after this year all appointments to replace members whose terms have expired will be for 3 years.

David M. Walker,

Comptroller General of the United States.

[FR Doc. 99–4163 Filed 2–18–99; 8:45 am]

BILLING CODE 1610–02–U

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Agency Information Collection Activities: Submission for OMB Review; Comment Request

The Department of Health and Human Services, Office of the Secretary publishes a list of information collections it has submitted to the Office of Management and Budget (OMB) for clearance in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35) and 5 CFR 1320.5. The following are those information collections recently submitted to OMB.

Title and Description of Information Collection: Multi-site Evaluation of the Welfare-to-Work Grants Program—Baseline Forms—NEW—As required by the Balanced Budget Act of 1997, DHHS is planning a four-year project to evaluate the effectiveness of welfare-to-work initiatives undertaken through competitive and formula grants awarded by the US Department of Labor. DHHS' Office of the Assistant Secretary for Planning and Evaluation, in conjunction with DoL and the US Department of Housing and Urban Development (HUD), has designed an evaluation that will involve several rounds of data collection from grantees and grant program participants. The information collection instruments in this request for OMB approval consist of a sample intake form, a contact information form, and a study participation consent form to be used to gather baseline and administrative information on study participants. Respondents: Individuals, State and Local Governments, Businesses or Other For-profit Organizations, Not-for-profit Institutions; Burden Information for the Intake Form—Number of Respondents: 10,000; Number of Responses per Respondent: one; Average Burden per Response: 5 minutes; Total Burden for Intake Form: 830 hours—Burden Information for the Contact Information Form—Number of Respondents: 10,000; Number of Responses per Respondent: one; Average Burden per Response: 5 minutes: Total Burden for Contact Information Form: 830 hours—Burden Information for the Consent Form—Number of Respondents: 10,000; Number of Responses per Respondent: one; Average Burden per Response: 5 minutes: Total Burden for Consent Form: 830 hours. Total Burden: 2,490 hours. Total Annual Burden: 1,245 hours.

OMB Desk Officer: Allison Eydt

Copies of the information collection packages listed above can be obtained by calling the OS Reports Clearance Officer on (202) 690–6207. Written comments and recommendations for the proposed information collection should be sent directly to the OMB desk officer designated above at the following address: Human Resources and Housing Branch, Office of Management and Budget, New Executive Office Building, Room 10235, 725 17th Street NW., Washington, DC 20503.

Comments may also be sent to Cynthia Agens Bauer, OS Reports Clearance Officer, Room 503H, Humphrey Building, 200 Independence Avenue SW., Washington, DC 20201. Written comments should be received within 30 days of this notice.

Dated: February 11, 1999.

Dennis P. Williams,

Deputy Assistant Secretary, Budget.

[FR Doc. 99–4028 Filed 2–18–99; 8:45 am]

BILLING CODE 4150–04–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Notice of Publication of the Executive Summary of the Report, Research Involving Persons With Mental Disorders That May Affect Decisionmaking Capacity by the National Bioethics Advisory Commission (NBAC)

SUPPLEMENTARY INFORMATION: The President established the National Bioethics Advisory Commission (NBAC) on October 3, 1995 by Executive Order 12975 as amended. The functions of NBAC are as follows:

(a) provide advice and make recommendations to the National Science and Technology Council and to other appropriate government entities regarding the following matters:

(1) the appropriateness of departmental, agency or other governmental programs, policies, assignments, missions, guidelines, and regulations as they relate to bioethical issues arising from research on human biology and behavior; and (2) applications, including the clinical applications, of that research.

(b) identify broad principles to govern the ethical conduct of research, citing specific projects only as illustrations for such principles.

(c) shall not be responsible for the review and approval of specific projects.

(d) in addition to responding to requests for advice and recommendations from the National Science and Technology Council, NBAC also may accept suggestions of issues for consideration from both the Congress and the public. NBAC may also identify other bioethical issues for the purpose of providing advice and recommendations, subject to the approval of the National Science and Technology Council. The members of NBAC are as follows:

Harold T. Shapiro, Ph.D., Chair
Patricia Backlar
Arturo Brito, M.D., Alexander M. Capron, LL.B.
Eric J. Cassell, M.D., M.A.C.P.
R. Alta Charo, J.D.
James F. Childress, Ph.D.
David R. Cox, M.D., Ph.D.
Rhetaugh G. Dumas, Ph.D., R.N.
Laurie M. Flynn
Carol W. Greider, Ph.D.
Steven H. Holtzman
Bernard Lo, M.D.
Lawrence H. Miike, M.D., J.D.
Thomas H. Murray, Ph.D.
Diane Scott-Jones, Ph.D.

Executive Summary, Research Involving Persons With Mental Disorders That May Affect Decisionmaking Capacity

In this report, the National Bioethics Advisory Commission (NBAC) considers how ethically acceptable research can be conducted with human subjects who suffer from mental disorders that may affect their decisionmaking capacity; whether, in this context, additional protections are needed; and, if so, what they should be and how they should be implemented. In addition, this report provides an opportunity for investigators, Institutional Review Board (IRB) members, persons with mental disorders and their families, and the general public to become better informed about the importance of such research and what we believe are the appropriate protections for the human subjects involved.

This report stands in a long line of statements, reports, and recommendations by governmental advisory groups and professional organizations on the ethical requirements of research involving human subjects that have been developed in the United States and elsewhere. Much has changed in the research environment since the National Commission for the Protection of Human Subjects of Biomedical and

Behavioral Research completed its work 20 years ago, and yet one finding is as true today as it was then: all research involving human beings as subjects must satisfy appropriate ethical and scientific standards. This moral imperative is especially acute for potentially vulnerable populations such as children, pregnant women, prisoners, or, NBAC believes, individuals with mental disorders that may affect their decisionmaking capacity. Mental disorders—which can be heartbreakingly burdensome for patients and their families and frustrating for the professionals who treat them—have in recent years been the focus of research studies that have produced important new methods of diagnosis and treatment. At the same time, some of these investigations have generated public controversy, government sanctions, and at times lawsuits. Although existing federal regulations for research involving human subjects provide special protections for certain populations that are regarded as particularly vulnerable, persons with mental disorders (who may have impaired capacity to make decisions about research participation) have not received any such special protections. NBAC believes that a cogent case can be made for requiring additional special protections in research involving as subjects persons with impaired decisionmaking capacity, but has chosen to focus this report on persons with mental disorders, in part because of this population's difficult history of involvement in medical research. Moreover, NBAC believes that in addition to the regulations that are already applicable, research involving subjects with mental disorders that may affect decisionmaking capacity should be governed by specific further regulations.

In its consideration of these issues over 18 months, NBAC received input through public comments provided at every meeting, expert testimony, commissioned papers, interactions with professional and patient groups, and a 45-day comment period during which interested parties could submit written comments on the final draft report. In addition, NBAC reviewed a sampling of research protocols and consent forms relevant to research on individuals whose decisionmaking capacity might be affected by mental illness. Based on these varied inputs and careful deliberations, NBAC came to the following conclusions:

- During the nearly two decades in which the current federal regulations for the protection of human subjects have been in place, important scientific research on the cause and treatment of mental disorders has continued and expanded. Further, NBAC believes that important opportunities to develop new therapies will continue to emerge, and that the research community may be on the verge of some momentous breakthroughs. NBAC's challenge, therefore, was to develop recommendations that would sustain the continued acquisition of new knowledge and the development of new therapies, while ensuring the protection of those who participate as subjects in such research.
- Although IRBs have considerable authority and discretion to review, approve, and monitor research involving persons with mental disorders, they have received little practical guidance for reviewing such protocols. However, more than additional guidance is needed. Because of significant gaps in the current federal regulation additional regulations are necessary at this time. NBAC believes that enhanced protections will promote broad-based support for further research by engendering greater public trust and confidence that subjects' rights and interests are fully respected.
- More research is being conducted than ever before, and the research environment has become far more complex, involving both a larger societal investment and a greater role for the private sector. NBAC shares what it believes to be a broad base of support for continuing efforts to more fully understand and treat mental disorders. NBAC recommends additional new protections with the deepest respect for the many people involved in research on these disorders: those with a disorder that may affect decisionmaking capacity, whose autonomy must be protected and, when possible, enhanced; the clinical investigators who are dedicated to the alleviation of these disorders; and informal caregivers, whose own lives are often absorbed by the tragedy that has befallen their loved ones. NBAC does not believe, however, that the additional protections recommended in this report will excessively burden research or hamper the development of effective new treatments. Moreover, it is useful to note that many share in the responsibility to protect the interests of those without whom this research could not be done—especially those who may be unable to give full informed consent and who may not themselves directly benefit from the research.

Overview of the Report

The report is divided into five chapters. Chapter 1 provides an overview of the issues that arise in research involving persons with mental disorders. It discusses the justification for the scope of the report, the nature of mental disorders, and the values that should guide research in these populations. Chapter 2 discusses informed consent and limitations on decisionmaking capacity. Chapter 3 examines the mechanisms that may be used to permit enrollment of persons who are now incapable of providing an informed consent: advance planning and surrogate decision making. It also considers the role of assent and objection. Chapter 4 explains NBAC's views on the assessment of risk and potential benefit in research. In particular, this chapter provides the rationale for distinguishing research protocols involving minimal risk, protocols involving greater than minimal risk that do not offer the prospect of direct medical benefit to the subjects, and protocols involving greater than minimal risk that do offer the prospect of direct medical benefit to the subjects. Chapter 5 presents NBAC's recommendations for regulatory reform and suggested additional guidance to IRBs and institutions.

The several recommendations for changes in federal regulations and for other governmental, institutional, and organizational actions are interconnected. Even though only a few recommendations are explicitly cross-referenced, it is important to view each recommendation in the context of the others. Only then is it possible to see exactly how NBAC proposes to protect human subjects with mental disorders that may affect decisionmaking capacity and also allow important research to proceed.

Recommendations

This report presents not only NBAC's recommendations but identifies where possible those who should be responsible for their implementation. Twenty-one recommendations are proposed. A number propose the development of new regulations for the protection of human subjects; others are directed to investigators and IRBs, state legislatures, the National Institutes of Health (NIH), the Department of Health and Human Services (DHHS), health professionals, federal agencies subject to the Federal Policy for the Protection of Human Subjects (''the Common Rule''), and others responsible for human subjects protection. These recommendations provide both a set of requirements that NBAC believes must be satisfied in all research protocols involving persons with mental disorders, and several additional or optional protections that may be

considered, as appropriate, in particular circumstances. Taken together, these recommendations would both enhance existing protections and facilitate broad public support for continued research on mental disorders.

Although NBAC proposes a number of recommendations that would require changes in the Common Rule, it is aware that the time frame for such reforms might be long and the process labor intensive. Many of the regulatory proposals made by NBAC could, therefore, be accomplished by the creation of a new subpart in 45 CFR 46. Regardless of which regulatory route is selected, NBAC encourages researchers and institutions to voluntarily adopt the spirit and substance of these recommendations immediately. The recommendations are clustered into six sections related to: review bodies; research design; informed consent and capacity; categories of research; surrogate decision making; and education, research, and support.

I. Recommendations Regarding Review Bodies

Institutional Review Board (IRB) Membership

Recommendation 1. All IRBs that regularly consider proposals involving persons with mental disorders should include at least two members who are familiar with the nature of these disorders and with the concerns of the population being studied. At least one of these IRB members should be a member of the population being studied, a family member of such a person, or a representative of an advocacy organization for this population. These IRB members should be present and voting when such protocols are discussed. IRBs that only occasionally consider such protocols should involve in their discussion two ad hoc consultants who are familiar with the nature of these disorders and with the concerns of the population being studied; at least one of these consultants should be a member of the population being studied, a family member of such a person, or a representative of an advocacy organization for this population.

Creation of a Special Standing Panel (SSP)

Recommendation 2. The Secretary of the Department of Health and Human Services should convene a Special Standing Panel (SSP) on research involving persons with mental disorders that may affect decisionmaking capacity. The panel's tasks should include:

(A) Reviewing individual protocols that cannot otherwise be approved under the recommendations described in this report, that have been forwarded by IRBs to the SSP for its consideration. If the SSP finds that a protocol offers the possibility of substantial benefit to the population under study, that its risks to subjects are reasonable in relation to this possible benefit, and that it could not be conducted without the proposed population, then the SSP may approve the protocol if it is satisfied that all appropriate safeguards are incorporated. Under no circumstance, however, should the SSP approve a protocol that reasonable, competent persons would decline to enter;

(B) Promulgating guidelines that would permit local IRBs to approve protocols that cannot otherwise be approved under the recommendations described in this report. Such guidelines could suggest that a particular class or category of research, using specified research interventions with certain identified populations, could be considered by local IRBs without the need to resort to the SSP for further approval. Under no circumstances, however, should the SSP promulgate guidelines permitting IRBs to approve research that would enroll subjects who lack decisionmaking capacity in protocols that reasonable, competent persons would decline to enter.

The SSP should have members who can represent the diverse interests of potential research subjects, the research community, and the public. The panel's protocol approvals and guidelines should all be published in an appropriate form that ensures reasonable notice to interested members of the public.

Those federal agencies that are signatories of the Common Rule should agree to use the SSP, and the SSP's effectiveness should be reviewed no later than 5 years after inception.

II. Recommendations Regarding Research Design

Appropriate Subject Selection

Recommendation 3. An IRB should not approve research protocols targeting persons with mental disorders as subjects when such research can be done with other subjects.

Justifying Research Design and Minimizing Risks

Recommendation 4. Investigators should provide IRBs with a thorough justification of the research design they will use, including a description of procedures designed to minimize risks to subjects. In studies that are designed to provoke symptoms, to withdraw subjects rapidly from therapies, to use placebo controls, or otherwise to expose subjects to risks that may be inappropriate, IRBs should exercise heightened scrutiny.

Evaluating Risks and Benefits

Recommendation 5. Investigators should provide IRBs with a thorough evaluation of the risks and potential benefits to the human subjects involved in the proposed protocol. The evaluation of risks includes the nature, probability, and magnitude of any harms or discomforts to the subjects. The evaluation of benefits should distinguish possible direct medical benefits to the subject from other types of benefits.

III. Recommendations Regarding Informed Consent and Capacity

Informed Consent To Research

Recommendation 6. No person who has the capacity for consent may be enrolled in a study without his or her informed consent. When potential subjects are capable of making informed decisions about participation, they may accept or decline participation without involvement of any third parties.

Objection to Participation in Research

Recommendation 7. Any potential or actual subject's objection to enrollment or to continued participation in a research protocol must be heeded in all circumstances. An investigator, acting with a level of care and sensitivity that will avoid the possibility or the appearance of coercion, may approach people who previously objected to ascertain whether they have changed their minds.

Assessing Potential Subjects' Capacity To Decide About Participating in a Research Protocol

Recommendation 8. For research protocols that present greater than minimal risk, an IRB should require that an independent, qualified professional assess the potential subject's capacity to consent. The protocol should describe who will conduct the assessment and the nature of the assessment. An IRB should permit investigators to use less formal procedures to assess potential subjects' capacity if there are good reasons for doing so.

Notifying Subjects of Incapacity Determinations and Research Enrollment

Recommendation 9. A person who has been determined to lack capacity to consent to participate in a research study must be notified of that

determination before permission may be sought from his or her legally authorized representative (LAR) to enroll that person in the study. If permission is given to enroll such a person in the study, the potential subject must then be notified. Should the person object to participating, this objection should be heeded.

IV. Recommendations Regarding Categories of Research

Research Protocols Involving Minimal Risk

Recommendation 10. An IRB may approve a protocol that presents only minimal risk, provided that:

(A) Consent has been waived by an IRB, pursuant to federal regulations; or

(B) The potential subject gives informed consent; or

(C) The potential subject has given Prospective Authorization, consistent with Recommendation 13, and the potential subject's LAR gives permission, consistent with Recommendation 14; or

(D) The potential subject's LAR gives permission, consistent with Recommendation 14.

Research Protocols Involving Greater Than Minimal Risk That Offer the Prospect of Direct Medical Benefit to Subjects

Recommendation 11. An IRB may approve a protocol that presents greater than minimal risk but offers the prospect of direct medical benefit to the subject, provided that:

(A) The potential subject gives informed consent; or

(B) The potential subject has given Prospective Authorization, consistent with Recommendation 13, and the potential subject's LAR gives permission, consistent with Recommendation 14; or

(C) The potential subject's LAR gives permission, consistent with Recommendation 14.

The research must also comply with Recommendations 7, 8, and 9.

Research Protocols Involving Greater Than Minimal Risk Research That Do Not Offer the Prospect of Direct Medical Benefit to Subjects

Recommendation 12. An IRB may approve a protocol that presents greater than minimal risk but does not offer the prospect of direct medical benefit to the subject, provided that:

(A) The potential subject gives informed consent; or

(B) The potential subject has given Prospective Authorization, consistent with Recommendation 13, and the potential subject's LAR gives permission, consistent with Recommendation 14; or

(C) The protocol is approved on the condition of its approval by the panel described in Recommendation 2, or falls within the guidelines developed by the panel, and the potential subject's LAR gives permission, consistent with Recommendation 14.

The research must also comply with Recommendations 7, 8, and 9.

V. Recommendations Regarding Surrogate Decision Making

Prospective Authorization

Recommendation 13. A person who has the capacity to make decisions about participation in research may give Prospective Authorization to a particular class of research if its risks, potential direct and indirect benefits, and other pertinent conditions have been explained. Based on the Prospective Authorization, an LAR may enroll the subject after the subject has lost the capacity to make decisions, provided the LAR is available to monitor the subject's recruitment, participation, and withdrawal. The greater the risks posed by the research protocol under consideration, the more specific the subject's Prospective Authorization should be to entitle the LAR to permit enrollment.

Legally Authorized Representatives (LARs)

Recommendation 14. A LAR may give permission (within the limits set by the other recommendations) to enroll in a research protocol a person who lacks the capacity to decide whether to participate, provided that:

(A) The LAR bases decisions about participation upon a best estimation of what the subject would have chosen if capable of making a decision; and

(B) The LAR is available to monitor the subject's recruitment, participation, and withdrawal from the study; and

(C) the LAR is a person chosen by the subject, or is a relative or friend of the subject. Expansion of the Category of Legally Authorized Representatives and of the Powers Granted Under Statutes for Durable Powers of Attorney (DPA) for Health Care

Recommendation 15. In order to expand the category of LARs:

(A) An investigator should accept as an LAR, subject to the requirements in Recommendation 14, a relative or friend of the potential subject who is recognized as an LAR for purposes of clinical decision making under the law of the state where the research takes place.

(B) States should confirm, by statute or court decision, that:

(1) An LAR for purposes of clinical decision making may serve as an LAR for research; and

(2) Friends as well as relatives may serve as both clinical and research LARs if they are actively involved in the care of a person who lacks decisionmaking capacity.

Recommendation 16. States should enact legislation, if necessary, to ensure that persons who choose to plan for future research participation are entitled to choose their LAR.

Involving Subjects' Family and Friends

Recommendation 17. For research protocols involving subjects who have fluctuating or limited decisionmaking capacity or prospective incapacity, IRBs should ensure that investigators establish and maintain ongoing communication with involved caregivers, consistent with the subject's autonomy and with medical confidentiality.

VI. Recommendations Regarding Education, Research, and Support

Reviewing and Developing Educational Materials Regarding Research

Recommendation 18. Professional associations and organizations should develop (or review their existing) educational materials pertaining to research involving persons with mental disorders to ensure that they are adequate to inform the health care community and the public of ethical issues related to the involvement of such persons as research subjects, and to convey the importance of measures to ensure that their rights and welfare are adequately protected.

Expanding Knowledge About Capacity Assessment and Informed Consent

Recommendation 19. The National Institutes of Health (NIH) should sponsor research to expand understanding about decisionmaking capacity, the best means for assessing decisionmaking capacity, and techniques for enhancing the process of informed consent, and the possible roles of surrogate decision makers in research. It should sponsor research to evaluate the risks of various research interventions, and the attitudes of potential subjects toward the prospect of participating in research. Particular attention should be paid to attitudes toward participating in research of greater than minimal risk that does not offer the prospect of direct medical benefit to subjects. These data may be of particular value to the panel described in Recommendation 2.

The NIH should ensure that proposals for training grants and center grants include appropriate provisions for training and technical assistance in the issues discussed in this report. Where appropriate, the NIH and the Office for Protection from Research Risks (OPRR) should consider using consensus development conferences or workshops to advance discussion of these issues.

Institute of Medicine Review of Research Studies

Recommendation 20. The Department of Health and Human Services should contract with the Institute of Medicine to conduct a comprehensive review and evaluation of the nature and extent of challenge, washout, and placebo controlled studies with subjects with mental disorders that may affect decisionmaking capacity.

Increased Funding To Support Necessary Protections of Human Subjects

Recommendation 21. Compliance with the recommendations set forth in this report will require additional resources. All research sponsors (government, private sector enterprises, and academic institutions) should work together to make these resources available.

FOR FURTHER INFORMATION ABOUT THE REPORT CONTACT: Eric M. Meslin, Ph.D., Executive Director, National Bioethics Advisory Commission or to obtain copies of the report contact: Ms. Patricia Norris, National Bioethics Advisory Commission, 6100 Executive Boulevard, Suite 5B01, Rockville, Maryland 20892–7508, telephone 301–402–4242, fax number 301–480–6900. Copies may also be obtained through the NBAC website: www.bioethics.gov.

Dated: February 12, 1999.

Eric M. Meslin,

Executive Director,

National Bioethics Advisory Commission.

[FR Doc. 99–4190 Filed 2–18–99; 8:45 am]

BILLING CODE 4160–17–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Healthcare Infection Control Practices Advisory Committee (formerly Hospital Infection Control Practices Advisory Committee), Notice of Charter Renewal

This gives notice under the Federal Advisory Committee Act (Public Law 92–463) of October 6, 1972, that the Healthcare Infection Control Practices Advisory Committee (HICPAC), National Center for Infectious Diseases (NCID), of the Department of Health and Human Services, has been renewed for a 2-year period through January 19, 2001.

For information, contact Michele Pearson, M.D., Executive Secretary, HICPAC, NCID, CDC, 1600 Clifton Road, m/s A07, Atlanta, Georgia 30333. Telephone 404/639–6400.

The Director, Management Analysis and Services Office has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: February 11, 1999.

Carolyn J. Russell,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 99–4089 Filed 2–18–99; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Program Announcement 99017]

Evaluating Potential Exposures To Blood and Risk of Hepatitis C Virus (HCV) Infection Among Persons Without Traditional Risk Factors; Notice of Availability of Funds

A. Purpose

The Centers for Disease Control and Prevention (CDC) announces the availability of fiscal year (FY) 1999 funds for a cooperative agreement program for evaluating potential exposures to blood and risk of hepatitis C virus (HCV) infection among persons without traditional risk factors. This program addresses the ''Healthy People 2000'' priority area of Immunization and Infectious Diseases. The purpose of the program is to provide assistance for addressing the risk of HCV or hepatitis B virus (HBV) transmission through potential but unproven mucosal or percutaneous exposures to blood in the United States. Specifically, applications are solicited for projects aimed at determining if there is an increased risk of HCV or HBV infection associated with illegal intranasal drug use (e.g., cocaine or heroin), anabolic steroid abuse, tattooing, or body piercing in populations with a low prevalence of illegal injection drug use.

B. Eligible Applicants

Applications may be submitted by public and private nonprofit organizations and by governments and their agencies, that is, universities, colleges, research institutions, hospitals, other public and private nonprofit organizations, State and local governments or their bona fide agents, and federally recognized Indian tribal governments, Indian tribes, or Indian tribal organizations.

Note: Public Law 104–65 states that an organization described in section 501(c)(4) of the Internal Revenue Code of 1986 that engages in lobbying activities is not eligible to receive Federal funds constituting an award, grant, cooperative agreement, contract, loan, or any other form.

C. Availability of Funds

Approximately $150,000 is available in FY 1999 to fund one award. It is expected that the award will begin on or about June 1999 and will be made for a 12-month budget period within a project period of one year. The funding estimate may change.

D. Program Requirements

In conducting activities to achieve the purpose of this program, the recipient will be responsible for the activities under (Recipient Activities), and CDC will be responsible for the activities listed under (CDC Activities).

Recipient Activities

1. Conduct research to determine if there is a risk of HCV or HBV infection, independent of known risk factors for transmission, associated with percutaneous exposures, such as tattooing, body piercing, or illegal injection of anabolic steroids, or permucosal exposures, such as use of illegal intranasal drugs.

2. Develop a study protocol to determine the prevalence of potential exposures for bloodborne pathogen transmission (i.e., illegal intranasal drug use, anabolic steroid abuse, tattooing, body piercing) in populations with a low prevalence of illegal injection drug use and their prevalence of HCV and HBV infection.

3. Based on the protocol, conduct an epidemiologic study of the potential association between HCV or HBV infection and illegal intranasal drug use, anabolic steroid abuse, tattooing, and body piercing.

4. Analyze, interpret, and publish results.

CDC Activities

1. Upon request of recipient, provide technical assistance in the design, conduct, and analysis of the research,