CHARTER

Rockville, Maryland 20857

The Health Resources and Services Administration Human Subjects Committee

Purpose

The Health Resources and Services Administration(HRSA) Human Subjects Committee is an internal body established to advise the Administrator, Deputy Administrator, and HRSA Bureaus and Offices on policies and procedures for protection of human subjects of research carried out by HRSA or its grantees or contractors.

Functions

The Committee will review and develop recommendations for action by HRSA components in the following areas:

1. Policies and procedures for protection of human subjects of research;
2. Compliance with HHS regulations for the protection of human subjects of research;
3. Monitoring and evaluation of subject protections in HRSA-sponsored research activities;
4. Technical assistance and professional education in subject protection and research ethics matters, including internal education activities required by Executive Order 12975; and
5. Other relevant issues pertaining to human subjects of research.

The Committee will review all claims of exemption referred to it by HRSA components under the provisions of Policy Circular 96.05 or other guidance, determine whether any proposed claim of exemption is proper, and give such guidance as may be appropriate to the circumstances.

The Committee will review all questions relating to research subject protection referred to it by HRSA components or other HHS ethics bodies, and give such advice and technical assistance as may be appropriate to the circumstances.

Membership and Staff Support

Director, Center for Quality or designee - Chair

Director, OPEL or designee - Vice Chair

Representatives and alternates from each Bureau and Office that performs or supports research utilizing human subjects.

Staff support for the Committee will be provided by the Center for Quality, HRSA.

Meetings and Records

The Committee will meet regularly at least once a year to review human subjects protection in intramural research projects. It will meet on additional occasions as scheduled by the Chair to review research proposals, respond to requests for advice or technical assistance, or perform other required duties. The Committee will publish summary minutes, an explicit report of all approvals or disapprovals granted during reviews of claims of exemption from regulatory oversight, and an annual summary report.

Duration of the Council

Indefinite.

Approved ✓ Disapproved: _____ Date: 7/6/97

Claude Earl Fox, M.D., M.P.H.
Acting Administrator