[Model Transmittal letter from FDA to CDC]

This letter accompanies agency records that the Food and Drug Administration (FDA) is sharing with the Center for Disease Control and Prevention (CDC) in response to CDC's request, dated_____. These agency records contain one or more of the following categories of non-public information, including information the public disclosure of which may be prohibited by law:

[FDA checks applicable numbers below]

___ trade secrets;
___ confidential commercial or financial information;
___ information the disclosure of which would constitute a clearly unwarranted invasion of personal privacy;
___ information subject to the Privacy Act;
___ intra-agency records;
___ records or information compiled for law enforcement purposes or
___ information protected for national security reasons

CDC shall notify the appropriate office of the information-sharing agency if there are any attempts to obtain shared information by compulsory process, including by not limited to, Freedom of Information Act requests, subpoenas, discovery requests, and litigation complaints or motions.

CDC shall notify the information-sharing agency before complying with any judicial order that compels the release of such information so that FDA and/or CDC may take appropriate measures, including filing a motion with the court or an appeal.

CDC has agreed, by this letter or e-mail and by a signed request letter dated _____, not to publicly disclose the above-described information without prior written permission of FDA. CDC acknowledges that applicable laws and regulations may prohibit the disclosure of such information. See, e.g., 21 U.S.C. §331(j); 18 U.S.C. §1905, 21 C.F.R. Parts 20 and 21, 42 C.F.R. Parts 5 and 5b and 42 U.S.C. §301(d). CDC also agrees to comply with the principles and procedures set forth in the Memorandum of Understanding between FDA and CDC, *cite*.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

[CFDA 93.996]

Bioterrorism Training and Curriculum Development Program; Notification of Exception to Competition

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notification of exception to competition.

SUMMARY: The Health Resources and Services Administration's (HRSA) Healthcare Systems Bureau, Division of Healthcare Preparedness Bioterrorism Training and Curriculum Development Program (BTCDP) will provide supplemental funding to approximately five fiscal year (FY) 2006 BTCDP awardees to plan, test and evaluate the expansion of regional healthcare preparedness training efforts to a nationwide focus. A limited competition within the existing 19 awardees will be used to identify the recipients.

Authority: This activity is under that authority of the Public Health Service Act, Title III, Section 319F(g), 42 U.S.C. 247d–6(g).

Purpose: The purpose of supplemental awards is to expand the reach of the originally approved BTCDP awards from the currently approved geographic region to include the entire Nation. The intended recipients of this limited eligibility program expansion will be the successfully competed and objectively reviewed applicants from the already supported 19 regional BTCDP awardees. The program expansion will enhance consistency in preparedness training by providing proven training through a nationwide

focus. Previous efforts have consisted of a more limited approach focusing training at a local/regional level.

Amount: The anticipated award amount of $1.8 million will be distributed among the 4 or 5 most highly ranked (by objective review) applicants from the existing 19 BTCDP awardees. Awards will average $360,000.

Project Period: The period of support is from September 30, 2006, to August 31, 2007, and will align with the existing budget period.

Justification for the Exception to Competition: Open competition applications for the BTCDP program were received and reviewed by an objective review panel in the summer of FY 2005, at which time BTCDP's local and regional training plans, curriculum and evaluation strategies were reviewed and approved. A total of 74 Continuing Education applications were reviewed and 50 applications were approved. Nineteen projects were funded after careful review from a strongly competitive pool of applicants, emerging as the strongest entities with proven experience and track records to expand their accomplishments to a nationwide target of healthcare providers. Since that time, the awardees have continued to use Federal funds to align their training with the National Preparedness Goal and to deliver training consistent with HRSA's goals.

BTCDP funded programs are uniquely suited to participate in this geographic expansion based upon their authorship and mastery of tested curriculum. BTCDP awardees have been awarded funds specifically to develop training strategies for all healthcare professionals. Their experiences have made them uniquely aware of potential pitfalls to be overcome in developing and testing a national training plan and have the expertise to respond to such barriers as they arise. Since the inception of the program in FY 2003, BTCDP awardees have been responsible for the training of 225,000 healthcare providers on a locality-by-locality basis and stand ultimately poised to deploy and evaluate national training strategies.

BTCDP awardees are highly regarded academic institutions which have dedicated staff and infrastructure to create quality training opportunities for healthcare providers. Curriculum created with BTCDP dollars has already been approved by the academic institutions from which they emanate and has already secured the approval of healthcare professional continuing education accreditation bodies. Awardees possess the building blocks of the infrastructure necessary to efficiently test a national training system, and they have the knowledge and experience necessary to ensure the efficient use of funds for healthcare preparedness training.

The BTCDP is the only Federal program solely committed to the preparedness training of healthcare providers. As such, BTCDP awardees share curriculum, accomplishments and lessons learned through an established network on a regular basis, a network vital to the development of a national plan. Awardees stand uniquely prepared to respond to congressional demand for an efficient and effective national training strategy within the fiscal and time constraints of this supplement. This supplement is the first step in meeting this demand through the efficient use of proven curriculum by experienced trainers on a national basis.

FOR FURTHER INFORMATION CONTACT: For further information, please contact Terri Spear, Chief, Emergency Training Branch, 5600 Fishers Lane, Room 13–103, Rockville, Maryland 20857. E-mail: *tspear@hrsa.gov.*

Dated: July 25, 2006.

Elizabeth M. Duke,

Administrator.

[FR Doc. E6–12267 Filed 7–31–06; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, Public Health Service, HHS.

ACTION: Notice.

SUMMARY: The inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

ADDRESSES: Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852–3804; telephone: 301/496–7057; fax: 301/402–0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

Complement Regulatory Gene Variants as Predictive Tests for Age-Related Macular Degeneration (AMD)

Description of Technology: Age-related macular degeneration (AMD) is a complex multigenic disorder that affects the central region of the retina (macula) and is the leading cause of legal blindness in developed countries. Age, lifestyle (*e.g.* smoking, diet) and genetic predisposition are major risk factors for AMD and 1.75 million adults over 40 are affected by advanced AMD in the United States with a further 7 million considered to be at risk (defined by the presence of large retinal deposits or drusen, which are the hallmark of this disease). A variety of immune-associated molecules including immunoglobulins, complement components, activators and regulators, etc. are associated with drusen and evidence suggests that AMD, like other age-related diseases such as Alzheimer's disease and atherosclerosis, involves a major inflammatory component. Several disease-susceptibility genes have been identified in family studies of macular degeneration and in patient cohorts by several groups including NIH researchers and their collaborators, and variants in the factor H gene (CFH)), a major inhibitor of the alternative complement pathway, have been associated with the risk for developing AMD.

NIH researchers and their collaborators have now extended this work to two other regulatory genes of this pathway, Factor B (BF) and complement component 2 (C2). These genes were screened for genetic variation in two independent cohorts comprised of ~900 AMD cases and ~400 matched controls. Haplotype analyses revealed a significant common risk haplotype (H1) and two protective haplotypes (H7 and H10). Combined analysis of the C2/BF haplotypes and CFH variants shows that variation in the two loci can predict the clinical outcome in 74% of the cases and 56% of the controls (Nature Genetics (2006) 38, 458). This suggests that these variants can be used as predictive genetic tests in combination with other potential risk factors.

Available for licensing are methods for identifying a subject at increased risk for developing AMD by determining the presence of protective genotypes at either the BF/C2 locus and at the CFH locus. Microarrays and kits are also provided. The complex and polygenic nature of AMD suggests that the protective and risk haplotypes claimed