Department of the Treasury
Internal Revenue Service
P.O. Box 2508
Cincinnati, OH 45201

Number: **201701022**
Release Date: 1/6/2017

Date: October 13, 2016

Employer ID number:

Contact person/ID number:

Contact telephone number:

Form you must file:

Tax years:

UIL: 501.03-21, 501.03-24, 501.33-00

Dear

This letter is our final determination that you don't qualify for tax-exempt status under Section 501(c)(3) of the Internal Revenue Code (the Code). Recently, we sent you a proposed adverse determination in response to your application. The proposed adverse determination explained the facts, law, and basis for our conclusion, and it gave you 30 days to file a protest. Because we didn't receive a protest within the required 30 days, the proposed determination is now final.

Because you don't qualify as a tax-exempt organization under Section 501(c)(3) of the Code, donors can't deduct contributions to you under Section 170 of the Code. You must file federal income tax returns for the tax years listed at the top of this letter using the required form (also listed at the top of this letter) within 30 days of this letter unless you request an extension of time to file.

We'll make this final adverse determination letter and the proposed adverse determination letter available for public inspection (as required under Section 6110 of the Code) after deleting certain identifying information. Please read the enclosed Notice 437, *Notice of Intention to Disclose*, and review the two attached letters that show our proposed deletions. If you disagree with our proposed deletions, follow the instructions in the Notice 437 on how to notify us. If you agree with our deletions, you don't need to take any further action.

We'll also notify the appropriate state officials of our determination by sending them a copy of this final letter and the proposed determination letter (under Section 6104(c) of the Code). You should contact your state officials if you have questions about how this determination will affect your state responsibilities and requirements.

If you have questions about this letter, you can contact the person listed at the top of this letter. If you have questions about your federal income tax status and responsibilities, call our customer service number at 1-800-829-1040 (TTY 1-800-829-4933 for deaf or hard of hearing) or customer service for businesses at 1-800-829-4933.

Sincerely,

Jeffrey I. Cooper
Director, Exempt Organizations
Rulings and Agreements

Enclosures:
Notice 437
Redacted Letter 4036, *Proposed Adverse Determination Under IRC Section 501(c)(3)*
Redacted Letter 4038, *Final Adverse Determination Under IRC Section 501(c)(3) - No Protest*

Department of the Treasury
Internal Revenue Service
P.O. Box 2508
Cincinnati, OH 45201

Date: August 8, 2016

Employer ID number:

Contact person/ID number:

Contact telephone number:

Contact fax number:

Legend:
B = Date
BB = Date
C = Organization
CC = Website
D = Organization
E = Date
F = Date
G = Medication
H = Date
J = Date
K = Date
L = Organization
M = Organization
N = Organization
O = Organization
P = Year
Q = Year
R = Year
S = Organization
T = Director
U = Organization
V = Director
W = Organization
X = State
Y = Date
Z = Organization

UIL:
501.03-21
501.03-24
501.33-00

Dear :

We considered your application for recognition of exemption from federal income tax under Section 501(a) of the Internal Revenue Code (the Code). Based on the information provided, we determined that you don't qualify

for exemption under Section 501(c)(3) of the Code. This letter explains the basis for our conclusion. Please keep it for your records.

Issues

Do you qualify for exemption under section 501(c)(3) of the Code? No, for the reasons stated below.

Facts

You were incorporated in the state of X on Y. Article III of your Articles of Incorporation states that you are organized and operated exclusively for charitable, educational, and scientific purposes. Articles III also states:

> Within the limitations, guidelines, and restrictions of Section 501(c)(3) of the Internal Revenue Code and regulations thereunder as the same now exist or as the same may be amended and any successor provisions, the Corporation shall have all powers and authority permitted by the X Nonprofit Corporation Act and shall be operated exclusively for charitable, educational, cultural, scientific, and civic purposes and to general receive and administer gifts of property for charitable, educational, scientific, cultural, and civic purposes as before provided and within the meaning of section 501(c)(3) of the Internal Revenue Code, as the same now exists or as the same may be amended.

Article II of your bylaws states that your mission is to, "facilitate the development of research in multiple sclerosis and other neurodegenerative disease, to support the development and delivery of educational opportunities for multiple sclerosis patients, families and caregivers, and to assist in the advancement of alternative care delivery systems for multiple sclerosis patients across the State of X."

You state that your objectives are to:

1. Provide a medium in which neurological research can be supported within the state of X.
    a. Open up the opportunity for individuals in the state of X and the surrounding region to participate in cutting edge research in neuroscience, particularly MS and Parkinson's Disease.
    b. Help provide funding for investigator initiated research within the W.
2. Help support non-branded educational opportunities for patients of the Z and the surrounding community.
3. Help establish and support a MS community with innovative and research based care within the region.

You have a close connection with the Z. The Z is owned by your director, V, and also employs your director, T. V is a board certified by the S and his specialties include Multiple Sclerosis and Parkinson's Disease. You explained that you have your own office, officers, and director and that only the medical director, V, is involved with both organizations. V sees patients and manages their medical conditions for Z. For you, V conducts research visits and records and submits the data for those visits. You stated that functions you perform are clearly designated and you do not run joint events with Z. You also have your own medical record keeping.

You sublease space from Z for your activities including office use and medical research. You occupy a portion of the facility where Z operates. The letter to the landlord requesting consent for Z to sublease the facility to you states the following:

V and T, PhD, nurse practitioner, are actively involved in the research activities of the W while the Board of Directors consists of highly regarded members of the multiple sclerosis research community. While the W is a separate and distinct entity from Tenant, its activities and mission are closely linked. The W will use the subleased space to conduct its research activities, including patient care. The use of the space by the W is similar to how the Premises are used by Tenant.

You stated that the testing and research you perform is to help patients who are on medication understand the potential side effects and efficacy of their treatment. You perform blind medical research studies on patients who have been medically screened for participation in the drug studies. You initially indicated that your research department has several ongoing studies being conducted at the research center and planned to enroll in new studies. You decide which studies are appropriate for you based on staff availability, patient population, and patient interest. The results of these studies would not be made available directly to the general public. They would only be distributed via the pharmaceutical companies sponsoring the studies. Your research department and the sponsoring pharmaceutical company are the only entities that will retain ownership of the information generated from the research.

You later submitted additional information to clarify your activities. You currently conduct clinical trials sponsored by pharmaceutical companies. You stated that your research is currently being sponsored by pharmaceutical companies in Phase III and Phase IV studies examining interventions and quality of life measures related to medications which have already been approved by the N and are market ready or currently on the market. You stated that you frequently gather information from your studies that differ from the original studies on the medications. The pharmaceutical companies are interested in the studies because they often uncover further information such as safety issues that was not found in the initial studies.

You indicated that the sponsors do publish their research and it is available for public consumption. You explained that after research is completed it is finalized and findings such as safety information is made available to the public by publishing it on CC. It may also be published in professional journals or meetings. The published information includes the objective of the study, the methods of the study, the results and the declaration of interests if the authors have a potential conflict of interest. You stated the research for your sponsors is as described in Rev. Rul. 76-296. You plan to eventually conduct investigator driven research.

When conducting the research activities, you occasionally use two of Z's clinical support staff who have been trained on the study procedures and added to the clinical trial delegation log. The majority (approximately 85-90%) of the subjects used in the studies come from Z. Z patients are informed of the studies but are not under any obligation to participate and can opt out at any time if they enroll in a study. The subjects are obtained when either a clinical decision has been made to initiate a patient on a particular pharmacological intervention that is congruous with a current trial or when a patient who is already receiving pharmacological intervention that is congruous with a current trial is identified. You state that the clinical decision making, "is in no way whatsoever affected by any clinical trials being conducted, the W has absolutely no influence on the decision making of the providers."

None of your current research projects are directly carried out for Z. However, you indicated that the projects do benefit the Z population, and therefore the multiple sclerosis community, because the projects you participate in directly impact the Z patient population. All of your current research is sponsored by pharmaceutical companies. You currently conduct one research project sponsored by L and six projects that are sponsored by M. You have an additional planned research project that will be sponsored by M. The pharmaceutical

companies provide you with grant payments to carry out the direct research they compile from other clinics throughout the United States or globally. You stated that the sponsors receive the research results and hold title to them along with you.

The first Master Clinical Trial Agreement you submitted is dated K and is between M and Z, the Institution. The Agreement is signed by V as the President of Z. The term of the Agreement is five years. The Agreement is for a clinical study on one of M's investigational new drugs and states that each trial shall be conducted with the applicable clinical research protocol prepared and provided by M. M will register each trial and post the trial results on a publicly accessible website. It is the responsibility of Z to employ one or more physicians (investigators) experienced in conducting clinical studies of investigational new drugs and to arrange for qualified personnel to support its trial obligations. Z and the employed physicians are responsible for maintaining complete and accurate records of the status and progress of each trial including case report forms, signed subject informed consent and authorization documents, and all other records. M shall have access to all information obtained from each trial by Z but Z shall not disclose any confidential information to any third party. Section 8(a) of the Agreement states, "All right, title and interest in and to (i) all data collected and databases generated in performance of a Trial, (ii) all compilations of data related to a Trial (including the selection, coordination or arrangement of such data), that are created for a Trial, and (iii) all case report forms and other Trial documents and reports, including copyrights in any of the foregoing, is and shall remain the sole and exclusive property of M." Section 8(b) states that, "M hereby grants the Institution a limited right to use the results of a Trial generated by the Institution for publication purposes, and for the Institution's own non-commercial internal research, training or educational purposes, subject to the terms and provisions of Sections 7 (Confidentiality) and 9 (Publication) of this Agreement." Finally, Section 9(a) states, "Except as otherwise provided in this Section 9, following completion of a Trial and evaluation of the results b M, or abandonment of a Trial, the Institution (by or through the Investigator or other Personnel) may, for non-commercial purposes only, publish or otherwise publicly disclose the results and methods of the Trial. Notwithstanding the foregoing, the Institution shall not disclose any of M's Confidential Information, other than the results and methods of the Trial." If a trial is part of a multi-center clinical study then Z cannot make any publication or disclosure until the results from all centers have been received and analyzed or the trial has been abandoned at all centers. Z must provide M with a manuscript for review of any proposed publication or public disclosure at least 60 days prior to disclosure to any other party. All the results of the trial including any discoveries, inventions, or other intellectual property will be owned by M.

The second agreement you submitted is an Observational Study Agreement between M, Z as the Institution, and V as the Physician. The agreement was signed by V as President of Z on J. The Agreement states that the Physician is experienced in conducting studies of investigational and market drugs and M desires that Z and V conduct an observational study on one for the medicinal products it markets to collect information on safety and document the drug utilization when used in routine medical practice in the treatment of multiple sclerosis. Z and V shall conduct the study for M according to protocol and make the results available to M. Z shall record all data from the study for M. Z and V shall not disclose any Confidential Information to any third party. Section 5.1 of the Agreement states, "All inventions, ideas, improvements, discoveries, enhancements, modifications, know-how, data, designs and information of every kind and description conceived, generated, made or reduced to practice, as the case may be, relating in any way to the performance of the Study…..shall be owned solely and exclusively by M." Section 6.1 states, "M and its agents shall have unrestricted access to and exclusive rights to use all information resulting from the Study for any and all lawful purposes." Section 6.2 states, "Except as otherwise provided in this Article 6, following completion of the Study and evaluation the results by M, or abandonment of the Study, the Institution (by or through its Physician or Staff) may, for non-commercial purposes only, publish or otherwise publicly disclose the results and methods of the Study. Notwithstanding the

foregoing, the Institution shall not disclose any of M's Confidential Information, other than the results and methods of the Study." If the study is part of a multi-center clinical study then Z cannot make any publication or disclosure until the results from all centers have been received and analyzed or the study has been abandoned at all centers. Z must provide M with the text relating to the study that Z plans to present or publish at least 60 days prior to disclosure to any other party. Section 7 of the Agreement shows that compensation for the study will be paid to Z.

You submitted another Observational Study Agreement dated H between M, Z as the Institution, and V as the Physician. The Agreement was signed by V as the President of Z. The study is on the same medical product/drug as the Observational Study Agreement above. This 12 month observational study is to evaluate the clinical effectiveness of the product and its impact on quality of life and health economic-related outcomes in patients with relapsing forms of multiple sclerosis who switch to the product from G. All study results are to be made available to M and Z shall not disclose any confidential information to any third parties. Section 5.1 of the Agreement is the same as above and indicates that all inventions and data from the study shall be owned by M. The publication requirements in this Agreement are also the same as those above and as above, compensation for the study is to be paid to Z.

The next Observational Study Agreement you submitted is between M, Z, the Institution, and T, the Physician. T signed the agreement for herself as physician as well as for Z. The study is to assess the efficacy and safety of a medical product different from the one in the other observational studies above. The study will begin in P and last 60 months with all results being made available to M. Z and T shall not disclose any confidential information to third parties. Section 5 indicating that M owns all inventions and data is the same as the agreements above. The publication requirements in Section 6 are also the same as above. Compensation for the study is to be paid to Z.

Another Observational Study Agreement was submitted between M, Z, the Institution, and T, the Physician. The agreement is signed by T on F for herself as physician as well as for Z. This Agreement is for two medicinal products and the observational study is to evaluate real world clinical outcomes in relapsing-remitting multiple sclerosis patients who transition from one medicinal product to the other. All study results are to be made available to M and T and Z shall not disclose any confidential information to third parties. Section 5 indicating that M owns all inventions and data is the same as the agreements above. The publication requirements in Section 6 are also the same as above. Compensation is to be paid to Z.

The next Observational Study Agreement you submitted is between D who was contracted by M, C, the institution, and V as the physician affiliated with C. V signed the Agreement on B. The Chief Operating Officer of C signed for C. The observational study is to be conducted on one medicinal product according to the protocol given with results going to D and M. C and V shall not disclose any confidential information to third parties. Sections 5 and 6 relating to inventions, data ownership, and publication are similar to those above. Per Section 7, compensation is to be paid to C.

The last Observational Study Agreement you submitted is dated E and is between M, U, the institution, and T as the physician. The study is on a medicinal product marketed by M. All confidentiality, invention and data ownership, and publication requirements are the same as above. T signed the agreement for U and as physician/nurse practitioner.

The final agreement you submitted is a Master Clinical Trial Agreement dated BB between O as the sponsor and Z as the institution. The Agreement is signed by V as President of Z. The Agreement is to establish an

ongoing arrangement between O and Z for the conduct of one or more clinical studies. Clinical studies will be described in separate work orders which will set for the clinical trial protocol, the study budget, the name of the drug to be investigated, the name of the investigator, and any other terms and conditions. Each executed work order will become part of the Agreement. Per the Agreement, Z agrees to conduct the study in accordance with the protocol. O will pay Z for the services rendered. Z and its study personnel shall not use confidential information for any purpose other than the study and shall not disclose confidential information to any third party except as permitted. Z and the investigator have the right to publish or present the results of their activities under the Agreement and work order, including study data, in accordance with the requirements set forth in the Agreement. Any presentation or publication should be submitted to O for review at least 30 days before submitting the information for publication. If the study is part of a multi-center study then Z shall not independently publish information until a multi-center publication is published. Any inventions or discoveries made by Z and/or the study personnel and/or O during the performance of the study will become the sole property of O. Any other inventions or discoveries made in relation to work under the Agreement should be disclosed to O. Z and/or the study personnel may jointly own rights to any such jointly made other inventions. O has the first option to obtain a worldwide, exclusive license to Z's and the study personnel's rights in any other inventions. The license will be offered on commercially reasonable terms that are customary for similar inventions in the pharmaceutical industry. O does grant Z a perpetual, non-exclusive, non-transferable, paid-up license, without right to sublicense, to use inventions for Z's internal, non-commercial research and educational purposes.

Work Order No. 1 was submitted with the Master Clinical Trial Agreement. The Work Order is between O, Z as the institution, and V as the investigator. The Work Order was signed by V as President of Z and as the investigator. The Work Order is for a study to be performed on a study drug. The study is a clinical-setting study to describe the efficacy, tolerability, and convenience of the study drug treatment using patient reported outcomes in relapsing multiple sclerosis patients. O shall pay Z for services rendered.

You stated that the name on the contracts is Z because the studies or their contracting originated prior to your existence.

You stated that approximately 80% of your activities are devoted to research. You also previously conducted free educational sessions/seminars for the public on topics related to improving the quality of life. You have educated patients with multiple sclerosis and families on navigating disability benefits for patients with multiple sclerosis, exercise, and physical activity. You have also sponsored a holiday lights tour to raise funds and allow patients with multiple sclerosis to have a fun and educational evening.

The majority of your revenue from your date of formation to the end of P came from research income payments received from pharmaceutical companies for patients that are enrolled in studies that have completed the set protocols. You generally receive these payments quarterly from the sponsoring companies for study activities that occurred the previous quarter. These activities may have included subjects coming in for study related visits including physical assessments, blood draws, or questionnaires. Additionally the Research Coordinator would be responsible for completing data entry. You show just under 10% of your revenue from donations. The majority of your expenses were for salaries and wages, occupancy expenses, and laboratory fees. Your expected expenses for Q and R are similar to those in 2014. However, you show no anticipated revenue from donations. All of your revenue is expected to be from income payments from pharmaceutical companies. You also state that you plan to conduct four fundraising events per year as well as solicit donations from merchants, the pharmaceutical industry, and vendors at your health fair. You will use funds raised to support research or for educational activities or the support of innovative care initiatives.

Law
Section 501(c)(3) of the Internal Revenue 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.

Treasury Regulation Section 1.501(c)(3)-1(a)(1) 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.

Treas. Reg. Section 1.501(c)(3)-1(c)(1) 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.

Treas. Reg. Section 1.501(c)(3)-1(d)(1)(ii) 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.

Treas. Reg. Section 1.501(c)(3)-1(d)(5)(i) 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.

Treas. Reg. Section 1.501(c)(3)-1(d)(5)(ii) states that 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 or the designing or construction of equipment, buildings, etc.

Treas. Reg. Section 1.501(c)(3)-1(d)(5)(iii) provides, in part, that scientific research will be regarded as carried on in the public interest if the results of such research (including any patents, copyrights, processes, or formulae resulting from such research) are made available to the public on a nondiscriminatory basis, if such research is performed for the United States, or any of its agencies or instrumentalities, or for a State or political subdivision thereof, or if such research is directed toward benefiting the public.

Rev. Rul. 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.

Rev. Rul. 76-296, 1976-2 C.B. 141, holds 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.

Better Business Bureau of Washington D.C., Inc. v. United States, 326 U.S. 279 (1945), held that the presence of a single nonexempt purpose, if substantial in nature, will preclude tax exemption under section 501(c)(3) of the Code.

In B. S. W. Group, Inc. v. Commissioner, 70 T.C. 352 (1978), the organization provided consulting services for a fee to various tax-exempt and non-profit organizations. The organizations fees were set at or close to cost. The court concluded that those activities are not inherently charitable because they are of the type typically conducted by for-profit organizations. Even though the organization argued that its fees may in fact be lower than those charged by other firms, the court concluded that it was not enough to prove that organization's purposes are primarily exempt. The Court concluded that the petitioner is not an organization described in section 501(c)(3) because its primary purpose is neither educational, scientific, nor charitable, but rather commercial.

In Schoger Foundation v. Commissioner, 76 T.C. 380 (1981) it was held that if an activity serves a substantial nonexempt purpose, the organization does not qualify for exemption even if the activity also furthers an exempt purpose.

In Old Dominion Box Co. v. United States, 477 F2d 344 (4th Cir. 1973) cert. Denied 413 U.S. 910 (1973), the court held that operating for the benefit of private parties constitutes a substantial non-exempt purpose.

In Washington Research Foundation v. Commissioner, T.C. Memo 1985-570 (1985), the Tax Court held that an organization that facilitates transfer of technology from nonprofit organizations' labs for public use through licensing arrangements with private industry did not qualify for exemption under section 501(c)(3) of the Code, because the immediate benefit of its activities rebounds to private industry and the nonprofit research institutions and only indirectly to the general public. It was found that these activities are commercial in nature and not in direct furtherance of exempt purposes.

Application of law

You are not described in section 501(c)(3) of the Code because you are not operated exclusively for an exempt purpose under section 501(c)(3) of the Code. (Treas. Reg. Section 1.501(c)(3)-1(a)(1)) Per Treas. Reg. Section 1.501 (c)(3)-1 (c)(1), you are not operated exclusively for one or more exempt purposes because more than an insubstantial part of your activities involves providing research services in a commercial manner which is not in furtherance of an exempt purpose.

While you plan to eventually conduct investigator driven research, your only research activities thus far have been for the sponsoring pharmaceutical companies. You are providing a service for the pharmaceutical companies which is incident to their commercial operations and to the marketing of their products. Clinical testing to determine the efficacy of the drugs is merely a service performed for the pharmaceutical companies and serves the private interests of the pharmaceutical companies rather than an exclusively public purpose and is not scientific research within the meaning of Treas. Reg. Section 1.501(c)(3)-1(d)(5)(1).

Operating in a manner similar to a for profit corporation is not an exempt charitable activity for the purposes of section 501(c)(3) of the Code. See B.S.W. Group, Incorporated v. Commissioner, supra. The contracts you submitted show that you conduct research for pharmaceutical companies for a fee. Your primary purpose is

therefore not scientific, but rather commercial.

You research is not regarded as being carried on in the interest of the public because you are limited to when and what you will be allowed to publish. Further, you have no rights to the resulting intellectual property created through your research. It remains the sole property of the sponsoring pharmaceutical company. (Treas. Reg. Section 1.501(c)(3)-1(d)(5)(iii) of the Regulations)

You are similar to the organization described in Rev. Rul. 68-373, because a majority of your operations consist conducting clinical trials for pharmaceutical companies. You state that the research you are currently conducting is Phase III and Phase IV studies examining interventions and quality of life measures related to medications which have already been approved by the N and are market ready or currently on the market. However, since the studies are Phase III and Phase IV studies, it appears that you are assisting the pharmaceutical companies in meeting N requirements for marketing. Treas. Reg. Section 1.501(c)(3)-1(d)(5)(ii) states that scientific research does not include activities of a type ordinarily carried on as an incident to commercial operations. Clinical testing is an activity that is normally carried on as an incident to a pharmaceutical company's commercial operations. You are conducting testing based on the specifications of the pharmaceutical companies. The pharmaceutical companies have given you the experimental methods and procedures to follow. Therefore, the testing you conduct is not considered scientific research under section 501(c)(3) of the Code. Additionally, you are providing a service for a fee to the pharmaceutical companies and therefore serving the private interests of the pharmaceutical companies rather than the public interest.

Rev. Rul. 76-296 pertains to research that has already been deemed to be scientific. Although you indicated that your research results are published on CC, you research is not considered scientific as indicated above so Rev. Rul. 76-296 would not apply. Your testing is operated in a manner that precludes it from being recognized as "scientific research" because it related to normal commercial operations of the for-profit pharmaceutical companies. Rev. Rul. 76—296 addressed itself to research of a scientific nature, it was not intended to modify Rev. Rul. 68—373.

Similar to Old Dominion Box Company v, your operations benefit private parties and constitute a substantial nonexempt purpose. You are also similar to the organizations in Better Business Bureau and Schoger Foundation v. Commissioner because your activities serve substantial nonexempt purposes and because you have failed to establish that you are organized or operated exclusively for the benefit of public interests rather than those of the pharmaceutical companies you are working for. As in Washington Research Foundation v. Commissioner, the immediate benefit of your activity rebounds to private industry. Treas. Reg. Section 1.501(c)(3)-1(d)(5)(iii) provides, in part, that scientific research will be regarded as carried on in the public interest if such research is directed toward benefitting the public. The majority of your activities consist of drug testing and evaluations for the sponsoring pharmaceutical companies. Your research is therefore directed toward benefitting the pharmaceutical companies, not the public.

Additionally, you are not operated for one or more exempt purposes because you have not clearly shown that you are not serving the private interests of your director, V, and the related for-profit entity owned by him, Z. (Treas. Reg. Section 1.501(c)(3)-1(d)(1)(ii)) Z also employs your director, T. You sublease space from Z for your activities including office use and medical research. You occupy a portion of the facility where Z operates. The letter to the landlord requesting consent for Z to sublease the facility to you states your activities and mission are closely linked. You perform blind medical research studies on patients who have been medically screened for participation in the drug studies. When conducting the research activities, you occasionally use two of Z's clinical support staff who have been trained on the study procedures and added to the clinical trial

delegation log. The majority (approximately 85-90%) of the subjects used in the studies come from Z. Of further note, while you state in the application that you are the one conducting the research and that the functions you perform are clearly designated, you are not listed as a party on any of the research contracts submitted. Z is named as the institution in all but one of the contracts. U is named in that contract. V is listed as the physician in some contracts and T is listed as the physician in others. The contracts show that compensation is paid to Z. There is no clear separation between you and the related for-profit entity Z and it appears these contracts serve the private interests of Z.

Conclusion
Based on the facts and information submitted, you are not operated exclusively for exempt purposes. Your operations do not further an exempt purpose, but rather, substantially promote the nonexempt business purpose of for-profit entities. Therefore, you are not described in section 501(c)(3) of the Code.

If you don't agree
You have a right to file a protest if you don't agree with our proposed adverse determination. To do so, you must send a statement to us within 30 days of the date of this letter. The statement must include:

- Your name, address, employer identification number (EIN), and a daytime phone number
- A copy of this letter highlighting the findings you disagree with
- An explanation of why you disagree, including any supporting documents
- The law or authority, if any, you are relying on
- The signature of an officer, director, trustee, or other official who is authorized to sign for the organization, or your authorized representative
- One of the following declarations:

  For an officer, director, trustee, or other official who is authorized to sign for the organization:
  Under penalties of perjury, I declare that I examined this protest statement, including accompanying documents, and to the best of my knowledge and belief, the statement contains all relevant facts and such facts are true, correct, and complete.

  For authorized representatives:
  Under penalties of perjury, I declare that I prepared this protest statement, including accompanying documents, and to the best of my knowledge and belief, the statement contains all relevant facts and such facts are true, correct, and complete.

Your representative (attorney, certified public accountant, or other individual enrolled to practice before the IRS) must file a Form 2848, *Power of Attorney and Declaration of Representative*, with us if he or she hasn't already done so. You can find more information about representation in Publication 947, *Practice Before the IRS and Power of Attorney*.

We'll review your protest statement and decide if you provided a basis for us to reconsider our determination. If so, we'll continue to process your case considering the information you provided. If you haven't provided a basis for reconsideration, we'll forward your case to the Office of Appeals and notify you. You can find more information about the role of the Appeals Office in Publication 892, *How to Appeal an IRS Decision on Tax-Exempt Status*.

If you don't file a protest within 30 days, you can't seek a declaratory judgment in court at a later date because the law requires that you use the IRS administrative process first (Section 7428(b)(2) of the Code).

Where to send your protest
Please send your protest statement, Form 2848, if needed, and any supporting documents to the applicable address:

U.S. mail:

Internal Revenue Service
EO Determinations Quality Assurance
Room 7-008
P.O. Box 2508
Cincinnati, OH 45201

Street address for delivery service:

Internal Revenue Service
EO Determinations Quality Assurance
550 Main Street, Room 7-008
Cincinnati, OH 45202

You can also fax your statement and supporting documents to the fax number listed at the top of this letter. If you fax your statement, please contact the person listed at the top of this letter to confirm that he or she received it.

If you agree
If you agree with our proposed adverse determination, you don't need to do anything. If we don't hear from you within 30 days, we'll issue a final adverse determination letter. That letter will provide information on your income tax filing requirements.

You can find all forms and publications mentioned in this letter on our website at www.irs.gov/formspubs. If you have questions, you can contact the person listed at the top of this letter.

Sincerely,

Director, Exempt Organizations

Enclosure:
Publication 892