TAX EXEMPT AND
GOVERNMENT ENTITIES
DIVISION

DEPARTMENT OF THE TREASURY
Internal Revenue Service
WASHINGTON, D.C. 20224

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Contact Person:

Identification Number:

Telephone Number:

Employer Identification Number:

Dear :

This is in reply to your June 17, 2007 ruling request that your proposed support of certain activities related to clinical research involving drugs designed to treat patients suffering from a certain disease will not jeopardize your status as an organization described in section 501(c)(3) of the Code.

FACTS

You are a nonprofit corporation exempt from taxation under section 501(c)(3) of the Code. Your purpose is to discover treatments and ultimately a cure for a disease that has "orphan" status under FDA regulations. You currently conduct a variety of activities in furtherance of this purpose, including facilitating collaborative research between academic institutions and maintaining a bank of tissue samples used in genomic research related to the disease.

You now propose to fund clinical testing of a variety of drugs in order to find a cure for the disease. Currently, clinical tests are the only method available for testing new drugs and drug combinations on human subjects. These tests would not normally be conducted by commercial organizations because the likelihood of developing a marketable treatment is small and there are few potential customers.

These tests will be conducted by a variety of institutes and clinics. Your steering committee will select which drugs and compounds to test based upon recommendations from academic and medical scientists on a project review committee. The committee will evaluate the drugs with the best chance of providing a cure using various scientific criteria. You plan to investigate the effectiveness of new drugs as well as exploring new uses or combinations of existing drugs. Some of the combinations you are considering would not normally be conducted because the drugs involved are owned by different drug manufacturers.

Only individuals currently suffering from the disease (or one of its precursor diseases) would be eligible to participate in your tests. You will share the results of these tests with other researchers in the field. You will also require the principal investigator of each test to publish

the results.

After determining which drugs to test, you will negotiate with the owners of the drugs for their permission to use the drugs. The organizations owning the drugs may be both for profit and nonprofit organizations. They will get the results and may use them in qualifying the drugs for initial commercial use or for new applications.

LAW

Section 501(c)(3) of the Code exempts from federal income tax corporations organized and operated exclusively for charitable, educational, scientific, and other purposes, provided that no part of its net earnings inures to the benefit of any private shareholder or individual.

Section 1.501(c)(3)-1(a)(1) of the Income Tax Regulations provides that, in order to be exempt as an organization described in section 501(c)(3), an organization must be both organized and operated exclusively for one or more of the purposes specified in such section. If an organization fails to meet either the organizational test or the operational test, it is not exempt.

Section 1.501(c)(3)-1(c)(1) of the regulations provides that an organization will be regarded as "operated exclusively" for one or more exempt purposes only if it engages primarily in activities that accomplish one or more of such exempt purposes specified in section 501(c)(3). An organization will not be so regarded if more than an insubstantial part of its activities is not in furtherance of an exempt purpose.

Section 1.501(c)(3)-1(d)(1)(ii) of the regulations provides that an organization is not organized or operated exclusively for one or more exempt purposes unless it serves a public rather than a private interest. Thus, to meet the requirement of this subdivision, it is necessary for an organization to establish that it is not organized or operated for the benefit of private interests such as designated individuals, the creator or his family, shareholders of the organization, or persons controlled, directly or indirectly, by such private interests.

Section 1.501(c)(3)-1(d)(5)(i) of the regulations provides that since an organization may meet the requirements of section 501(c)(3) only if it serves a public rather than a private interest, a "scientific" organization must be organized and operated in the public interest. The term "scientific" therefore includes the carrying on of scientific research in the public interest.

Section 1.501(c)(3)-1(d)(5)(ii) of the regulations provides that scientific research does not include activities of a type ordinarily carried on as an incident to commercial or industrial operations, such as ordinary testing.

Section 1.501(c)(3)-1(d)(5)(iii) of the regulations provides, in part, that scientific research will be regarded as carried on in the public interest if it is carried on for the purpose of discovering a cure for a disease.

Revenue Ruling 68-373, 1968-2 C.B. 206 holds that an organization which performs clinical testing of drugs for commercial pharmaceutical companies according to specifications

and procedures set out by the pharmaceutical companies is not engaged in scientific research, but is engaged in testing incident to normal commercial operations.

Revenue Ruling 76-296, 1976-2 C.B. 141, provides, in part, that otherwise qualifying scientific research will not constitute an unrelated trade or business by reason of its being undertaken pursuant to contracts with private industry and where the commercial sponsor retains the ownership rights to the research and any rights in patents resulting from the research. The ruling also provides that if patent rights are involved, publication of the research results may be delayed pending reasonable opportunity to establish those rights.

In IIT Research Institute v. United States, 9 Cl. Ct. 13 (Cl. Ct. 1985), a U.S. Claims Court reviewed the activities of an organization exempt under section 501(c)(3) of the Code. The organization contracted with a variety of industry members to perform research for them. The court defined the term "scientific" to include "the process by which knowledge is systematized or classified through the use of observation, experimentation, or reasoning." The court found that the organization was "not involved in the commercialization of the products or process developed as a result if its research. IIT Research Institute only developed a project to the point where the research principles were established. At this point, the sponsors would make the principles available to different customers, usually in the form of newly developed products or equipment. The court found significance in the fact that IIT Research Institute did not engage in any consumer or market research or ordinary testing of the type which is carried on incident to commercial operations. The court therefore found that the organization's activities were research and not ordinary testing carried on as an incident to commercial or industrial operations.

In Midwest Research Institute v. United States, 554 F.Supp. 1379 (W.D. Mo. 1983), aff'd 744 F.2d 635 (8th Cir. 1984), the court held that the Midwest Research Institute did not jeopardize its tax exempt status by performing projects for private sponsors. The court stated that a project is scientific research "if professional skill is involved in the design and supervision of a project intended to solve a problem through a search for a demonstrable truth." The court stated that projects are "ordinary testing" if the work is generally repetitive and done by scientifically unsophisticated employees to determine if the item tested meets certain specifications, "as distinguished from testing done to validate a scientific hypothesis."

ANALYSIS

An organization's activities will be in furtherance of exempt purposes if those activities further scientific purposes within the meaning of section 501(c)(3) of the Code. Section 1.501(c)(3)-1(d)(5) of the regulations defines the term "scientific" to include the carrying on of scientific research in the public interest. Thus, the regulation sets out a three-part test for determining whether an organization is operated for "scientific" purposes:

1. The organization's activities must be scientific.
2. The organization's activities must constitute research.
3. The organization's activities must be in the public interest.

Under section 1.501(c)(3)-1(d)(5)(i) of the regulations, the determination that an activity

is "scientific" is made without regard to whether it is "fundamental" or "basic" as opposed to being "applied" or "practical." Courts have broadly defined the term "scientific" to include a process by which knowledge is systematized or classified through the use of observation, experimentation, or reasoning. IIT Research Institute v. United States. See also Midwest Research Institute v. United States, supra. Your proposed testing involves gathering and analyzing complex data on patient reactions to various treatments. Thus, your proposed testing involves systematizing knowledge through the use of experimentation and the activities are scientific within the meaning of section 1.501(c)(3)-1(d)(5) of the regulations.

Section 1.501(c)(3)-1(d)(5)(i) of the regulations states that the term research, when taken alone, is a word with various meanings; it is not synonymous with "scientific." The regulations go on to state that scientific research does not include activities that are ordinarily carried on as an incident to commercial operations, such as ordinary testing or inspection of materials. See section 1.501(c)(3)-1(d)(5)(ii) of the regulations. The court in IIT Research Institute identified several facts indicating IIT was engaged in research, not commercial testing: IIT did not develop the commercial potential of products, it did not conduct market research, and it did not perform any product testing. Its activities were focused on determining whether particular research principles were valid. Similarly, you do not consider market or commercial applications when designing your tests and they are intended to discover effective treatments, not to certify products for sale.

Rev. Rul. 68-373 states that where clinical trials are conducted so that drug manufacturers can use the results in FDA applications and they select the drugs tested, such trials are an activity ordinarily carried on as an incident to the commercial operations of the drug manufacturers. Your proposed testing activity is significantly different from that described in Rev. Rul. 68-373 because it is based on patient needs. Although the proposed clinical tests may benefit some drug manufacturers by revealing new uses for their drugs, the tests primarily serve to aid those suffering from the disease and they add to the body of available scientific knowledge used in finding a cure for it. You select which compounds will be tested, rather than the owners of the drugs, and only patients currently suffering from the disease or its precursors will be eligible for your trials. Your proposed activity is also distinguishable because it is not closely related to the manufacturers' obtaining FDA approval for uses of a drug. Your proposed clinical tests are not incidental to the commercial operations of the drug manufacturers and they constitute scientific research within the meaning of section 1.501(c)(3)-1(d)(5) of the regulations.

Section 1.501(c)(3)-1(d)(5)(iii)(c) of the regulations provides in part that scientific research is carried on in the public interest if it is carried on for the purpose of discovering a cure for a disease. Your proposed activities are carried on for the purpose of discovering a cure for the disease, which would constitute scientific research in the public interest.

Section 1.501(c)(3)-1(d)(5)(iii)(c) of the regulations also provides that scientific research may be carried on in the public interest even though a commercial sponsor retains the rights to any intellectual property produced by the research. See also Rev. Rul. 76-296, supra. Thus, although a private benefit may be conferred on the intellectual property holders or other private individuals, the regulations consider that benefit to be incidental to the public benefit of facilitating scientific research. While the results of your tests may be useful to the owners of the drugs used in your tests, because your activities are directly related to discovering a cure for a disease this benefit is incidental and does not result in a conclusion that the research is not in

the public interest.

For the reasons stated above, we conclude that your proposed clinical testing activity constitutes "scientific research in the public interest" and is therefore in furtherance of scientific purposes within the meaning of section 501(c)(3) of the Code.

RULING

Your proposed funding of clinical research involving drugs designed to treat patients suffering from a certain disease will not jeopardize your status as an organization described in section 501(c)(3) of the Code.

This ruling will be made available for public inspection under section 6110 of the Code after certain deletions of identifying information are made. For details, see enclosed Notice 437, *Notice of Intention to Disclose.* A copy of this ruling with deletions that we intend to make available for public inspection is attached to Notice 437. If you disagree with our proposed deletions, you should follow the instructions in Notice 437.

This ruling is directed only to the organization that requested it. Section 6110(k)(3) of the Code provides that it may not be used or cited by others as precedent.

This ruling is based on the facts as they were presented and on the understanding that there will be no material changes in these facts. Because it could help resolve questions concerning your federal income tax status, this ruling should be kept in your permanent records.

If you have any questions about this ruling, please contact the person whose name and telephone number are shown in the heading of this letter.

Sincerely,

Steven Grodnitzky
Manager, Exempt Organizations
Technical Group 1

Enclosure
Notice 437