An overriding concern in HIV/AIDS related research is confidentiality. The Office for Protection for Research Risks (OPRR), currently the U.S. Office for Human Research Protections (OHRP), guidance on HIV/AIDS related research states that subject identifiers should not be recorded when they are not required by the design of the study. In instances where subject identifiers are recorded, they should be separated, if possible, from data and stored securely, with linkage restored only when necessary to conduct the research.

Before agreeing to participate in an HIV/AIDS study, subjects must be informed of exactly what information will be recorded, and whether any state laws require notification to authorities of HIV/AIDS infection or other disclosures of information. Participants must be given a clear explanation of how information about them will be handled and used as a part of the proposed research.

Information about the subject is not to be disclosed without the subject’s consent. The research protocol must clearly state who is entitled to see records with subject identifiers both within and outside the project. As such, this statement must take into account the possibility that these records may be reviewed by the funding agency and the Institutional Review Board (IRB). Lists identifying people who have elected not to participate in the proposed research should not be retained.

**Requirements of Informing Subjects of Test Results**

As required by the U.S. Public Health Service, it is IRB policy that when HIV testing is conducted as a part of research, individuals who can be identified must be informed of their own test results and provided the opportunity to receive appropriate counseling. Individuals may not be given the option “not to know” the result, either at the time of consenting to be tested or thereafter.

In situations involving special circumstances, however, the IRB may approve exceptions to informing subjects of their HIV/AIDS serostatus. In the view of OPRR, acceptable “special circumstances” include compelling and immediate circumstances such as an indication that the individual would commit suicide if informed that he or she was HIV/AIDS seropositive, that extremely valuable knowledge might be gained from research involving subjects who would be expected to refuse to learn of their HIV test
results, or research activities conducted at foreign sites where cultural norms, the health resource capabilities, and official health policies of the host country preclude informing subjects of the HIV serostatus. Subjects must be informed, as a part of the consent process, of any plans to notify subjects’ sexual or needle-sharing partners.

Whenever subjects will be informed of their HIV/AIDS serostatus, appropriate counseling must be provided. This includes both pre-test and post-test counseling. Counselors should be qualified to provide HIV test counseling as well as partner notification services.