



## RESEARCH POLICY 8 (RP-8) RESEARCH AGREEMENTS AND PRIVATE BUSINESS USE

### 1. Introduction

Sponsored grant or award agreements with corporations, the federal government or other sponsoring entities may give rise to private business use.

### 2. Policy Statement

Certain facilities owned by Duquesne University may be financed in whole or in part with proceeds of tax-exempt or other tax-advantaged bonds (a “financed facility”). Federal tax law places limits on the private business use (“PBU”) of such financed facilities. PBU may arise from leases, management contracts, research agreements, and other contracts with the federal government, corporations, and other private or non-profit entities depending on the nature and the duration of the agreement, the identity of the parties, and other factors.

In order to comply with federal tax law and accurately report PBU, Duquesne must determine PBU in every financed facility. No more than 5% of the direct or indirect use of that property may be PBU. A change in use that creates excessive PBU requires timely refinancing of a debt issuance or other action such as voluntary settlement with the IRS. Excessive PBU can result in significant monetary penalties from the IRS. For these reasons, PBU requires periodic review and monitoring by Duquesne. The Treasurer’s Office will provide information sessions on PBU to relevant departments on a periodic basis and conduct an annual survey on research agreements and PBU.

### 3. Policy Scope

This Policy applies to all University employees who are engaged in submitting, receiving, and administering sponsored grants and awards.

### 4. Definition of Terms

Certain terms are used in this document with specific meanings, as defined in this section. These definitions may not necessarily conform to customary usage.

<b>Basic research</b>	Any original investigation for the advancement of scientific knowledge not having a specific commercial objective. For example, product testing supporting the trade or business of a specific nongovernmental person is not considered basic research.
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<b>Private business use (PBU)</b>	<p>An actual or beneficial use of tax-exempt financed property by any person or organization other than (1) a Section 501(c) (3) organization such as the borrower, or an affiliate, pursuing its exempt purposes or (2) a state or local government.</p> <p>Private business use means:</p> <ul style="list-style-type: none"> <li>• use (directly or indirectly)</li> <li>• of the “facilities” (the facilities financed by, or the proceeds of, a tax-exempt financing)</li> <li>• in a “trade or business” (any activity carried on by a person other than a natural person)</li> <li>• carried on by a “nonqualified user” (any user other than a “qualified user,” as defined above) including: <ul style="list-style-type: none"> <li>○ Corporations, partnerships or any other entity engaged in business</li> <li>○ Federal government and federal government agencies</li> <li>○ Natural persons engaged in a trade or business</li> </ul> </li> </ul>
<b>Qualified user</b>	<p>A state or local governmental unit or, in certain circumstances, a nonprofit, charitable organization described in Section 501(c)(3) of the Internal Revenue Code (a “501(c)(3) Organization”) using Duquesne facilities in furtherance of its tax-exempt purpose, so long as it is not an unrelated trade or business for that entity.</p>
<b>Sponsored Research Agreement (SRA)</b>	<p>A contract between Duquesne and a sponsoring entity for the purposes of funding and conducting research at Duquesne. An SRA may be supported by funding from for-profit (e.g. private industry) or non-profit (state or federal government, foundations, etc.) sponsors.</p>
<b>Sponsoring entity</b>	<p>Any party other than the qualified user that is sponsoring the research.</p>

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**5. Sponsored Research Agreements**

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- Sponsored Research Agreements generally include terms governing areas such as:
- Scope of work to be conducted, including reporting and other deliverables
  - Budget for the research
  - Payment obligations and timing
  - Publication of the research results
  - Options to license the intellectual property arising from the research
  - Care of data and confidential information exchanged during the research
  - Compliance with export control and other laws and regulations
  - Rights and procedures to terminate the project

- Taxes, indemnification, choice of law, and other items necessary for contracts

The Office of Research and Innovation (ORI) is responsible for negotiation of SRAs where any part of the funding in support of the research project is received from a sponsoring entity.

Preliminary discussions regarding proposed sponsored research may begin long before a sponsoring entity is ready to establish a SRA. To officially begin the SRA process, the Principal Investigator (PI)/ Project Director (PD) on the project must first submit a Proposal Approval Form (PAF) to the ORI for review and approval. At a minimum, a proposal must include a statement of work, project budget, and budget justification. Additional information and documents may be requested during the proposal review process. If the sponsoring entity and PI/PD desire to move forward with the proposed project, a draft SRA will be prepared and will incorporate the approved statement of work and budget along with the agreed upon funding amount, payment schedule, and any background intellectual property known to the PIs/Co-PIs.

A sponsoring entity may agree to use either Duquesne's standard SRA (Cost Reimbursable) or Duquesne's standard SRA (Fixed Price). In other instances, the parties may deem it advantageous to develop negotiated key terms. PIs/PDs and potential sponsoring entities may contact the ORI for more information regarding SRAs at Duquesne.

A Research agreement with a sponsoring entity may give rise to private business use except as otherwise discussed below.

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## **6. Private Business Use**

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For SRAs, the IRS has created specific exceptions to private business use via "safe harbors." IRS Revenue Procedure 2007-47, Qualified Research Contracts, sets forth these conditions under which an SRA does not result in private business use. The guidance addresses basic research.

The safe harbors in IRS Revenue Procedure 2007-47 address SRAs with the following sponsoring entities: corporate sponsors, industry sponsors, and federal sponsors as follows:

1. A Sponsored Research Agreement with a corporate sponsoring entity will not create private business use so long as:
  - The activity is basic research;
  - Transfer of any license or other use of resulting technology to the sponsor is priced at fair market value; and
  - Fair market value is determined at the time the technology is available for use, not earlier.
2. A Sponsored Research Agreement with an industry sponsoring entity will not create private business use so long as:

- The University controls the design and performance of the study;
  - The University retains title to any patent or product incidentally resulting from the basic research; and
  - The sponsor receives no more than a nonexclusive royalty-free license (NERF).
3. A Sponsored Research Agreement with a federal sponsoring entity, will not create private business use so long as:
- The University controls the design and performance of the study; and
  - The University retains title to any patent or product incidentally resulting from the basic research; and
  - The sponsor receives no more than a NERF.

If a contract or agreement meets every requirement of a “safe harbor,” it is deemed not to create private business use.

*Note on Corporate vs. Industry Sponsors:* The distinction between a “corporate” and “industry” sponsoring entity is inconsequential as a practical matter as Sponsored Research Agreements generally can qualify under either safe harbor described above. Most corporate sponsoring entities may prefer to qualify under the first, because it provides them with greater control over the product of the research.

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## **7. The Bayh-Dole Act**

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The Bayh-Dole Act (The Patent and Trademark Law Amendments Act of 1980, as amended, 35 U.S.C. § 200 et seq. (2006)) generally applies to any contract, grant, or cooperative agreement with any federal agency for the performance of research funded by the federal government. The policies and objectives of the Bayh-Dole Act include promoting the utilization of inventions arising from and encouraging maximum participation of small business firms in federally supported research and development efforts, promoting collaboration between commercial concerns and nonprofit organizations and ensuring that such inventions are used in a manner to promote free competition and enterprise, and promoting the commercialization and public availability of inventions made in the United States by United States industry and labor.

Section 6.04 under IRS Revenue Procedure 2007-47 specifies that the rights of the federal government and its agencies mandated by the Bayh-Dole Act will not cause a research activity to result in private use, even though some federal government’s rights under the Bayh-Dole Act do not meet the safe harbor conditions for research agreements with a federal sponsor listed above.

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## **8. Clinical Trials**

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Clinical trials are generally not considered research activities since they are typically conducted in furtherance of patient care or to validate products, not the invention of products. Clinical trials will not create private business use so long as:

1. Clinical trials are performed on members of the general patient population (either patients that would always independently be treated or new patients brought in for the trial);
2. Clinical trials are performed at facilities that serve the general patient population;
3. Clinical trials are related to patient care and treatment
4. The University is paid an objective fee for performing the trials according to the protocols previously developed by the sponsor;
5. All of the data that is collected is given to the sponsor, except for records of the type normally retained by the University for non-clinical trial patients;
6. The clinical trial is not undertaken for the purposes of discovering patentable inventions or technology and the possibility of such a discovery is remote;
7. The University retains the right to publish the results of the clinical trial;
8. The sponsor does not dictate or control bond financed property; and
9. The sponsor has no right to be physically present in bond financed property.

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## **9. Procedure for Approval of Private Business Use**

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Under Duquesne policy, no new PBU may be conducted unless the same is first determined to be exempt from the requirement to obtain approval or approved in accordance with this Research Policy. A new PBU will be approved if there is a compelling reason to do so that somehow advances an important University objective that cannot be met without incremental PBU, and does not exceed the allowable IRS-mandated levels of threshold for private business. For this purpose, the fact that the proposed activity will generate revenue will not in itself be considered compelling, even if the revenue will in turn support a Duquesne objective. In no event will a transaction be approved if doing so will cause Duquesne to exceed the applicable limits on private use.

The following is a list of exceptions from the requirement to obtain approval for a particular activity.

1. Activities that are deemed to be “basic research.” Basic research means any original investigation for the advancement of scientific knowledge not having a specific commercial objective.
2. Activities that may not be deemed “basic research” but falling under the Bayh-Dole Act.
3. Activities where the user is a “qualified user” as defined above.
4. Activities that are private use but which qualify under one of the regulatory safe harbors described herein.

In order to seek approval, the involved Duquesne department is required to prepare and submit a memo for approval to the Associate Provost for Regulatory Affairs and Applied Innovation which identifies and describes the PI/PD, project title, purpose of research, commercial objective (if any), location of research, budget, time period, and sponsoring entity.

Following a review of the memo by the Associated Provost for Regulatory Affairs and Applied

Innovation, including an investigation and analysis, the memo is forwarded for approval by the Dean of the school in which the PI/PD is located. If approved by the Dean, the memo is forwarded for approval by the Bond Compliance Committee. Finally, if approved by the Bond Compliance Committee, the memo is forwarded for approval by the Vice Provost for Research for final approval.

Under the tax code there are broad record retention requirements applicable to documentation evidencing use of facilities financed with tax-exempt debt (e.g., copies of management contracts, research agreements, etc.). Applicable records must generally be retained for the life of the debt plus three years, including any refinancing.

**10. Exceptions**

Exceptions to this Research policy and procedures require approval from the Vice Provost for Research and normally will be made with the agreement of those involved in the Bond Compliance Committee and the administrators having supervisory responsibility for the employee.

**11. Related Documents**

This Research Policy works in conjunction with the following Research and University Policies, which are fully applicable. To the extent there is any conflict between this Research Policy and any of the Research or University Policies listed below, the University retains the sole discretion to determine which takes precedent.

<b>Research Policy</b>	<b>Title</b>	<b>Web Address</b>
RP-1	Procedure for Submitting External Sponsored Grants and Awards	<a href="https://www.duq.edu/research/research-conduct">https://www.duq.edu/research/research-conduct</a>
RP-2	The Use of Human Subjects in Research	<a href="https://www.duq.edu/research/research-conduct">https://www.duq.edu/research/research-conduct</a>
RP-3	Effort Reporting on Sponsored Grants and Awards	<a href="https://www.duq.edu/research/research-conduct">https://www.duq.edu/research/research-conduct</a>
RP-4	Faculty Research Proposals to Governmental, Corporate, Foundation and Private Sources	<a href="https://www.duq.edu/research/research-conduct">https://www.duq.edu/research/research-conduct</a>
RP-5	Intellectual Property	<a href="https://www.duq.edu/research/research-conduct">https://www.duq.edu/research/research-conduct</a>
RP-6	Research Integrity	<a href="https://www.duq.edu/research/research-conduct">https://www.duq.edu/research/research-conduct</a>
RP-7	Conflicts of Interest in Sponsored Grants and Awards	<a href="https://www.duq.edu/research/research-conduct">https://www.duq.edu/research/research-conduct</a>

TAP-33	Conflict of Interest	<a href="https://www.duq.edu/work-at-du/human-resources-home/the-administrative-policies-(taps)/33-conflict-of-interest">https://www.duq.edu/work-at-du/human-resources-home/the-administrative-policies-(taps)/33-conflict-of-interest</a>
TAP-46	Commercial Entities—Faculty, Staff and Student Participation	<a href="https://www.duq.edu/work-at-du/human-resources-home/the-administrative-policies-(taps)/46-commercial-entities%E2%80%94faculty-staff-and-student-participation">https://www.duq.edu/work-at-du/human-resources-home/the-administrative-policies-(taps)/46-commercial-entities%E2%80%94faculty-staff-and-student-participation</a>

**12. Contacts**

Office	Telephone Number	Email Address and/or URL
Office of Research and Innovation	412-396-6326	duq.edu/research ORI@duq.edu

Web Address for this Research Policy: <https://www.duq.edu/research/research-conduct>

**13. Effective Date and Revision History**

This Research Policy is subject to periodic review and update by the Office of the Provost and the Vice Provost for Research.

Effective 11/7/2022