 of the Public Health Service Act, 42 U.S.C. 300b-8 and 9.
- Legislation gives Committee responsibility and authority to provide technical information to the Secretary for the development of policies and priorities for the administration of grants under section 1110.

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