Tax Issues in Clinical Research

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Three Topics:
1. Clinical Research: related to mission and UBTI issues
2. Private Use Issues: research activities in bond-financed facilities
3. Medical Device Tax
Clinical Research: Related To Mission?

- Hospitals and health care organizations today are involved in a wide variety of clinical research activities.
- Depending on the status of these activities, various contract and business planning choices can have crucial impacts on the tax status of the tax-exempt organizations and income derived from clinical research activities.

General Definitions

- “Medical research organization” engaged in activities in conjunction with a hospital also is a public charity under Code § 170(b)(1)(A)(iii).
- Scientific organization can qualify as a Code § 501(c)(3) org if its purpose is “scientific research carried on in the public interest” as defined under Treas. Reg. § 1.501(c)(3)-1(d)(5)(iii).
General Definitions

• Tax authority and guidance applicable to clinical research is surprisingly unclear; background on terminology is helpful.

• “Scientific” research involves the use of the scientific method, when the researcher makes a hypothesis and designs a project to test this hypothesis, usually using a control group or other widely accepted method in the scientific community. Scientific research is not industrial or commercial research including, for example, activities that help determine the construction, design, or safety of products (Treas. Regs. § 1.501(c)-1(d)(5)(i)).

General Definitions

• “Research”--IRS has noted an important distinction between “research” and “testing.”

• For example, activities determining the safety of drugs for FDA approval may be defined as “testing,” as opposed to preliminary design trials, which may qualify as “research.”
Scientific Research: Definition

*ITT Research Institute v. United States* — court defined activities as scientific research if they
• (i) involve the use of observation or experimentation to formulate or verify facts or natural laws,
• (ii) could only be performed by an individual with advanced scientific or technical expertise,
• (iii) add to the knowledge of a particular scientific field,
• (iv) involve mathematical reasoning, or
• (v) attempt to systematize or classify a body of scientific knowledge by collecting information and presenting it in useful form.

Scientific Research: Definition

General Counsel Memorandum 39883, IRS took three elements and formed a loosely defined three-part test, which has its origins in the *Midwest Research* opinion
• (i) There must be project supervision and design by professionals;
Scientific Research: Definition

• (ii) Researchers must design the project to solve a problem through a search for demonstrable truth. This component suggests the use of the scientific method to solve a problem. The scientific method requires the researcher to form a hypotheses [sic], design and conduct tests to gather data, and analyze data for its effect on the verity of falsity of the hypotheses; and

Scientific Research: Definition

• (iii) The research goal must be discovering a demonstrable truth. Information on the novelty and importance of the knowledge to be discovered is also important to determine whether a particular activity furthers a scientific purpose.
Public Interest Requirement

Research benefiting the public generally includes:
• research carried out for educational purposes,
• research to obtain scientific information that will be published and available to the public, or
• research that discovers a cure or advances a treatment for a disease (Treas. Reg. § 1.501(c)(3)-1(d)(5)(iii)).

Public Interest Requirement

Research in these contexts is still scientific research for the public interest even if a private entity retains intellectual property rights resulting from the research (Rev. Rul. 76-296, 1976-2 C.B. 150).
Unrelated Business Taxable Income

Code § 512(a) defines unrelated business taxable income (UBTI) as income derived from an unrelated trade or business regularly carried on by the exempt organization.

An unrelated trade or business is defined under Code § 513(a) as an activity that is not “substantially related” to the exercise or performance of the organization’s tax-exempt purposes.

Unrelated Business Taxable Income

• Treasury Reg. § 1.513-1(d)(1) provides that a trade or business is related to an organization’s tax-exempt purposes only where the conduct of the business activities has a causal relationship to the achievement of its tax-exempt purposes.
• To be substantially related, the trade or business must contribute importantly to the accomplishment of the exempt purpose.
Unrelated Business Taxable Income
EXCEPTIONS

• Code § 512(b)(8) provides: In the case of a college, university, or hospital, there shall be excluded all income derived from research performed for any person, and all deductions directly connected with such income. . . .

Unrelated Business Taxable Income
EXCEPTIONS

• Code § 512(b)(9) provides: In the case of an organization operated primarily for purposes of carrying on fundamental research the results of which are freely available to the general public, there shall be excluded all income derived from research performed for any person, and all deductions directly connected with such income. . . .
Unrelated Business Taxable Income

EXCEPTIONS

• In the case of Code § 512(b)(9), Treas. Regs. § 1.512(b)-1(f)(3) provide that the exception only applies to organizations that engage primarily in “fundamental” research but not to “applied” research. . . .

Unrelated Business Taxable Income

EXCEPTIONS

Treas. Regs. § 1.512(b)-1(f)(4) provide:

• the term “research” does not include activities of a type ordinarily carried on as an incident to commercial or industrial operations, for example, the ordinary testing or inspection of materials or products or the designing or construction of equipment, buildings, etc. The term “fundamental research” does not include research carried on for the primary purpose of commercial or industrial application.
Relevant Tax Authority

• Due to the varying types and definitions of “research,” a combination of revenue rulings, private letter rulings and case law provides essential guidance as to the tax treatment of clinical research activities.


• IRS held that clinical testing of drugs for FDA approval was not scientific research and the income derived was UBTI. In this situation, all of the nonprofit organization’s income was derived from assisting pharmaceutical companies with clinical trials required for FDA approval.
• Although the results of the tests were widely published in medical and scientific journals and “highly qualified professionals” were required to run the tests, the Service held that the testing was incidental to commercial operations of the pharmaceutical company and therefore not scientific research.

- Org performed research studying quality, utilization, and effectiveness. To meet the public interest standard, the Service ruled that commercially sponsored research must be published in an adequate and timely manner.
- Publication may be delayed during the time necessary to obtain patents or other intellectual property rights, but may not be kept secret beyond this time to protect other business interests.
- Even if research qualifies as scientific research, if the results are not made generally available after intellectual property rights are protected, it would not be in the public interest and related income would result in UBTI.

PLR 7936006 (May 23, 1979)

IRS found that clinical trials for pharmaceutical companies researching new applications for existing drugs were scientific research in the public interest because the trials were not conducted for the purpose of meeting FDA certification requirements.

Here, an important factor was that the testing performed by a medical school for pharmaceutical companies was substantially related to its exempt purposes of teaching and research.
PLR 7936006 (May 23, 1979)

IRS identified the following facts in support of its finding: (1) the faculty (not the pharmaceutical companies) developed the protocols; (2) the studies involved the search for new or improved treatments; (3) results were published; (4) the results were used in teaching students of the medical school.


Court concluded that while income obtained from performing pap smears for non-patients would normally be UBTI, in this case it was not UBTI because St. Luke’s needed a large number of smears to provide adequate training and education to its medical students and residents.
PLR 200852036 (Dec. 26, 2008)

More recently the Service held that clinical trials using new drugs or drug combinations to treat orphan diseases qualified as scientific research because the tests “primarily serve to aid those suffering from disease and they add to the body of available scientific knowledge used in finding a cure for it.” This was despite the fact that commercial entities may benefit from the research.

Analysis

• Is the research related to an exempt purpose of patient treatment, teaching of students, residents or fellows or the research mission (and therefore not UBTI)?

• Even if not related to an exempt purpose, does the research fall into any of the UBTI exceptions described in Code § 512(b)(7)-(9)?
Checklist

• The rights and obligations of the parties define the research as scientific research.
• The provisions contain publication rights for the researchers or guarantees by the sponsor, with allowances for reasonable time to protect intellectual property rights and complete patent applications.

Checklist

• The researcher provided by the hospital assists in developing or monitoring the protocol for the research and managing the data.
• The clinical trials incorporate the hospital’s existing patients.
• The provisions state the purpose of the clinical trials in language that directly relates to the individual hospital’s tax-exempt purpose.
Checklist

• The clinical trials are structured to involve medical students at related academic institution.
• The provisions demonstrate how the faculty of a related academic institution will use the clinical trials in student instruction.
• The provisions contain research objectives of the hospital that are independent of the commercial entity’s objectives.
• The provisions show how the purpose of the trials will cure a disease or advance current medical treatments.

Documentation

To support the argument that the research was scientific and conducted in the public interest maintain:

• The results of the trials and related publication.
• The identity of the principal investigator responsible for the design of the trials and management of the research.
• Documentation of the scientific purpose of the trials, as defined in the contract.
Documentation

• Documentation of the **educational benefits** of the trials, including student and faculty involvement.

• Documentation of any contributions the trials made to the **care and treatment of the hospital’s patients**, both during the trials and into the future.

Actual Examples/Experiences

• Multi-disciplined approach to compliance – Front end contract review process

• Tracking tools – Contract management System

• Comprehensive Policies & Procedures in place

• Master Sponsor Agreement/Contract Templates
  – Negotiate critical E/O issues once with regular sponsors
  – Each new trial/project is a separate addendum or SOW

• State Charitable purpose & intent to fulfill mission
Private Use of Facilities Funded with Tax-Exempt Bonds

It is crucial that any organization using tax-exempt bonds for financing carefully consider the impact of engaging in a research partnership or activities with a for-profit entity.

Private Use of Facilities Funded with Tax-Exempt Bonds: GENERAL RULE

While the majority of the funds must be spent on the tax-exempt purpose, a limited portion may be spent to benefit private business or an unrelated trade activity. If the tax-exempt organization is a public organization, up to 10% is allowed; private institutions may only spend 5% minus the costs of issuing the bonds, which usually results in 2–3% of the proceeds available to be used to benefit private business.
Private Use of Facilities Funded with Tax-Exempt Bonds

• Private business use can be as expansive as ownership, actual or beneficial use of property under a lease, management agreement, or incentive payment contract.
• If a private business uses the property financed by tax-exempt bonds this use of facilities is treated as a use of the proceeds.

Private Use of Facilities Funded with Tax-Exempt Bonds

For example, if a hospital enters into a clinical research agreement with a pharmaceutical company to conduct the trials at a hospital building financed with tax-exempt bonds, unless the agreement contains a provision preserving the public benefit of the research, the tax-exempt use purpose would fail because a for-profit company has beneficial use of the facility.
Safe Harbors

Revenue Procedure 97-14, 1997-1 C.B. 634.

• Safe harbor includes “basic research” pursuant to corporate or industry sponsorship as exempt use, if the research is an “original investigation for the advancement of scientific knowledge not having a specific commercial objective.” The Service clarified that clinical testing of a product for a specific business did not fall under the definition of basic research.

Safe Harbors

• Revenue Procedure 07-47, 2007-2 C.B. 108 expanded the definition of basic research to include cooperative business agreements, which meet these requirements:

--An individual sponsor, or multiple, unrelated sponsors.
Safe Harbors

– The government or tax-exempt entity determines the type and manner of performance of the research.
– Title to intellectual property rights result in only the qualified user (the tax-exempt entity).
– The sponsor(s) gets only a non-exclusive royalty free license to use any products of the research.

Safe Harbors

Rev. Proc. 07-47 also stated that there is no private business use if the sponsor purchases the license or resulting technology at a competitive price.
Planning Tips

1. Avoid engaging in clinical research agreements using a facility that currently has outstanding tax-exempt bonds.
2. If unavoidable, the Org should satisfy the safe harbor under Rev. Pro. 07-47.
   To that end, a research agreement should address how the goal of the research furthers patient care, and state that the for-profit entity may have no beneficial rights to use the property and that publication rights are reserved to the tax-exempt entity.

Actual Example & Approach

• Strive to be compliant with Rev Proc’s 97-14 & 2007-47
• Specific standard contact provisions regarding
  – Publication rights; Furthering exempt goals; I/P rights, etc.
• Legal & Tax contract review
• Detailed analysis performed annually for Form 990 Schedule K reporting
Medical Device Tax

- Enacted as part of the Patient Protection and Affordable Care Act (ACA) and amended by the Health Care and Reconciliation Act of 2010.
- See Code § 4191 that imposes a tax of 2.3% on the sale of medical devices by the manufacturer, producer, or importer of the device.
- Treasury Regulation § 48.4191-1(c) imposes the payment of the tax on the manufacturer, producer, or importer of the device.

Medical Device Tax

- Purpose of Tax:

to generate revenue to fund portions of the ACA and to spread the costs of medical care throughout the health care industry.
What is a covered medical device?

• The medical device tax applies to any medical device that is intended for use in humans, as defined under Code § 201(h) or listed in § 510(j) of the Federal Food, Drugs, and Cosmetics Act (FFDCA).
• This category encompasses devices that can be used in non-medical or veterinary contexts.
• Replacement parts for medical devices are taxed at the rate the user must pay the manufacturer for the part.

What is a covered medical device?

• Software sales and upgrades that are not separately listed with the FFDCA are not taxable.
• The tax does not apply to services bundled with software products, and advice is forthcoming as to whether the tax applies to each new license of software products (Treas. Reg. § 48.4191-1, Supplementary Information to Final Regulation, pp. 8, 31).
What is a taxable event?

• The sale of a covered device.
• Use by manufacturer of the device in any way other than the manufacture of more covered devices (in such case the tax is owed on the amount for which the device would have sold).

What is a taxable event?

• This tax affects “convenience kits” when two or more medical devices are packaged together by taxing the devices upon sale by the manufacturer, not the sale of the final kit.
• If a hospital is an exempt self-kitter, the use of the self-made kit will not be considered a taxable event (Treas. Reg. § 48.4191-2(b)(2)(iv) (example 3)).
Exemptions

• The primary exemption from the medical device tax is the retail exemption. The retail exemption excludes devices available at retail to the general public for individual use (I.R.C. § 4191).

• The devices must be regularly available for purchase by consumers and not intended to be used by a medical professional or in a medical institution or office.

Exemptions

Determining whether a device meets the retail exemption is a facts and circumstances test, but the final regulation relating to the tax includes a list of safe harbor products, including FDA designated over-the-counter products, prosthetic and orthotic devices that do not require implantation or insertion by a medical professional and are eligible for payment under Medicare Part B.
Exemptions

Payments for the sale of medical devices made after January 1, 2013 pursuant to a contract that was in place prior to March 30, 2010 are exempt from the medical device tax, unless the contract was materially modified, including the terms or amount of payment, or the type of property provided, after March 30, 2010 (Treas. Reg. § 48.4191-1(f)).

Current Issue

• Since the medical device tax was imposed earlier this year, medical device manufacturers have attempted to pass on the cost of the tax either directly or as a device price increase to medical device purchasers.
• In some cases passing on this tax may violate previously negotiated contract provisions.
Current Issue

- It is widely agreed among the provider industry that the tax should not be passed on to purchasers because the intent of the tax was to spread the costs of providing health care to various players in the system (not to concentrate all the costs at the provider or patient level).
- Purchasers of medical devices are currently lobbying Congress to clarify the purpose of the tax by adding this intention to the statute, since the IRS declined to take this position in the related regulation.

Actual Example & Approach

- Initial lack of guidance caused confusion
- Legal, Finance, and Supply Chain worked together to assess issues and application of MDET
- Primary concerns: International purchases; “Kitting”; Supplier’s pass through: Technology Spin Off affiliates
- Alerted Accounts Payable & Supply Chain to look for pass through attempts
- Issued letter to all suppliers advising that we will NOT pay any MDET pass through
- Several vendors attempted to directly pass through the tax in 2013 invoices
Template Letter

- See materials for a template letter that can be used by a purchaser of medical devices to communicate the purpose of the tax and the purchaser’s refusal to pay the tax to a manufacturer who attempts to pass the tax on to the purchaser.