

be made. Informed consent, on the other hand, apprises potential research subjects of the possible risks and benefits associated with participating in the clinical investigation and, when executed, indicates their willingness to participate in the clinical investigation and their understanding of those risks and benefits. The Privacy Rule permits but does not require clinical investigators to combine an HIPAA authorization with informed consent documents, known as a compound authorization (see 45 CFR 164.508(b)(3)).

FDA and the HHS Secretary received requests for clarification of IRBs' responsibilities to review and approve stand-alone HIPAA authorizations under the Privacy Rule, Federal regulations governing human subject protection and IRBs (see 45 CFR part 46 and parts 50 and 56 (21 CFR parts 50 and 56)), and international guidelines (see, for example, International Conference on Harmonisation (ICH) Good Clinical Practice guidelines (E6)). The requests expressed concern that when the Privacy Rule went into effect, clinical investigations might be impeded because IRBs would be backlogged with requests to review thousands of stand-alone HIPAA authorizations. The requests further stated that some IRBs would halt enrollment in clinical investigations pending their review of these stand-alone HIPAA authorizations.

In response, the Office of Civil Rights, HHS, issued a letter, dated April 15, 2003, clarifying that IRBs are not required to review and approve stand-alone HIPAA authorizations under the Privacy Rule, HHS Protection of Human Subjects Regulations at 45 CFR part 46, ICH guidelines, or FDA regulations, so long as an IRB's written procedures, adopted under § 56.108(a), do not require such review and approval. The letter also announced FDA's intent to publish guidance on this subject, in accordance with its good guidance practice regulations.

FDA is issuing this guidance to address those cases in which IRBs have adopted written procedures that would require them to review and approve stand-alone HIPAA authorizations. Under § 56.108(a), IRBs must follow their written procedures. The guidance announces FDA's intention to exercise ongoing enforcement discretion with respect to the requirements of § 56.108(a) to the extent that an IRB's written procedures require the review and/or approval of stand-alone HIPAA authorizations. FDA is exercising this discretion in order to encourage IRBs to permit the continued enrollment of

subjects in clinical investigations without IRBs' prior review and approval of stand-alone HIPAA authorizations. FDA believes that enrollment in well-designed and well-conducted clinical investigations should not be interrupted for the purpose of IRB review and approval of stand-alone HIPAA authorizations. Accordingly, FDA does not intend to take enforcement actions against IRBs that decide not to review stand-alone HIPAA authorizations even though the IRB's written procedures would otherwise require this review and/or approval. FDA's exercise of enforcement discretion in these limited circumstances is intended to allow important studies to proceed in the best interests of the public health.

This guidance is being issued consistent with FDA's good guidance practices regulation § 10.115 (21 CFR 10.115). This guidance document represents the agency's current thinking on IRBs' responsibilities under FDA regulations for reviewing and approving stand-alone HIPAA authorizations. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if it satisfies the requirements of the applicable statutes and regulations.

## II. Comments

FDA is issuing this document as a final guidance that will be implemented upon posting on FDA's Web site. In accordance with § 10.115(g)(2) and (g)(3), FDA is implementing this guidance prior to seeking public comment because the agency has determined that this guidance is needed in conjunction with the HHS Office of Civil Rights guidance to help ensure that ongoing clinical trials are not halted while IRBs review HIPAA stand-alone authorizations, and therefore, prior public participation is not feasible or appropriate. However, FDA will review comments received after issuance of the guidance and revise the document when appropriate.

Interested persons may, at any time, submit written or electronic comments to the Division of Dockets Management (see ADDRESSES) regarding this guidance document. Two paper copies of mailed comments are to be submitted, except individuals may submit one copy. Comments should be identified with the docket number found in the brackets in the heading of this document. A copy of the document and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

## III. Electronic Access

Persons with access to the Internet may obtain the document at either <http://www.fda.gov/oc/gcp/guidance.html> or <http://www.fda.gov/ohrms/dockets/default.htm>.

Dated: October 31, 2003.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Government-Owned Inventions; Availability for Licensing

**AGENCY:** National Institutes of Health, Public Health Service, DHHS.

**ACTION:** Notice.

**SUMMARY:** The invention listed below is owned by an agency of the U.S. Government and is 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 application 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 application.

#### Eosinophil-Derived Neurotoxin, an Antimicrobial Protein With Ribonuclease Activity, Is an Immunostimulant

De Yang *et al.* (NCI).

U.S. Provisional Patent Application

Nos. 60/466,797 and 60/466,796, filed 29 Apr 2003 (DHHS Reference Nos.

E-175-2003/0-US-01 and E-191-2003/0-US-01).

**Licensing Contact:** Brenda Hefti; 301/435-4632; [heftib@mail.nih.gov](mailto:heftib@mail.nih.gov).

Eosinophil-derived neurotoxin (EDN) has in vitro anti-viral activity that is dependent on its ribonuclease activity. This invention discloses that EDN is a selective chemoattractant and activator of dendritic cells, resulting in dendritic