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:

UIL: 4944.03-01

Legend:
Hospital =
Agreement =

Dear

This is in reply to your ruling request regarding the proper treatment of certain transactions you wish to conduct under the Internal Revenue Code ("Code").

FACTS

You are recognized as an organization exempt from federal income taxation under section 501(c)(3) of the Internal Revenue Code ("Code") and are classified as a private foundation under section 509(a). You are controlled by a self-perpetuating board of five Trustees, comprised of two Family Trustees and three Independent Trustees.

Your purpose is to fund innovative and promising diabetes research programs and projects that will lead to a cure for the disease and alleviate complications caused by it.

You now pursue your purpose primarily through an agreement (the Agreement) with the Hospital. The Agreement obligates you to provide several million dollars to the Hospital over a three year period for research in the field of diabetes and, specifically, to advance the conduct of human clinical trials for the treatment of Type 1 diabetes in humans, including preliminary research necessary for conducting such clinical trials.

The Agreement allows you to retain a royalty interest in the event the Hospital or its licensing entity receives payments of any kind in return for the use of any invention resulting from the research funded under the Agreement. The Agreement specifies that you will receive payments equal to one-sixth (16.667 percent) of the payment paid. At this time, no royalties have been paid and it is uncertain any royalties will be generated.

RULING REQUESTED

The Agreement is a program-related investment as defined by section 4944(c) of the Code.

LAW

Section 170(c)(2)(B) of the Code describes the purposes for which a charitable deduction will be permitted, including religious, charitable, scientific, literary, and educational purposes.

Section 170(c)(2)(D) of the Code describes organizations not disqualified for exemption by reason of attempting to influence legislation, and that do not participate in, or intervene in, any political campaign on behalf of, or in opposition to, any candidate for public office.

Section 501(c)(3) of the Code provides, in part, for the exemption from federal income tax of corporations organized and operated exclusively for charitable, scientific, or educational purposes, provided no part of the organization's net earnings inures to the benefit of any private shareholder or individual.

Section 4944(a) of the Code imposes a tax on a private foundation and on its management where investments are made which jeopardize the carrying out of any of the exempt purposes of a private foundation.

Section 4944(c) of the Code provides for an exception from this tax in the case of program-related investments. Program-related investments are defined as investments, the primary purpose of which is to accomplish one or more of the purposes described in section 170(c)(2)(B), and no significant purpose of which is the production of income or the appreciation of property. Program-related investments shall not be considered as investments which jeopardize the carrying out of exempt purposes.

Section 1.501(c)(3)-1(c)(1) of the Income Tax Regulations ("regulations") states that an organization will be regarded as operated exclusively for one or more exempt purposes only if it engages primarily in activities which accomplish one or more of such exempt purposes specified in section 501(c)(3) of the Code. 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)(2) of the regulations states that the term "charitable" is used in section 501(c)(3) of the Code in its generally accepted legal sense.

Section 1.501(c)(3)-1(d)(5)(i) of the regulations provides an organization organized and operated for scientific purposes can qualify under section 501(c)(3) of the Code only if it serves a public rather than a private interest. See section 1.501(c)(3)-1(d)(5)(iii) and (iv).

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

Section 1.501(c)(3)-1(d)(5)(iii) of the regulations provides scientific research will be regarded as carried on in the public interest if –

(a) The research results "including any patents, copyrights, processes or formulae ... are made available to the public on a nondiscriminatory basis;"

(b) The research is carried out for the United States, or any of its agencies or instrumentalities, or for a state or a political subdivision thereof; or

(c) The research "is directed toward benefiting the public." The regulations provide the following four examples of research that benefits the public, to include research that is:

(1) intended to aid in the scientific education of college or university students;

(2) published in a form that is "available to the interested public;"

(3) carried on for the purpose of discovering a cure for a disease; or

(4) carried on for the purpose of aiding a geographical area by attracting, developing, or retaining industry in the area.

Section 1.501(c)(3)-1(d)(5)(iv) of the regulations provides an organization will not be regarded as organized and operated for the purpose of carrying on scientific research in the public interest if either (or both) of the following two conditions is true:

• *Condition 1:* The organization conducts research only for persons who are directly or indirectly its creators, if such persons are not section 501(c)(3) organizations.

• *Condition 2:* The organization (1) directly or indirectly retains "ownership or control of more than an insubstantial portion of the patents, copyrights, processes, or formulae" that result from its research activities, *and* (2) "does not make such patents, copyrights, processes, or formulae available to the public" on a nondiscriminatory basis. However, the organization may satisfy the public availability requirement through an exclusive license of its intellectual property if an exclusive license "is the only practicable manner" to ensure that the intellectual property will be used to benefit the public.

Section 53.4944-3(a)(1) of the regulations state that a program-related investment shall not be classified as an investment which jeopardizes the carrying out of exempt purposes of a private foundation. A "program-related investment" is an investment which possesses the following characteristics:

(i) The primary purpose of the investment is to accomplish one or more of the purposes described in section 170(c)(2)(B);

(ii) No significant purpose of the investment is the production of income or the appreciation of property; and

(iii) No purpose of the investment is to accomplish one or more of the purposes described in section 170(c)(2)(D).

Section 53.4944-3(a)(2)(i) of the regulations provides that an investment is considered as made primarily to accomplish one or more of the purposes described in section 170(c)(2)(B) if it significantly furthers the accomplishment of the private foundation's exempt activities, and the investment would not have been made but for the relationship between the investment and the accomplishment of the foundation's exempt activities.

Section 53.4944-3(a)(2)(iii) of the regulations states that in determining whether a

significant purpose of an investment is the production of income or the appreciation of property, a relevant factor is whether for-profit investors would likely make the investment on the same terms as the private foundation.

Rev. Rul. 68-373, 1968-2 C.B. 206, states that clinical testing incident to a pharmaceutical company's ordinary commercial operations served the private interests of the drug manufacturers rather than the public interest and was not exempt under section 501(c)(3) of the Code.

Rev. Rul. 76-296, 1976-2 C.B. 141, states that commercially sponsored research otherwise qualifying as scientific research under section 501(c) (3) of the Code, the results of which, including all relevant information, are timely published in such form as to be available to the interested public, constitutes scientific research carried on in the public interest. Research, the publication of which is withheld or delayed significantly beyond the time reasonably necessary to establish ownership rights, however, is not in the public interest and constitutes the conduct of unrelated trade or business within the meaning of section 513.

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."

In *IIT Research Institute v. United States*, 9 Cl. Ct. 13 (Cl. Ct. 1985), the court found research is scientific when it (i) involves observations or experimentation to formulate or verify facts or natural laws; (ii) adds to knowledge within the medical field; or (iii) can only be performed by individuals with advanced scientific or technical expertise.

In *Washington Research Foundation v. C.I.R.*, T.C. Memo 1985-570 (U.S. Tax Court Memos 1985), the court held that a nonprofit organization formed to assist the transfer of technology from universities and tax-exempt research institutions to the private sector was not exclusively operated for charitable purposes because its major activity of providing patenting and licensing services was commercial in nature.

ANALYSIS

In order to qualify as a "program related investment" as defined in section 4944(c) of the Code, an investment must meet three specific characteristics set forth in the regulations. The first requirement is that the investment's primary purpose must be to accomplish one or more exempt purposes described in section 170(c)(2)(B). Treas. Reg. § 53.4944-3(a)(1). An investment is considered as made primarily to accomplish one or more of the purposes described in section 170(c)(2)(B) if it significantly furthers the accomplishment of the private

foundation's exempt activities, and the investment would not have been made but for the relationship between the investment and the accomplishment of the foundation's exempt activities. Treas. Reg. § 53.4944-3(a)(2)(i).

One of your activities is to support scientific research. The term "scientific" in section 501(c)(3) includes "scientific research" carried on in the public interest. Treas. Reg. § 1.501(c)(3)-1(d)(5)(i). An activity is scientific research in the public interest if (1) it is scientific; (2) it is research; and (3) it is in the public interest.

Section 1.501(c)(3)-1(d)(5)(i) of the regulations states the determination of whether research is "scientific" for purposes of section 501(c)(3) does not depend on whether such research is classified as "fundamental" or "basic" as contrasted with "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. *See IIT Research Institute v. United States*. The Agreement involves gathering and analyzing preliminary data to develop pre-clinical infrastructure and to aid in creating a clinical trial program, and the activities are conducted by physicians and scientists. Thus, your activities involve 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." 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; *see also* Rev. Rul. 68-373. The court in *Midwest Research Institute* held that section 1.501(c)(3)-1(d)(5)(ii) of the regulations may be interpreted to apply to the type of "ordinary or routine testing" performed by testing laboratories. This work was described as generally repetitive work done by scientifically unsophisticated employees for the purpose of determining whether the item tested met certain specifications, as distinguished from testing done to validate a scientific hypothesis. *Midwest Research Institute v. United States*, 554 F.Supp. at 1386. 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.

Your activities are similar to those conducted by IIT. The Agreement provides for the evaluation of whether a particular cellular process can be standardized and formatted to achieve similar testing results in multiple patients. The Hospital is not testing any commercial product to qualify it for sale nor is it testing a product to evaluate if it meets FDA safety standards, unlike the organization described in Rev. Rul. 68-373. Any results generated by the Agreement could provide the basis for commercial products, but would not constitute marketable products on their own. The activities covered by the Agreement do not include any market research or evaluation of the commercial practicality of the method.

Your activities are not similar to those conducted by the organization in *Washington Research Foundation v. C.I.R.*. You are not assigned the right to the results of the Agreement's

research projects. You cannot secure patents and license agreements. Finally, only one-sixth (16.667 percent) of the royalties will flow towards you. Therefore, your activities are 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 that scientific research is carried on in the public interest if the results of the research are made available to the public, such as through a treatise or trade publication. It 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* Rev. Rul. 76-296. Although a private benefit may be conferred on the intellectual property holders or other private individuals, that benefit is incidental to the public benefit of facilitating scientific research. Section 1.501(c)(3)-1(d)(5)(iii)(c)(3) of the regulations states that scientific research carried on for the purpose of discovering a cure for a disease will be considered as directed toward benefiting the public and regarded as carried on in the public interest.

While the Agreement may confer a tangential benefit upon both you and the Hospital, as long as the requirements in section 1.501(c)(3)-1(d)(5)(iii) of the regulations are satisfied, this benefit is incidental and does not result in a conclusion that the research is not in the public interest. The fact that the Agreement has the potential to create research which may be later sold to a third-party and may create royalties which will be received by you does not prevent the research from qualifying as "scientific research in the public interest" because this potential benefit is incidental to your activities. Furthermore, the information you submitted demonstrates that the purpose of the Agreement is to develop a cure for Type I diabetes, and not to receive royalties from the license or sale of this research. Finally, the Agreement allows the Hospital the ability to publish any research that may be of interest to the scientific community. Therefore, your activities are scientific research carried on in the public interest within the meaning of section 1.501(c)(3)-1(d)(5) of the regulations.

Because the Agreement funds research that will be scientific, research, and in the public interest, the Agreement will further scientific purposes within the meaning of section 1.501(c)(3)-1(d)(5) of the regulations and section 501(c)(3) of the Code. Therefore, the Agreement meets the first requirement for a "program-related investment."

The second requirement of the "program related investment" definition contained in section 53.4944-3(a)(1) of the regulations is that no significant purpose of the investment is the production of income or the appreciation of property. As part of the Agreement, you retained a royalty interest in the event the Hospital or its licensing entity received payments of any kind in return for use of any invention resulting from the research funded by the Agreement equal to one-sixth (16.667 percent) of the payment received.

When determining whether a significant purpose of an investment is the production of income or the appreciation of property, it is relevant to consider whether for-profit investors would make a similar investment. Treas. Reg. § 53.4944-3(a)(2)(iii). In this case, it is unlikely that any for-profit investor would be willing to make the Agreement under the same terms. To date, no royalties have been paid and it is uncertain any royalties will be generated. You represent that most investors would demand royalties well above percent of future sales

revenue in return for funds provided at this stage of research because of the uncertainty of any useful results being generated.

You have agreed to fund research in return for a royalty rate equal to percent of future sales associated with the research. In addition, this is the only research in which you have any type of interest. Because the chance for profit is very low at this stage, your primary purpose is not commercial. Therefore, because no significant purpose of the royalty interest in the Agreement is the production of income or the appreciation of property, your interest in the Agreement meets the second requirement for a "program-related investment" in section 53.4944-3(a)(1) of the regulations.

The third requirement of a "program related investment" is that no purpose of the investment may be to accomplish one or more of the prohibited purposes described in section 170(c)(2)(D) of the Code.

You and the Hospital entered into the Agreement for the purpose of funding innovative and promising diabetes research programs and projects that will lead to a cure for the disease and alleviate complications caused by it. No part of the activities described involve attempts to influence legislation or to intervene in (including the publishing or distributing of statements) any political campaign on behalf of (or opposition to) any candidate for public office within the meaning of section 170(c)(2)(D) of the Code. Therefore, your interest in the Agreement meets the third requirement for a "program-related investment" in section 53.4944-3(a)(1) of the regulations.

As set forth above, your investment in the form of the Agreement satisfies the three requirements contained in section 53.4944-3(a)(1) of the regulations. Therefore, the Agreement qualifies as a "program-related investment" within the meaning of section 4944(c) of the Code.

RULING

The Agreement is a program-related investment as defined by section 4944(c) 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,

Debra Cowen for

Laurice Ghougasian
Acting Manager, Exempt Organizations
Technical Group 1

Enclosure
Notice 437