

Atlanta, GA 30328, Telephone (770) 395-3900.

**Status:** Portions of the meeting will be closed to the public in accordance with provisions set forth in Section 552b(c) (4) and (6), Title 5 U.S.C., and the Determination of the Director, Management Analysis and Services Office, CDC, pursuant to Public Law 92-463.

**Matters To Be Discussed:** The meeting will include the review, discussion, and evaluation of applications received in response to Program Announcement Number 04064.

**For Further Information Contact:** Beth Wolfe, Resource Funding Analyst, National Center for HIV, STD, and TB Prevention, CDC, 1600 Clifton Road, NE., MS-E07, Atlanta, GA 30333, Telephone (404) 639-8531.

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

Dated: January 30, 2004.

**Alvin Hall,**

*Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.*

[FR Doc. 04-2397 Filed 2-4-04; 8:45 am]

**BILLING CODE 4163-18-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

#### Prospective Grant of Exclusive License: Diagnostics of Fungal Infections

**AGENCY:** Technology Transfer Office, Centers for Disease Control and Prevention (CDC), Department of Health and Human Services.

**ACTION:** Notice.

**SUMMARY:** This is a notice in accordance with 35 U.S.C. 209(e) and 37 CFR 404.7(a)(1)(i) that the Centers for Disease Control and Prevention (CDC), Technology Transfer Office, Department of Health and Human Services (DHHS), is contemplating the grant of a worldwide, limited field of use, exclusive license to practice the inventions embodied in the patent application referred to below to TNB Laboratories, Inc. (TNB) having a place of business in St. Johns, Newfoundland. The patent rights in these inventions have been assigned to the government of the United States of America. The patent application to be licensed is:

**Title:** "Latent Human Tuberculosis Model, Diagnostic Antigens, and Methods of Use," U.S. Patent

Application Serial No.: 10/250,930 (TBC).

**Status:** Pending.

**Issue Date:** N/A.

The prospective exclusive license will be royalty-bearing and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR 404.7.

#### Technology

This technology adds a new level of specificity in the identification of Tuberculosis. It can be incorporated into a device to diagnose Latent Human Tuberculosis.

**ADDRESSES:** Requests for a copy of this patent application, inquiries, comments, and other materials relating to the contemplated license should be directed to Andrew Watkins, Director, Technology Transfer Office, Centers for Disease Control and Prevention (CDC), 4770 Buford Highway, Mailstop K-79, Atlanta, GA 30341, telephone: (770) 488-8610; facsimile: (770) 488-8615. Applications for a license filed in response to this notice will be treated as objections to the grant of the contemplated license. Only written comments and/or applications for a license which are received by CDC within sixty days of this notice will be considered. Comments and objections submitted in response to this notice will not be made available for public inspection, and, to the extent permitted by law, will not be released under the Freedom of Information Act, 5 U.S.C. 552. A signed Confidential Disclosure Agreement (available under Forms @ <http://www.cdc.gov/tto>) will be required to receive a copy of any pending patent application.

Dated: January 29, 2004.

**Joseph R. Carter,**

*Deputy Chief Operating Officer, Centers for Disease Control and Prevention.*

[FR Doc. 04-2396 Filed 2-4-04; 8:45 am]

**BILLING CODE 4163-18-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

#### Reporting of Pregnancy Success Rates From Assisted Reproductive Technology Programs

**AGENCY:** Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (DHHS).

**ACTION:** Notice.

**SUMMARY:** The CDC is tasked with implementing the Fertility Clinic Success Rate and Certification Act of

1992 (FCSRCA), Public Law 102-493. As mandated by this law CDC publishes annual reports of pregnancy success rates from ART clinics and embryo laboratory certification status of these clinics. Section 2(a) of Public Law 102-493 (42 U.S.C. 263a-1) requires that each assisted reproductive technology (ART) program shall annually report to the Secretary, through the Centers for Disease Control and Prevention, (a) pregnancy success rates achieved by such ART programs, and (b) the identity of each embryo laboratory used by such ART programs, and whether the laboratory is certified or has applied for such certification under this act. Section (6) states that the Secretary, through the CDC, shall annually publish and distribute to the States and the public, pregnancy success rates reported to the Secretary under section 2(a)(1) and, in the case of an assisted reproductive technology program which failed to report one or more success rates as required under each section, the name of each such program and each pregnancy success rate which the program failed to report.

CDC first implemented the FCSRCA in 1997, and has obtained and published data for ART procedures performed in 1995, 1996, 1997, 1998, 1999 and 2000. Currently, CDC has a contract with the Society for Assisted Reproductive Technology (SART) to annually obtain a copy of their clinic-specific database. The existing contract will be used to obtain and publish data for ART procedures performed in 2001, 2002 and 2003. Details on the current process are outlined in the September 1, 2000 **Federal Register** notice (Volume 65, No. 171, pages 53310-53316).

CDC is currently in the process of selecting a contractor for the 2004, 2005, 2006, 2007, and 2008 data reporting years. We anticipate awarding the contract in February, 2004. Based on that timeframe, we anticipate that the data collection system for 2004 data reporting will be available to clinics in summer, 2004. The new contract to be awarded will cover clinic tracking, data collection and quality assurance and validation processes for ART procedures performed in 2004, 2005, 2006, 2007 and 2008. The data collection process is expected to be similar to the current data collection process (see September 1, 2000 **Federal Register** notice, Volume 65, No. 171, pages 53310-53316).

Under the new contract, the contractor shall furnish all personnel, facilities, equipment, supplies, and materials necessary to assist CDC to produce and publish an annual report of pregnancy success rates and embryo laboratory certification status, as

mandated by the Fertility Clinic Success Rate and Certification Act of 1992. (FCSRCA), Public Law 102-493. The Contractor shall meet the following requirements:

a. The contractor shall track all clinics performing ART in the United States and its territories that are known to be in operation for each reporting year and track all clinic reorganizations and closings.

b. The contractor shall develop a standardized data collection system, subject to Office of Management and Budget (OMB) requirements, that appropriately collects all specified data from clinics.

c. The contractor shall implement a quality assurance system each year to ensure that the data delivered to CDC are of acceptable quality and completeness.

d. The contractor shall distribute the data collection software, along with instructions, to all clinics by preset deadlines.

e. The contractor shall provide ongoing technical assistance to each site as needed by developing, implementing, and maintaining a Web site and telephone help line for technical assistance in all data collection issues.

f. The contractor shall deliver to the CDC, preliminary and final clinic and cycle specific data for each reporting year. The contractor shall deliver all necessary documentation pertaining to the annual data sets.

g. The contractor shall provide: (1) A listing of all assisted reproductive technology clinics that are included in the clinic and cycle specific datasets each reporting year; and, (2) a listing of all assisted reproductive technology clinics that were performing assisted reproductive technology cycles and were thus required to report data under FCSRCA, but failed to report such data to the contractor. The lists of reporting and non-reporting clinics shall include all clinics known to be in operation during a given reporting year.

h. Each year, the contractor shall prepare and describe a data validation quality assurance plan in conjunction with the CDC. The contractor shall perform data validation site visits, enter the data collected during these visits into an electronic data system, and provide both the electronic datafile and a hard copy of all abstraction forms to the CDC.

The amount and type of data collected will be similar to the current system requirements and will include clinic information, patient demographic information, patient history, ART cycle information, and ART outcome

information. A detailed listing of current data elements and definitions for data to be collected are outlined in the **Federal Register** notice (see September 1, 2000 **Federal Register** notice, Volume 65, No. 171, pages 53310-53316).

The current database system is based on Microsoft Access. In this new contract, CDC will require that the contractor develop a new database system. The database system developed under this new contract must have the capability to record data for every treatment cycle of ART initiated, convert collected data to a database such as Microsoft Access (and ultimately the database must be converted into SAS System Version 8.0 or later). CDC will also require that the database developed include all programming necessary to take the data entered for each ART cycle initiated and compute all statistics needed for presentation in the report. The contractor will submit two datasets to CDC—one organized such that each ART cycle initiated is a unique observation, and one organized such that summary statistics by each clinic is a unique observation.

Each ART program should be aware that the Paperwork Reduction Act is applicable to this data collection. Under the Paperwork Reduction Act of 1995, a Federal agency shall not conduct or sponsor a collection of information from ten or more persons other than Federal employees, unless the agency has submitted a Standard Form 83, Clearance Request, to the Director of the Office of Management and Budget (OMB), and OMB has approved the collection of information. A person is not required to respond to a collection of information unless it displays a currently valid OMB control number. CDC has obtained OMB approval to collect this data under OMB control No. 0920-0556.

Currently, each ART program must use the required database system (developed by SART) to enter and submit data. Under the new contract, CDC will continue to require a single data collection system (to be developed by the contractor). In addition, each ART program currently submits its dataset output from the required software to the contractor at a central site. The contractor then compiles all the datasets from specific sites into a single dataset. That requirement will continue.

Currently, all ART programs reporting their data are subject to an annual external validation of their data collection and reporting activities by appropriately trained professionals from

outside the clinic staff. This review includes but is not limited to examination of medical and laboratory records and comparison of data in the reporting database with the data in the medical record. External validation will continue with the new contract.

Every clinic will maintain a copy of all information included in the reporting database and must be able to link each patient, cycle and oocyte retrieved from the reporting database to the appropriate medical and laboratory records for external validation activities. The new contractor will provide the necessary personnel to perform the validation visits.

ART success rates will be similar to those currently presented in the annual reports and will be defined and characterized as described below:

Success rates for fresh, nondonor cycles will be defined as—

1. The rate of pregnancy after completion of ART according to the number of:

- All ovarian stimulation or monitoring procedures.

2. The rate of live birth after completion of ART according to the number of:

- a. All ovarian stimulation or monitoring procedures.

- b. Oocytes retrieval process.

- c. Embryo (or Zygote, or oocyte) transfer procedures.

3. The rate of singleton live birth after completion of ART according to the number of:

- a. All ovarian stimulation or monitoring procedures.

- b. Embryo (or zygote, or oocyte) transfer procedures.

Success rates for cycles using thawed embryos and cycles using donor oocytes or embryos will be defined as—

4. The rate of live birth after completion of ART according to the number of:

- Embryo (or zygote, or oocyte) transfer procedures.

5. The rate of singleton live birth after completion of ART according to the number of:

- Embryo (or zygote, or oocyte) transfer procedures.

Reporting requirements, data elements, definitions, and success rates will be periodically reviewed and updated as new knowledge concerning ART methods and techniques becomes available.

Until a new contract has been awarded, ART programs are advised to refrain from entering 2004 data into the current data collection system. CDC will continue to provide information to all

ART programs regarding the status of the new contract and future years' data collection activities as information becomes available.

**FOR FURTHER INFORMATION CONTACT:**

Victoria Wright, Assisted Reproductive Technology Epidemiology Unit at (770) 488-6370.

Dated: January 29, 2004.

**Joseph R. Carter,**

*Deputy Chief Operating Officer, Centers for Disease Control and Prevention.*

[FR Doc. 04-2395 Filed 2-4-04; 8:45 am]

**BILLING CODE 4163-18-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Administration for Children and Families**

**Submission for OMB Review; Comment Request**

*Title:* Grants Application Data Summary Administration for Native Americans Language Application Information.

*OMB No.:* New collection.

*Description:* Grants Application Data Summary (GADS) information is collected as part of a grant application. The GADS provides information used to prepare the legislatively mandated annual report to Congress on the status of American Indians, Native Alaskans,

Native Hawaiians and Pacific Islander communities.

The purpose of this information collection is to collect information from applicants that the Administration for Native Americans can use for more accurate reporting to the Administration for Children and Families and to Congress on the status of American Indians, Native Alaskans, Native Hawaiians and Pacific Islander communities. This information collection is conducted in accordance with 42 USC 2991b-2(4) of the Native American Programs Act of 1974, as amended.

*Respondents:* Tribal governments, native non-profits, tribal colleges & universities.

*Annual Burden Estimates:*

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Language GADS Form .....	650	1	28	18,200

*Estimated Total Annual Burden Hours:* 18,200.

*Additional Information:* Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Administration, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Office. All requests should be identified by the title of the information collection. E-mail address: [rsargis@acf.hhs.gov](mailto:rsargis@acf.hhs.gov).

*OMB Comment:* OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office

of Management and Budget, Paperwork Reduction Project, Washington, DC, Attn: Desk Officer for ACF, E-mail: [katherine\\_t.\\_astrich@omb.eop.gov](mailto:katherine_t._astrich@omb.eop.gov).

Dated: January 29, 2004.

**Robert Sargis,**

*Reports Clearance, Officer.*

[FR Doc. 04-2324 Filed 2-4-04; 8:45 am]

**BILLING CODE 4184-01-M**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Administration for Children and Families**

**Submission for OMB Review; Comment Request**

*Title:* Grants Application Data Summary Administration for Native Americans Environmental Application Information.

*OMB No.:* New collection.

*Description:* Grants Application Data Summary (GADS) information is collected as part of a grant application. The GADS provides information used to prepare the legislatively mandated annual report to Congress on the status of American Indian and Native Alaskan communities.

This information collected from applicants will allow the Administration for Native Americans to more accurately report to the Administration for Children and Families and to Congress on the status of American Indians and Native Alaskans. This information collection is conducted in accordance with 42 USC 2991b-2(4).

*Respondents:* Tribal governments, native non-profits, tribal colleges & universities.

*Annual Burden Estimates:*

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Environmental GADS Form .....	650	1	28	18,200

*Estimated Total Annual Burden Hours:* 18,200.

*Additional Information:* Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Administration, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF

Reports Clearance Officer. E-mail address: [rsargis@acf.hhs.gov](mailto:rsargis@acf.hhs.gov). All requests should be identified by the title of the information collection.

*OMB Comment:* OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**.

Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, 725 17th Street, NW., Washington, DC 20503, Attn: Desk