recommended a comprehensive public review of the scientific and ethical issues raised by such studies. In response, NIH convened a national Gene Therapy Policy Conference on Prenatal Gene Transfer: Scientific, Medical, and Ethical Issues (January 7–8, 1999) to further explore these issues.

The findings and conclusions of the Conference indicated that, at present, there is insufficient preclinical data to support the initiation of clinical trials involving in utero gene transfer clinical research. A substantial number of critical scientific, safety, ethical, legal, and social issues must be addressed before clinical trials proceed in this arena including: (1) Efficiency of gene transfer to target cells; (2) specificity of delivery to target cells; (3) level, duration, and regulation of gene expression; (4) appropriate disease candidates; (5) fetal immune response to transgene products and/or vectors; (6) emergence of fetal immune tolerance; (7) effects of gene transfer on pre- and post-natal development; (8) possibility of generation and activation of transmissible vector or virus; (9) possibility of initiating oncogenic or degenerative processes; (10) limitations related to the accuracy of disease diagnosis; (11) implications of diagnostic limitations on the design and conduct of clinical trials; (12) elements of optimal clinical trial design and analysis; (13) potential risk to the fetus and acceptable level of risk to the fetus in human experimentation; (14) potential risk to the pregnant woman; (15) detection and assessment of inadvertent germ-line transmission; (16) ethical issues specific to the fetus; (17) ethical issues specific to the pregnant woman; (18) patient recruitment/enrollment processes; (19) informed consent issues; (20) societal issues; and (21) legal issues. (See http://www4.od.nih.gov/oba/gtpcreport.pdf for further information.)

In March 1999, RAC discussed the findings and conclusions of the conference and developed the following consensus statement: ''The RAC continues to explore the issues raised by the potential of in utero gene transfer research. However, at present, the members unanimously agree that it is premature to undertake any human in utero gene transfer experiment.'' After providing an opportunity for public comments (64 FR 43884), the RAC unanimously recommended that this consensus statement be adopted as policy and incorporated into the NIH Guidelines (Appendix M). The NIH is implementing this recommendation through this notice of action.

Action Amending the NIH Guidelines

Appendix M. Points to Consider in the Design and Submission of Protocols for the Transfer of Recombinant DNA Molecules into One or More Human Research Participants (Points to Consider)

Appendix M is amended by adding the following paragraph after the third paragraph:

''The RAC continues to explore the issues raised by the potential of in utero gene transfer clinical research. However, the RAC concludes that, at present, it is premature to undertake any in utero gene transfer clinical trial. Significant additional preclinical and clinical studies addressing vector transduction efficacy, biodistribution, and toxicity are required before a human in utero gene transfer protocol can proceed. In addition, a more thorough understanding of the development of human organ systems, such as the immune and nervous systems, is needed to better define the potential efficacy and risks of human in utero gene transfer. Prerequisites for considering any specific human in utero gene transfer procedure include an understanding of the pathophysiology of the candidate disease and a demonstrable advantage to the in utero approach. Once the above criteria are met, the RAC would be willing to consider well rationalized human in utero gene transfer clinical trials.''

OMB's ''Mandatory Information Requirements for Federal Assistance Program Announcements'' (45 FR 39592) requires a statement concerning the official government programs contained in the Catalog of Federal Domestic Assistance. Normally, NIH lists in its announcements the number and title of affected individual programs for the guidance of the public. Because the guidance in this notice covers virtually every NIH and Federal research program in which recombinant DNA techniques could be used, it has been determined not to be cost effective or in the public interest to attempt to list these programs. In addition, NIH could not be certain that every Federal program would be included as many Federal agencies, as well as private organizations, both national and international, have elected to follow the NIH Guidelines. In lieu of the individual program listing, NIH invites readers to direct questions to the information address above about whether individual programs listed in the Catalog of Federal Domestic Assistance are affected.

Dated: December 28, 2000.

Ruth L. Kirschstein,

Acting Director, National Institutes of Health.

[FR Doc. 01–337 Filed 1–4–01; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Proposed Collection; Comment Request

In compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 concerning opportunity for public comment on proposed collections of information, the Substance Abuse and Mental Health Services Administration will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the information collection plans, call the SAMHSA Reports Clearance Officer on (301) 443–7978.

Comments are invited on: (a) Whether the proposed collections of information are necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project: Pilot Testing of Outcome Measures in Programs Providing Services to Persons Who are Homeless and Have Serious Mental Illnesses—New—SAMHSA's Center for Mental Health Services (CMHS) provides funds to states and territories to provide services to individuals who are homeless and have serious mental illnesses. These services enable persons who are homeless and have serious mental illnesses to be placed in appropriate housing situations and linked to mental health services. To comply with requests for client outcome data, State and local providers have sought measures which could help them more effectively monitor and manage their programs as well as demonstrate program effectiveness.

Interest in performance measurement and evaluation of policies, programs and individual services has increased

dramatically with the passage of the Government Performance and Results Act (GPRA) in 1993. GPRA focuses new attention on the quality of outcome measures used to collect information about publicly funded programs. Programs that provide services to persons who are homeless and have serious mental illnesses are facing greater need to document their effectiveness. These outcome data will ultimately be used in responding to Congressional and HHS oversight, GPRA requirements, and the requests of other governmental levels, managed care companies, and private funding sources.

The project will test the appropriateness and feasibility of selected indicators to measure the outcome of services to persons who are homeless and have serious mental illnesses. Outcome measures to be evaluated include housing status, sobriety or drug-free status, mental health treatment status, enrollment in an educational program, and employment.

In addition, the project will evaluate process measures pertaining to outreach, service delivery and linkage stages of intervention. These process indicators include the type of contact (*i.e.*, referrals, walk-ins, fixed outreach, and mobile outreach); whether the person contacted agreed to services, reasons for any non-enrollment, and referral to, and provision of, specific services.

The project will test these outcome and process measures in a total of approximately six provider agencies in each of five participating States. The findings of the pilot test will serve as the basis for recommendations for a voluntary national implementation of data collection in similar programs, nationwide. It will also test the feasibility of compiling such data in a central data collection point.

Local providers will report information on services provided to individuals served. Providers will report aggregate information from their records for all new clients during a one-month period. Information will be reported on the initial client contact, on services clients receive over the next six months and on client outcomes at the end of six months. In addition, half of the provider agencies will report client followup information at a period 60 days after the conclusion of the six-month period. It is anticipated that this information will be collated from existing provider records. Data will be submitted to the central data point in aggregate form, not by individual client. Projected response burden for the project is summarized in the table below.

	Estimated number of respondents	Estimated number of responses per respondent	Average burden hours per response	Estimated total annual burden hours requested
Initial and six-month aggregate report	30	1	10	300
Follow-up aggregate report	15	1	10	150
Total	30	.....	.....	450

Send comments to Nancy Pearce, SAMHSA Reports Clearance Officer, Room 16–105, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Written comments should be received within 60 days of this notice.

Dated: December 29, 2000.

Richard Kopanda,

Executive Officer, SAMHSA.

[FR Doc. 01–309 Filed 1–4–01; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Current List of Laboratories Which Meet Minimum Standards To Engage in Urine Drug Testing for Federal Agencies

AGENCY: Substance Abuse and Mental Health Services Administration, HHS.

ACTION: Notice.

SUMMARY: The Department of Health and Human Services notifies Federal agencies of the laboratories currently certified to meet standards of Subpart C of Mandatory Guidelines for Federal Workplace Drug Testing Programs (59 FR 29916, 29925). A similar notice listing all currently certified laboratories will be published during the first week of each month, and updated to include laboratories which subsequently apply for and complete the certification process. If any listed laboratory's certification is totally suspended or revoked, the laboratory will be omitted from updated lists until such time as it is restored to full certification under the Guidelines.

If any laboratory has withdrawn from the National Laboratory Certification Program during the past month, it will be listed at the end, and will be omitted from the monthly listing thereafter.

This Notice is also available on the internet at the following website: *http://www.health.org/workplace*

FOR FURTHER INFORMATION CONTACT: Mrs. Giselle Hersh or Dr. Walter Vogl, Division of Workplace Programs, 5600 Fishers Lane, Rockwall 2 Building, Room 815, Rockville, Maryland 20857; Tel.: (301) 443–6014, Fax: (301) 443–3031.

Special Note: Please use the above address for all surface mail and correspondence. For all overnight mail service use the following address: Division of Workplace Programs, 5515 Security Lane, Room 815, Rockville, Maryland 20852.

SUPPLEMENTARY INFORMATION: Mandatory Guidelines for Federal Workplace Drug Testing were developed in accordance with Executive Order 12564 and section 503 of Pub. L. 100–71. Subpart C of the Guidelines, ''Certification of Laboratories Engaged in Urine Drug Testing for Federal Agencies,'' sets strict standards which laboratories must meet in order to conduct urine drug testing for Federal agencies. To become certified an applicant laboratory must undergo three rounds of performance testing plus an on-site inspection. To maintain that certification a laboratory must participate in a quarterly performance testing program plus periodic, on-site inspections.

Laboratories which claim to be in the applicant stage of certification are not to be considered as meeting the minimum requirements expressed in the HHS Guidelines. A laboratory must have its letter of certification from SAMHSA, HHS (formerly: HHS/NIDA) which attests that it has met minimum standards.

In accordance with Subpart C of the Guidelines, the following laboratories