NATIONAL INSTITUTE ON DRUG ABUSE (NIDA)

The mission of the NlDA is to lead the nation in bringing the power of science to bear on drug abuse and addiction, through support and conduct of research across a broad range of disciplines and by ensuring rapid and effective dissemination and use of research results to improve prevention, treatment, and policy. For additional information about areas of interest to the NIDA, please visit our home page at http://www.nida.nih.gov/.

Phase II Competing Continuation Awards

(See http://grants.nih.gov/grants/guide/pa-files/PA-03-154.html.)
NIDA will accept competing continuation Phase II SBIR/STTR grant applications from Phase II SBIR/STTR awardees to continue the process of developing products that require approval of a Federal regulatory agency. Such products include, but are not limited to: medical implants, drugs, vaccines, and new treatment or diagnostic tools that require FDA approval. This continuation grant should allow small businesses to get to a stage where interest and investment by third parties is more likely.
Please contact Dr. Cathrine Sasek (contact information provided below) before beginning the process of putting an application together. Prospective applicants are strongly encouraged to contact NIH staff prior to submission of a type 2 competing continuation application. Prospective applicants are strongly encouraged to submit to the program contact a letter of intent that includes the following information:

- Descriptive title of the proposed research
- Name, address, and telephone number of the Principal Investigator
- Names of other key personnel
- Participating institutions
- PA, RFA or Solicitation Number (e.g., PA-03-154; PHS 2004-2)

Although a letter of intent is not required, is not binding, and does not enter into the review of a subsequent application, the information that it contains allows NIH staff to estimate the potential review workload and plan the review. It is expected that only a portion of NIDA SBIR/STTR Phase II awards will be eligible for a competing continuation grant.
The following examples would make appropriate topics for proposed SBIR or STTR Phase II competing continuation projects. These are meant for illustrative purposes only and are not exclusive of other appropriate activities.
Research and development efforts can be focused on medications for the treatment of cocaine, methamphetamine, and other stimulant abuse, as well as towards opiate, cannabis, PCP and club drugs. The medications under development should be targeted towards attainment of abstinence, maintenance, and/or relapse prevention.

- Preclinical studies, including pharmacology and toxicology, beyond those conducted under the initial SBIR Phase I and Phase II grants. The studies conducted under the previous grants should be sufficient to provide a sound rationale for continued development of the entity or entities.
- Completion of studies as required by the FDA for an IND application.
- Human laboratory clinical trials to determine a medication's safety profile, metabolism, cardiovascular

effects, interaction with drugs of abuse, etc.

- Clinical studies to assess the efficacy of the medication under development.

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Division of Treatment Research and Development

The NIDA Division of Treatment Research and Development (DTR&D) supports research aimed at the development and testing of pharmacological and behavioral treatments for drug abuse and addiction. This includes the identification, evaluation, development, approvability, and efficacy testing of new and improved pharmacotherapeutic agents, as well as the testing of marketed medications, and of behavioral treatments used alone or integrated with medications. The DTR&D also advances a human neuroscience research and training program focused on understanding the neurobiological substrates of drug abuse and addiction processes.

A. ***Chemistry and Pharmaceutics Branch (CPB).*** The CPB supports research in the design (including molecular modeling and structure-activity relationship studies) and synthesis of novel compounds, formulation development, bioanalytical methods development, and pharmacokinetics/ pharmacodynamics aimed at the discovery and development of new medications for treating drug addiction. Areas that may be of interest to small businesses include, but are not limited to *research related to the design and development of new compounds and improved drug products (drug delivery) for the treatment of drug addiction*:

1. Synthesis of new chemical compounds that would have potential as treatment agents for the medical management of stimulant (e.g., cocaine, methamphetamine, or nicotine) addiction. Consideration should be given to the design of partial agonists or pure antagonists that diminish the reinforcing effects of stimulants, as well as full agonists that could function to normalize physiological activity following discontinuation of stimulant use.

   Compounds of interest include those that are designed to affect dopaminergic (i.e., D1 agonists, D3 agonists and D3 antagonists) activity, CRF antagonists, compounds affecting glutamate activity, GABAergic activity, small molecule neuropeptide antagonists and compounds acting through other mechanisms for which justification has been supplied.

2. The development of combinatorial libraries for discovery of drug addiction pharmacotherapies.

3. Synthesis of new chemical compounds with potential for the treatment of opioid dependence and/or craving. Compounds which may prevent relapse to opiate use following a period of drug abstinence are of special interest. Kappa antagonists are of particular interest.

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4. Development of new approaches for the administration of potential addiction treatment drugs with poor bioavailability.

5. Development of controlled release dosage forms for addiction treatment medications in order to maintain therapeutic drug levels for extended periods of time to

alleviate compliance problems associated with addiction treatment.

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B. ***Medications Discovery and Toxicology Branch (MDTB).*** The MDTB supports research on the development of preclinical behavioral models (e.g., of craving, drug-seeking behavior, dependence, or relapse), biochemical assays, gene expressional assays and electrophysiological methods to identify and characterize new medications to treat substance abuse, as well as pharmacological screening of novel compounds to identify potential drug abuse medications. The Branch also supports research on toxicity studies of potential medications for the treatment of substance abuse, and interactions of potential treatment medications with abused substances. Areas that may be of interest to small businesses include, but are not limited to *development of new methods for discovery of medications useful in treating drug addiction*. Of special interest would be the development of new animal models of addiction, incorporating established drug self-administration techniques that show increased relevance to the clinical setting. Development of relevant biochemical or electrophysiological screening methods is also encouraged.

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C. ***Behavioral Treatment Development Branch (BTDB).*** The BTDB supports research on behavioral treatments and combined behavioral and pharmacological treatments for drug abuse and dependence. Behavioral treatments include psychotherapies, behavior therapies, family therapies, group therapies, counseling strategies, rehabilitative techniques, brief behavioral interventions, therapeutic community treatments, and other psychosocial treatments. Research on these treatments may be carried out in any setting, including both academic and community or "real-world" settings. Areas that may be of interest to small businesses include, but are not limited to:

1. *Behavioral Strategies for Increasing Compliance in Taking Treatment Medication*. Research to develop and to evaluate strategies to induce recovering addicts to take medication for a prolonged time, especially antagonists such as Naltrexone; to induce HIV infected drug users to comply with medical treatments (HAART) in drug abuse treatment settings; or to adapt existing behavioral strategies to increase patient compliance and cooperation in long-term treatment for drug abuse or for diseases associated with drug abuse such as tuberculosis or hepatitis. An important consideration should be cost and practicality of use in actual clinical practice or in an aftercare program. The product of such research might be a manual, which describes the behavioral strategy, and its implementation by treatment staff or scientific data regarding evaluation.

2. *Integration of Behavioral Therapies and Pharmacotherapies*. Development and testing of integrated therapeutic approaches for individuals who abuse various drugs, including methamphetamine, cocaine, nicotine, and opioids; in addition this may include individuals with co-occurring substance abuse and mental disorders, since effective treatment of both disorders may lead to improved treatment outcomes. Integrated behavioral therapies and pharmacotherapies may enhance the efficacy of both types of therapeutic interventions. For instance, the maintenance and detoxification of heroin addicts could perhaps be optimized by the integration of distinctive behavioral therapies devised specifically for

opioid agonists, antagonists or partial agonists determined by the heterogeneity of the subgroup of addicts and the pharmacological differences of the medications. Integration of medications and behavioral therapies could possibly enhance compliance with medication regimens, *increase* retention allowing pharmacological effects to occur and prevent relapse to drug abuse and addiction.

3. *Behavioral Treatment Research for Drug Abuse and Addiction in Primary Care*. Recent research has shown that physicians and other clinicians often fail to recognize drug abuse or addiction among their primary care patients. In addition, a significant number of these clinicians reported that they did not know how to intervene with their patients if drug abuse or addiction was suspected. Drug abuse related illnesses and morbidity often occur in adults and may have begun in adolescence. However, very little research has been done to develop or test behavioral treatment approaches or combined pharmacological and behavioral treatments for drug abuse and addiction in primary care settings. The objectives of this initiative are to encourage research on the development and testing of innovative brief behavioral treatment approaches, alone or in combination with pharmacological treatments that may be used in various primary care patient populations and primary care settings. Other goals of this research initiative are to encourage additional research on the development and evaluation of culturally sensitive screening and assessment instruments for use in primary care; and to encourage research on the transportability of efficacious behavioral treatments to primary care settings, as well as research on science-based training approaches for changing primary care clinicians' behaviors regarding their recognition and intervention with drug abusing or addicted patients. While motivational enhancement approaches for some drug abusing populations have been found to be effective, this behavioral approach has not been widely used in primary care.

4. *Woman and Gender Differences in the Provision of Behavioral Treatments, and HIV/AIDS Risk Reduction Approaches*. Develop and evaluate specific behavioral treatment approaches targeting drug-addicted women. This may include behavioral therapies, skills training techniques, counseling strategies, and HIV and other infectious disease behavioral risk reduction strategies. This may also include development and testing of training materials that specifically address women and gender differences in drug addiction treatment to promote effective use of research-based treatment approaches. Training materials may involve treatment manuals, training videos, CD ROM or DVD technologies, Internet or computer based programs to manage aspects of treatment administration, or other innovative educational strategies for health professionals using new technologies.

5. *Transporting Behavioral Treatments to Community Practitioners*. There is a need for effective methods of transferring behavioral therapies found to be effective in clinical trials to clinical practice. Cognitive-behavioral therapy, operant behavioral therapy, group therapy, and family therapy are among the therapies that have been shown to be efficacious in a highly controlled setting and may be helpful treatment approaches in community treatment programs as well. However, community practitioners may have been

trained using other approaches and may not have been exposed to these scientifically-based approaches. This is a call for proposals that examine mechanisms to transfer effective research-based drug abuse treatment information and skills-based techniques to practitioners in the community. This may involve the development and testing of innovative training materials and procedures to use in the training of community practitioners to skillfully administer these treatments, including the development of highly innovative technology transfer and communication approaches. Research testing the transportability of empirically supported therapies to the community is an important component of the Behavioral Therapies Development Program.

There is also a need for the development of educational methods to train non-drug abuse health care workers in relating to drug abusers; eliciting medical histories regarding past or present drug abuse; recognition of the signs and symptoms of drug abuse; identification of those at high-risk for HIV and other drug abuse related medical problems such as tuberculosis or hepatitis. Development and validation of a drug abuse screening instrument which can be administered by primary health care providers, and training in administering such an instrument.

6. *Using Telemedicine to Disseminate Drug Addiction Research Findings to Primary Health Care Providers*. Telemedicine programs are being used in urban medical centers to rapidly disseminate science-based information on new medical treatments. In addition, approximately one-third of the rural hospitals are now using telemedicine to improve patient care. Health care professionals need science-based information on drug abuse prevention and treatment. Research to develop and evaluate telemedicine programs to transport science-based information on drug addiction to the primary health care community is encouraged.

7. *Developing, Evaluating, and Transporting Culturally Sensitive Behavioral Therapies for Racial and Ethnic Minorities*. Minority populations are disproportionately affected by the consequences of drug abuse. Research to develop and evaluate behavioral treatments that are culturally sensitive and relevant for diverse racial and ethnic minority populations is encouraged. This may include studies of behavioral treatments, alone or in combination with pharmacological treatment, or studies of behavioral strategies for increasing adherence to taking medications. In the development and evaluation of the behavioral treatment, attention needs to be directed at examining medical, social, and cultural factors that may influence adherence to the behavioral treatment approach and treatment outcome. Also, little is known about the transportability of efficacious behavioral treatments for minority populations. Research is needed on how to transport science-based treatments to various racial/ethnic populations.

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8. *Behavioral Therapy Development*. Development of new or refinement of existing psychotherapies, behavioral therapies, skills training techniques or drug counseling strategies for the treatment of drug abusers/addicts. Incorporation of HIV risk reduction strategies as an integral component in routine counseling or other behavioral interventions. This would include the development of: therapy

manuals, to define exactly what the therapy is and how to administer it optimally; competence and adherence scales, to evaluate the extent to which therapists and counselors are actually providing the therapy intended; process measures, to measure various aspects of the therapeutic interaction; and measures of the integrity and fidelity of the therapy. The following are of particular interest:

a. Development of behavioral therapies or components of such therapies that are based on developments and findings from the basic behavioral or cognitive sciences.

b. Discrete therapy components that address specific problems common among drug addicted individuals and that can be implemented in conjunction with other therapeutic services. For example, an investigator may wish to develop a four session, highly focused, job seeking skills module that can be easily implemented by a wide range of practitioners to effectively increase appropriate job seeking behavior. Other examples include, but are not limited to, modules to engage ambivalent drug dependent individuals in treatment, modules to increase assertiveness in female drug addicts who feel pressured by others to use drugs, or to incorporate effective HIV risk reduction techniques.

c. Therapies designed specifically to engage and retain individuals in treatment, especially those at high risk for HIV. An example could be a therapy that is: (1) sensitive to the motivational level of the client; (2) is specifically designed to respond to the needs of the individual, whatever his or her motivational level might be; and (3) actively works to increase an individual's desire to remain in treatment.

d. Therapies designed to intervene with understudied populations including users of drugs such as MDMA and other club drugs, marijuana, and inhalants, as well as personality disordered drug abusers.

e. Therapies for drug abusers who are not yet dependent on drugs to reduce risk of escalation to dependence and therapies for drug abusers who have not considered or claim little interest in seeking treatment for their drug problems. For these populations treatments are needed which interest and engage the potential client and intervene with them. Treatments which participants in their natural environment, such as treatments delivered over the Internet or in neighborhood settings such as churches and recreation centers are desired.

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9. *Development of HIV Risk Reduction Interventions*. Research to develop and evaluate behavioral strategies to reduce HIV risk behaviors in HIV-positive and HIV-negative substance abusing treatment populations. Risk reduction interventions should be specially adapted to patients' age, gender, cultural background and potential cognitive impairments and should address compliance with medical regimens. The product of such research might be educational materials, such as manuals or videotapes that describe the intervention and its implementation by treatment staff.

10. *Complementary and Alternative Therapies (CAT) for Drug Abuse Treatment*. Research is encouraged on complementary and alternative interventions for drug abuse treatment. CAT interventions could be the sole treatment or could be adjunctive strategies to enhance the therapeutic potency of existing drug abuse treatments. An example of an adjunctive CAT intervention might be where the intervention reduces withdrawal symptoms thus enhancing retention in treatment. Included would be interventions that are commonly used in "real world" treatment settings, but whose therapeutic efficacy has not been scientifically demonstrated. Such interventions include acupuncture, bioelectrical stimulation, exercise, biofeedback, meditation, among others. The product of this research might be a manual or video, which illustrates the intervention and how it is implemented by treatment staff.

11. *Translation of Cognitive and Affective Neuroscience Findings Towards Development of Behavioral Treatments.* Recent studies using neuroimaging and neuropsychological evaluations provide ample evidence that chronic drug use is associated with neuroanatomical changes that alter cognitive function and the ability to regulate affective states. Further, these changes vary over time and may depend on the current state of the individual (e.g., acute administration of one or more drugs; during initial vs protracted abstinence). Such comorbid conditions make it difficult for many chronic drug users to engage in and participate meaningfully in efficacious behavioral drug treatments. However, knowledge from neuroimaging and neuropsychological studies has not yet been utilized to benefit the patient. In addition, knowledge about fundamental cognitive and affective functioning even in the intact brain, typically has not led to tools that can be used for treating substance abuse. Thus, research that integrates basic research findings on cognition (e.g., decision-making, problem-solving, learning, memory, attention, motivation) and affect (e.g., anxiety, anger, depression) in the following areas are encouraged: Development of interventions to (a) reduce the negative impact of cognitive dysfunction and affective dysregulation on drug use outcome; (b) prevent relapse; (c) reduce the severity and course of the dysfunctions; (d) improve specific areas of cognitive and affective functioning; and (e) improve daily functioning in addition to reducing clinical symptoms. Other goals of this initiative are to: Develop reliable and valid methods for assessing basic cognitive and affective processes as part of clinical diagnosis; evaluate cognitive and affective functioning as indicators of risk for exacerbated drug use during treatment or for developing other disorders; determine if and how current efficacious treatments rehabilitate altered cognitive and affective functioning; modify and test current efficacious treatments tailored to the needs of cognitively impaired individuals.

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12. *Incorporating Smoking Cessation in Drug Abuse Treatment*. Research is encouraged to develop and test behavioral treatments for nicotine-addicted individuals who also are addicted to other substances, such as heroin, cocaine, methamphetamines and alcohol. Prevalence of cigarette smoking is extremely high among drug dependent individuals attending drug treatment. Many treatment providers are reluctant to

address smoking cessation with clients either because they believe that substance abusers are not interested in quitting or because they fear smoking treatment will have a negative impact on drug abuse treatment outcome. However, studies have shown that many drug abuse clients are interested in quitting smoking and that the concurrent treatment of tobacco dependence and other drug dependencies does not threaten abstinence and might even assist in maintaining it. Research is needed to develop and test smoking cessation treatments that can be incorporated into treatments for illicit drugs of abuse.

13. *Developing Treatments for Smokers with Comorbid Disorders*. Research is encouraged that focuses on the development, refinement, and testing of behavioral treatments for smokers with psychiatric comorbidity, such as depression, schizophrenia, or anxiety disorders. Smoking prevalence is very high in individuals with psychiatric disorders. These populations generally respond poorly to traditional smoking cessation treatments. Research is needed to develop and test innovative behavioral and combined behavioral and pharmacological treatments that address the unique needs of these individuals.

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14. *Development of New or Improved Addiction Assessment Measures and Procedures*. Research directed at the improvement of a currently available measure or the design of a new psychosocial, social or environmental measure appropriate for use in the clinical assessment of substance abusing populations. Special consideration should be given to a specific screening or diagnostic tool, or to a specific measure of treatment readiness, treatment compliance, service utilization, therapeutic process or drug treatment outcome. The NIDA DTR&D supports research aimed at the development and testing of pharmacological and behavioral treatments for drug abuse and addiction. This includes the identification, evaluation, development, approvability, and efficacy testing of new and improved pharmacotherapeutic agents, as well as the testing of marketed medications, and of behavioral treatments used alone or integrated with medications. The DTR&D also advances a human neuroscience research and training program focused on understanding the neurobiological substrates of drug abuse and addiction processes.

15. *Behavioral Therapies for Pre-Adolescents and Adolescents.* Behavioral therapies for pre-adolescents and adolescents that incorporate HIV risk reduction counseling as an integral component of the treatment. This includes the development of new, or refinement of existing psychotherapies, behavioral therapies, and counseling (group and/or individual). This also includes the development and testing of manuals as well as other creative, interactive approaches for therapy delivery that may consider different settings for delivery, such as primary care, school-based health programs, juvenile justice settings, etc. Also the behavioral treatments should be culturally and gender sensitive.

16. *Behavioral Therapies for Couples and Families*. This includes the development of new psychotherapy approaches, the modification or testing of existing behavioral treatments, and the design and/or testing of innovative clinical training and supervision methods for

dissemination of efficacious treatments to community settings. Treatments that target domestic violence or other forms of interpersonal abuse along with substance abuse are encouraged.

17. *Behavioral Therapies for Groups*. This includes the development of new psychotherapy approaches, the modification or testing of existing behavioral treatments, and the design and/or testing of innovative clinical training and supervision methods for dissemination of efficacious treatments to community settings. Examples of relevant projects are: traditional group therapies, such as 12-step and therapeutic community approaches, and newer group therapies such as cognitive-behavioral and acceptance-oriented approaches; groups for various populations, such as adolescents, adults, couple and family groups, gender-specific groups, and groups tailored for racial or ethnic minority populations. Of particular interest are projects that address the recent findings suggesting possible contraindications of group treatments for some populations (e.g., delinquent adolescents), or in some formats (e.g., less-structured, emotion-focused group treatments).

18. *Behavioral Therapies Drawing from Stress Research or Stress-Management Interventions*. Projects are encouraged that apply concepts from stress research (such as appraisal, coping, and social support) to drug abuse in innovative ways, or that test the extent to which stress-management interventions can be applied to the treatment of drug abuse and interventions to reduce risk of HIV and other infectious diseases. Examples of stress-management techniques that may have novel application to drug abuse and HIV risk include techniques that teach problem-solving and affect-management, restore one's sense of purpose and meaning, prevent burnout in the face of chronic stressors, increase self-efficacy for managing stress, inoculate against stressors, train relaxation and meditation, intervene during crises, enlist social support and system support, and others.

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19. *Modifying Efficacious Behavioral Treatments to be Community Friendly*. Several behavioral interventions have been found to be efficacious for the treatment of drug addiction. However, there are barriers to implementation of behavioral therapies in community-based settings. Community settings that treat drug addicted individuals are reluctant or unwilling to adopt these interventions for a variety of reasons. Reasons that scientifically-based behavioral treatments are not accepted by community providers could include the excessive cost of implementation, the length of time for administration of treatment, inadequate training available for therapists and counselors, treatments not shown to be generalizable for different patient populations or for polydrug abusing populations, etc. Research aimed at modifying efficacious behavioral treatments to make them more acceptable to community settings is needed. Settings might include, drug abuse treatment facilities, primary care, managed care, and the criminal justice system. Examples of possible studies are those that are designed to reduce the cost of implementation of treatments, reduce the time of administration of treatments, aid in training of therapists, counselors

and nurses, adapt individual therapies for group situations, etc.

20. *Innovative Technologies for Drug Abuse Treatment, HIV Risk Reduction, and Training Clinicians*. Relevant research would be directed at the development and evaluation of innovative technologies to treat substance abuse, enhance adherence to medications, and/or reduce risk for HIV infection or transmission. Approaches should be capable of being readily incorporated at reasonable cost into various treatment settings. Areas of interest include Internet-based treatment or training programs, CD-ROM technology, audio delivery devices, photo therapeutic instruments, and hand-held computers. Also of interest are creative approaches for disseminating science-based behavioral treatments and for training therapists to use scientifically based treatments for drug abuse and addiction. Such approaches might include Internet-based education, interactive computer programs, telemedicine, etc. Finally, approaches which apply therapies with evidence of efficacy through new media such as web-based platforms, over email, or through chat rooms and bullet boards are also desirable.

21. *Virtual Reality Applications for Drug Abuse Treatment Provider Training*. Recently virtual reality simulations have been used to train medical personnel in demanding medical procedures such as microsurgery techniques. Virtual training allows trainees to gain familiarity with both the environment in which services are delivered as well as the intervention techniques without the danger of mistakes impacting live patients. Virtual reality interfaces can assess skill acquisition and provide detailed feedback during procedures to help trainees correct mistakes or avoid making them altogether. In the drug abuse field, training and dissemination efforts have been hampered by a dearth of knowledge about ways to conduct dissemination. Although trainees often practice on actual clients, this approach has drawbacks including its reliance on the client or participant's schedule and willingness to participate in training sessions and potential danger to the client or if the intervention is delivered incorrectly. Libraries of virtual reality simulations of drug users in treatment or "virtual patients" are needed to provide experiential training for treatment providers without relying on existing patients. This will help facilitate the rapid and effective dissemination of proven treatment strategies.

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D. ***Clinical Neurobiology Branch (CNB).*** The CNB supports research on the biological etiology (determining the biological basis for vulnerability to drug abuse and progression to addiction, including studies on individual differences and genetics) and clinical neurobiology of addiction (exploring alterations of the structure and/or function of the human central nervous system following acute or chronic exposure of drugs of abuse), and the neurobiology of development (neurobiological effects of drugs of abuse and addiction during various stages of development and maturation, effects of drug exposure on neurobiological processes, development of methodologies and refinement of techniques used in pediatric neuroimaging). The Branch also supports investigations on the cognitive neuroscience of drug abuse and addiction, the neurobiology of treatment, neuroAIDS, and human pain and analgesia. Areas that may be of interest to small businesses include, but are not limited to:

1. *Development of Novel Approaches in Human Neuroscience*. Development of innovative, noninvasive research methods or novel approaches are needed to identify various neurobiological markers of brain alterations in humans induced by acute or chronic exposure drugs of abuse. This may include the identification of neurobiological (including genetic) markers that might be associated with risk for, or resilience to drug abuse and addiction. Of particular interest are noninvasive methods (e.g., brain imaging) that could be used to determine the effects of drug abuse/ addiction treatments on neurobiological systems in an attempt to understand the neurobiological processes underlying therapeutic efficacy.

   In recent years, there has been an increase in studies employing functional magnetic resonance imaging (fMRI) to understand brain processes and functional neuronal systems. In particular, these neuroimaging techniques are being used to probe how drugs of abuse alter brain functioning. Consequently, there is a need for the development of stimulus generation hardware to be used within an fMRI magnet that can display stimuli important in drug studies. As the studies of brain function become more sophisticated, task-related assessments of brain activation are increasingly important. Shielded goggles or other types of stimulus-generating hardware and software are necessary for presentation, for example, of neurocognitive tasks, drug-related images for the induction of craving, or other "virtual reality" types of dynamic stimuli important in studies of drug abuse and addiction. Responses to this type of stimulation then could be correlated with brain measures using neuroimaging techniques. These types of studies will provide new insights into drug-brain-behavior interactions.

   Development of the human central nervous system and how drugs of abuse perturb this process is of great interest. Little is currently known about the effects of exposure to drugs of abuse, either prenatally or during childhood or adolescence, on the development of the human nervous system. Further, the application of newly emerging technologies (such as neuroimaging) to these populations presents unique challenges due to the fact that the central nervous system, and its capabilities, are changing rapidly. The development of novel techniques, or the refinement of existing methods, to provide direct noninvasive measures of brain structure and/or function that are adapted specifically for use in pediatric and adolescent populations is strongly encouraged. Also, neurocognitive and other neurobehavioral tasks for use in these populations, especially where they can be designed to probe underlying neurobiological processes, need to be developed.

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2. *Virtual Reality for the Neurobiological Study of Drug-Brain-Behavior Interactions and Drug Abuse Treatment*. Virtual Reality (VR) is an emerging technology useful in a variety of research-related, therapeutic and instructional settings. By immersing a person's senses in a synthetic world or Virtual Environment (VE) that characterizes VR, a highly flexible and programmable set of stimuli can be used to enhance the standard approaches used in assessment of neurobiological and neurobehavioral processes.

Collection of real-time data and bulk data recording can provide a correlation of a stimulus reference signal with simultaneously collected fMRI scanner and physiological data over time. Unlike most computer access systems that accept only one or two modes of precise and/or discrete input at a time, VR systems have the potential to monitor movement or action from any, or many, neurobiological functions at once. In addition, the multimodal feedback inherent in VR provides a way to vary nonvisual stimulus components (e.g., resistance, temperature, pitch) in a way that is impossible to achieve via standard computer systems. Finally, VR systems provide a bypass for keyboard entry or direct manipulation environments (e.g., pointing instruments like the mouse), by allowing the manipulation of multi-sensory representations of entire environments by natural actions and gestures.

VE can provide a completely controlled, noninvasive, safe and alternative methodology for a variety of important studies of drug abuse and addiction. For example, VR allows for the presentation of a variety of complex, multi-sensory stimuli for neurocognitive tasks or, alternatively, the dynamic stimuli important for producing drug-related images for the induction of craving. VR can also be tested as an alternative to traditional behavioral therapies in the treatment of drug abuse. Responses obtained as a result of the above can then be correlated with brain measures using state-of-the-art neuroimaging techniques. We, therefore, invite studies employing VR, especially to probe brain processes in drug abuse/addiction combined with neuroimaging methods or to be developed or applied as a potential treatment for substance abuse.

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3. *Development of Interactive Computer Applications for Neuropsychological/ Neurocognitive Assessment to Determine Functional Brain Deficits in Acute and Chronic Drug Abusers*. In addition, a neurobehavioral test battery to assess other neurobehavioral/neurocognitive deficits resulting from drug abuse/addiction is encouraged. Of particular interest is the development of such assessments for use in children and adolescents exposed to drugs of abuse to better define and understand the effects of early exposure on brain function and development (for developmental issues, contact Larry Stanford, Ph.D.).

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4. *Development of Ligands for Brain Imaging*. Development of novel radioligands for PET and SPECT imaging in human brain for molecular targets (e.g., receptors, intracellular messengers, disease-related proteins) is of broad interest to the neuroscience and drug abuse research community. The primary application of these radiotracers will be in basic neuroimaging research. Ultimately, these radiotracers may also be used as potential biological markers and surrogate endpoints for translational and clinical research, drug discovery and development, and clinical trials. The scope of the projects may encompass pilot or clinical feasibility evaluation in pre-clinical studies, model development, or clinical studies. Alternatively, the

focus may be on research and development of new technologies for radiotracer development.

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5. *Novel Approaches in the Clinical Neurobiology of Drug Addiction.* Given the array of interdisciplinary solutions across the NIH for a variety of existing conditions, NIDA has a strong interest in novel approaches, devices and strategies, which have not, until now, focused on the drug abuse arena. We, therefore, invite proposals to determine which, if any, pre-existing assessments, research tools and/or intervention strategies can be effectively applied to issues specifically related to neurobiology of human drug abuse and the addiction process (e.g., neurobiologic mechanisms underlying drug abuse or addiction, neurobiologic/genetic determinants of risk/protective factors, the prevention of initiation, the onset of dependence, the longevity of maintenance, the termination of use and the mitigation of residual neurobiologic sequelae). As an example, under a separate announcement (see above), NIDA has solicited and continues to solicit proposals using virtual reality to increase our understanding of the neurobiology of addiction, (e.g., drug cues, craving), comorbidity (e.g., post-traumatic stress disorders) and pain (e.g., distraction). Additional novel approaches, devices and strategies are now being sought to further our understanding of the cognitive neuroscience of drug abuse and addiction, neuroplasticity and repair, the neurobiology of treatment (including training tools, assessment and neurolobiologic correlates of treatment outcome), neuroAIDS, and human pain/analgesia. Techniques such as hyperbaric oxygenation, used to increase oxygen in blood in experimental and treatment protocols, may improve drug-induced cognitive deficits. Transcranial magnetic stimulation, utilized to modulate cortical excitability, deep brain stimulation to improve refractory comorbid conditions, and biofeedback control of cortical function are other examples of untested possibilities in the study of addiction. We are casting a wide, interdisciplinary net to encourage cutting-edge, state-of-the-art proposals. As with all NIDA-funded research, the conceptual framework, design, methods, and analyses must be adequately developed, well-integrated, and appropriate to the aims of the project. The applicant must acknowledge potential problem areas and consider alternative approaches. Whereas the proposal must employ novel concepts, approaches or methods that are not mainstream to drug abuse, the inclusion of established analytic tools to determine the efficacy of the approach is required. The aims must be original and innovative and the proposal should challenge existing paradigms or develop new methodologies or technologies. In addition, the investigator must be appropriately trained and well suited to carry out this work and the work proposed must be appropriate to the experience level of the principal investigator and team of other researchers (if any).

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E. ***Medications Research Grants Branch (MRGB).*** The MRGB supports investigations of the use of therapeutic agents (including vaccines and monoclonal antibodies) for the treatment of substance related disorders, with the aim of assisting in reducing drug use, becoming drug free,

prolonging abstinence, decreasing associated psychosocial, medical or legal problems, or surviving drug overdose. In general, therapeutic agents are expected to be investigated using a platform of appropriate psychosocial interventions. The program funds extramural grants in the following areas:

- Clinical trials to test the safety, find the optimal dose, and/or obtain preliminary efficacy data for new agents or new indications of marketed medications. This phase includes interaction studies to test the safety of the agent when used in combination with drugs of abuse.

- Clinical trials to assess the efficacy of new agents or marketed medications for the treatment of substance related disorders. In general, these types of trials use a randomized double blind placebo controlled design.

- Clinical studies of the efficacy of medications for the treatment of the comorbidity of substance related disorders (e.g., alcohol and cocaine dependence) or the comorbidity of these disorders with other medical or psychiatric conditions.

- Clinical evaluation of the efficacy of medications for the treatment of substance related disorders in specific groups of the population. For example, adolescents, the elderly, women of childbearing age, pregnant and/or postpartum women, as well as racial and ethnic minorities.

- Evaluation of biological and/or psychosocial factors that may affect the outcome of the pharmacotherapy of substance related disorders.

Specific areas that may be of interest to small businesses include, but are not limited to:

1. *Pharmacogenetics and Substance Use Disorders*. The emergence of new genetic techniques may allow the use of genetic information to improve the safety and efficacy of treatments. The field of pharmacogenetics focuses on the genetic determinants of response to medications and other in humans and animals. The goal is to discover novel single nucleotide polymorphisms (SNPs) and test their relevance to the underlying genetic differences that determine the safety and efficacy of medications for the treatment of SUD. It includes the study of genes encoding drug metabolizing enzymes, transporters, receptors and other drug targets, polygenic determinants of drug disposition and effects in humans, the role of genes in the clinical response to and medical safety of medications, and application of genetic information to disease prevention and to optimize treatments in humans. It also includes novel methods for phenotyping the diagnosis, safety and treatment outcome of SUD. Ultimately, it is expected that pharmacogenetics research will help clinicians to individualize the treatment of their patients based on their genetic information. Research is needed to study the genetic factors that may be associated with drug abuse treatment safety and outcome.

2. *Medications Development for the Treatment of Drug Abuse in Adolescents*. Drug abuse among adolescents is a significant and growing public health concern. It is known that the pharmacokinetics and pharmacodynamics of some medications are different in adolescents. Therefore, adolescents may present overdoses, underdoses or lack of efficacy, or different safety profiles when administered medications at the doses studied only in adults. Unfortunately, little is known about the safety and efficacy of medications for the treatment of drug abusing adolescents because

most of the drug abuse medication research has focused on adults. Research is needed to test medications for the treatment of nicotine and drug abuse in adolescents.

3. *Medications for the Treatment of Pregnant and Post-Partum Drug Abusing Women and Their Children*. Little is known about the safety and efficacy of medications for the treatment of substance abusing pregnant women and their children. There is a need for safe and effective medications for the treatment of nicotine and drug abuse among pregnant and post-partum women and the effect of the medications on their children. Research is also needed to study the effects on the newborn of the medications taken by the mother and medications for treatment of children born to substance abusing mothers who may present drug withdrawal and other symptoms.

4. *Medications for the Treatment of Comorbid Medical or Mental Disorders and Drug Abuse*. Comorbid medical and psychiatric conditions are frequently found among substance abusing patients. Co-occurring mental disorders, such as depression, post-traumatic stress disorder, and anxiety disorder, and medical conditions such as hepatitis C, AIDS related disorders, and pain, are common among substance abusing patients. Unfortunately, there are presently no commonly prescribed safe and effective medications for the treatment of substance abusing patients with other comorbid medical and psychiatric conditions. Research is needed to study the safety and therapeutic profiles of medications for treatment of substance abuse in patients with other comorbidities. There is also a need to study the effects of medications for the treatment of substance use disorders in patients taking medications for other comorbid conditions and the necessary dose adjustments.

5. *Development of Software and/or Other Tools for Data Collection and Statistical Analysis of Clinical Trials Testing the Safety and Efficacy of Therapeutic Agents for the Treatment of Substance Related Disorders.* Current data collection techniques often have questionable validity and reliability and statistical data analysis pose particular challenges. These problems include lack of well defined outcome measures or having a large amount of missing data, which may be due to intermittent missing data points or early subject drop out (attrition). To solve those challenges, investigators have developed pragmatic methods to analyze their data. For example, carry forward data from the last timepoint, data replacement by regression, end point analysis by regression, or worst case scenario, they all have important statistical limitations. The purpose of this initiative is to stimulate research on innovative data management tools to improve data collection and analysis of data from nicotine and drug abuse clinical trials.

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6. *Immunotherapy for Addiction Treatment.* The MRGB supports research on the advanced stage development of monoclonal antibodies and vaccines for the treatment of drug and nicotine addiction and/or overdose. Monoclonal antibodies have been reported as possible treatment agents through passive immunization for PCP, methamphetamine, MDMA, and cocaine overdose and may also serve to minimize abuse and prevent relapse. New vaccines are being developed as therapies for drug or nicotine cessation and relapse prevention. New

technologies, such as the production of antibodies in plants, are emerging as cost-effective and efficient ways for the large scale manufacture of immunotherapy agents, represent another facet of this area for development.

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7. *Development of GHB Detection Kits and Antidotes to Treat GHB Poisoning.* A DAWN report states that there were over 3000 emergency room visits connected to GHB poisoning in the United States in 2001. GHB poisoning results in respiratory depression and coma, and can be fatal. Clinical interventions are needed to facilitate recovery from intoxication and/or poisoning from gamma-hydroxy butyric acid (GHB). There is also a need for the development of diagnostic kits for the rapid detection of GHB, gamma-butyrolactone (GBL), and 1,4-butane-diol (BD) in body fluids (plasma, saliva, urine). The method of detection should be fairly rapid and specific, and could be either qualitative or quantitative. Detection kits are needed to assist emergency room doctors in the rapid diagnosis of GHB poisoning, which is very difficult and critical for the selection of a proper treatment strategy. The availability of such kits would aid in the reduction of mortality and treatment costs.*8. Development of Neurotechnology for the Treatment of Drug Dependence.* MRGB is interested in clinical research evaluating the efficacy of emerging neurotechnological diagnostic and therapeutic modalities for treating drug dependence and addiction, with particular emphasis on psychostimulants, opiates, nicotine and cannabinoids. An example of such a therapy would be Transcranial Magnetic Stimulation (TMS) of the brain. TMS is a noninvasive technique currently used as a diagnostic and therapeutic tool in neurology and psychiatry. It has been reported to reduce symptoms of depression, PTSD, OCD, epilepsy, migraine, Tourette's syndrome, Parkinson's disease, and hallucinations in schizophrenic patients. The therapeutic uniqueness of this technique lies in the relative neuroanatomical specificity of its effects, in contrast to generalized effects of pharmacotherapies. TMS may be used to rapidly, either laterally or focally, alter cortical brain activity, which might be helpful in the treatment of drug dependence. Repetitive TMS may alleviate drug craving by the brief deactivation of certain brain regions. It may also improve mood and enhance cognition, thus facilitating abstinence from drugs of abuse and increasing effectiveness of cognitive therapies.

9. *Research and Development of Psychobiological Markers of Resilience or Refractoriness of Drug Dependence as a Tool for Optimization of Treatment.* Difficulties in finding rapid and effective therapies for drug dependence, especially dependence on psychostimulants, appear to result, in part, from the heterogeneity of drug addicts entering treatment programs or trials. This heterogeneity may ensue from different psychobiological and genetic determinants, including psychiatric comorbidities, which contribute to the development and persistence of drug dependence. Studies and clinical observations show that some addicts recover relatively easily after standard treatments for stimulant dependence, while others relapse early or drop out of the treatment. Identifying psychobiological markers distinguishing different groups of addicts may permit selection of optimal treatment strategies for

these groups, which may or may not include selective pharmacotherapy in addition to standard psychotherapeutic modalities. Research is needed to identify potential biological and psychological markers, which correlate with resiliency or refractoriness of drug/stimulant addicts. Identification of such markers may guide development of novel treatments for drug dependence. There is a need for analytic kits for simultaneous detection of several hormones such as PS, DHEAS, THP, THDOC, cortisol and testosterone in body fluids, optimally in saliva. Detection kits for steroid hormones may also have broader utility as aids for diagnosis of other psychiatric disorders, such as depression and PTSD.

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Division of Neuroscience and Behavioral Research (DNBR)

DNBR's basic neuroscience and behavioral research focuses on understanding the mechanisms, characteristics, and processes of drug abuse. Basic behavioral, cognitive, neurobiological, cellular, molecular, chemical, and genetics research aims at characterizing and understanding drug seeking, compulsive behavior, and addictive processes. These research areas necessarily include studies of normal processes.

Using both animal and human studies, basic behavioral research focuses on behavioral and cognitive processes that may or do lead to drug initiation, and the behavioral and cognitive consequences of drug abuse. Neurobiology research focuses on the neural mechanisms and substrates underlying behavioral and cognitive processes and vulnerability factors associated with drug abuse, addiction, sensitization, tolerance, and relapse.

DNBR supports basic chemistry and pharmacological studies focusing on structure/activity relationships, definition, and characterization of systems involved in drug actions, chemical synthesis of new ligands, pharmacokinetics, analytical methods, understanding basic mechanisms of drug action and drug testing.

Computational and theoretical modeling of biological systems and behavioral processes, biomedical computing and/or information science and technology development is supported by DNBR.

A. *Research Related to the Design of New Therapeutic Approaches.*
Development of new therapeutic approaches based on the application of nanoscale particle formulations for drugs that are either poorly water-soluble or otherwise unstable under physiological conditions, and development of methods for using nanoscale formulations for targeting specific brain sites or to control drug delivery over extended periods of time.

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B. *Virtual Reality for Treatment of Pain.*
Recent findings (Hoffman et al., 2000, Pain, 85, 305-309) have suggested that Virtual Reality (VR) exposure can reduce reported pain during wound care. Grant proposals are sought to examine the utility of VR technologies in the treatment of various types of pain. Development of treatments for both acute and chronic pain are sought. These treatments can be based in clinical settings or the patient's homes. Phase I testing should establish the feasibility of the use of this technology in the particular population to be tested. Phase I should also produce data that demonstrates that this methodology is effective for the particular type of pain being treated. Phase II should involve larger-scale testing (e.g., more subjects

and treatment trials) examining various treatment parameters (e.g., timing of treatment, types of VR environments). The focus of Phase II testing should be the refinement of this treatment for use in pain patients.

C. *Virtual Reality for the Treatment of Drug Abuse.* Recent findings (Hoffman et al., 2000, Pain, 85, 305-309) have suggested that Virtual Reality (VR) can be a useful clinical tool. In this particular study, VR exposure was used to allow patients to selectively not attend to an otherwise painful procedure. Drug abuse, like pain, is a problem that is strongly impacted by stimuli in the abuser's environment and psychological factors. Thus, it is reasonable to assume that VR may be useful in allowing individuals to ignore drugs cravings, withdrawal symptoms or environmental cues that promote drug abuse. Grant proposals are sought to examine the utility of VR technologies in the treatment of various types of drug abuse. These treatments can be based in clinical settings or the patient's homes. These treatments can be developed to address drug withdrawal, drug craving or on-going drug related behaviors. The development of VR technologies to address abuse of all types of drugs (e.g., cocaine, marijuana, nicotine, alcohol, inhalants) are sought. Phase I testing should establish the feasibility of the use of this technology for the particular drug problem addressed (e.g., cocaine craving, opioid withdrawal) and should also produce data that demonstrates that this methodology is effective for the particular drug problem. Phase II should involve larger-scale testing (e.g., more subjects and treatment trials) examining various treatment parameters (e.g., timing of treatment, types of VR environments). The focus of Phase II testing should be the refinement of this treatment for use in the treatment of drug abusers.

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D. *Chemical Libraries for Drug Development.* The development and biological screening of lead compounds and their combinatorial libraries for use in the area of drug abuse treatment research are encouraged, such as generation of new ligands having opiate receptor selectivity, or ligands with NMDA or serotonergic agonist/antagonist activity and/or related. These are designed as lead compounds either for drug design or as tools to elucidate mechanisms of action of drug abuse.

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E. *Genetic Studies.* The National Institute on Drug Abuse is interested in SBIR proposals that would greatly facilitate the identification of genetic loci that confer vulnerability to substance abuse and addiction. Areas of interest include but are not limited to:

1. Collection and genotyping of human pedigrees and sib-pairs for vulnerability or resistance to drug abuse.
2. Isolation and identification of mutant strains in genetic model systems such as Zebrafish, Drosophila, C. elegans, mice, and rats that are more vulnerable or resistant to drugs of abuse.
3. Design, development, and marketing of behavioral apparatuses to conduct rapid behavioral throughput screens for identifying genetic vulnerability to addiction in genetic model systems.
4. Development of transgenic models for drug abuse using bacterial artificial or yeast artificial chromosomes.
5. Development of software and databases for candidate genes for drug abuse.
6. Identification and mapping of functional polymorphisms of candidate genes for drug abuse.

7. Placement of candidate genes for drug abuse on biochips.

8. Marker-assisted breeding of congenic mouse and rat strains for mapping quantitative trait loci associated with addiction and drug abuse.

9. Vectors for gene transfer into neurons.

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F. *Drug Testing Development.*
Development of new, more refined or more practical drug testing methodologies. Studies may focus, but are not limited to the following topics: drug testing methods; drug extraction procedures; methods to control for possible environmental contamination factors; and reference materials. Methodologies with special application to the workplace, the emergency room, the transportation environment, or other specific settings are welcome. Methodologies with an emphasis upon circumstances for testing such as post-accident testing or readiness for work testing are also encouraged.

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G. *Effects of Drugs at the Cellular Level.*
Development of new imaging techniques, reagents and related hardware and software for dynamic investigations of the effects of drugs of abuse on cellular activities and communications. For example, these techniques might include, but are not limited to, development and utilization of reagents for magnetic resonance microscopy and other MRI methods; development of methodologies applying functional MRI to drug abuse studies; the use of dyes, intrinsic signals, and other optical indicators for studying signal transduction mechanisms, the regulatory control of protein entities (such as phosphorylation), and neuronal excitatory and inhibitory pathways.

Areas of interest may include, but are not limited to:

1. Studies using molecular biological techniques to scale-up protein production for investigations aimed at enhancing understanding of the structure, function and regulation of molecular entities involved in the cellular mechanisms through which abused drugs act.

2. Validated in vitro test systems can reduce the use of animals in screening new compounds that may be of potential benefit in treating drug abuse. Test systems are needed to evaluate activity at receptors or other sites of action, explore mechanism(s) of action, and assess potential toxicity.

3. With the recent success in molecular cloning of various drug abuse relevant receptors, enzymes, and other proteins, researchers will elucidate the molecular mechanism of action of these drugs. Studies to generate strains of transgenic animals carrying a gene of interest are solicited. Of special interest are knockout and tissue-specific knockout animals. These animals can be used to identify gene function, and to study the pharmacological, physiological, and behavioral role of a single gene.

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H. *Toxicity Studies*

1. Studies on abused drugs and their metabolites to develop methodologies that may be potentially useful in addressing medical emergencies. Such studies might include investigations involving development of pharmacokinetic models, methodologies, and data.

2. Concern remains about the potential acute and chronic neurotoxicity of drugs of abuse.

Information is needed about the possible neurotoxicity of pharmacotherapeutic agents with potential for treating drug abuse. Improved methods are needed for identifying, assessing, and quantifying the nature and extent of neurotoxicity. Such studies might include the development or application of quantitative chemical, physiological, or behavioral measurements relating to nervous system injury or methods for quantitative analysis of damage.

I. *Predisposition to Cardiovascular Complications Associated with Abused Substance(s).* Development of experimental animal models to assess a genetic predisposition or increased sensitivity to cardiac and vascular complications associated with drug use. Such studies might include, but are not limited to, investigations involved with biochemical, physiological and pathological indices of cardiovascular system function.

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J. *Opioid Peptides.* Research and development directed at the medicinal chemistry and molecular pharmacology of opioid peptides, especially in methods development. Areas of interest include but are not limited to:

1. Development of innovative methodologies for the synthesis of opioid peptides to be made available to researchers. Syntheses proposed should be limited to single analogs.
2. Methods to identify new ligands for opioid receptors and the design of new opioid peptide analogs with therapeutic potential.
3. Development of analytical methodologies for the quantitation of synthetic and endogenous opioid peptides, peptide precursors, and processing enzymes. The innovation may be limited to a part of the method, such as development of a special detector or a sample cell. Methods might include antibody development and development of innovative immunoassays.

K. *Dopamine and Serotonin Receptor Ligands.* Both dopamine and serotonin receptors exhibit multiple subtypes. Applications are solicited using chemical combinatorial library techniques to develop ligands having a high degree of selectivity to these receptor subtypes, which can be useful both as pharmacological tools and lead compounds in medicinal chemistry/drug development.

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L. *Systems Biology.* The National Institute on Drug Abuse is interested in SBIR proposals that would facilitate global analysis of biological systems relevant to drug abuse. Technologies and resources developed should be applicable and relevant to drug abuse research. Areas of interest include, but are not limited to:

1. Improved technology for analysis of membrane proteomes for the identification of targets and validation of leads.
2. Development of technology or new strategies that will improve dynamic range to allow the analysis of a broader spectrum of the proteome of neural cells.
3. Single cell analysis and the development of model systems for proteomic analysis of neuronal function and drug effects.
4. Development of real-time proteomics technology for the analysis of processes such as cellular responses to drug exposure.
5. High throughput, high resolution 3-dimensional in situ proteome profiling such as optical projection tomography, improved methods for

high throughput sectioning of neural tissue and the development of tools for identifying and mapping protein expression, localization and movement relevant to addiction and other medical consequences of drug abuse.

6. High throughput, functional, molecular interaction screening methods for proteins implicated in drug abuse.
7. Strategies to characterize post-translational modifications related to addiction and drug effects.
8. Development of proteomic tools for identifying biomarkers to track therapeutic efficacy, to monitor effects of drug interactions, and to advance biological understanding of relationships between drug use and infectious disease, and therapies for HIV, hepatitis C and other diseases.
9. Development of computational tools such as knowledge bases, information systems and computational models for protein data related to addiction and other medical consequences of substance abuse. Tools that enable the integration of proteomics, genomics, transcriptomics, metabolomics and other data into applications leading to systems understanding of drug effects upon biological systems.
10. Technologies to identify parameters of molecular, cellular, or physiological systems important in addiction, and the properties of the system, such as redundancy and robustness.
11. New approaches for characterizing cell phenotypes and mapping those phenotypes.

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M. *Research Resources.* The National Institute on Drug Abuse is interested in SBIR proposals that would generate the following resources for drug abuse research:

1. Resources for the application of genetic engineering to dynamically monitor neuronal function.
2. C57BL6 Mouse embryonic stem cells and spermatogonial stem cells.
3. Turnkey technology for proteomics such as the development of protein and peptide chips to study drug effects on neuronal mechanisms.
4. Antibodies, aptamers, ligands, etc. relevant to drug abuse research.

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N. *Development of Innovative Pulmonary Nicotine Delivery Systems.* NIDA is seeking SBIR grant applications for development of devices that achieve the pulmonary delivery of nicotine in human subjects. A major effort in smoking cessation centers on nicotine replacement. Pulmonary delivery of nicotine should permit more reliable replication of the delivery that occurs during the inhalation of tobacco smoke. Thus, such devices would prove valuable as resources in support of research studying the efficacy of rapid nicotine replacement, and as potential future aids in smoking cessation. The devices should be small, portable, and deliver a “smoking-dose” of nicotine in a reliable manner.

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O. *Development of Innovative Synthetic Probes, Drug Dosage Forms, and/or Drug Metabolites For Drug Abuse Research.* Proposals are solicited for the synthesis of new chemical compounds, drug metabolites, peptidomimetics, and/or development of drug dosage forms for studying the

mechanism of action of drugs of abuse and drug addiction.

Specifically proposals are encouraged in the following areas:

1. Synthesis of chemical probes, drug metabolites, peptidomimetics, and/or development of drug dosage forms that are needed by drug abuse research investigators, and they are not commercially available, and/or available with great difficulty.
2. Alternate synthetic methods for existing chemical probes that improve the yield and produce these chemicals at lower costs as compared to commercially available substances.
3. Development of alternate drug dosage forms of existing drugs/drug products for enhancing their efficacy.

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P. ***Development of Analytical Techniques.*** The development of new analytical methods for measuring drugs of abuse and their metabolites in biological matrices, such as urine, blood, saliva, sweat, hair, breast milk, brain tissue, and meconium is encouraged. The new methods should be efficient, sensitive, convenient, and cost effective. Modifications and improvements in existing analytical techniques are also encouraged particularly those improving sensitivity and selectivity.

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Office of Science Policy and Communications (OSPC)

SCIENCE POLICY BRANCH (SPB)

Science Education. In order to improve science education in the area of drug abuse research (e.g., disciplines such as neuroscience, psychology, epidemiology), efforts are needed to develop innovative methods for improving knowledge of and generating interest in science among school children, the general public, and health care providers, including providers involved in drug abuse treatment. These might include but are not limited to:

A. Development of methodologies to present drug abuse and science information to particular groups, such as kindergarten and elementary school students, African Americans, Hispanics, persons with disabilities and health care providers.

B. Development of methodology to transfer new knowledge and directions of scientific growth to teachers, curriculum developers and health care providers.

C. Development of computer-based learning systems that allow students to experience the scientific process.

D. Development of specific materials, activities, or programs that promote science education related to drug abuse, such as exhibits, curriculum materials, coloring books, videos, teacher education workshops, partnership programs with scientists and educators, or workshops for health care providers.

E. Development of specific materials, activities or programs that promote the teaching of scientific and research ethics to middle and high school students.

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Division of Epidemiology, Services and Prevention Research (DESPR)

A. ***Prevention Research Branch (PRB).*** The Prevention Research Branch (PRB) supports a program of research in drug abuse and drug related HIV prevention to (1) examine the efficacy and effectiveness of new and innovative theory-based prevention

approaches for drug abuse, drug-related HIV/AIDS and other associated health risks, (2) determine the cognitive, social, emotional, biological and behavioral processes that account for effectiveness of approaches, (3) clarify factors related to the effective and efficient provision of prevention services, and (4) develop and test methodologies appropriate for studying these complex aspects of prevention science.

Prevention Research. Rigorous scientific prevention research is encouraged to study novel approaches to substance abuse prevention for use at multiple levels of the social environment including: the family, schools, peer groups, community and faith-based organizations, the workplace, health care systems, etc. The purpose of this research is to determine the efficacy and effectiveness of novel program materials, training strategies, and technologies developed to prevent the onset and progression of drug abuse and drug-related HIV/AIDS infection. Materials and technologies may target a single risk-level or may take a comprehensive approach encompassing audiences at the universal, selective, and/or indicated levels. Universal interventions target the general population; selective target subgroups of the population with defined risk factors for substance abuse; indicated interventions target individuals who have detectable signs or symptoms foreshadowing drug abuse and addiction, but who have not met diagnostic criteria. NIDA encourages the development and testing of innovative prevention intervention technologies that are sensitive and relevant to cultural and gender differences.

1. Laboratory studies of the underlying mechanisms and effects of various prevention approaches such as persuasive communication (e.g., mass media and print media) as they are affected by and affect drug related cognition, emotion, motivation and behaviors.
2. Decomposition of prevention programs to understand components that account for program effectiveness.
3. Research on design features of prevention curricula, materials, and approaches that result in positive outcomes.
4. Training modules for program implementers of research based substance abuse prevention programming strategies.
5. Prevention intervention dissemination technologies and mechanisms that integrate research with practice; specifically the transfer of drug abuse prevention information to decision-makers, funders, and practitioners.
6. Prevention services research on the organization, financing, management, delivery, and utilization of drug abuse prevention programs.
7. Strategies for the integration of proven prevention approaches into existing service delivery systems.
8. Studies that develop and assess reliability and validity of developmentally appropriate self-report, physiological, and biochemical measures for use in prevention trials in a variety of settings and a variety of audiences.
9. Development of community needs assessment tools and services.
10. Drug abuse prevention methodological research on promising data collection, data storage, data dissemination, and reporting techniques.

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B. ***Epidemiology Research Branch (ERB).*** The ERB supports a research program on drug abuse epidemiology that includes (1) studies of trends and

patterns of drug abuse and related conditions such as HIV/AIDS in the general population and among subpopulations, (2) studies of causal mechanisms leading to onset, escalation, maintenance, and cessation of drug abuse across stages of human development, (3) studies of person–environment interactions, (4) studies of behavioral and social consequences of drug abuse, (5) bio-epidemiologic studies including genetic epidemiology studies, (6) methodological studies to improve the design of epidemiologic studies and to develop innovative statistical approaches, including modeling techniques.

1. *Improvement of Reliability and Validity of Reporting of Sensitive Data*. The reliability and validity of self-report of drug use and related behaviors (e.g., HIV risk behavior) is a matter of great concern. Use of new technologies for real time data collection in ecological settings is of great interest because these technologies enable collection of drug consumption data in context. Studies to improve methodologies based on variations of standard survey protocols or computer-assisted self-interview (CASI) and personal interview (CAPI) are also encouraged.

2. *Instrument Development.* Easy-to-use assessment instruments are needed to enhance epidemiology research. Areas of interest include but are not limited to:

   a. *Community Assessment.* The development of community diagnostic instruments for psychometrically sound assessment of community characteristics is essential to improve our understanding of how community factors affect drug abuse and ensuing behavioral and social consequences. Standardized assessments of community characteristics are needed to better understand the full impact of drug use and to develop targeted interventions to specific community needs.

   b. *Assessment of Psychiatric Comorbidity in Community Settings.* Easy to use, reliable, and valid instruments are needed to assess psychiatric comorbidity in different populations of drug abusers, including adolescents and those in community drug abuse treatment settings.

   c. *Assessment Instruments to Measure CNS Function Related to Drug Abuse.* The development of age-appropriate assessment instruments to measure behavioral and cognitive function over the course of development will contribute to our understanding of vulnerability to drug abuse and functional impairment due to drug use.

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C. ***Services Research Branch (SRB).*** The SRB supports a program of research on the effectiveness of drug abuse treatment with a focus on the quality, cost, access to, and cost-effectiveness of care for drug abuse dependence disorders. Primary research foci include: (a) the effectiveness and cost-benefits and cost-effectiveness of drug abuse treatment, (b) factors affecting treatment access, utilization, and health and behavioral outcomes for defined populations, (c) the effects of organization, financing, and management of services on treatment outcomes, (d) drug abuse service delivery systems and models, such as continuity of care, stages of change, or service linkage and integration models, and (e) drug abuse treatment services for HIV seropositive patients and for those at risk of infection.

1. *Drug Abuse Treatment Economic Research*. This initiative will

support research to design and develop data systems for financial management and economic analysis of treatment programs and larger systems in new healthcare settings and managed care networks. Managerial decision-making requires the implementation of sophisticated data systems to facilitate routine budgeting processes, allocation of resources, performance measurement, and pricing decisions. The focus is on the needs of managers within the organization and managers outside of the organization. Data system development must be based on standard cost behavior and profit analysis. Data systems must be designed with correct cost concepts (accounting and economic) in order to permit cost and pricing decisions to be developed for new treatment technologies and management of on going systems. In research settings, such an initiative is vital for the assessment of new technologies developed for transfer to practice.

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2. *Personnel Selection Technology Research for Drug Abuse Treatment Clinics*. NIDA would be interested in supporting small innovative research that develops and validates generic selection systems that could be adopted and tailored for use by drug abuse treatment clinics. Like many small businesses, drug abuse treatment clinics have problems attracting and retaining qualified personnel. Also like many small businesses, treatment clinics have limited resources to apply to the recruiting and hiring of new and replacement personnel. Though reliable data are lacking, a great many clinic directors complain of high annual staff turnover rates. This has been attributed anecdotally to poor quality of work life, low wages, low skill levels, incompatibilities with the clinic's treatment philosophy, and the high stress of working with drug abusers. Research has shown that the application of standardized selection methods designed to maximize person-job fit can cost-effectively reduce staff turnover. Systematic methods such as background inventories, protocol-driven interviews, aptitude tests, and credit checks have demonstrated validity for improving person-job fit. Examples of possible projects might include development of easy-to-understand guidance about legal considerations in hiring practices, software that transform job task analysis into selection criteria, interview protocols to standardize applicant screening, tolls to help improve recruitment, and/or self-paced training for hiring officials or interview panels to improve screening reliability.

3. *Customer Retention Technology*. Premature disengagement from drug abuse treatment participation is a common problem and ranges from approximately 30 to 60% based upon the clinic and modality studied. Past research has very frequently attributed dropping out of treatment to participant characteristics (e.g., motivation, addiction severity, comorbidity) and/or environmental factors (e.g., social pressures, unemployment, homelessness). Seldom has the dropout problem been studied in the context of customer satisfaction. That is, there is little research looking at the causes of dropping out of treatment attributable to organizational factors (e.g., policies, practices, context) that influence participant withdrawal decisions. Needed are tools and system for assessing and survey drug abuse treatment program participant perceptions and satisfaction levels,

summarizing and report participant assessments, interpreting results and adjusting policies and practices to improve satisfaction and participant retention in treatment.

4. *Effective Management and Operation of Drug Abuse Treatment Services Delivery*. The bulk of drug abuse treatment is conducted in small clinical settings with therapeutic staffs of less than a dozen people. Small clinics lack resources to help improve efficiency and effectiveness in both business and therapeutic practices. Areas that may be of interest to small businesses include, but are not limited to:

    a. Computer-based leader/manager self assessment tools to enable those supervising the delivery of drug abuse treatment services to gain insights about strengths and weaknesses, and to help guide them to improved leadership and management practices.

    b. Organizational change tools: Handbooks describing step-by-step way to introduce more efficient business practices such as quality management/monitoring, creating empowered work teams, formalized goal setting, improved customer relations, forming organization linkages, and adopting new fiscal and resource management techniques.

    c. Organizational change tools: Handbooks describing step-by-step ways to introduce more efficient or effective therapeutic practices such as, adding pharmacotherapy in a previously drug-free clinic, adopting new medical/pharmacotherapy or behavioral interventions, and adopting new approaches to clinical collaboration and/or case management.

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5. *Web-Based Technologies: Transporting Services Research to Practice*. This initiative will support the development and testing of the effectiveness of web-based technologies that facilitate the translation of drug abuse prevention and treatment services research into practice. The ultimate goal is the delivery of efficacious, low-cost interventions to the greatest number of individuals in community settings. Delivery of evidence-based services in community settings often is hampered by lack of state-of-the-art information about the contents of efficacious interventions, the organizational structures and processes that make effective implementation possible, and available training and technical assistance. Applications may include, but are not limited to, the development and testing of new and innovative Internet-based systems that provide practitioners with (a) current information on evidence-based treatments with the greatest promise for defined populations of drug abusers; (b) assistance in translating clinical trials data into clinically useful information; (c) information and training on how to effectively organize, manage, and deliver evidence-based prevention and treatment services; (d) strategies for organizational change and capacity building; and (e) access to training and technical assistance on the adoption of new prevention and treatment interventions.

6. *New Technologies for Screening, Assessing, and Preventing Problem Drug Use and Matching Patients with Appropriate Treatment Services.* Increased understanding of the complexities

of problem drug use has sparked growing interest in and increased need for new user-friendly technologies to assist in the screening, assessment, and prevention of drug abuse and in the matching of patients with appropriate treatment services. New technologies, including CD-ROM, hand-held, Internet, videotape, videodisc, and other electronic means have great potential for helping treatment providers in specialty and non-specialty care settings including primary care contexts to (a) screen for problem drug use and associated health problems and risk behaviors, (b) assess the nature and degree of drug use, (c) embed items for screening or assessing problem drug use within existing clinical tools, (d) deliver appropriate prevention interventions, and (e) identify appropriate types and levels of treatment services for patients based on their individual treatment needs. These new technologies potentially can provide a more cost effective way of identifying problem drug use and associated health problems in a variety of health care settings, speeding the assessment process, preventing the escalation of use to abuse, and improving treatment placement decisions.

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7. *Reintegration of Criminal Offenders into the Community.* Many offenders enter the criminal justice system with drug abuse problems and related health issues. In addition to addressing these health care issues within the prison walls, treatment programs are increasingly called upon to help offenders successfully reintegrate into the community following incarceration. This often means helping offenders to manage their recovery through monitoring, linkage with continuing care services, development of social support networks, and education of friends and family members about the nature of drug abuse and the challenges facing the offender upon release from prison. It is estimated that over the next several years, more than 600,000 criminal justice offenders, many of whom have drug abuse problems, per year will be released to return to their communities. New technologies are needed to help treatment providers in the criminal justice system and in the community coordinate efforts to effectively (a) monitor offenders' recovery once they have been released into the community, (b) prevent relapse, (c) identify relapse early and efficiently re-engage released offenders in appropriate treatment, (d) link released offenders with continuing care services in the community, (e) develop social support networks for recently released offenders in recovery, and (e) educate offenders' family members so that they can more effectively support offenders in recovery once they have been released from prison.

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Center on AIDS and Other Medical Consequences of Drug Abuse (CAMCODA)

The Center on AIDS and Other Medical Consequences of Drug Abuse (CAMCODA) develops and administers a national and international program of research on HIV/AIDS and other medical/health, mental health, and developmental consequences of drug abuse. CAMCODA also coordinates research activities, and collaborates with other NIDA components, on issues concerning HIV/AIDS and consequences of drug abuse.

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A. ***Develop Improved Technology for Assessment of Prenatal Drug Exposure and Passive Postnatal Drug Exposure***

1. Develop and refine methods for the detection and quantification of infant exposure to drugs of abuse during pregnancy, including cocaine, marijuana, opiates, and methamphetamines.

2. Develop and refine methods for the detection and quantification of passive exposure to illicit drugs during infancy and childhood.

B. ***Develop Interactive Database Systems on Human Subjects Issues for Use by Drug Abuse Researchers Studying School-Age Children and Adolescents Drug Use.*** Develop systems to assist investigators in obtaining technical and legal information relevant to involvement of children and adolescents in research on drug abuse. Examples of pertinent situations include tracking long-term health and development of children exposed to drugs during pregnancy, and investigating vulnerability and possible pathways to drug abuse among school-age children and adolescents. These database systems should address issues such as assent and consent, should provide information on variation in laws and guidelines across jurisdictions, should include the capacity for interactive communication on numerous situations potentially facing investigators, and should serve as sources of referral for additional assistance.

C. ***Develop Improved Methods of Neuroimaging to Assess Structural and Functional Status of the Brains of Children and Adolescents Exposed to Drugs.*** Document the feasibility and accuracy of appropriate and acceptable methods for assessing brain structure and function of children and adolescents, with special attention to any or all of the following groups: those exposed to drugs during pregnancy, those passively exposed during infancy and childhood, and those actively using illicit substances. Documentation should include attention to such matters as technological difficulties and risks, and standardization issues relevant to testing conditions and image analysis.

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D. ***Develop and Refine Methodologies for Drug Use Measurement Among Adolescents.*** Research to develop and refine methodologies for drug use detection and quantification, with special application to the adolescent with HIV infection or at high-risk for HIV infection. This research should address issues of acceptability, reliability, and validity of one or more methods (e.g., interviews, computerized questionnaires, and biological indicators such as saliva or sweat).

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E. ***Develop and Test Reagents for the Diagnosis of Hepatitis C in Drug Users.*** Research to develop novel reagents such as virus particles, for use in community based testing for hepatitis C.

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F. ***Develop and Test Reagents for the Treatment of Liver Disease in Drug Users.*** Research to develop novel reagents either biological or chemotherapy based for treatment of liver disease in drug users. For example, reagent that modulation specific lipoproteins may reduce the progression of liver fibrosis.

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G. ***Develop a Diagnostic Test for Mitochondrial Dysfunction due to Illegal Drug Use.*** Research to develop a diagnostic test for mitochondrial dysfunction in Amphetamine/ Methamphetamine users to determine tissue pathology, such as neurological disease.

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H. ***Develop Methods/Batteries for Assessment of Vulnerability to and Emergence/ Remission of Psychiatric Symptoms in Drug Abusers Under Treatment for Hepatitis C.*** As drug abusers undergo Hepatitis C treatment, symptoms of pre-existing mental disorders may re-emerge and/or psychiatric symptoms may develop de novo. The context may include symptoms attributable to (1) significant pre-existing or emerging neuropsychological impairment, (2) drug intoxication/withdrawal, (3) active Hepatitis C and (4) comorbidities associated with the above. This effort will develop reliable, valid, easily administrable test methods/batteries to promote the early detection and ease of ongoing assessment of these symptoms, including discrimination of symptoms attributable to each of the above in ways that effectively guide interventions in all of these areas.

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I. ***Develop New or Improved Prescription Drug Adherence Assessment Measures and Procedures.*** Develop measures and procedures to assess adherence to prescribed regimens for medications with significant abuse liability, e.g., opiates, benzodiazepines, sedative-hypnotics but which are extremely useful in the treatment of comorbid psychiatric/medical conditions (such as depression, anxiety, dyssomnias, pain) in drug abusing populations. In this context there is concern about both the development of and relapse to patterns of abuse of these prescribed medications as well as continued use in accordance with medical instruction. Thus, this effort encourages the development of methods to monitor levels and patterns of use/abuse.

Methods may range from biological and physiological to psychological. Examples of biological methods include quantitative detection of the medication or a metabolite in body fluids and administration of a more easily detectible indicator substance in conjunction with the active medication. Physiological methods may include such efforts as monitoring of parameters related to heart rate, blood pressure, galvanic skin response and electroencephalographic measures. Psychological methods may include such efforts as automated cognitive or perceptual performance assessment and methods for systematic monitoring of administration patterns by significant others. Methods must be able to detect and quantify deviation from prescribed patterns of use in the directions of overuse or underuse in order to detect such phenomena as steady increases in amount used, sequestration of medications for binges or overdoses and diversion.

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J. ***Develop Assessment Instruments to Detect Occult Drug Abuse in Clients/Patients Seen in the Mental Health, Medical Care, Social Service and Criminal Justice Systems.*** Develop diagnostic measures to be used by mental health, primary and specialty health care providers, and workers in the social service and legal systems to detect drug abuse in patients/clients whose drug abuse otherwise would remain undiagnosed. Such assessment instruments, could include (1) instruments based on structured or semi-structured interviews assessing such domains as symptom profiles, medical/psychiatric history, illness patterns consistent with drug abuse, (2) paper-and-pencil and/or

computer-based questionnaires, surveys, or other testing modalities, (3) psychophysiological methods such as galvanic skin response, electroencephalography, eye movement/ pupillometry testing, reaction time measures, heart rate/blood pressure responses, and functional brain imaging and/or (4) tests involving body fluids or other samples, such as gene activation patterns diagnostic of drug abuse. Portable, easily administered and highly sensitive and specific test batteries for drug abuse would be of great value in that they would (a) provide health care/social services providers with an awareness of a patient's otherwise undisclosed drug abuse -- which likely would have medical consequences in the form of drug interactions and other adverse effects related to the presence of drugs of abuse in patients undergoing treatment, receiving social services and/or having involvement in the criminal justice system and (b) provide a basis for the linkage of drug abuse treatment to the other interventions required.

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K. ***Development, Testing, and Dissemination of Innovative HIV/AIDS Prevention Intervention Technologies.***

Development and standardization (including assessment of psychometric properties) of self-report, physiological, and/or biological measures for use in HIV/AIDS prevention intervention in a variety of settings.

Development and validation of risk profiles and assessment methodologies for identification of individuals at-risk for HIV/AIDS.

Development and evaluation of HIV/AIDS prevention curricula, materials and implementation methods, for HIV/AIDS prevention service delivery.

Development of HIV/AIDS prevention intervention dissemination technologies, mechanisms, and links that integrate research with practice; specifically the transfer of HIV/AIDS prevention information to practitioners, policy makers, and the public.

Development of training modules for program implementers of research based HIV/AIDS prevention programs.

Development of strategies for the integration of proven HIV/AIDS prevention approaches into existing service delivery systems.

Development of innovative methodologies for data collection, data storage, data dissemination, and reporting techniques pertaining to HIV/AIDS prevention.

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L. *Development, Testing, and Dissemination of Innovative HIV/AIDS Epidemiological Tools to Better Estimate the Magnitude and Spread of Drug Related Infectious Diseases and Identify Optimal Intervention Strategies.*
Development of estimation procedures (including enhanced surveillance systems, modeling techniques, and ethnographic methods) and software applications for obtaining more accurate and time-relevant forecasting estimates of rates of diffusion of HIV within and across population subgroups.

Development of computer based applications that integrate improve methods for forecasting and modeling the relative efficacy of various intervention strategies to contain diffusion of HIV.

Development epidemiological systems that integrate behavioral, (risk behaviors), biological (STI, HIV molecular epidemiology), environmental/contextual, and social factors (policies, laws) to better inform and direct prevention resources to populations with greatest needs.

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M. *Development of training manuals for peer educators and mentors working with youth in HIV/AIDS and other infectious disease prevention.*
Development of training of trainers (TOT) manuals with modules on HIV/AIDS, STDs and other infectious disease prevention.

Development of culturally sensitive training manuals for minority youth (various ages) in drug use, HIV/AIDS and STD prevention and intervention.

Development of gender-specific training modules with particular emphasis on minority young women in drug use, HIV/AIDS and STD prevention and intervention.

Development of assessment and evaluation instruments to test effectiveness of the training modules in risk reduction behaviors among youth.

N. *Development of culturally sensitive presentation packages and communication modules utilizing emerging multimedia technologies that are age appropriate for use by youth peer educators targeting minority youth.*

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Other Research Topic(s) Within the Mission of the Institute

NIDA encourages applications in other areas of research that may not be listed. For additional information on research topics, contact:
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