TAX EXEMPT AND
GOVERNMENT ENTITIES
DIVISION

DEPARTMENT OF THE TREASURY
INTERNAL REVENUE SERVICE
WASHINGTON, D.C. 20224

Number: **201114035**
Release Date: 4/8/2011

Date: January 10, 2011

UIL: 501.03-24

Contact Person:

Identification Number:

Telephone Number:

Employer Identification Number:

Legend:
Project =

Dear :

This is in reply to your ruling request regarding the implementation of a new program on your exempt status under section 501(c)(3) of the Internal Revenue Code.

FACTS

You are an organization described in section 501(c)(3) of the Code and classified as a medical research organization described in sections 509(a)(1) and 170(b)(1)(A)(iii) of the Code. You are governed by a self-electing five member board of directors.

Your purpose is to engage in genomic research to aid in the treatment of genetic based diseases. You operate as a collaborative undertaking, involving participation by academics, tax-exempt hospitals and medical centers, representatives or government and quasi-governmental agencies, health oriented charities and foundations, and representatives of the pharmaceutical, information technology and genetic measurement industries. Using this consortium model, you seek to conduct fundamental biomedical research with input and advice from scientists and physicians from the non-profit, academic, and commercial sectors. You will develop standardized protocols and procedures for collecting, processing and testing specimens and for reporting test results. By standardizing these key elements of the research process, you will foster better communication, energize shared insights, facilitate collateral studies, and accelerate understanding of the underlying causes of human disease. You intend to develop new ways to diagnose diseases, to discern insights that better predict the course of the disease and to uncover key biochemical steps whose manipulation would improve patient outcome. You also will encourage the development of related sciences.

For each specific research project, you intend to create a separate formal membership structure. You will enter into Membership Agreements with interested participants willing to provide funding, primarily pharmaceutical companies ("Funding Members"). For each project, you will also establish various Advisory Committees, which will be comprised of experts and specialists from your membership base who are particularly involved or interested in the objectives of the research, and who will be almost exclusively from the non-profit and academic sectors. The purpose of these project-specific advisory committees is to enhance your ability to

utilize the accumulated knowledge and experience of others and to ensure that the research project is conducted in a way that will be most useful and accessible to others working in the same field.

The Project

Your initial focus has been on the Project, which involves the creation of an extensive, publicly-accessible database that contains clinical presentations and outcomes along with the patterns of gene expressions of tissue samples of a particular disease in different individuals. This database will be freely available to the public on the Internet. You have entered into specimen collection agreements with various medical centers for acquisition of patient tissue and peripheral blood samples, under standard patient consent procedures. The Project also involves the development and implementation of common standards for data generation and handling in gene expression analysis that will allow for consistent representation of data among educational, scientific, and commercial entities.

Funding Members for the Project appoint a member to the Executive Steering Committee. There is no restriction on the number of Funding Members. The Executive Steering Committee is an advisory committee set up primarily to provide advice regarding the structure and implementation of the database, including methods of formatting the data and analysis for easiest access. The Executive Steering Committee also advises on the disease types that should be analyzed and budget uses. The Executive Steering Committee's role is solely advisory and its recommendations are not binding.

Specimen Redistribution Program

You now intend to utilize the residual tissue accumulated in the course of the Project by redistributing it to other persons for follow-on studies that you do not have the resources or expertise to conduct ("Specimen Redistribution Program"). Under this Program, you will make residual tissue and blood samples and related clinical information ("Residual Specimens") available to both tax-exempt and for-profit organizations and will utilize an application procedure to ensure that the specimens are allocated to projects that have the greatest chance of producing useful results. The majority of the Residual Specimens will be reserved for academics and researchers at tax-exempt medical institutions, though some of the specimens will be available to for-profit applicants, such as pharmaceutical companies. You intend to make the specimens available to for-profit organizations because you have determined that they have the expertise and funding necessary to conduct extensive clinical studies utilizing the Residual Specimens and that such studies can produce significant additional information that will be added to your database. In particular, these studies will allow the identification of effective targets for therapeutic intervention as well as indicators of unfavorable responses to the tested treatments.

Outside organizations utilizing your Residual Specimens are required to sign a research agreement which limits the use of the specimens and requires recipients to report to you the results of all research done using the specimens. You then make the results of that research public by incorporating it into the Project's database, which is freely available to the public on the Internet. However, the researcher does retain the rights to any intellectual property

discoveries made through the use of the specimens. The researcher may delay transmitting the results to you if needed in order to secure intellectual property rights to any discoveries, but the results must be shared after a reasonable time.

You have a limited amount of Residual Specimens available for redistribution; therefore, you will utilize an application process to determine who receives the specimens. These applications will be evaluated by a "Specimen Allocation Subcommittee" consisting of three members. The members of this subcommittee will be appointed by the Executive Director of the Project, who is one of your officers. The Executive Director will solicit nominations from the Executive Steering Committee and other sources, but no person affiliated with any pharmaceutical company is eligible for appointment to the Specimen Allocation Subcommittee.

In determining which for-profit organizations applying for Residual Specimens will be allocated specimens, the Specimen Allocation Subcommittee will examine various factors, including the description of the proposed research, the applicant's commitment to devote adequate resources for the completion of the project, the competency of the researchers, their familiarity with the operation of the Project and the database's architecture and operating protocols, and the ability to design follow-up studies to provide additional data. You intend to provide tissue only to the for-profit applicants that are likely to produce the greatest amount of useful data because there is a limited amount of tissue available for redistribution. The Funding Members are likely to have an advantage in this application process because of their close involvement with the set up and operation of the Project through their participation in the Executive Steering Committee.

RULING REQUESTED

The implementation of the Specimen Redistribution Program will not jeopardize your status as an organization described in section 501(c)(3) of the Code or your classification as a "medical research organization" under section 170(b)(1)(A)(iii).

LAW

Section 170(b)(1)(A)(iii) of the Internal Revenue Code describes organizations "the principal purpose or function of which are the providing of medical or hospital care or medical education or medical research."

Section 501(c)(3) of the Code describes organizations organized and operated exclusively for charitable, educational, scientific, and other purposes, and requires that no part of its net earnings inures to the benefit of any "private shareholder or individual."

Section 1.170-2(b)(4)(ii)(b) of the Income Tax Regulations ("regulations") defines a medical research organization as one whose principal purpose or function is to engage in medical research. Medical research may be defined as the conduct of investigations, experiments, and studies to discover, develop, or verify knowledge relating to the causes, diagnosis, treatment, prevention, or control of physical or mental diseases and impairments of man.

Section 1.501(c)(3)-1(a)(1) of the regulations provides that, in order to qualify as an organization described in section 501(c)(3) of the Code, 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) 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)(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 this requirement, 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) of the Code only if it serves a public rather than a private interest, a "scientific" organization must be organized and operated in the public interest. Therefore, the term "scientific" includes the carrying on of scientific research in the public interest. For "research" to be "scientific," it must be carried on in furtherance of a "scientific" purpose.

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)(c) of the regulations states that scientific research will be regarded as carried on in the public interest if such research is directed toward benefiting the public. If the research is carried on for the purpose of obtaining scientific information, which is published in a treatise, thesis, trade publication, or in any other form that is available to the interested public, such research will be considered as directed toward benefiting the public, and, therefore, will be regarded as research carried on in the public interest. Scientific research "will be regarded as carried on in the pubic interest even though such research is performed pursuant to a contract or agreement under which the sponsor or sponsors of the research have the right to obtain ownership or control of any patents, copyrights, processes, or formulae resulting from such research."

Rev. Rul. 74-146, 1974-1 C.B. 129, considered an organization whose activities included the preparation of accreditation standards, the identification of schools and colleges meeting those standards, and the dissemination to the public of the names of accredited institutions. The accreditation program was designed to foster excellence in education and to develop criteria and guidelines for assessing educational effectiveness. The organization was controlled by its dues-paying members and only accredited institutions were eligible for membership. Because

some of the organization's members were for profit, these schools derived benefits from accreditation and as members of the organization were in a position to exercise some influence over its activities. The ruling concludes that the benefits provided to the for-profit members were incidental to the overall public benefit of improved quality of education derived from the organization's activities. Consequently, the organization qualified as an organization described in section 501(c)(3) of the Code.

Rev. Rul. 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 described in 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."

In American Campaign Academy v. Commissioner, 92 T.C. 1053 (1989), the court held that an organization operating a school to train individuals for careers as political campaign professionals did not exclusively serve purposes described in section 501(c)(3) of the Code because it did not operate on a nonpartisan basis and it served private interests more than incidentally. The court found that the organization was created and funded by persons affiliated with one political party and that most of the organization's graduates worked in campaigns for the party's candidates. The court concluded that the organization conducted its activities to benefit the party's candidates and entities. Although the candidates and entities benefited were not organization "insiders," the court stated that the conferral of benefits on disinterested

persons who are not members of a charitable class may cause an organization to serve a private interest within the meaning of section 1.501(c)(3)-1(d)(1)(ii) of the regulations.

ANALYSIS

For an organization to be operated for "scientific" purposes, within the meaning of section 501(c)(3), its activities must be "scientific" and must constitute "research," which must be carried on in the "public interest." The term "scientific" has been broadly defined 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, supra; see also, Midwest Research Institute v. United States, supra. The Specimen Redistribution Program will involve compiling experimentation data gathered from the residual tissue and assembling it into a useful central resource of effective targets for therapeutic intervention and indicators of unfavorable outcomes. Thus, because the Specimen Redistribution Program involves systematizing and classifying knowledge, it is "scientific" within the meaning of section 1.501(c)(3)-1(d)(5) of the regulations.

In addition, the Specimen Redistribution Program will not result in the creation of any commercial products and will not consist of any product testing or similar activities, as prohibited by section 1.501(c)(3)-1(d)(5)(ii) of the regulations. Rather, it will consist of fundamental data gathering and analysis. While these activities may provide the basis for commercial products or indicate further avenues of research, they will not constitute marketable products on their own. Therefore, the Specimen Redistribution Program constitutes scientific "research" within the meaning of section 1.501(c)(3)-1(d)(5) of the regulations.

Furthermore, conducting scientific research alone is not sufficient to qualify as an organization described in section 501(c)(3) of the Code. The scientific research must be in the public interest rather than serving a private interest. Section 1.501(c)(3)-1(d)(1)(ii) of the regulations.

While the recipients of the Residual Specimens will be able to retain the rights to any intellectual property produced, the results of that research will be transmitted to you and incorporated into the Project's database within a reasonable time. The Project's database will be freely available to the public on the Internet. Therefore, the results of experiments conducted using the Residual Specimens are considered as directed toward benefiting the public, and, therefore, is regarded as research carried on in the public interest within the meaning of section 1.501(c)(3)(1)(d)(5) of the regulations.

While your activities constitute scientific research in the public interest, you must also comply with section 1.501(c)(3)-1(d)(1)(ii) of the regulations, which requires organizations to serve a public rather than a private interest. Your membership structure is similar to that of the organization described in Rev. Rul. 74-146. Your Funding Members receive benefits by becoming members of the Executive Steering Committee and having an advantage in the application process for the residual specimens. However, the advantage in the application process is because the Funding Members are in the best position to efficiently and effectively utilize the residual specimens to generate additional information due to their familiarity with the Project's public database and research procedures. Efficient and effective utilization of the residual tissue is particularly important because there are limited amounts of the tissue

available. Therefore, while Funding Members will have an advantage over other for-profit applicants, this advantage is directly related to furthering your exempt purpose, namely increasing the amount of public data on the disease. In addition, the Funding Members are not a closed group. Any organization with sufficient funds could become a Funding Member. The benefits conferred are similar to those conferred on members of the organization described in Rev. Rul. 74-146. This benefit is directly related to producing the highest quantity and quality of data for the Project and is incidental in relation to the benefit to the public. Therefore, you will be serving a public interest.

Similarly, all recipients of the residual specimens will receive a benefit in the form of rights to potential intellectual property arising from the research. However, as long as the requirements in section 1.501(c)(3)-1(d)(5)(iii) of the regulations and Rev. Rul. 76-296 are satisfied, this benefit is incidental and does not result in a conclusion that the research is not in the public interest. As explained previously, you meet these requirements with respect to the Specimen Redistribution Program. Consequently the benefits to the recipients are incidental in relation to the benefit to public through fostering scientific research, unlike the benefit conferred on the political party in American Campaign Academy, supra.

Therefore, the Specimen Redistribution Program will not be considered to be operated for the benefit of private individuals within the meaning of section 1.501(c)(3)-1(d)(1)(ii) of the regulations.

A medical research organization under section 170(b)(1)(A)(iii) of the Code is defined as an organization whose principal purpose or function is to engage in medical research. Section 1.170-2(b)(4)(ii)(b) of the regulations. Such research includes the conduct of investigations, experiments, and studies to discover, develop, or verify knowledge relating to the causes, diagnosis, treatment, prevention, or control of physical or mental diseases and impairments of man. Id. The Specimen Redistribution Program is designed to produce more information on the treatment of a particular disease. You will then study and incorporate the information into your publicly available database. This will develop knowledge related to the treatment and control of the disease and therefore will further medical research within the meaning of section 1.170-2(b)(4)(ii)(b).

RULING

The implementation of the Specimen Redistribution Program will not jeopardize your status as an organization described in section 501(c)(3) of the Code or your classification as a "medical research organization" under section 170(b)(1)(A)(iii).

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