Rationale for Modifications to the 2001 National Institute on Drug Abuse Policy on Counseling and Testing for HIV/AIDS and other Infectious Diseases (NOT-DA-01-001).

This document identifies and provides the rationale for proposed changes to the 2001 National Institute on Drug Abuse Policy on Counseling and Testing for HIV/AIDS and other Infectious Diseases (NOT-DA-01-001). The purpose of the revised policy is to provide investigators with a range of options for helping to promote HIV prevention and intervention. The policy is intended to give investigators utmost flexibility to select the strategies most appropriate to their research populations, research methods, research context, and availability of educational, assessment, and intervention resources.

Inclusion of "Education" and "Educational Materials": There is a substantial body of empirical evidence demonstrating that education is an essential component of an effective HIV prevention and management. The inclusion of "education" throughout the modified policy is intended to alert NIDA grantees to this literature and to require that at minimum, NIDA sponsored researchers should make efforts to provide appropriate education/educational materials to subjects at-risk for drug-related HIV/AIDS. NIDA sponsored research can vary in design, recruitment methods, research personnel, location of research, research methodology, intervention or follow-up protocols, and resources available for HIV counseling, testing and treatment. However, the majority of studies can provide at minimum, essential HIV-related educational materials. Easy-to-understand materials will enable participants to acquire knowledge that can assist them develop skills to protect and promote their sexual health, and to minimize their risks (both sexual and injection) of acquiring and transmitting HIV, including knowledge about HIV testing and the benefits of HIV/AIDS treatment early in the course of the disease. The proposed policy includes updated information on educational materials available to investigators through NIDA and other government agencies. The policy does not require that these specific educational materials are used and investigators are encouraged to construct materials appropriate to their subject populations. For example, investigators working with pregnant mothers might provide educational information on best parenting practices for HIV infected newborns and/or information about services available; those working with children could provide parents or caretakers with appropriate educational materials or with appropriate approval create age-sensitive educational material for child participants; and those working with adolescents would provide age appropriate materials.

The 2001 policy described education as "easy-to-read" materials. However, since these may not be appropriate for illiterate populations of drug users the revised draft includes "education in a verbal format or easy-to-read materials". These materials can be obtained from NIDA (http://www.nida.nih.gov/infofacts/DrugAbuse.html), the Centers for Disease Control and prevention (CDC) (http://www.cdc.gov/hiv/HIVinfo.htm), the Substance Abuse and Mental Health Services Administration (http://www.samhsa.gov/Matrix/matrix_HIV.aspx), and the National Institute of Allergy and Infectious Diseases (NIAID) (http://www.niaid.nih.gov/publications/aids.htm).

Inclusion of "Provision of or Referral to Testing and Treatment": The 2001 policy limited recommended investigator activities to "counseling and testing." The proposed policy includes "treatment" and the option of providing "referrals or provision of such services" depending on the nature of the study. The inclusion of "treatment" reflects advancements in HIV/AIDS management since 2001. The policy also recognizes that management of HIV infection is complex and involves a wide range of behavioral, psychosocial, and medical services. Thus "treatment" may be broadly defined by investigators. Moreover, NIDA funds a range of social science and public health studies whose designs fall along a continuum from basic and descriptive studies to preventive and intervention research. While investigators funded to conduct ethnographic, survey, and epidemiological studies are rigorously trained in research design, implementation and analysis (e.g. social science researchers), they and their staff may not possess the disciplinary training or credentials necessary to provide competent and appropriate diagnostic and medical services; nor may their research be based in or affiliated with a medical setting. For these types of NIDA sponsored studies, the proposed policy encourages investigators and their staff to become knowledgeable about the counseling, testing and treatment options available in the participants' local communities and refer subjects to health-care providers or facilities experienced in managing HIV infected patients.

The policy encourages investigators to develop educational, counseling, testing, or treatment procedures that are most compatible and appropriate with the research team's skills, research context, and resources. It does not however require testing or treatment. It does state (as was stated in the 2001 policy) that research that includes HIV testing and is being conducted in medical settings will more likely be able to provide counseling and perhaps services--or at least referrals for services. Viewed within the context of the addition of the inclusion of "education" in the proposed policy, the modifications to the 2001 policy acknowledge variations in investigator discipline-specific training, research site resources, and available community services to encourage NIDA grantees to provide the information, referrals or services most appropriate to the research context. For example, a street survey that includes a brief single contact with participants might at minimum provide participants with some educational material or a hand-out containing a list of HIV resources in the community. A study conducted in a medical setting that tests for HIV and includes several follow-up interviews might be able to include counseling and guidance on different types of services available to HIV + individuals. HIV clinical trial studies (e.g., vaccine or microbicide trials) conducted in medical settings should comply with the obligation to treat trial-related medical conditions. The goal of the policy is to have investigators recognize their responsibility toward HIV prevention and treatment and creatively construct procedures appropriate to the research design and resources.

Inclusion of "Domestic and International Research": Recruitment for research participation of active drug users at risk for acquiring or transmitting HIV presents serious medical, legal, ethical, economic and social challenges. The complexity of these issues is further compounded by the unique local, social, economic, and public health conditions of participants in developed and developing nations. With respect to medical research in general there is growing emphasis worldwide on issuing or adopting standards

of research ethics that apply to both domestic and international research settings. However, no international consensus has emerged on standards pertaining to the nature and extent of subject referral or access to counseling, assessment, or medical services [see for example conflicting opinions expressed in the latest revision of the Declaration of Helsinki: *Ethical Principles for Medical Research Involving Human Subjects* and in statements by the Council for International Organizations of Medical Sciences (CIOMS, 2002) and the U.S. President's National Bioethics Advisory Commission (NBAC, 2001) on whether regardless of country of origin, every research participant should be provided access to the best and proven treatment methods available]. With respect to HIV-specific policies, the Joint United Nations Program on HIV/AIDS (UNAIDS, 2000) recommends that all research participants in HIV vaccine trials conducted in developing countries have access to HIV counseling, testing, and treatment services defined as "the highest level of care attainable in the host country".

In the United States, when specific policies on services and protections for research subjects are mandated, investigators are expected to ensure equal protection of subjects both in the U.S. and abroad. For example, the U.S. Public Health Service (PHS) policy on HIV testing mandates that "when HIV testing is conducted or supported by PHS, individuals whose test results are associated with personal identifiers must be informed of their own test results and provided with the opportunity to receive appropriate counseling. This policy applies to all intramural and all extramural PHS activities, including both research and service activities, domestic and foreign" (OPRR Reports, 1988). Similarly, under U.S. regulations 45CFR46 for protection of human subjects, an agency may approve protections for human subjects based on the local national policies only if such practices afford protections that are at least equivalent to U.S. policy (OHRP, HHS, 2006). Inclusion of international research under a revised NIDA policy is thus consistent with current U.S. and international laws and guidelines.

Inclusion of "Ethnographic and Field Studies" and exclusion of the phrase "contacts occur only once and are brief": The 2001 policy strove to encourage investigators to at minimum provide subjects with "educational materials" when studies (such as "surveys") were not conducted at sites that provided HIV related "services to participants over period of time" or when investigator-participant contact occurred "only once and are brief". In the 2001 policy, the phrase "contacts occur only once and are brief" is modified because it did not do justice to the intent of the policy. The intent of this language was to recognize that provision of educational materials would be most feasible for research studies on drug use and HIV (e.g., social science surveys or interviews) that do not include collection of medical data and involve a single and brief contact with a subject. However, there are studies that involve only single and brief investigator-subject contact for which educational materials would not be a sufficient response to the policy. For example, an investigator studying the prevalence of HIV may need to see a subject only once to conduct an interview and a rapid HIV test. The spirit of the policy is that for such research at minimum, the subjects should be provided their test results and a provision or referral to HIV counseling and treatment.

The "once and are brief" language might also be misunderstood as encouraging non-medical investigators to provide counseling, assessment, or treatment. For example, investigators conducting an ethnographic or field study may have a protracted period of

engagement with their research subjects that does not include HIV testing and is not affiliated with a medical setting. In these research contexts, providing participants with educational materials may best reflect the spirit of the policy. For these reasons, the proposed policy (1) adds to the original policy language of "education and counseling" encouragement of "testing and treatment" for research that provides health or social services to participants over a period of time" (2) includes "ethnographic and field studies"; and (3) clarifies that at "minimum education in a verbal format or easy-to-read materials on drug abuse and HIV/AIDS should be available to study participants when the research (e.g., surveys, ethnographic or field studies) is not based in or directly affiliated with a counseling, testing or treatment facility".

Inclusion of "Progress Reports": As HIV prevention policies and research designs continue to rapidly evolve domestically and internationally, it appears premature for a description of how the investigator plans to comply with the NIDA education, counseling, testing and treatment policy to be evaluated as part of the initial scientific review of a proposal. All NIDA grantees are required to submit an annual noncompeting continuation progress report for multi-year funded research projects and a final report for completed projects. As a first step in encouraging implementation and in providing NIDA a means of monitoring investigator compliance and developing guidance on policy implementation, the proposed revised policy requires that "NIDA grantees should provide in all Progress and Final Reports submitted to the Agency a rationale and description of the services provided under this policy". The policy recognizes that some studies do not have resources that would make testing, counseling, or treatment feasible or appropriate and that in rare instances educational approaches may not be possible. The progress report section should provide procedural decisions and the rationale for selecting among the various recommended procedures. If an investigator believes that implementing any of these procedures creates greater risk or is not feasible, the investigator should provide the rationale for this decision. In summary, as a public health research institute, NIDA believes that researchers share the responsibility for preventing the acquisition and transmission of HIV and helping individuals to find treatment for drug abuse and its co-morbid conditions. The revisions proposed in this policy offer guidance for how NIDA-sponsored researchers can contribute to this important aspect of NIDA's mission.

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