R2B Contracts: Complexities And Considerations When Contracting With Universities And Other Not-For-Profit Research Organisations

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Abstract

1. *Universities, research institutes, hospitals, U.S. federal labs, and other research-practicing entities (together, RPEs) are increasingly entering into contracts with commercial enterprises, for funding of research, licensing of intellectual property, and other forms of collaboration.*
2. *RPEs' primary purpose is to generate and disseminate knowledge (and in some cases, to teach), and their staff may be evaluated on the quality and number of their publications. They may also be required by law and by public funding terms to act in the public interest, rather than to support the private interests of commercial enterprises.*
3. *RPEs may need to involve multiple internal stakeholders in any decision to contract with a commercial business.*
4. *The mismatch of priorities and decision-making processes between RPEs and industry can be a source of frustration for both parties, both in the negotiation and in the performance of contracts. Those frustrations can be mitigated if each party takes the time required to understand what the other wants and needs from any collaboration.*
5. *This article describes some of the legal and cultural features and constraints that RPEs face when entering into and performing contracts with the industry.*

Introduction

Universities, research institutes, hospitals, U.S. federal labs, and other non-profit research practicing entities (together, RPEs) are increasingly entering into contracts with commercial enterprises, for funding of research, licensing of intellectual property, and other forms of collaboration.

This article considers the different expectations of RPEs and commercial enterprises when entering into such contracts, with particular reference to RPEs based in the UK and the U.S.A. Collectively, the UK and U.S.A. represent a significant percentage of the world's interactions between RPEs and industry. Although the approaches of RPEs in the UK and the U.S.A. may differ

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in their details, there are some underlying similarities, based on legal requirements, academic priorities, and institutional cultures. By highlighting some of those similarities and differences, the authors hope to shed light on why negotiations between RPEs and industry can sometimes be frustrating for all concerned, and how their differences of approach can be reconciled.[1]

There are many types of contracts between RPEs and commercial companies, including those mentioned above. Most of the issues discussed in this article apply to most of these types of contracts.

When commercial entities enter into contracts with each other (B2B contracts), the parties may have different objectives and have different levels of bargaining power, but they typically have the same fundamental motivation: a good commercial deal that ultimately helps to generate profits for their shareholders. There is often a common commercial language among the parties, and a common approach to business, both of which help the parties to strike (or not strike) their B2B deal.

When RPEs enter into contracts with each other (R2R contracts), there is likewise often a common set of motivations, but they are different from those of commercial entities. In place of the profit motive, the parties' priorities may be academic excellence and reputation, knowledge generation and dissemination, acting for the public benefit, prudent use of public resources, including avoiding legal risk, and (last but not least) the funding of these priorities through government grants, corporate sponsorships, and philanthropic donations. There is also a common understanding that RPE contracts departments are sometimes significantly under-resourced, which can result in very considerable delays in contract negotiations, particularly where several RPEs are negotiating a multi-party contract.

Part of the focus of the R2R contract may be compliance with the terms of a public or charitable funder of the research. The RPEs may be unlikely to enforce their contractual rights against each other through court action, in view of the financial and reputational risks involved. As a result, some of the template agreements that are used for R2R contracts[2] tend to be more "light touch" than many B2B contracts. Even so, at least in the U.S., gaining consensus among academic institutions on template agreements has been extremely difficult, as exemplified by the National Institutes of Health (NIH) attempt to shepherd institutions toward agreement on common forms of a materials transfer agreement (MTA). While templates such as the Uniform Biological Material Transfer Agreement (UBMTA) and the Simple Letter Agreement (SLA) were eventually produced, they are not as commonly used as envisioned, even among NIH-funded institutions.[3]

In recent years, there has been a significant increase in the number of contracts between RPEs and industry (R2B contracts), as government grants for research have decreased in some fields, and academics have looked for new sources of funding. The trend is not entirely driven by RPE pressures. Some commercial entities increasingly rely on RPEs as outsourced providers of R&D services. In addition, government funding sources have increased their emphasis on making economic, innovation, and societal impacts from the outputs of research.[4] To this end, government agencies have enhanced training, funding, and expectations for translational, entrepreneurial, and commercial development activities.[5] The parties to R2B contracts likely have different fundamental objectives, as described above. They need contracts that are tailored to their differing institutional priorities, rather than standard B2B or R2R contracts.

R2B contracts tend to require more negotiation than either R2R contracts or the funding terms of government agencies. R2B contracts also require greater communication and relationship management while in force and beyond to ensure compliance as they often include responsibilities that are unfamiliar to key personnel. For many RPEs, R2B contracts may still be the exception rather than the rule: a majority of RPE research funding still comes from non-commercial sources such as charities, particularly at the earlier research stages, despite the huge growth in commercial funding in recent years. The contract negotiation departments of RPEs have become more experienced in dealing with R2B contracts, but their capacity has not always kept up with the growth in demand for their services.[6] This lack of capacity has sometimes resulted in negotiations that take too long, the recruitment of negotiators who are not used to working with industry, insufficient explanation of RPE priorities, and frustrations on the part

1. The complex contractual requirements of European Union research funding, and the terms of associated "consortium agreements" are considered to be beyond the scope of this article.

2. E.g., in the UK, the so-called Brunswick collaboration agreements are commonly used. See *https://arma.ac.uk/updated-brunswick-agreements/*.

3. See Jorge L. Contreras and Liane Hancock, "Consensus Templates," *Case Western Univ. L. Rev.* (2025), (describing NIH's MTA standardization effort).

4. See for example, the drive in the UK for research impact through the Research Excellence Framework (*https://www.ukri.org/who-we-are/research-england/research-excellence/ref-impact/*) and for UKRI funding schemes: *https://www.ukri.org/what-we-do/delivering-economic-impact/*.

5. UK Research and Innovation, 'UKRI strategy 2022-2027: transforming tomorrow together' priority 4.2 *https://www.ukri.org/publications/ukri-strategy-2022-to-2027/* also U.S. National Science Foundation 2022-2026 Strategic Plan, pg 39 *https://new.nsf.gov/about/performance/strategic-plan*.

6. The authors have heard, anecdotally, of increases in the workload of RPE contracts departments, in recent years, in the region of 30 to 40 percent.

of academics as well as funders about the RPE's contracting process.

An illustration of RPE priorities can be seen in a definition of "sponsored research," which has been set by Research England and the UK Charity Commission. Many UK universities use this definition to test whether the terms of a research contract support the university's charitable objectives.[7] If the research does not support the charitable objectives, it may either be impermissible (and, if conducted by the university as a research contract, prejudice the university's charitable status) or needs to be conducted in a different way, *e.g.*, as private consultancy in the name of the academic rather than the university, or through a subsidiary company of the university. A core component of this definition is that the research should meet the so-called Frascati definition of research.[8] To quote the UCL website,[9] the research should meet the following criteria, among others:

The project needs to meet the Frascati Definition of Research, *i.e.*, creative work undertaken on a systematic basis to increase the stock of knowledge, including knowledge of man, culture, and society, and the use of this stock of knowledge to devise new applications. It should be:

- Novel—aimed at new findings
- Creative—based on original, not obvious, concepts and hypotheses
- Uncertain—about the final outcome
- Systematic—planned and budgeted
- Transferable—leads to results that can be reproduced.

Funding terms should support publication within a reasonable timeframe and allow results to be used for academic purposes.

Public benefit should not be incidental (*i.e.*, the benefit to the funder or collaborator, if not a public body, should not significantly outweigh the benefit to the public).

Readers will note that the above wording focuses on several points that might not be obvious to a commercial enterprise whose main experience of research contracts is with commercial suppliers, including:

1. Novel research with no guarantee of results.
2. Rights for the university to publish and use the results for academic purposes.
3. Public benefit should be a significant element, rather than just private benefit to the company.

Some attempts have been made to create standard templates for R2B contracts that address the above issues, and which would reduce the time taken in negotiations; but the uptake of these templates varies between sectors.[10,11] Where they are used, there is often still some negotiation of terms as parties prepare drafts that are "based on" the template, rather than accept the template, as is.[12] There are similar expectations also from U.S. federal labs for R2B type contracts embodied in the Cooperative Research and Development Agreement (CRADA) that was established for use under the Federal Technology Transfer Act (FTTA) of 1986.

A further issue is that RPEs' expectations may differ between jurisdictions and types of RPE entities, and this can present challenges in negotiations based on a template designed for a particular entity or jurisdiction. By way of examples, there may be different expectations in relation to compliance with charity laws, data privacy laws, government sanctions, and contract law and jurisdiction.[13] Some of these topics are discussed further, below.

7. For example, see the definition that appears on the University College London website at *https://www.ucl.ac.uk/research-innovation-services/award-services/applying-funding/first-steps/what-sponsored-research*.

8. This is an international definition, but its use by universities seems to be found mainly in the UK, and to a lesser extent in other European countries. It does not seem to be commonly used in the U.S.A. See the Frascati Manual at *https://www.oecd.org/en/publications/2015/10/frascati-manual-2015_g1g57dcb.html*.

9. *https://www.ucl.ac.uk/research-innovation-services/award-services/applying-funding/first-steps/what-sponsored-research*.

10. For example, in the UK see the Lambert research collaboration agreements, which were originally negotiated between universities and industry to try to address a complaint from industry representatives that universities were too slow in negotiating contracts and took an unreasonable approach to IP terms. See *https://www.gov.uk/guidance/model-agreements-for-collaborative-research*.

11. For example, in Ireland, see the model agreements for use between universities and industry at *https://www.knowledgetransferireland.com/Model-Agreements/Catalogue-of-Model-Agreements/*. One of the authors of this article (Mark Anderson) was involved in creating most of these templates. There is no direct equivalent set of template documents for use by universities in the U.S., though see later comments about the use of CRADAs in U.S. government labs.

12. The original intention of the authors of the Lambert agreements was that the parties would negotiate which of the Lambert agreements was most appropriate for their circumstances, using a decision tree, but would not negotiate the wording of the chosen template agreement. However, in practice, this very rarely happens, as one or more of the parties seek to negotiate specific wording. See further *https://www.gov.uk/government/publications/university-and-business-collaboration-agreements-decision-guide*.

13. To take one example, contract wording that asks a UK RPE to certify that it understands and complies with U.S. laws in areas such as foreign corrupt practices or export controls, or that it meets the U.S. definition of a charity, may be very difficult for a UK RPE (having neither the budget nor the inclination to obtain U.S. legal advice) to accept, though the U.S. entity may regard such obligations as standard.

Sometimes, the corporate partner will refuse to accept an R2B template and instead produce a draft agreement that is more suited to a commercial supplier than an RPE, and which contains terms that are difficult for the RPE to accept, such as:

- Services focused on (private) product development, and not meeting the Frascati definition
- Company to own resulting IP
- No RPE control over the company's use of that IP
- No payments for that IP to the RPE
- Automatic free licence to RPE's background IP
- RPE to guarantee that licensed IP doesn't infringe third-party rights
- Company veto over RPE publications (or a very long delay in publication)
- Company veto over RPE use of results for academic purposes
- Unlimited liability of the RPE

It can take time for the RPE to explain to the company why some or all of these terms are not acceptable, or in some cases are forbidden by law, and suggest alternative strategies where possible. For example, in the case of U.S. federal labs, often terms proposed by corporate partners are prohibited by statute or in conflict with institutional policy.

A further difficulty in R2B negotiations is that RPEs sometimes have opaque decision-making processes, which make it difficult to react quickly and clearly when terms are proposed that are outside the "comfort zone" of the RPE. Contract negotiations are typically led by a contracts department, rather than the academic department that is to perform the research. For various reasons, there may be insufficient communication between the two departments, and sometimes the academic may feel that they have not been sufficiently involved or consulted.[14] This may lead to internal conflict within the RPE and mixed messages to the external party.

To overgeneralise, the contracts department may find the company's terms unacceptable, but the academic just wants the deal to be done, and senior RPE management may lack the commercial experience to know whether to support their contracts department's objections, in the face of lobbying from the academic, and the perception of turning away a golden opportunity. If the risk to the organisation depends on the subtleties of contract language, it may be difficult for non-specialists to assess the (legal) meaning of a clause. It can take time to resolve these internal disagreements, particularly as the culture of RPEs may incline more towards debate and reaching a consensus, in contrast to the more hierarchical decision-making process of many companies.

14. On other occasions, the academic may be irritated by being asked to be involved in the contracting process.

Different Priorities of RPEs and Commercial Enterprises

It may be argued that every deal and contract party is different, but experience suggests that there are some commonly encountered themes when looking at the parties' priorities in R2B contracts.

Table 1 on page 145 highlights some areas where the parties' priorities may differ—not in all cases, but in some.

Sources of RPE Priorities: Legal Framework

Some of an RPE's priorities are based on legal requirements, which will vary depending on the jurisdiction in which the RPE is established, and the type of RPE.

In the UK and the U.S.A., universities are subject to a range of laws that may affect the terms of their R2B contracts, including the following:

1. **Charter Documents**. Most of the older, research-intensive universities in the UK are incorporated by Royal Charter. This is an ancient method of incorporation that pre-dates modern company law and is mostly used for non-commercial organisations, *e.g.*, universities and bodies representing professions. The constitutional documents of a university typically consist of the Royal Charter, and a set of statutes and other documents, variously described as ordinances, by-laws, and regulations.

   In the U.S., universities are typically organized as non-profit corporations with independent boards of trustees or governors (so-called private universities like Harvard, MIT, and Caltech) or state government entities, which may also have non-profit status (state universities such as the University of Michigan, the University of Texas at Austin and the University of California (with campuses at Berkeley, Los Angeles, Davis, Irvine, San Francisco and elsewhere)). A number of prominent U.S. research universities also have religious affiliations, including Notre Dame and Georgetown (Catholic), Baylor (Baptist), Yeshiva (Jewish), and Brigham Young (Mormon). Finally, the five U.S. military academies (*e.g.*, at West Point, Annapolis, etc.) and over 300 U.S. federal research laboratories are federal government entities. Major hospitals and non-profit research institutions that do not have teaching missions are structured as non-profit entities in both the U.S. (*e.g.*, Howard Hughes Medical Institute, the Broad Institute, Massachusetts General, the Dana Farber Cancer Institute, and the Mayo Clinic) and the UK (*e.g.*, most hospitals are non-profit "NHS trusts" while funders such as the Wellcome Trust

Table 1: Priorities In R2B Contracts

RPE Objective	Business Objective	Examples of Negotiated Deals
Funding support for research that is focused on academic inquiry	Outsourced (commercially-focused) R&D activity	Written research programmes that seek to preserve academic priorities (*e.g.*, publications, discussed below), while focusing on the company's areas of interest
Use the funding to help pay for the research, and see where that research leads	Predictable, commercially useful results	Commitment to undertake an agreed research project, but no guarantee of results. Where more commercial focus is required by the business, consider other routes, *e.g.*, private consultancy with academics or for the corporate partner to use a Contract Research Organization (CRO) instead
Funding to support PhD students or post-doctoral fellows during their research	Outsourced (commercially-focused) R&D activity	Funding terms that enable students or fellows to pursue academically focused research projects that can lead to the award of a degree
Ability to write up results in PhD thesis (public document)	Obtain results to support the sponsor's commercial R&D activities. Protect results from competitors, through patenting and/or keeping the results secret.	No control over the content of PhD thesis but agree to keep it in a confidential section of the university library for a limited period (1-3 years)
Publish research results in journal articles, to advance academic knowledge and support the academic's career Disseminate the results to the world	Obtain results to support the sponsor's commercial R&D activities. Protect results from competitors, through patenting and/or keeping the results secret	Review of proposed publications, with the right for a sponsor to require: (a) Limited delay to publications to allow patent filing (*e.g.*, 3 months) (b) Removal of the sponsor's pre-existing confidential information If total or longer confidentiality of results is required, find an alternative route, *e.g.*, a private consultancy agreement with an academic, or instead use a CRO for this work
Ensure the application of the fundamental research exclusion to comply with U.S. export control laws More generally, avoid legal and regulatory risk, *e.g.*, deciding to consult with the UK government over compliance with National Security and Investment Act 2021	Avoid breach of export control laws and pass responsibility to service providers. Avoid government intervention in research contracts on national security grounds	Sometimes, the differences in approach between RPE and the company cannot be resolved U.S. federal laboratories are permitted to work with non-U.S. corporate entities but projects with those entities located in "countries of concern" require more extensive review and clearances
Ownership of valuable IP to ensure (a) control (see below) and (b) share of revenue	Ownership of valuable IP to ensure (a) control (see below), (b) protection from competition, and (c) financial asset that can be licensed or sold to maximise profits	Exclusive licence to sponsor (or option to acquire a licence) Sometimes, licence is converted to an assignment once milestones are met For CRADAs, U.S. federal laboratories provide options for exclusive licenses to subject inventions in advance without competition. CRADAs are the only means for providing such incentives for collaboration

Table 1, Continued on page 146

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Control of valuable IP to ensure it is used for the public benefit	**Control of valuable IP to ensure it is of commercial benefit to the sponsor and not available to competitors**	**Detailed commercialization terms (see below) to enable the sponsor to bring products to market for the public benefit, but prevent the sponsor from "sitting on" IP, including performance obligations, and termination of licence in appropriate circumstances**
Revenue sharing to ensure financial benefit/incentive to academics and no "state aid" or use of public resources to provide a private benefit	**Minimise financial obligations**	**Negotiated licence terms that include fees, royalties, and sometimes equity in the sponsor or a liquidity event fee**
Minimise financial commitments, *e.g.*, patent costs	**Allocate financial costs between the parties**	**Patenting costs are to be borne by the sponsor**
Minimise commercial risk, bearing in mind (a) use of public resources, and (b) RPE unlikely to have done FTO searches	**Allocate commercial risk between the parties**	**Knowledge-based warranties or representations, caps on liability, no indemnities given by RPE, sometimes indemnities given by sponsor (*e.g.*, product liability)**

Limited and LifeArc[15] are "companies limited by guarantee").

In both the UK and the U.S., an institution's charter documents typically include a statement of the purpose of the institution (*e.g.*, education and teaching for a university, or the promotion of health for a hospital or non-profit research institution)[16] and internal rules on issues such as who may sign contracts and apply the organisation's seal. In the authors' experience, engagement with industry is rarely, if ever, explicitly stated as one of the objects, perhaps reflecting the fact that such engagement was, at the time most universities were created, very much secondary to research and teaching in the university's priorities.[17] More recent international initiatives on the roles and responsibilities of higher education institutions, such as the Talloires Declaration on the Civic Roles and Social Responsibilities of Higher Education, also do not expressly acknowledge engagement with industry as a means to achieve those ends.[18]

The charters of many U.S. state universities are directed toward the betterment of the economy, health, and quality of life in the state. Hospitals typically have purposes directed toward public health. The U.S. military academies and federal laboratories have purposes supportive of the federal government and the mission of the federal agency to which they belong along with supporting U.S. manufacturing and economic development. Universities with religious affiliations often express goals that are supportive of, or at least consistent with, those of the relevant church.

2. **Charitable Status.** Most UK and U.S. universities are charities or tax-exempt not-for-profit entities. As such, they must act in accordance with their charitable objectives, as set out in their constitutional documents, as described above. They must also comply with applicable tax and charity law, including acting for the public benefit. They would be well-advised to follow guidance on compliance with their legal obligations from relevant regulators. For example, the UK Charity Commission has issued detailed guidance on points that university trustees (or their delegated staff) must consider when deciding whether certain com-

15. As a company limited by guarantee, its company name would otherwise be LifeArc Limited, but UK law allows it to omit the word "Limited" from its title as (in simple summary) it is set up as a non-profit body.

16. For example, the University College London charter states: "The objects of the University shall be to provide education and courses of study in the fields of Arts, Laws, Pure Sciences, Medicine and Medical Sciences, Social Sciences, and Applied Sciences and in such other fields of learning as may from time to time be decided upon by the University and to encourage research in the said branches of knowledge and learning and to organise, encourage and stimulate postgraduate study in such branches." See *https://www.ucl.ac.uk/governance-compliance/sites/governance_compliance/files/charter.pdf* (last checked 10/10/24). By contrast, the University of Leicester charter states "The University shall be both a teaching and an examining body…" and then lists its detailed powers in subsequent numbered paragraphs. See *https://le.ac.uk/about/who-we-are/governance/documents/charter* (last checked 10/10/24).

17. David Watson, "The University in the Modern World: Ten Lessons of Civic and Community Engagement" (2008) 3(1) *Education, Citizenship and Social Justice* 43-55.

18. Talloires Network of Engaged Universities, 'Talloires Declaration' (2005). *https://talloiresnetwork.tufts.edu/who-we-are/talloires-declaration/?c=7* (accessed 14 December 2024).

mercial activities (*e.g.*, a commercially funded research project) are aligned with the university's charitable objectives.[19] Of particular interest in the UK are the following bullet points from the Charity Commission's guidance:

- Research must be in a subject, or be directed towards establishing an outcome, that is of value and calculated to promote in a meaningful and direct way the particular charitable aims indicated in the body's objects (typically to advance or enhance knowledge and understanding in an area which education may cover for the public benefit).
- Research must be undertaken with the intention that the useful knowledge acquired from the research will be disseminated (and so advance the particular charitable aims) to the public and others able to utilise or benefit from it.
- Research must be justified and undertaken for the public benefit and not solely or mainly for self-interest or for private or commercial consumption.[20]

3. **Tax Exemptions.** Where a university acts in accordance with its charitable purposes, it will largely be exempt from corporate tax that would otherwise be due on its "profits." In the UK, the tax exemption is potentially at risk if the university provides research services to a commercial company that does not comply with the Charity Commission guidelines mentioned above.[21] In the U.S., an important factor in determining restrictions on an RPE's activities is whether the activities will take place in a building funded by tax-exempt bonds.[22] Use of such buildings for activities that are unrelated to the RPE's trade or business (as described in the Charitable Status section) or licensing of intellectual property on terms that are not arms-length (what would be available to any third party) or on terms defined prior to the time the technology has been created may forfeit the tax exemption of the RPE's bonds.[23] U.S. federal laboratories, as part of various U.S. government agencies, have tax-exempt status in the U.S. and similar status as well in other countries as a result of tax treaties.

4. **Public Authorities**. UK universities are public authorities,[24] as noted above, many U.S. universities are state government entities. As such, they are bound by various laws applicable to public entities, *e.g.*, the UK Subsidy Control Act 2022 and various "freedom of information" laws at the national and state levels. The UK Subsidy Control Act is similar in principle to the State Aid rules applicable within the European Union. It prevents a public authority from giving a financial subsidy to a private company, *e.g.*, by undercharging for goods or services, including the assignment or licensing of university-owned intellectual property (IP). Subsidy control laws or State Aid rules are often cited by European universities as a reason why any assignment or licensing of IP to a private company must be on commercial terms. Where the IP in question arises from a research contract with a commercial company, the university will typically require separate payments for the IP and reject the argument that the price for the research includes an element covering the purchase or licensing of the IP.
5. **The Bayh-Dole Act**. In the U.S., the Bayh-Dole Act of 1980[25] applies to all research by non-profit institutions that are funded, in whole or in part, by the federal government. Similarly, the Stevenson-Wydler Act of 1980 and the Federal Technology Transfer Act of 1986 apply to research conducted directly by the U.S. federal laboratories themselves. Given that federal agencies such as the National Institutes of Health and the National Science Foundation fund upwards of $90 billion per year in non-defense R&D,[26] most scientific research in U.S. academic institutions has some degree of federal support. The Bayh-Dole Act is complex and has numerous provisions, requirements, and restrictions,[27] but among those most relevant to R2B agreements are the following:
   - The institution may not transfer patents on inventions that are based on federally funded research (meaning that patents on research results, even if largely funded by a corporate sponsor, will be retained by the university and licensed to the corporation).

19. Charity Commission guidance, Research by Higher Education Institutions 2009.

20. See section C2 of Charity Commission guidance above.

21. See further, Part 10 of the Income Tax Act 2007 and Part 11 of the Corporation Tax Act 2010.

22. *https://uidp.org/wp-content/uploads/2022/01/Tax-Exempt-Bonds-and-Their-Impact-on-Industry-Sponsored-Research-Agreements.pdf.*

23. *https://www.cogr.edu/sites/default/files/University-Industry_Relations_brochure.pdf.*

24. See, for example, paragraph 53 of Schedule 1 of the Freedom of Information Act 2000.

25. 35 USC. §§ 200 *et seq.*

26. See AAAS, House FY 2025 R&D Appropriations (Jul. 22, 2024), *https://www.aaas.org/sites/default/files/2024-07/House%20Recap%202025_1.pdf.*

27. For a more detailed discussion, see Jorge L. Contreras, "Intellectual Property Licensing And Transactions: Theory And Practice," 424-39 (*Cambridge Univ. Press*, 2022).

- There is a preference for U.S. manufacturing of products based on federally funded research unless a waiver is granted.
- The government retains the right to use federally funded inventions for governmental purposes. This government use license is for any governmental purpose but would typically be used for conducting further research.
- Though the institution may grant a private company an exclusive license to exploit a patent covering federally funded technology, the government has the right (so far never exercised) to "march in" to authorize additional licensees if needed to support public needs in the U.S.

6. **Export Controls**. National governments have an interest in preventing the sharing of information about sensitive technologies with persons and entities of other countries. Export controls are laws and regulations implemented to avoid such dissemination, and many countries, including the U.S. and the UK, have export control laws. In the U.S. RPEs generally are exempt from such controls, because they qualify for what in the U.S. is called a fundamental research exemption (FRE).[28] The FRE is predicated on the fact that the research is 1) basic and applied research, 2) the results are intended to be published, 3) publication is not subject to approval by a sponsor, and 4) the research team has no citizenship-based restrictions for who may contribute.[29] While many RPE contracting officers are familiar with how contracts with businesses need to be carefully negotiated with regard to maintaining the FRE, many businesses and researchers may be less familiar with those requirements. Businesses generally have export-controlled information that they avoid publishing and exporting. Conversely, RPE researchers often only have experience performing fundamental research intended for publishing. The impact on R2B contracts is that sponsors may feel uncomfortable with the RPE's understandable insistence on limiting sponsor review of publication for the protection of a company's background confidential information.
7. **National Security and Sanctions**. Other laws affect the ability of RPEs to enter into contracts with corporate partners. For example, in the UK, the National Security and Investment Act 2021 gives the government certain powers to prohibit transactions, which it has exercised in relation to the licensing of university technology to a Chinese company.[30] Similarly, for U.S. federal laboratories there are additional reviews and clearances necessary in order for agreements with partners in "countries of concern."[31]

The legal framework for other types of RPEs may be different from that for universities. For example, many hospitals in the UK are established by legislation as "NHS trusts," while some research institutes are established as "companies limited by guarantee." Despite differences in detail, they are usually closer in outlook to a university than to a commercial company. The same applies to U.S. non-university RPEs. U.S. federal laboratories are considered to be part of the U.S. federal government (unless contractor-operated), but certain authorities relevant to research operations and contracts are delegated down to the individual agency or laboratory.

Contracting Practices and Limitations

In addition to the above-mentioned legal frameworks, RPEs are subject to a range of contractual and cultural obligations and expectations, which are non-commercial in character, and which can significantly influence the terms of R2B agreements. These include:

1. **Government Funding Terms**. Government funding terms may be relevant, for example, if a project is part-funded or conducted by a government agency, and part-funded by a commercial company. The funding of some PhD studentships falls into this category. The company may have to live with funding terms set by the government agency. As the company is only part-funding the project, its bargaining strength may be reduced.
2. **Full Economic Costing**. Since 2005, all UK universities have had to adopt Full Economic Costing (FEC) as their costing model. FEC is defined as the "price, which, if recovered across an organisation's full programme, would recover the total cost (direct, indirect and total overhead) including an adequate investment in the organisation's infrastructure."[32] Typically, this costing model increased the prices that universities were required to charge commercial companies for research projects. Where FEC is achieved in a particular case may depend partly on how

28. *https://research.columbia.edu/sites/default/files/content/RCT%20content/Export%20Controls/COGR_Export_Controls.pdf.*

29. *https://exportcontrol.lbl.gov/research-technology/fundamental-research-exclusion-exemption/*.

30. *https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1092802/aquisition-scamp5-scamp7-know-how-final-order-notice-20220720.pdf.*

31. See *https://ofac.treasury.gov/* (last accessed 15/12/24).

32. See further, the TRAC pages of the Office for Students website at *https://www.trac.ac.uk/about/* (last accessed 10/10/24).

robust the university's costing procedures are, and how aggressive the company is in pricing negotiations. Where a university obtains FEC plus a surplus, it may be more inclined to accept disadvantageous IP terms in a research contract. In the U.S., universities negotiate their overhead percentages with the government. If the universities provide a lower overhead to commercial sponsors, they may jeopardize the rate they get from the government for the bulk of their funding.[33] As U.S. federal laboratories have their operations directly funded by the U.S. Congress in an annual appropriation, their standard overhead rate for conducting collaborative research would be zero.

3. **National Research Assessment Exercises**. Every few years, UK universities must make submissions to an external body that assesses the quality of their research, knowledge exchange, or other activities.[34] The results of such assessments provide performance metrics and feed into league tables that are of major importance to universities, their departments, and individual academics. The criteria for such assessments, therefore, affect how universities go about conducting research and other activities. These different assessment frameworks can, however, sometimes create competing priorities. For example, the Knowledge Exchange Framework (KEF) encourages universities to collaborate with industry and to commercialise research, while the Research Excellence Framework (REF) focuses on evaluating research quality through peer-reviewed academic publications. This dichotomy typically applies to commercially sponsored research as well as government-sponsored research, creating some tensions—RPEs would wish to secure publication rights in research contracts, even when working with commercial partners.
4. **Career Development**. Linked to the previous point, individual academics are nowadays judged on the quality of their research, the quality and number of their publications, and the impact of their research beyond publication, *i.e.*, knowledge exchange, license, spin-out; this affects the terms that universities will seek in their research contracts. Some university and U.S. federal laboratory policies directly or indirectly consider this translational aspect alongside the traditional as part of the promotion criteria. In some disciplines and sectors, research quality may be found in collaborations with industry. For example, the authors have found that some academic engineering disciplines typically involve close collaboration with industry. In some cases, this interdependency may result in more favourable contract terms for the commercial partner, with improved access to resources and expertise for the academic partner.
5. **Public-oriented Policies**. In the mid-2000s, U.S. and UK institutions began to review their technology transfer and licensing practices and policies in light of both their charitable and educational missions. One result of this introspection was the development of a consensus document known as the *Nine Points to Consider in Licensing University Technology*.[35] The *Nine Points* document, which has been signed by nearly 200 research institutions around the world,[36] sets out nine areas that universities have been particularly attuned to in their technology transfer policies. These range from export controls and retention of educational rights to making the products of university technology available to underserved populations around the globe. While there is not much evidence that the Nine Points or similar university pledges with respect to improved access to health-related technologies have had a significant impact on university licensing practices, some universities have taken these commitments to heart and have insisted on access and pricing commitments for licensed products, particularly for underserved markets.[37] Likewise, some non-profit research institutions have adopted "ethical licensing" policies that mandate limitations on the activities that licensees may undertake using university technology.[38] Similarly, "equitable access" and other public benefit provisions are being considered or

33. Association of American Universities and Association of Public and Land-grant Universities, Frequently Asked Questions (FAQs) about the Indirect Costs of Federally Sponsored Research prepared in 2013, *https://www.aau.edu/sites/default/files/AAU%20Files/Key%20Issues/Research%20Administration%20&%20Regulation/FAQs-on-Indirect-Costs-of-Federally-Sponsored-Research.pdf* (last accessed 12/17/24).

34. For example, see the results of the Research Excellence Framework 2021 at *https://results2021.ref.ac.uk/* (last accessed 10/10/24).

35. AUTM, Nine Points to Consider in Licensing University Technology (Mar. 7, 2007), *https://www.autm.net/AUTM-Main/media/Advocacy/Documents/Points_to_Consider.pdf*.

36. AUTM, Nine Points to Consider in Licensing University Technology—Signatories, *https://autm.net/about-tech-transfer/principles-and-guidelines/nine-points-to-consider-when-licensing-university* (visited Nov. 27, 2024).

37. See Jorge L. Contreras, "In The Public Interest"—University Technology Transfer And The Nine Points Document—An Empirical Assessment," 13 U.C. *Irvine L. REV.* 435 (2023).

currently utilized by U.S. federal labs. Moreover, both state and charitable research funders often include access requirements or limitations in their funding terms.[39] Provisions implementing policies like these may be difficult or impossible to remove from R2B agreements, though this will depend in part on the policy and the institution concerned.

6. **Liability**. Anyone who has negotiated an agreement with an academic institution or U.S. federal laboratory knows that seeking warranties regarding services or intellectual property or indemnification for harms caused, including third-party IP infringement suits, is near impossible. Most U.S. and UK universities will categorically refuse to offer what might be viewed as normal commercial liability warranties and terms, pleading that they are unable to do so under their charitable charters, etc. While this rationale may or may not always be supported by the relevant documentation, it is typically a firm position of these institutions and their U.S. federal laboratory counterparts and not negotiable. By the same token, universities typically expect full indemnification from their licensees and corporate partners with respect to any and all liability arising from the commercial use of their licensed technology. Notwithstanding what might otherwise be perceived as an imbalance in the negotiation position, this demand is usually non-negotiable.
7. **Reservations of Rights**. Universities are often willing to grant exclusive licenses to corporate entities, particularly in fields such as biotechnology and pharmaceuticals in which significant costs are involved in bringing a research discovery to the commercial market. However, these exclusive licenses are seldom absolutely exclusive. For example, such licenses can include provisions that allow the university to retain the right to use the technology for academic research or teaching purposes, make the license subject to commercialisation/performance obligations and, as discussed above, allow academic researchers to publish their findings.[40] As noted above, U.S. universities are subject to federal government usage and march-in rights. Moreover, most universities, particularly after the Nine Points document, insist on retaining the right to utilize licensed technology internally for research and educational purposes, and often to share that technology with other academic and non-profit collaborators.[41] For U.S. federal laboratories this right to share technology for research purposes also extends to other for-profit collaborators. Finally, universities and federal laboratories will want to ensure that their researchers are permitted to publish academic papers and make academic presentations on the subject matter of their research, even if sponsored commercially. This final point is more negotiable than the others, and universities today are sensitive to corporate confidentiality requirements, though the precise constraints on publication and presentation must often be negotiated.
8. **Litigation**. In the U.S., the owner of a patent is required to be a party to any lawsuit seeking to enforce that patent. While an exclusive licensee has standing to initiate patent litigation, the patent owner must eventually join the litigation in order for it to proceed.[42] And, as noted above, the Bayh-Dole Act requires that universities retain ownership of their patents on technologies developed using any federal funding. As a result, a patent lawsuit may often require the involvement of a university that holds the infringed patents. Notwithstanding this fact, universities are sometimes reluctant to engage in litigation against private companies (*e.g.*, if they are large donors to the university). As a result, many R2B patent licensing agreements will give universities the first right to decide whether to initiate patent litigation against an infringer and, if they elect not to participate in that litigation, to permit them to decline (notwithstanding any negative effect on the lawsuit). Additionally, U.S. state universities are, by virtue of the sovereign immunity recognized under the Eleventh Amendment to the U.S. Constitution, immune from suit in federal court—the sole jurisdiction

38. See Christi J. Guerrini *et al.*, "The Rise of the Ethical License," 35 *Nature Biotechnology* 22 (2017).

39. Wellcome Trust. Wellcome's approach to equitable access to healthcare interventions (accessed 5 January 2024); *https://wellcome.org/what-we-do/our-work/access-healthcare-interventions/wellcomes-approach-equitable-access-healthcare-interventions*; U.S. National Institutes of Health. Intellectual property policy (accessed 3 Dec 2024); *https://grants.nih.gov/policy/intell-property.htm.media/5acf1bcee5274a76c13df8e5/university-ip-commercialisation-research.pdf* (accessed 15 December 2024).

40. RSM, "Research into issues around the commercialisation of university IP" (2018) *https://assets.publishing.service.gov.uk/media/5acf1bcee5274a76c13df8e5/university-ip-commercialisation-research.pdf* (accessed 15 December 2024).

41. See Contreras, *Nine Points*, at 456-57.

42. See Contreras, *IP Licensing and Transactions*, at 321-28.

for patent and copyright litigation in the U.S. As a result, state universities typically cannot be sued for patent or copyright infringement. However, if a university voluntarily appears in federal court to assert a patent or copyright, it could be deemed to have waived that immunity.[43] This is another reason that some U.S. universities may refuse to agree to join lawsuits to enforce patents that they hold. For U.S. federal laboratories, it is always the U.S. Department of Justice that retains the first right to intervene in any litigation matter involving a U.S. federal laboratory though this right is not often exercised, and such litigation matters are often handled (and paid for) by a licensee. In addition, U.S. enforcement of patent rights owned by a U.S. federal laboratory can be undertaken by a non-exclusive licensee.

Conclusions

Increasing engagement between RPEs and industry presents opportunities for all concerned. A full understanding of each other's priorities, obligations, and legal constraints is necessary if the engagement is to avoid protracted, and sometimes frustrating, negotiations. This article has focused on some of those priorities and constraints, particularly those that apply in the UK and the U.S.A. Where parties enter into global collaborations, it may be necessary to navigate additional national or regional legal and cultural issues, not mentioned in this article.[44]

As the length of this article has demonstrated, the issues are many and varied and are not always fully understood by the negotiators of R2B contracts. Before embarking on the detailed negotiation of a major R2B contract, parties may wish to consider spending time in discussion of their respective priorities, obligations, and legal constraints. In the authors' experience, research funders are sometimes willing to allow a significant project budget for legal expenditure. Legal support (*e.g.*, in areas such as data privacy compliance, contract drafting, and obtaining legal advice on the other parties' legal constraints) may help to facilitate the smooth negotiation of the necessary agreements, as the parties are then not wholly reliant on their under-resourced contracts departments to provide support. ■

43. See *Cambridge Univ. Press v. Patton*, 769 F.3d 1232 (11th Cir. 2014) (copyright suit against state university after university was deemed to have waived sovereign immunity).

44. *E.g.* the complex research funding terms of the European Commission, and the terms of consortium agreements that are designed to comply with those funding terms.