7. Conduct data analysis with CDC and other collaborators as well as present research findings.

B. CDC Activities

1. Provide technical assistance in the design and conduct of the research;
2. Provide technical guidance in the development of study protocols, consent forms and questionnaires;
3. Assist in designing a data management system;
4. Perform selected laboratory tests;
5. Coordinate research activities among the different sites; and
6. Participate in the analysis of research information and the presentation of research findings.

Determination of Which Instrument to Use

Applicants must specify the type of award for which they are applying, either project grant or cooperative agreement. CDC will review the applications in accordance with the evaluation criteria. Before issuing awards, CDC will determine whether a grant or cooperative agreement is the appropriate instrument based upon the need for substantial Federal involvement in the project.

Evaluation Criteria

Applications will be reviewed and evaluated based on the evidence submitted, which specifically describes the applicants' abilities to meet the following criteria:

A. The inclusion of a detailed review of the scientific literature pertinent to the study being proposed and specific research questions and/or hypotheses that will guide the research. (25 points)

B. The originality and need for the proposed research and the extent to which it does not replicate past or present research efforts. (25 points)

C. The plans to develop and implement the study describing how study participants (including racial/ethnic minority populations) will be identified, enrolled, tested and followed. (25 points)

D. The ability to enroll and follow an adequate number of eligible study participants to assure proper conduct of the study. This includes both demonstration of the availability of HIV-infected potential study participants and the experience of the investigator in enrolling and following such persons in a culturally and linguistically appropriate manner. (25 points)

E. The applicant's current activities in AIDS and HIV or related research and how they will be applied to achieving the objectives of the study. Letters of support from cooperating organizations which demonstrate the nature and extent of such cooperation should be included. (20 points)

F. The applicant's understanding of the research objectives and their ability, willingness and/or need to collaborate with CDC and researchers from other study sites in study design and analysis, including use of common forms, and sharing of specimens (when appropriate) and data. (25 points)

G. The plan to protect the rights and confidentiality of all participants. (25 points)

H. The size, qualifications and time allocation of the proposed staff and the availability of facilities to be used during the research study. Description of how the project will be administered to assure the proper management of the daily activities of the program. (10 points)

I. The proposed schedule for accomplishing the activities of the research, including time-frames. (10 points)

J. A detailed evaluation plan which specifies methods and instruments to be used to evaluate the progress made in attaining research objectives. (10 points) (A maximum of 200 cumulative points can be awarded.)

The budget will be reviewed to determine the extent to which it is reasonable, clearly justified, and consistent with the intended use of funds. All budget categories should be itemized.

Funding Priorities

Priority will be given to competing continuation applications from satisfactorily performing projects over applications for projects not already receiving support under the program. Projects to evaluate the implementation of policies to reduce mother-to-child transmission will be awarded so that the composite of projects represents the geographic and demographic characteristics of HIV-infected childbearing women.

Public comments are not being solicited regarding the funding priority because time does not permit solicitation and review prior to the funding date.

Executive Order 12372 Review

Applications are not subject to review under Executive Order 12372, Intergovernmental Review of Federal Programs.

Public Health System Reporting Requirements

This program is not subject to the Public Health System Reporting Requirements.

Catalog of Federal Domestic Assistance Number

The Catalog of Federal Domestic Assistance Number is 93.943, Epidemiologic Research Studies of Acquired Immunodeficiency Syndrome (AIDS) and Human Immunodeficiency Virus (HIV) Infection in Selected Population Groups.

Other Requirements

A. Paperwork Reduction Act

Projects that involve the collection of information from 10 or more individuals and funded by cooperative agreement will be subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act.

B. Human Subjects

This program involves research on human subjects. Therefore, all applicants must comply with the Department of Health and Human Services Regulations, 45 CFR Part 46, regarding the protection of human subjects. Assurance must be provided to demonstrate that the project or activity will be subject to initial and continuing review by an appropriate institutional review committee. The applicant will be responsible for providing assurance in accordance with the appropriate guidelines and form provided in the application kit.

In addition to other applicable committees, Indian Health Service (IHS) institutional review committees also must review the project if any component of IHS will be involved or will support the research. If any American Indian community is involved, its tribal government must also approve that portion of the project applicable to it.

C. HIV Program Review Panel

Recipients must comply with the document entitled Content of AIDS-Related Written Materials, Pictorials, Audiovisuals, Questionnaires, Survey Instruments, and Educational Sessions (June 1992) (a copy is in the application kit). To meet the requirements for a program review panel, recipients are encouraged to use an existing program review panel, such as the one created by the State health department's HIV/AIDS prevention program. If the recipient forms its own program review panel, at least one member must be an employee (or a designated representative) of a State or local health department. The names of the review panel members must be listed on the Assurance of Compliance Form CDC 0.1113, which is also included in the application kit. The recipient must submit the program