

UNICO PRACTICAL GUIDES
Commercialisation Agreements

8

key issues in managing technology transfer agreements


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Foreword

Over recent years, the Knowledge Commercialisation profession has grown and matured, creating a huge wealth of knowledge, experience and best practice relating to University commercialisation contracts. The UNICO Practical Guides have been produced specifically to share this knowledge, experience and best practice within the profession.

The UNICO Practical Guides are practical guidebooks on University Contracts. They are designed primarily for use by people in the profession, both new and experienced, in order to tap into the collective learning of colleagues and peers.

The Practical Guides have been produced as a resource for Knowledge Commercialisation professionals in the UK. They are not designed to replace or compete with existing manuals or guides, but to provide a new and, we believe, vitally important set of support materials to those of us in the UK who deal with University commercialisation contracts on a daily basis.

We hope that you find the UNICO Practical Guides useful.

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The UNICO Practical Guides were prepared by UNICO in association with Anderson & Company, The Technology Law Practice™

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Chapter 1

General Introduction

This UNICO Practical Guide covers a selection of topics that are relevant to the management of technology transfer (TT) agreements and relationships. These range from the initial 'due diligence' that is done prior to the decision to engage in TT activities, through to the monitoring of a licensee's performance under, and the termination of, the TT agreement. These are 'generic' issues, common to many types of contracts that universities encounter. For a detailed discussion of particular types of agreement, please refer to other Practical Guides in the series.

Each topic is relatively 'self-contained' and the authors have therefore decided to adopt a different format in this Practical Guide to some of the others in the series. Each topic has its own chapter, covering both introductory and in-depth aspects of the topic under discussion. It is hoped, therefore, that the material will be useful both to the beginner and the more experienced TT professional. The Appendices include some templates for due diligence questionnaires, assignments, publications clauses and conflict of interest policies, but (unlike other volumes in the series) do not include any additional, in-depth discussion of the topics covered in earlier chapters.

In addition to this Practical Guide, users can also access a password-protected page on the UNICO web site at www.unico.org.uk which (now or in the future) will contain:

- (a) an electronic copy of this Practical Guide;
- (b) additional material as it becomes available, which may include additional precedent material and updates to the Practical Guides; and
- (c) an email discussion forum, where UNICO members can exchange information, ask questions, etc on issues concerning the subject matter of the Practical Guides.

Chapter 2

Introduction to key issues in managing TT agreements

Technology transfer executives (TTEs) are expected to manage a wide range of activities, including:

- identifying technologies that may be suitable for commercialisation;
- market research and marketing activities;
- managing relationships within the university and with external advisers (e.g. patent agents and lawyers);
- negotiating contracts and, in some cases, contract drafting; and
- managing relationships with existing licensees and others.

Within this large set of activities is a sub-set that is concerned with the TT agreement itself. Other Practical Guides in this series consider the detailed terms of a range of TT agreements, including spin-out transactions, licences, options, consultancies, and preliminary agreements such as CDAs and MTAs.

As well as negotiating the core agreements from which the university hopes to derive financial and other benefits, TTEs are involved in ancillary, but no less important activities that involve preparing or reviewing documentation. Key activities include:

- due diligence, particularly in relation to IP
- obtaining assignments from inventors and others
- negotiating term sheets
- implementing and devising policies on IP ownership, publications, liability, conflicts of interest, etc
- monitoring licensee performance and enforcing existing agreements

This Practical Guide focuses on some key issues that arise when managing these tasks.

Chapter 3

'Due diligence' investigations and IP ownership

Introduction

This chapter considers two main topics:

- The activities that a university may wish to conduct in the area of 'due diligence', particularly when establishing the ownership of IP that the university may wish to license to sponsors, licensees or spin-out companies.
- The 'default' position for ownership of IP generated by employees and others, which is clearly relevant when undertaking due diligence and deciding what steps need to be taken to 'clean up' the university's IP ownership position.

Due diligence

What is due diligence?

The concept of due diligence has its origins in Roman law. It seems that an obligation to exercise due diligence imposes a similar level of obligation to an obligation to take 'reasonable care'. Failure to take reasonable care may give rise to liability to a third party, e.g. as a result of breach of contract or negligence. Nowadays, the usage of the phrase in commercial transactions has very little to do with the original legal meaning.

In modern times, the phrase 'due diligence' started as an American expression, but is now more universal. In essence, it is a convenient name describing the process of investigating the condition and legal status of assets, particularly in the context of a sale of those assets. The assets might be property (e.g. land, buildings or IP), contracts, people (e.g. employees), companies or any other assets. Often, but not always, the focus of a due diligence investigation is documentary records, such as contracts, correspondence files, search reports, answers to questionnaires, expert reports, etc. A key objective of many due

diligence investigations is to understand the risks associated with the assets, including whether there are 'skeletons in the cupboard'.

In commercial transactions concerning technology (including IP assignments, licences and other transactions), due diligence might be undertaken to investigate such topics as:

- What intellectual property (IP) does the business or organisation have?
- Are there any third party rights in the IP?
- Is there any competing IP? Does 'our' IP risk infringing any third party IP?
- What existing contracts does the business or organisation have (R&D collaborations, IP licences, consultancy agreements, MTAs, etc)? What rights and risks do these create?
- Is the business founded on good science? Will the technology work? Have any proof of concept studies been done?
- Is there a market for the technology? Are there any competitors?

In corporate transactions such as the sale of a business, a convention has developed in which the seller will make relevant records available in a 'data room', usually at the offices of the seller's solicitors or financial advisers. Potential purchasers who wish to conduct due diligence can obtain access to such records by visiting the data room, usually under strict conditions as to confidentiality; this arrangement also gives the seller control over any copying of records that the purchaser may wish to make.

The amount of effort expended on the due diligence process will depend on the commercial importance of the particular transaction. There are certain key situations where it is prudent to conduct due diligence and these will be discussed later in this chapter.

What is the purpose of due diligence?

Most prudent house-buyers would not go ahead with the purchase without at least a basic surveyor's report on the property. Similarly, before buying a business or undertaking a significant commercial transaction, a potential purchaser will want to investigate what it is getting. Under English law there is an established principle of 'caveat emptor' – or 'buyer beware'. This is a doctrine

that purchasers buy at their own risk. Although both modern statutes and cases have now somewhat limited the importance of the legal principle there are still significant commercial reasons for undertaking prudent investigations.

The facts unearthed by due diligence enquiries may yield dividends in terms of:

- Understanding the nature and value of the assets
- Assessing and managing risks associated with the assets
- Allocating risk and liabilities (e.g. by including contract terms that place the risk on one party rather than the other)
- Strengthening one's bargaining position, e.g. to negotiate a price adjustment for the deal

When should due diligence be done?

TTEs may encounter three main scenarios where it is usual to undertake due diligence investigations:

- On a merger or acquisition of a company, including spin-out transactions. The potential buyer or investor will want to ensure that the business is viable and there are no hidden problems.
- Prior to an initial public offering (IPO) or listing of shares on a stock market. Here the due diligence is usually done by the business itself.
- Prior to commercial transactions (e.g. an IP licence agreement). The potential partner may wish to undertake certain investigations (e.g. of points mentioned under the heading 'what is due diligence' above).

The first two bullets above concern transactions that are outside the scope of this Practical Guide. The following paragraphs will focus on due diligence in relation to the commercial transactions that a TTE is likely to encounter. Before doing so, however, it is worth pointing out that there are two perspectives on due diligence – (i) that of a potential buyer, investor or licensee and (ii) that of the seller (or licensor).

The buyer/investor/licensee will want to undertake due diligence to be satisfied that they are not taking on problems which could give rise to future, unexpected liabilities.

The seller/licensor will approach due diligence with a view to:

- self protection (establishing that they are not committing to anything they can't deliver)
- expecting that the buyer will invariably ask for warranties – being prepared to negotiate limits (e.g. knowledge-based warranties)
- guarding against a future breach of warranty claim.

Due diligence in commercial transactions

- The TTE may encounter a number of situations where due diligence could or should be done:
- Before patenting
- Before licensing
- Before spin-out transactions
- Before signing significant research collaborations
- Before signing an MTA
- As part of an ongoing review of the status of IP or other assets

Instead of actively conducting due diligence, as in the above situations, some individuals conduct due diligence only when forced to – e.g. when asked to give warranties. Subject to cost constraints, this kind of reactive approach is not to be recommended, as it may lead to the TTE discovering a problem with the assets at the last moment, e.g. shortly before the parties intend to sign an agreement. As well as being embarrassing, this may lead to the other party seeking to renegotiate terms on “discovering” that the assets are not as sound as he assumed them to be.

Before patenting

Obtaining patent protection for key inventions is usually vital to a university or biotech company. The TTE will need to carry out an initial evaluation of the invention to assess both its patentability and commercial potential. This can be done using a questionnaire similar to that in Appendix A1. Sometimes it may be easier for the TTE to talk the academic through the invention, using the questionnaire as an aide memoire – and fill in the form themselves!

Leaving aside the question of cost, it is important to establish, or at least investigate:

- The likelihood of developing commercially valuable products or services from the invention
- What IP protection might be available for the invention and the extent to which such protection 'adds value' to the invention and any resulting products and services
- In the case of patenting, that the invention is novel, with a demonstrable inventive step
- that the invention has not previously been disclosed (other than under an appropriate confidentiality agreement)
- the identities of the relevant inventors – those contributing to the inventive step rather than those involved in the research in a more general capacity. (It is important to separate the inventors from those who would expect authorship on a published paper merely from being 'part of the team')
- that the inventors were university employees acting in the course of their duties, or have executed (or will execute) IP assignments to the university in respect of the invention
- details of the research funding – all relevant agreements (including MTAs) should be checked to ensure that a third party sponsor does not own the IP.

In some situations, it may also be considered appropriate to conduct patent searches to see whether the university's patent application is likely to be upheld and whether third party IP may be infringed when the invention is developed and commercialised.

Before licensing?

Before agreeing to take a licence to university IP, the potential licensee may wish to conduct due diligence enquiries. If the licensor is required to give warranties about the IP, it may also wish to conduct its own due diligence to check whether it is able to give the warranties and whether any disclosure should be made against them. See further the discussion of warranties in the *Practical Guide to General Legal Issues*.

Typical questions in a due diligence investigation, in addition to those already mentioned, might include detailed questions in the following areas:

- Are there any existing relationships of relevance?
 - Who contributed to the IP?
 - Who employed them?
 - Who funded them?
 - What contractual arrangements cover the above?
- Are there relevant (or competing) provisions in existing contracts?
 - Consider: IP rights, options, licences, non-compete clauses, consents etc
 - Have licences already been granted? Are they exclusive or non-exclusive?
Could there be any conflict with the proposed field of use?
 - Duration and termination provisions?
- Have relevant contracts been signed (and, if not, is it possible to re-negotiate certain provisions)?

Before spin-out transactions?

Usually, the university will give very few warranties in a spin-out transaction, other than those that might be found in an IP licensing agreement (as to which, see above). The founders (academics) may be asked to give personal warranties on other issues, including warranties about information contained in the business plan.

Before significant research collaborations?

Various types of due diligence may be required in the context of research collaborations, including:

- Commercial sponsors are usually keen to ensure that the IP arising from their significant investment is unencumbered and may seek to introduce various clauses to cover this.
- Charitable funders are also increasingly keen to ensure that the arising IP is efficiently exploited by including suitable obligations within the provisions of the grant award.

- A fairly recent source of funding is the Grand Challenges in Global Health initiative administered by the Bill and Melinda Gates Foundation in association with the Foundation for the National Institutes of Health. In addition to fairly onerous provisions in the grant award, these institutions also ask for significant due diligence to be done concerning both the background IP that will be contributed to the project and any arising IP.
- Since IP is a core asset of any university a certain amount of due diligence is prudent before entering into any significant research collaboration. Indeed, it should be regarded as 'good housekeeping' within the research contracts or technology transfer department even if the sponsors / funders don't specifically ask for it to be done.

Similar due diligence questions arise in relation to research collaborations as arise in relation to licensing, particularly those concerned with IP and contracts listed above under the heading "Before licensing?".

Before signing an MTA?

Inappropriate MTAs can have far reaching effects and may potentially encumber the IP arising from similar research in the same laboratory. Care should always be taken to ensure that (i) they do not contain broad, 'reach through' provisions and (ii) there is no conflict with other agreements involving the same Principal Investigator. A summary of checklist provisions concerning MTAs together with relevant questions to ask the Principal Investigator may be found in the Practical Guide on MTAs. The potential for an MTA to cause problems should never be underestimated!

Only when forced to – before giving warranties?

As discussed above, warranties should never be given lightly and appropriate thought should be given to the due diligence process in respect of any warranty sought. The authors' view is that due diligence should be an ongoing process and part of the departmental 'housekeeping' (see below).

Ongoing/housekeeping due diligence

In most universities there are so many different types of agreement entered

into on an annual basis that it is virtually impossible to keep track of them all unless details are entered into an electronic database. Good record-keeping is essential to the due diligence process. The ability to search on a variety of fields (such as Principal Investigator, date, Sponsor or Funder, exclusive or non-exclusive licence etc) and cross-reference is an obvious advantage of an electronic database.

Practicalities

Most TTEs have a heavy workload that needs to be prioritised. Inevitably, for any given contract, the time devoted to due diligence has to be assessed in relation to thoroughness vs. cost-effectiveness and available time. Undoubtedly extra care should be taken if there are contractual obligations that necessitate further investigation (particularly warranties) or are unusual or non-standard. An example of the latter could be the imposition of high-security precautions in relation to storing electronic data. Advice may be needed from the IT department to check whether it is feasible that the university could comply.

Due diligence may be seen as difficult (and potentially tedious) and also distracting (since it can take up considerable time and resource). However, with regard to avoiding future problems it should be regarded as a good investment.

Standard policies and procedures

In addition to maintaining a contracts database, the contracts or technology transfer department should have various standard procedures and policies in place – and these should be updated regularly in light of relevant day-to-day experiences. These may include:

- use of questionnaires for academics and departmental checklists
- standard agreements with students agreeing to assign IP to the university
- terms of employment for non-employees (Visiting Professors/Fellows, etc)
- MTA policy and associated questionnaire and checklist
- Invention disclosure questionnaire and checklist

Due diligence questionnaires

Appendix A includes a relatively simple questionnaire, which a TTE might use when asking an academic for core information about an invention. Depending on the answers given, and any other information that the TTE has about the invention, supplementary questions may need to be asked.

This type of questionnaire can be contrasted with the more detailed set of questions that an investor's lawyers might ask, when investigating the risks associated with a package of technology. The latter type of questionnaire, to be useful, usually needs to be tailored to the particular circumstances. Lawyers who specialise in this area are used to adapting standard templates to the circumstances. Sometimes, though, the TTE may be faced with an extensive list of rather general IP-related questions that has clearly been obtained from a precedent bank of IP due diligence questions, without much thought being given to the relevance of the questions to the particular circumstances. In appropriate cases, the TTE may need to work with the university's and the investor's lawyers to ensure that any due diligence exercise is proportionate to the value of the deal and that relevant questions are asked.

Default position on ownership of employee-generated intellectual property

Introduction

The next chapter of this Guide will discuss some practical aspects of obtaining assignments of intellectual property from an employee. First, though, it is worth considering the 'default' position, i.e. whether, under English law, an employee, or his employer, will own any intellectual property (IP) that the employee may generate.

In the authors' experience, some universities seem to make an assumption that intellectual property generated by their employees will automatically belong to the university. This assumption may be reflected in official university documents such as the university's financial regulations or policy statements, which may make legal-sounding, but sometimes legally inaccurate, statements such as "intellectual property generated in the course of the

employee's employment automatically belongs to the university". Typically, such statements have not been drafted or reviewed by the university's lawyers.

Whether an employee or employer owns intellectual property generated by the employee depends on a number of factors. Specifically:

- Underlying legal rules on ownership of employee-generated IP, mostly set out in IP legislation
- The terms of the employee's contract of employment, which may or may not incorporate any statements made in 'official' university documents such as the financial regulations
- The terms of any contract or grant award under which the IP was generated, which may vest IP in the sponsor.

The following paragraphs will focus on the question of ownership as between the employer and the employee.

Some preliminary points should be made:

- The legal rules for each type of IP (patents, copyright, etc) are different. The rules for the types of IP that are usually most relevant to technology transfer are considered briefly below.
- These rules are mostly set out in legislation. To understand these rules, it is necessary to consider carefully the exact wording of the legislation, and case law in which the legislation has been considered. The following description provides only a brief overview.
- In some, (but not all), cases, the statutory rules can be overridden by a term in the employee's contract of employment. The main difficulty is with patents – the rules on ownership of an employee's invention are set out in section 39 of the Patents Act 1977 and it is not possible to 'contract out' of these rules (e.g. in an employment contract), or at least not in respect of future inventions.

Default position under UK law

In brief summary, the default position for patents, copyright, database rights and designs, respectively, is as follows:

Patents

Default position: a patent may be granted to the inventor (or joint inventors).

Position of employees: an invention which is made by an employee will be belong to his employer if the invention was made during the performance of:

- the *normal* duties of the employee, or
- duties *specifically* assigned to the employee, or
- the duties of the *employee*, and because of the nature of the employee's duties, and the particular responsibilities arising from his duties, the employee had a *special obligation* to further the interests of the employer's undertaking.

Position of non-employees: a person working at a university who is not an employee, on making an invention, will be its first owner.

Points to note:

- The actual inventors of an invention have the right to be named as inventors in a patent application and the published grant. The right to be mentioned by name (and/or the address of the inventor) can be waived.
- In relation to *ownership* of inventions made by an employee, a key issue is 'what were the employment duties of the employee'? This is not always clear in the case of university employees (see further discussion, below).
- It is not possible to diminish any of the employee's rights in a future invention (or patent claiming that invention) by a provision in any contract with the employee. It is, however, permissible for the employee to agree to assign to his employer an *existing* invention or patent that belongs to the employee.
- Although a non-employee may be the owner of an invention, there is nothing to stop the university agreeing with the non-employee that the university should own the invention created by the non-employee.
- The Patents Act 1977, uniquely for UK intellectual property law, provides a statutory scheme to compensate an employee inventor. To qualify for compensation the invention or the patent for it (or the combination of the two) must be of outstanding benefit to the employer. The amount of compensation must be such as to secure the employee inventor a fair share (taking all the

circumstances into account) of the benefit which the employer has derived, or may be reasonably expected to derive, from the invention, or the patent for the invention, the assignment of the property or any right in the invention, etc. The employee is required to apply to the comptroller of the Patent Office. There are detailed provisions regarding this right to compensation which are beyond the scope of this Practical Guide. In the past, it has been difficult for employees to make a claim under this right. Principally because it is not likely that the patent would provide “outstanding benefit” to the employer. However, the law has recently changed so that both the invention and the patent (not just the patent) can be considered as to whether they have been of outstanding benefit.

- In practice, many universities would argue that their inventor compensation schemes, sometimes known as revenue sharing policies, provide for a more generous system of compensation than section 40 of the Patents Act 1977, and therefore a right to compensation under section 40 should not arise. However, as far as the authors are aware, this proposition has not been tested in the courts.

Medics – a special case?

The legal case of *Greater Glasgow Health Board Application 1995* provides an interesting illustration of some of these issues. Dr Montgomery (Dr M) was a Registrar employed by the Greater Glasgow Health Board. His job description set out that his principal duties were clinical. However, he was ‘expected to avail himself of the facilities’ at the local Tennent Institute for basic and clinical research. The Institute was used by researchers from both Glasgow University and the Glasgow Western Infirmary. As is often the case, some staff working at the Institute were paid by the University (and had clinical appointments at the hospital) whilst others were paid by the Health Board (but had honorary University posts). Some staff were paid by both the University and the Health Board.

Dr M was paid wholly by the Health Board and whilst employed by them invented a specialised ophthalmoscope. Although the Health Board agreed that the invention was made in Dr M’s own time, they disputed ownership of the invention. In order to proceed with patent protection it was mutually agreed that the patent application would be filed in the name of the Health Board but that the parties would apply to the Comptroller at the Patent Office to decide who was entitled to any patent.

The Comptroller decided that the Health Board should own the invention since it had been made by Dr M in the course of his employment. However, the decision was appealed to the Patents Court and overturned. Part of the reasoning was that the research had been done by Dr M in order to progress up the career ladder (and not just as part of his duties/ or in the course of his employment with the Health Board). Other evidence that was taken into consideration was that the provision of the research facilities at the Institute owed more to the University than to the Health Board.

Copyright

Default position: for the *main types of copyright*, the first owner will be the person who creates the copyright material.

Position of employees: if an employee creates the copyright work “in the course of his employment” under a contract of service, the employer will be the first owner of the copyright.

Position of non-employees: a person working at a university who is not an employee, on creating a copyright work, will be its first owner.

Points to note:

- Meaning of “main types of copyright”: literary works, dramatic works, musical works and artistic works. A “literary work” includes books, newspapers, etc, letters, tables or compilations (but not databases), computer programs, preparatory design material for computer programs, databases.
- For other forms of copyright (such as recordings or films) there are different provisions as to who is the first owner.
- Although a non-employee may be the first owner, there is nothing to stop the university agreeing with the non-employee that the university will own the copyright in any material created by the non-employee. Unless there is a specific agreement as to the ownership and use of the material created by a non-employee, the law will usually imply only a (very) limited licence for the university to use the material (although each case will turn on its own facts, and if university resources are used to create the work, the university may be able to claim some ownership rights).

- Unlike the position for patents, there is no statutory right for an employee to receive any compensation for any copyright material created during the course of his employment.

Designs

Note: there are now four types of design protection in the UK:

- UK design right
- UK registered designs
- EU design right
- EU registered designs

(Unregistered) UK design right

Default position: the first owner of the design right in a design will be the designer, unless the work has been commissioned, in which case the commissioner will be the first owner and not the designer. Note the different position for commissioned designs, compared to commissioned copyright and other intellectual property laws.

Position of employees: a design created by a person in the course of his employment will belong to the employer, unless the work has been commissioned by a third party, in which case the design will belong to the commissioner and not the employer.

Position of non-employees: if a university commissions the non-employee to produce a design then design will belong to the university and not the non-employee. However, if the non-employee creates a design while working for the university, but not to any specific commission, then the design may belong to him.

UK registered designs

Default position: The first owner of a registered design may be the person who creates the design, or the person commissioning the design (as long as the commission is for money or money's worth)

Position of employees: A design created by a person in the course of his employment will belong to the employer, unless the work has been commissioned by a third party, in which case the design will belong to the commissioner and not the employer.

Position of non-employees: If a university commissions the non-employee to produce a design then the design will belong to the university and not the non-employee (as long as the commission is for money or money's worth). However, if the non-employee creates a design while working for the university, but not to any specific commission, then the design may belong to him.

EU design right and EU registered designs

The position for ownership of EU design right and EU registered designs is similar to that governing the ownership of UK registered designs.

Applying these rules to university employees – key points

Some key points arising from the above summary include the following:

- Ownership of inventions (and resulting patents for those inventions) made by an employee depends on the duties of the employee. The detailed rules provide for three situations where an employer owns an invention made by an employee in the performance of his or her duties.
- These rules cannot be overridden by contract terms to the contrary, or at least not for future inventions. It is, however, permissible for an employee to agree to assign an existing invention to his or her employer (as to which, see next chapter).
- Therefore, sweeping statements in the contract of employment or other university documents that the employer owns all IP generated by the employee will usually go too far and not be legally binding.
- Ownership of copyright and designs generated by an employee will, in most cases, belong to the employer if they are generated *in the course of employment*.
- Where an employee, rather than the employer, would normally own any IP rights under the above rules, the employer may nevertheless be able

to claim an ownership stake if the IP was generated using the employer's resources (e.g. using experimental equipment that belongs to the employer).

- It is recommended that any IP terms in university contracts of employment or other university documents concerning the position of employees (e.g. financial regulations) should be drafted or reviewed by a specialist IP lawyer.
- In this context, a key issue in the employment contract is what are the duties of the employee. The employment duties of academic staff are not always clear. Commercial employers sometimes include a clause in the contract of employment stating that the employee is "employed to invent". Whilst some may regard this idea as potentially controversial in the context of academic staff, it is worth considering as one part of an overall strategy for dealing with the IP terms of university employees.
- Where a non-employee (e.g. a student, visiting academic or consultant) generates IP, the IP will usually belong to the non-employee (except in the case of some commissioned designs). In some situations, the court may be willing to imply a licence for the employer to use the IP, even though there is no contract to this effect. In general, it is strongly recommended that the university enter into written contracts with non-employees covering the ownership and use of IP generated by them in relation to university projects.
- Many universities have avoided these complex legal issues by entering into assignments and revenue sharing agreements with their staff (see examples at Appendix A and discussion in next chapter).

Investigating ownership of IP

In light of the above discussion, it can be seen that there are a number of practical and legal issues to consider when working out who owns the IP in an academic development. In particular, it is necessary to consider:

- *Who generated that IP?* In relation to patents, this means, who qualifies under patent law as an inventor of the inventions claimed in the patent? Academics sometimes assume that they should be generous and list all of their collaborators as joint inventors. This, after all, is what sometimes happens in relation to naming the authors of academic papers. But this is not to be recommended with IP and, in relation to US patents in particular,

incorrect naming may prejudice the IP rights. In cases of doubt, advice may need to be obtained from a patent agent as to who should be named as inventors.

- *Were the creators of the IP employees of your university when they created the IP?* The default position for non-employees is that they (or their employers) will usually own any IP that they generate, unless they have entered into an agreement that provides differently.
- *What were the employment duties of such employees?* Often, with academic employees, their duties are not as clearly stated (i.e. in their contracts of employment) as they tend to be for employees of commercial organisations. Sometimes, the employee's job title may give some clues as to the employee's duties.
- *Do the terms of the employee's contract of employment (which in the case of university employees may include terms set out in Financial Regulations or other official university documents) say anything about ownership of IP?* If they do say something on this subject, do the terms override the default position under IP laws?

Having established whether, in principle, the employer or employee is the owner of the relevant IP, it is also necessary to consider whether any *agreement with a third party* overrides the default position, e.g. if the IP is generated under a contract with a sponsor that provides for the sponsor to own the IP.

Chapter 4

Obtaining assignments of IP from the inventors

Introduction

As was mentioned in the previous chapter, the underlying legal rules on ownership of IP are not always easy to apply to academic staff, particularly when it comes to ownership of inventions. Whilst the position can to some extent be improved by clear terms in contracts of employment, some universities have been reluctant to 'rock the boat' by introducing stringent employment terms. Where new contract terms are introduced, they usually apply only to new members of staff; it can therefore be some years before a new IP policy 'bites' on all key inventors.

To some extent, the lack of legal certainty over ownership of IP generated by academic staff has not mattered greatly, as many academic institutions have ensured ownership of such IP by obtaining specific, written assignments of IP from their staff. In return, the university usually agrees to share with the inventor and his or her department any royalties or other income generated by the university from the IP. Many UK universities have established policies on the relative shares to be allocated to inventors, their departments and the university, respectively.

Templates

Templates for assignments and revenue sharing agreements with academic staff are included in Appendix A. These terms may need to be adapted to reflect your university's approach. For example, some universities conduct their technology transfer activities through a subsidiary company, and the IP should be assigned to the company rather than the university. The detailed financial arrangements also vary from university to university; some universities allow the technology transfer unit to deduct a 'top slice' of income, to cover their costs, before the net revenues are allocated. The template revenue sharing agreement includes financial provisions that reflect the particular approach of one university.

The template assignment includes:

- Some useful legal language, e.g. mentioning the right to sue for past infringements, stating that the assignment is “absolute”, etc. The wording of IP assignments raises some specialist points of property law and IP law that are beyond the scope of this Guide. For a brief discussion of the meaning of “full title guarantee”, see *Practical Guide to Legal Issues*.
- Some additional provisions that clarify the meaning of the assignment in relation to know-how and materials. Sometimes, parties simply add in references to know-how and materials in a template patent assignment, and assume that the terms of the assignment will ‘work’ for these other types of property. In the authors’ view, this approach is not desirable. It is hoped that the terms will prompt readers to consider whether an assignment of know-how and materials is appropriate and if so, what the terms should be.
- Some brief warranties to be given by the academic. These warranties reflect a ‘light touch’ approach and in appropriate cases more detailed and onerous warranties might be appropriate.

Assignments sometimes include other provisions, e.g. a power of attorney given by the academic to the university to sign further documents, etc. Each university will have its own preferred approach to these matters; it is hoped that the templates at Appendix A provide some useful, core documents.

Assignments by non-employees

In some situations, researchers who are not employees of the university may contribute to inventions made at the university. These researchers may include:

- staff from other universities working at the university for a short period (e.g. Visiting Professors, Visiting Fellows, certain Honorary positions)
- consultants
- students (undergraduate or postgraduate).

In some situations, the university may be willing to allow a non-employee inventor to benefit from the university’s revenue sharing policy as if he or she were an employee, in return for the inventor assigning their interest in the invention to the university. Usually, this occurs where the inventor is not an

employee of another organisation. In the latter case, it may be more appropriate to obtain an assignment from their employer and to negotiate revenue sharing arrangements with the employer.

There is a practical question as to when any assignment should be obtained.

Consultants

Consultants should not start work on a project until they have signed a consultancy agreement with their 'client' (i.e. the university). It is usual for the consultancy agreement to state that the university will own any IP generated by the consultant whilst he or she works on the project.

Visiting staff

The position with temporary staff such as Visiting Fellows isn't always so clear and depends on university policy and the formal documents that are sent out to the researcher when the job offer is made. Some universities clearly state that if IP rights arise then the university would expect the researcher to assign these to the university: in return the researcher would be treated like a university employee and be entitled to participate in the university's revenue sharing scheme.

Students

The subject of student-generated IP is discussed in detail in the Practical Guide to Students and IP. The following paragraphs discuss the subject very briefly.

University policies and procedures for students often depend on whether the students are undergraduate or postgraduate. In general, undergraduate students are less likely to come up with inventions than research based postgraduate students. Many undergraduates only undertake a small research project in their final year. Some postgraduate students (e.g. those undertaking 1 year taught MSc courses) are also less likely to generate significant IP than their peers who will be entirely lab-based. Many universities have separate guide-books on student IP policy (often reproduced electronically on the university website) setting out different procedures for students depending on whether they are non-research or research-based.

In general, undergraduate students may be given many documents to sign on registration and the IP policy may be part of this. If possible, it may be better to arrange for the undergraduates to be given (and asked to sign) the IP policy when joining their departments. This would avoid any later argument that they had not made an informed decision regarding IP as they had signed all the documents presented to them on registration presuming that it was part of the registration process. (For further discussion on this point see the Practical Guide on Students and IP).

Research-based postgraduate students may be asked to sign agreements regarding assignment of IP as a condition of participating in a particular research project. In the authors' experience this is the most practical way of dealing with the situation. Any agreement should cross refer to the student being given a copy of the university policy on IP and that in return for any assignment the student would be treated in the same way as an employee under the university's revenue sharing scheme.

Chapter 5

Executing a term sheet

What is a term sheet?

Sometimes, parties in negotiations agree certain key terms of their proposed agreement before they engage in detailed negotiations over the wording of the final contract. These key terms are recorded in a document that is given a variety of names, including:

- Heads of agreement
- Heads of terms
- Term sheet
- Memorandum of Understanding
- Letter of intent

What the document is called is less important than whether it is intended to be legally-binding (as to which, see below). For convenience, these documents will be referred to below by the single name of 'term sheets'. See also *Practical Guide to Legal Issues*, where the legal issues surrounding term sheets and contracts generally are discussed.

In the authors' experience, two distinct approaches to term sheets have emerged:

- The first approach, sometimes encountered in the US, involves a short document, typically no more than 2 pages, that is signed by both parties. This type of term sheet focuses solely on key commercial issues, at a 'headline' level, without getting into too much detail. Subsequent, detailed negotiations are conducted with one eye on the term sheet, and if a party proposes terms that are inconsistent with the term sheet, the other party may object strongly.
- The second approach, sometimes encountered in the UK, typically involves a somewhat longer document that is used by the commercial negotiators as a

record of their discussions, often held without legal advice. As more issues are discussed, they are added to the draft term sheet. Sometimes the parties are unable to agree points in their term sheet, and eventually decide to proceed to drafting of a full agreement. Often, the term sheet is never signed.

In the authors' view, term sheets are most useful when they are short, simple summaries of the key terms of the deal, as in the first approach above. The term sheet should avoid detailed definitions or complex IP provisions, particularly if a party is negotiating the term sheet without detailed legal advice.

A variation on this point arises where term sheets are negotiated by a university's business development team, which may be a different group of people to those responsible for negotiating the full agreement (e.g. a research contracts or technology transfer team). The business development team may not have the necessary training to negotiate complex, contractual language. If the commercial party (e.g. a sponsor) proposes detailed language in a term sheet, the university may need to establish a procedure for dealing with such proposals. For example, the university may decide not to accept detailed language in a term sheet, or may propose that the parties move to negotiation of the full agreement with the involvement of the contract negotiation team.

Key points to watch out for in term sheets

Is the term sheet legally-binding?

As discussed in *Practical Guide to Legal Issues*, there is no automatic assumption, under English law, as to whether or not a term sheet is legally-binding. This will depend on the intentions of the parties as expressed in the document. When the authors are asked to advise on term sheets, their first question is usually whether the term sheet is intended to be legally-binding. In most cases, the answer will be that it is *not* intended to be binding.

To make this point explicit, wording such as the following may be included in the term sheet.

"*Legal status.* This term sheet is not intended to create, evidence or imply any contract or other legal relationship between the parties. Either party may withdraw from the negotiations at any time, prior to signature of a full agreement, without liability. To the extent that any legal issue arises with

respect to this term sheet, the parties agree that this term sheet is made under English law.”

The second and third sentences of the above clause are intended for use where a UK university is in negotiations with a non-UK party. In some countries (particularly some countries in Continental Europe), signature of a term sheet may impose an obligation of good faith on the parties such that they cannot withdraw from the negotiations without incurring a liability to the other party. The second and third sentences are not guaranteed to work, but may help to avoid such other countries’ laws from applying. Local legal advice should be sought in appropriate cases.

Other types of preliminary document

Much of the above discussion applies equally to documents that are called memoranda of understanding (or MOUs), and which are intended to be pre-contractual documents that record the main terms of a proposed agreement. Sometimes, though, the name ‘MOU’ refers to a different type of document. Typically, when used in this other sense, an MOU records a strategic ‘understanding’ between parties. This type of document is more like an international treaty than a contract. For example the authors have been involved in advising a university on such an MOU with other universities in other countries, covering strategic, international cooperation.

There is also an old-fashioned name, ‘memorandum of agreement’, which usually just means ‘agreement’ and should not be confused with an MOU.

Letters of intent, or comfort letters, are sometimes used to give comfort to a party’s investors or others that it is in serious negotiations with a university. It is important to make clear that such documents are not legally-binding.

Hybrid term sheets

Sometimes, a term sheet will provide that some of its terms are legally-binding and the remainder of the term sheet is not legally-binding. Typically, the terms that are stated to be binding will include the following:

- Confidentiality provisions

- Exclusivity provisions (e.g. an obligation on the university not to enter into an agreement with anyone else during a defined period).

What happens if no 'full agreement' is reached?

Sometimes, parties agree a non-binding term sheet, and work begins, but no 'full agreement' is reached or signed. In such circumstances, if the matter came to court, the court might have to decide the terms of the contract. In the absence of any better terms, it might decide that some or all of the terms in the term sheet should apply. Or it might not. This uncertainty will usually be undesirable, so it may be unwise to start work on a project until the full agreement is signed.

Short term agreements

Sometimes, however, parties agree to start work before the full agreement is signed. For example, in the pharmaceutical industry a certain type of 'letter of intent' has emerged where a contractor agrees to start work, and be paid for it, for a limited period whilst negotiations are continuing. The letter of intent will usually also include some key terms on IP and liability. This type of document usually is intended to be legally-binding.

A problem with taking this approach in university contracts is that, often, 'the devil is in the detail'. The detailed terms of the contract are important, particularly in areas such as liability and intellectual property, not to mention duration, and work and financial obligations. Usually, it is unwise to start behaving as if a contract were in place until the full agreement has been signed.

Chapter 6

Dealing with IP rights

Introduction

This chapter considers:

- The different ways that rights in intellectual property can be sold or licensed;
- Some of the advantages and disadvantages of each method of sale or licence; and
- Some factors affecting how universities decide on which method to include in any particular agreement.

Types of rights that can be granted

Sale or use

There are, in simple terms, two methods that a university can use to grant rights in intellectual property:

- sell the ownership of the intellectual property – an assignment; or
- retain ownership of the intellectual property but allow use of the IP rights – a licence.

What can be licensed or assigned?

Universities normally grant rights to three different types of assets where the sale or licensing of intellectual property is involved:

- *The intellectual property itself*: This category concerns the established forms of intellectual property, such as copyright, designs, trade marks, patents, etc
- *Related know-how*: Know-how usually means information which assists the licensee or assignee in the use of the intellectual property. Know-how can include the following:

- technical information designed to assist a licensee or assignee to utilise the intellectual property, or
- non-technical information enabling the licensee or assignee to commercially exploit the intellectual property. This can include business or marketing information.
- Know-how may be protected under the law governing confidential information, and/or under intellectual property laws (for example, when expressed in any permanent form it may be protected by copyright).
- *Materials*: In some cases, a licensee or assignee, in order to carry out activities using the intellectual property, needs access to materials that only the university may have, e.g. biological or chemical compounds or human tissue. In some cases, materials are provided under a separate agreement, known as a materials transfer agreement (see the Practical Guide on MTAs).

Background and foreground IP

Often, university agreements will distinguish between what is sometimes called background IP and foreground IP. These expressions may have originated in the standard contract terms of the European Commission for 'Framework' research collaborations, although in Framework 6 different terms were used ('pre-existing know-how' and 'knowledge'). Whatever the categories are called, the agreement may need to distinguish between:

- Intellectual property or know-how existing at the time the agreement was entered into or work started. This is usually defined as "background intellectual property" or "background information" depending on whether intellectual property or know-how is involved.
- Intellectual property or know-how created in the performance of the agreement. This is usually defined as "foreground intellectual property" or "foreground information".
- Intellectual property or know-how created during the time period of the agreement but which does not arise from the performance of the agreement activities. This category is often specifically included in the definition of background intellectual property or background know-how.

- Intellectual property or know-how that is introduced to a project during its progress, but it was not anticipated at the outset of the project that such IP would be needed. This is occasionally known as 'side-ground' IP although more often it is within a background IP definition.

Different contract terms may govern these different categories, e.g. as to:

- who will own the intellectual property of a particular category;
- who can use that category of intellectual property and for what purposes (as to which, see below);
- whether any payments must be made for such use (e.g. royalties)

Rights to use foreground and background IP

Typically, the agreement will include provisions stating what right that each party has to use background and foreground IP. For example, in a research contract:

- each party may be permitted to use the other party's background IP for the purpose of performing its obligations in a defined research project
- the sponsor of the research may either own, or have a licence to use, foreground IP. Different ways of dealing with a sponsor's rights to foreground IP are set out in the 5 Lambert Agreements (as to which, see the end of this chapter).
- the university may retain ownership of, and/or the right to use, foreground IP for the purpose of teaching and research

Sometimes, agreements provide for broader rights to background IP, for example a right for a sponsor or licensee to use background IP in support of their commercial use of foreground IP. Any such provisions need to be carefully considered in the context of the university's overall IP commercialisation strategy. Such provisions may not be consistent with an objective to license that background IP exclusively to another organisation.

Distinguishing between exclusive, non-exclusive and sole licences

Where a party is granted a licence to use the other party's IP (foreground or background), the licence wording should state whether the licence is exclusive, sole or non-exclusive. Occasionally, more exotic variations are encountered, e.g. a semi-exclusive or co-exclusive licence.

There is no general, legal definition of the words “exclusive”, “non-exclusive” and “sole” when used in contracts. There are some statutory definitions of the meaning of “exclusive” in the context of UK IP legislation. But such meanings only relate to the use of the term in the legislation in question. However, most people understand that these terms mean the following when used in contracts:

- *Exclusive*. Once a university has granted an exclusive licence to particular rights (e.g. a particular patent in a particular field and territory) to one person, the university cannot grant another licence of the same rights to any other person. Nor can the university itself exercise those licensed rights.
- *Sole*. Once a university has granted a sole licence to particular rights to one person, the university cannot grant another licence of the same rights to any other person. The distinction between a sole licence and an exclusive licence is that with a sole licence the university can exercise those rights itself.
- *Non-exclusive*. Where a university grants a non-exclusive licence to one person, it can grant one or more licences of the same rights to other persons and can also use those rights itself.

A grant of an exclusive licence can, for some forms of intellectual property, entitle the licensee to commence litigation if there is an infringement of intellectual property. A non-exclusive licensee does not have this right; the licensee will have to persuade the licensor to take action. Alternatively, the licence agreement may have wording requiring the licensor to take action against an infringer.

The grant of exclusive or sole licences can raise competition law issues (under EU and/or English law). Appropriate advice should always be sought where these type of licences are being granted or sought.

Particularly in contracts with non-English parties, it may be desirable to define or spell out what a licensee can and cannot do with the rights it has been granted. Such an approach can help in avoiding any misunderstandings between the parties and hopefully avoid disputes at a later stage.

Particularly where a university grants exclusive rights to a commercial organisation, a university may wish to include diligence obligations on the licensee, and a mechanism for terminating the grant of rights if the diligence

obligations are not met. This subject is discussed in detail in the Practical Guide to Licence Agreements.

Some factors influencing whether a university should be granting a licence to, or assigning, its technology

Licensing, rather than assigning, IP can provide more flexibility to a university in that:

- The university retains ownership and (sometimes) control of the intellectual property;
- It is easier to terminate a licence than an assignment, e.g. if there is a right to do so in the licence agreement for breach of diligence obligations. To “terminate” an assignment and recover the IP, the university may need to sue the assignee to obtain a court order for re-assignment.
- Where the IP has been assigned, the assignee is the owner of the IP and can assign it on to a third party, who may or may not be bound by any contractual obligations that the original assignee has to the university (e.g. to pay royalties).

There are also some other issues with assignments:

- If the new owner goes into liquidation or bankruptcy, the liquidator or administrator of the assets of the new owner will try to sell the assigned intellectual property. This may mean that the intellectual property ends up with a person that the university might consider undesirable (e.g. for ethical reasons). Also, the intellectual property might be developed in directions not wanted by the university, or not developed at all by the person who obtains the intellectual property from the liquidator or administrator. With a licence, in the case of liquidation or bankruptcy, there would normally be a contractual provision that in such cases the licence would terminate and the university would have the licensed rights returned to it.
- Although it is not entirely clear legally, if the new owner goes into liquidation or bankruptcy any obligations on the new owner (such as the payment of royalties) may not “attach” to the intellectual property when the liquidator or administrator sells on the intellectual property.

- Some assignments contain provisions requiring the new owner to re-assign the intellectual property it has obtained from the university, if it has not fulfilled its obligations or has gone into liquidation or bankruptcy. Such a requirement can be difficult to enforce if the new owner chooses not to do so, particularly in the case of liquidation or bankruptcy (both legally and practically) where the liquidator or administrator may be able to avoid such provisions. See further Appendix D to the Practical Guide to Spin-out Transactions.

While licensing may be more attractive to the university, for the licensee a licence (whether exclusive or non-exclusive) may not provide the level of certainty the licensee requires in order to build a long-term business. There is always the danger that the licensor could terminate the licence (whether legitimately or not).

What type of rights should a university be granting?

Many US universities have developed firm (some would say, rigid) policies on the ownership and licensing of IP generated by their employees. A typical stance is that:

- the university owns all foreground IP generated by *employees of the university*
- a sponsor of research, or provider of materials to the university under an MTA, may be granted a non-exclusive licence to use foreground IP for its internal research purposes (sometimes, only non-commercial research purposes)
- in addition, the sponsor or provider of materials may be granted an option to negotiate the terms of an exclusive licence to commercialise the foreground IP

In the authors' experience, UK universities have not yet reached such a firm and unified approach to IP ownership. The Lambert Review made some key recommendations regarding ownership and the type of rights that should be granted by a university, including the following:

- That public funding of research is for the public good;
- there should be maximum flexibility in the use of intellectual property. Intellectual property should be exploited in as many ways as possible to obtain the maximum value from it;

- that companies should get secure rights to intellectual property they wish to commercialise;
- that the starting point for negotiations should be that universities own any resulting intellectual property and that companies should be able to negotiate licence terms to commercialise/ or exploit it.
- where companies make a substantial contribution they can own the intellectual property
- that companies should act in a timely fashion in exploiting the intellectual property they have acquired from any university; and
- that a university should not be restricted in carrying out future research.

The Lambert Review did not take a prescriptive review as to whether assigning or licensing intellectual property is the best approach (or whether exclusive or non-exclusive licences are preferred). This is reflected in the 5 agreements produced following the publication of the Lambert Review (<http://www.innovation.gov.uk/lambertagreements/index.asp>), which cater for a variety of situations, from where a university retains ownership and the sponsoring company takes (or can obtain) a licence, right through to where the university does not retain ownership and cannot use any resulting intellectual property for its own purposes or for publication.

Therefore, different solutions on IP ownership and use will be appropriate in different situations. However, it is (arguably) implicit from the Lambert Review recommendations mentioned above, and from the evidence collected by Lambert, that licensing should be the default option.

With the advent of full economic costing for research contracts, it seems likely that sponsors of research at UK universities will press for greater rights to foreground IP.

For a discussion of licensing versus assignment in spin-out transactions, see the Practical Guide to Spin-out Transactions.

Chapter 7

Publications and confidentiality

Introduction

It would be very unusual to find a research and development agreement or collaboration agreement involving a university that did not contain provisions relating to publications. Even where the university is involved in a consortium entirely with other universities or not-for-profit organizations, it is considered prudent to set out the parties' expectations regarding publications and the procedures for review. Where a commercial sponsor is involved in any collaboration, it is particularly important to do so – and to anticipate that negotiations may take a little longer.

For a number of reasons, it is important to universities and academic researchers to have the right to publish the results of their research. These reasons include the following:

- Academic research is intended to advance knowledge and understanding of a subject, and a primary way of communicating such knowledge is through scientific publications.
- Academics and their institutions are assessed, and academic careers are based, partly on the number and quality of their publications.
- In addition, most funding bodies have a publication or dissemination requirement and this is made clear in the terms and conditions of the grant award.
- Where a student is conducting research under a contract, it may be necessary for the student to have the right to include the results of the research in his or her dissertation or thesis, which in due course may be published. Some universities have procedures whereby dissertations or theses that include confidential information can be placed in a confidential section of the university library.

- Universities are usually charities, and as such are exempt from corporation tax on the income that they generate. The Charity Commissioners and Inland Revenue have, in the past, issued guidance that where the primary purpose of the charity is educational (as in the case of universities), the results of charitable research should not be subject to restrictions (e.g. in a research sponsorship agreement) preventing the publication of the results. However, it is considered permissible to agree to delay publication for up to 6 months to allow patent applications to be filed.

The need to publish must be set against the risks involved in premature publication. If publication is not controlled it may prejudice the process of patenting or the protection of a trade secret under the law of confidence.

Free dissemination of knowledge vs. commercial caution

Unfortunately, there is often a conflict (perceived or otherwise) in the expectations of both a university and a commercial company with respect to publication or dissemination of research results. On the one hand the university viewpoint may often be: *"They want to restrain our academic freedom and restrict our right to publish. Our research effort is supposed to benefit mankind."* Whereas the company perspective may run: *"Academics are a law unto themselves. They just can't stop themselves spouting results to all and sundry. Just one leak will wreck our chances of any patents and the commercial potential of the technology we've taken the risk to fund."*

It is certainly true that patentability can easily be undermined by a premature disclosure of the invention. In order to establish the patentability of an invention, the applicant must satisfy *all* the requirements of s1 of The Patents Act 1977, namely:

- (1) the invention is new;
- (2) it involves an inventive step;
- (3) it is capable of industrial application;
- (4) it is not within the exclusions.

For the purposes of this discussion we only need to consider point (1) above. It is the novelty requirement of patentability that can be easily lost by an inadvertent disclosure of the invention. The UK Patent Office evaluates novelty

at the invention's 'priority date'. Usually, that is the date on which an application is first made for a patent. It is vital that the subject matter of the patent must not form part of the 'state of the art' on the priority date. By s2(2) The Patents Act 1977:

'The state of the art in the case of an invention shall be taken to comprise all matter (whether a product, a process, information about either, or anything else) which has at any time before the priority date of that invention been made available to the public (whether in the United Kingdom or elsewhere) by written or oral description, by use or in any other way.'

The words 'made available to the public' are equivalent to saying that the information is 'in the public domain' (although some people, when using the latter phrase, mean 'available to the public and not protected by IP rights'). In either case a disclosure has been made and the information in question is no longer confidential. The UK Patent Office has helpful information on its website (www.patent.gov.uk/patents) regarding patenting and the importance of ensuring that inappropriate disclosures are not made that could prejudice obtaining a patent.

However, disclosures made under an appropriate, valid confidentiality agreement (CDA) do not count as public disclosure and hence any information released by an academic under cover of the CDA would not be regarded as in the public domain. Appropriate CDAs can be found in the Practical Guide on CDAs, and the UK Patent Office also has further guidance on its website. An important role of any TTE and the technology transfer office is to educate and/or provide guidance to the academics regarding disclosures and what constitutes the public domain. Although most academics will appreciate that publication in peer-reviewed journals constitutes disclosure, they may not be so clear in regard to oral disclosures, seminars, the web, etc. In reality, the 'public domain' is quite broad and includes the following fora:

- Journals (hard copy or web-based)
- Poster and oral presentations at conferences (including, for example, microscopic slide reviews and discussions); abstracts produced in advance of the presentations

- Meetings, seminars, discussions at conferences (including informal discussions over dinner)
- Theses and dissertations
- Grant reports (and abstracts of funded research reported on funders' websites), the NHS research register
- Unrestricted printed matter or publications available on the web.

Most publications clauses in contracts will require that a draft of any publication or proposed oral or poster presentation is submitted to the other party or parties for review. From the university's perspective, it will be important to check that the review clause does not give a right of veto to publishing the results. It is also important for the TTE to ensure that any review periods are time-capped.

Publications clauses in contracts

An example of a publications clause is included in Appendix A to this Practical Guide. The main issues that tend to come up in negotiating these clauses are:

- The time periods allowed for (a) the publishing party to give prior notice of an intended publication, (b) the reviewing party to review the proposed publication and (c) the reviewing party to delay publication whilst patent applications are filed. This topic is discussed below.
- Whether the reviewing party can delay or veto publication for any reason other than to file patent applications. Deletion of the sponsor's pre-existing confidential information is usually acceptable. However, general rights to veto publications, or to delay them because the sponsor would prefer to keep the results confidential, are not usually consistent with the charitable status of research as described above.

Time allowed for review

There are several variations on time periods for review:

- draft publication is submitted to the other party [30] [45] [60] days prior to publication
- the other party may delay publication for (an additional) [60] [90] days in order to protect intellectual property or remove its confidential information if such is found during the review process

- a maximum delay on any publications (e.g. total of 90 days) is specified at the outset.

When an agreement involves only academic or charitable institutions, the parties understand the issues and are usually fairly flexible. However, in the authors' experience, even large commercial concerns (such as pharmaceutical companies) are becoming more willing to negotiate. In the authors' experience, periods such as 30 days for the initial review, and 30 or 45 days for an additional delay period, are often agreed. Where a commercial party is adamant that there should be a delay of 6 months or more and that the issue is a 'deal breaker' it is advisable to refer the matter to a senior manager.

Theses and Dissertations

Where a graduate student is working on a research project that is funded by a commercial sponsor, special care needs to be taken to ensure that the publications clause also covers any thesis or dissertation. It may be preferable to have a separate clause dealing with this. In the authors' experience it is often small companies that are the most concerned about their proprietary confidential information and loss of competitive edge should details contained in the thesis enter the public domain. They may often try and insist that the thesis is kept on restricted access for two or three years. The TTE will need to make it clear to the company that any period of restricted access will be subject always to the regulations of the university – and this should be reflected in the wording of the agreement. Once the thesis or dissertation is ready for submission the TTE may need to liaise both with the university's registry department and the student's supervisor in order to comply with the relevant university procedures for justifying any period of restricted access.

Another aspect concerning theses or dissertations is whether or not a CDA should be in place with the external examiner. The TTE will need to check the university's arrangements for appointing external examiners and whether the examiner has agreed to confidentiality provisions (e.g. by countersigning a letter of appointment). If a particular thesis or dissertation contains very sensitive information or the company is particularly concerned, it may be simplest to arrange for the external examiner to sign a specific CDA.

Inadvertent disclosures - plugging potential leaks

The authors have been asked on several occasions whether it is possible to organise a CDA 'after the event'. This often happens where an academic has a potentially patentable invention and has either met in a small group with academics from another institution, or representatives from a company. One instance was where an academic gave a seminar at an Italian university, which was attended also by colleagues from the associated university hospital.

In these instances, a lot of further investigation is required, including:

- What exactly was said and disclosed?
- Are slides and notes available for verification?
- Was it made clear (e.g. verbally) that the presentation was 'in confidence'?
- How many people were at the meeting? Would they be willing to sign any subsequent CDA?
- If a seminar – is it feasible to identify everyone present and establish their affiliation (i.e. university or hospital) so any CDA is signed by the appropriate parties?
- Should advice be sought from patent agents?

It is highly debatable whether it is possible to 'back date' a CDA, in the sense of agreeing to treat as confidential information that was previously disclosed without an obligation of confidence, or at least it may be difficult to persuade a Patent Office that the information was not publicly disclosed. However, if the information was previously disclosed under an oral obligation of confidence, the written CDA may be doing no more than confirm a pre-existing obligation (but again, it may be difficult to persuade a Patent Office of this). Professional guidance will usually be required to check whether the particular disclosure will have lost its 'necessary quality of confidence' and prejudice a subsequent patent application. See further the Practical Guide on Confidentiality Agreements.

Open access publishing

As mentioned above many charitable funders seek to ensure that research findings are rapidly disseminated to a wide audience. Many UK funders

(including the Wellcome Trust and Cancer Research UK) are members of the Association of Medical Research Charities (AMRC). To date, the majority of published research articles have been available in hard copy journals held in libraries. The articles are submitted to the publishers by the academics (free of charge). However, the publishers then sell subscriptions to their journals to the university libraries. It has been argued that potentially this can hinder access to the research – which, ironically, has been publicly funded. This is particularly controversial due to the substantial increases in subscription costs in recent years. AMRC members are encouraging, and in some cases, mandating ‘open access’ publication. This is where research publications are freely available on the web via either: (i) a recognised open access repository (such as PubMed Central) or (ii) an open access journal – one whose income is derived from authors’ fees rather than from subscriptions.

It is argued that the quality of the research publications is maintained (as they are still subject to peer review). However, the authors pay to have the articles published (once these have been subject to the peer review process and accepted). It is the intention that the authors’ fees would be recoverable from any grant funding. The Wellcome Trust (www.wellcome.ac.uk) is actively promoting open access publishing and where grants have been awarded after 1 October 2005 there is a requirement that electronic copies of research papers will be deposited in PubMed Central (the U.S. National Institutes of Health free digital archive of biomedical and life sciences journal literature).

Although this new system will not affect the operation of the review clauses concerning draft publications in any agreement, the TTE should now bear in mind that it may be prudent to ensure that the relevant section does not contain anything which would preclude electronic dissemination.

Chapter 8

Liability issues

Introduction

Many commercial contracts include warranties, clauses limiting or excluding liability, and indemnities. By way of illustration, a university research contract or licence agreement might include:

- A warranty (i.e. a contractual promise) that a party is the registered owner of a named patent;
- A clause limiting liability for breach of contract to a defined amount (e.g. the price paid under the contract, or the limit of a party's insurance policy);
- A clause excluding liability for certain kinds of loss, sometimes referred to as indirect or consequential losses; and
- A clause under which one party agrees to indemnify the other against any liability that the other party incurs to third parties (e.g. liability to a patient who is injured in the course of a clinical trial of a drug).

For convenience, these types of clauses are referred to collectively below as "liability clauses". The purpose of liability clauses is to define and, in some cases, limit a party's obligations and liability to the other party. In the absence of such clauses, the extent of a party's contractual liability to the other party may be less clear. More specifically:

- If nothing is said in the contract about limiting liability, liability will usually be unlimited.
- If there are no indemnities in the contract, liability may ultimately fall on whichever party the court decides is legally responsible for the loss that has been suffered, or on whichever party is successfully sued by the injured claimant. Sometimes, this is appropriate, but there are occasions where a party would prefer that the other party take responsibility, irrespective of fault or who is sued. For example, a university might wish a licensee to deal with any 'product liability' claims that arise from a defective licensed

product, even if the source of the defect can be (or is alleged to be) traced back wholly or partly to negligent research work by the university.

- If there are no explicit warranties (or disclaimers, which can be viewed as negative warranties) in the contract, it will be for the court to decide whether there is an implied warranty in the contract. It may be difficult to predict whether the court would imply such a warranty.

Liability clauses raise difficult legal questions, and should be drafted by someone who understands the law in this field and the drafting issues involved. In some situations, if such provisions are drafted too aggressively the court may decide that they are not “reasonable” for the purposes of the Unfair Contract Terms Act 1977, and that they either have limited effect or are void. Legal aspects of these clauses are mentioned in *Practical Guide to Legal Issues*. This chapter will focus on some of the key policy and commercial issues for universities in relation to such clauses.

In some situations, a university might wish to ask the other party to a contract to give warranties and to accept unlimited liability. For example, in some licensing situations, it may be important for the university to have a remedy against the licensee if it fails to perform its obligations. Depending on the relative bargaining strength of the parties, it may be possible for a university to negotiate terms that impose such liabilities on the other party, whilst strictly limiting the university’s liabilities.

In other situations (some universities would say, in most situations), a university’s priority may be to strictly limit its liability, even if this results in the other party demanding, and getting, an equivalent limitation of its liability.

Often, the priority of those responsible for negotiating an agreement on behalf of a university will be:

- To give very few warranties;
- To limit the university’s contractual liability to the maximum extent possible;
- To seek indemnities from the ‘commercial’ party; but
- To avoid giving indemnities.

This approach may be thought desirable for a variety of reasons, some of which are discussed further below, including:

- Universities are funded by public money and are, or should be, risk averse. The commercial activities of a university are usually secondary to the university's main educational and research objectives, and should not be allowed to prejudice the main objectives.
- It may be standard commercial practice to limit liability for the provision of such services, and the university would wish to follow this practice.
- In the case of university research, it may be not known at the outset of the research what results will be found, so guaranteeing the outcome may not be appropriate.
- Where a university is asked to give warranties that certain statements are true (e.g. in relation to intellectual property rights), the university may not have the resources or inclination to conduct extensive 'due diligence' to verify the statements.
- Often, where a university accepts a contractual obligation (including warranties), performance of the obligation may depend on the cooperation of certain academic staff. The relationship between the university and its academics is generally less close than, say, between a commercial employer and its employees, and it may be difficult for the university to 'control' what its academics do.
- Academic research work is usually not priced to allow for significant, unexpected liabilities arising under the contract.

Which terms are accepted may depend on a number of factors, including:

- The determination of the other party to include terms that protect its interests and that, conversely, may expose the university to legal risk;
- The drafting and negotiating skills of the university's commercial executives;
- Whether the university has a clear position on the minimum terms that it will accept, and whether the university is willing to 'walk away' from a contract if those minimum terms are not included.

Many international companies are familiar with the consistently firm approach of the US universities on these issues. In the past, UK universities have tended not to make liability clauses 'deal breakers' in the same way, perhaps because UK universities have had very little experience of commercial litigation. In recent years, the senior management of UK universities has started to become

more familiar with, and give a greater priority to, liability issues. This is making it easier to formulate university policies on liability issues and to make them 'stick' when a university is faced with difficult negotiations.

Universities should consider formulating (if they have not already done so) commercial policies so that:

- they have a minimum set of liability clauses that are consistent with their role as universities, but
- which do not take such an extreme position that the university cannot enter into sensible commercial arrangements concerning the exploitation of its intellectual property and other resources with suitable commercial organisations.

The remainder of this chapter will consider some of the issues mentioned above, in greater detail. The purpose of the following discussion is to make readers aware of some of the policy issues that arise. In view of the legal complexity of some of these issues, it is vitally important that any university policy on liability clauses should be formulated with the active involvement of the university's legal advisers.

How universities differ from commercial organisations

Universities, in the main, cannot operate like commercial organisations in exploiting their intellectual property. There are three primary reasons for this:

- *Their educational role.* The primary role of a university is to provide educational services and to increase and foster knowledge, and not primarily to make a profit for shareholders;
- *Their charitable role.* Universities are, generally, established as charities. This legal status constrains the commercial aims that a university can have, and places limits on how the university can operate, e.g. in relation to trading and other related activities;
- *Their receipt of public funds.* A university's main funding comes from public funds (whether direct grants etc from central government or indirectly, from funding from public bodies such as the research councils).

In addition, the limited financial resources of many universities and the relatively low priority given to commercial activities may mean that they do not have the resources (both in terms of people and financial resources):

- to carry out extensive work on the administration of the creation, protection, investigation and exploitation of intellectual property; or
- to enter into litigation (intellectual property litigation being, notoriously, expensive);

Use of university policies on liability issues

Overview

It is suggested that a university should develop a clear and detailed policy as to the liability clauses that it requires and can accept in contracts. Such a policy may contain the following elements:

- educating university personnel as to the potential consequences of (i) giving warranties, (ii) not limiting or excluding liability, or accepting too high a limit of liability, and (iii) giving indemnities;
- developing different standard liability clauses for different types of agreement and different types of intellectual property;
- identifying which liability clauses are acceptable, acceptable only in certain circumstances or never acceptable. For examples, certain 'standard' warranties as to the ability of a party to enter into the contract may (subject to obtaining legal advice) be acceptable, whilst others (e.g. warranting that a university's patent is valid and enforceable) may be unacceptable;
- explaining the reasons for the university's stance on these issues;
- establishing a clear negotiation strategy for clauses which are suggested by commercial organisations and are not entirely consistent with the university's preferred approach, including
 - which are 'walk-away' or 'deal-breaker' liability clauses;
 - which clauses need to be referred to more senior staff at the university for discussion, approval or examination, and who has authority to waive or change the policy.

- understanding the relevant provisions of the university's insurance policy so that it is clear
 - what financial limit to liability is provided by the insurance policy;
 - what will happen if there is no clause limiting liability;
 - when it is necessary to refer matters to the insurers for consideration and discussion;
 - what type of liabilities, warranties, indemnities and other contractual provisions (e.g. some policies exclude US jurisdiction) cannot be accepted, if insurance cover is to be maintained;
 - what types of contract cannot be entered into at all (because they are not covered by the insurance policy).

Some detailed points to consider in liability clauses

The following paragraphs mention a (non-comprehensive) selection of practical points concerning individual liability clauses. This section is not intended to replace the relevant sections of *Practical Guide to Legal Issues* (and other Practical Guides) that discuss liability issues.

Warranties

Warranties are usually drafted as statements that certain facts are true. Before giving such warranties, the university needs to consider (a) whether it is in a position to know whether the statements are true or not; and (b) (if the answer to (a) is yes) what steps it needs to take to verify whether the statements are, in fact, true. For example, a warranty that the licensee's products will be 'fit for purpose' may be completely outside the university's knowledge or control and therefore not something that it should warrant.

In some transactions there are so-called "standard" or "routine" warranties which the other party may not wish to negotiate. Some of these concern the ability of a party to enter into the contract and have their origins in US contractual 'boilerplate' clauses. As with all warranties, they should be referred to the university's legal advisers; often the advice will be that a UK university is able to enter into most types of contracts and that certain of these boilerplate warranties are harmless and therefore acceptable.

A university's policy on liability clauses might include some or all of the following points:

- *No warranties*: starting position: do not give warranties;
- *List of acceptable warranties*: where required to provide warranties, provide warranties from an "acceptable" list of clauses. Such "acceptable" warranties should concern only simple factual matters and should be limited to those matters which can be properly (and easily) documented. For example, some universities are willing to give warranties such as the following in some intellectual property transactions:
 - that the university has the authority to enter into the contract;
 - that the university is registered as the proprietor of the licensed patents;
 - that the licensed patents are in existence and have not lapsed.
- *Qualified warranties*: where a warranty is given (and especially where the warranty is not in the "acceptable" list) it should be heavily qualified. Some techniques for qualifying warranties include the following:
 - liability under that warranty is limited to a defined amount;
 - claims for breach of warranty can only be brought within a fixed period;
 - no absolute warranties are given, but only knowledge-based ones (and then limited to actual knowledge (i.e. without investigation) of named individuals);
 - the remedies available in the event of a breach of the warranty are limited (e.g. that the sole remedy is the termination of the agreement, and that there are no financial or other remedies); and
 - there are no implied warranties (or any reliance on any warranties or representations made by the university other than those incorporated into the agreement—although this commonly dealt with an entire agreement clause).
- *Disclaimers*: state, in appropriate circumstances, which specific things are not warranted (as well as including a statement that there are no implied warranties);
- *List of unacceptable warranties*: compile a list of warranties which are always unacceptable. Although the type of warranties proposed by a commercial organisations will vary (and may only be limited by the

imagination of the person who drafted them), there are some warranties which are commonly used and which should always be avoided, such as:

- that the intellectual property will not infringe third party intellectual property rights;
- that the licensed intellectual property is valid;
- that any result can be achieved or guaranteed;
- as to the efficacy or usefulness of any licensed intellectual property;
- any requirement or duty on the university to bring proceedings against a party infringing the licensed intellectual property (or be required to defend proceeding).

These warranties will usually be unacceptable for two main reasons:

- the university would need to devote much time and money to carry out sufficient due diligence to establish whether the warranties could be given at all or could only be given subject to specified limitations;
- the consequences of a breach of some of the warranties cannot be easily quantified and/or to give the warranty (even with limitations) may take it outside the university's insurance policy.

Exclusion and limitation of liability

As has already been mentioned, legal advice should be sought when preparing a university policy in the area of liability clauses. Specific legislation in this field, as well as guidance from court cases, must be taken into account when formulating any policy. Moreover, as new laws are regularly introduced in this area (particularly, but not only, to protect consumers) and new court cases clarify which liability clauses are enforceable, it is important to keep the policy under regular legal review.

Subject to that legal advice, and in the area of clauses limiting or excluding liability, the following points may be considered for inclusion in the policy:

- *Exclusions*: a description of circumstances in which a total exclusion of liability should be sought (e.g. for indirect or consequential losses or for economic losses such as loss of profits);

- *Limitations*: a description of circumstances when liability should be accepted up to a stated level. Some typical levels for different types of contract might include (a) the amount of the university's professional indemnity insurance policy, (b) the price paid under the contract, or (c) a multiple of the price paid;
- *Exceptions*: instructions that the liability clauses should always include wording stating that the clause does not exclude liability for death or personal injury, or for fraud;
- *Unacceptable or uninsured clauses*: a non-exhaustive list of liability clauses which are not acceptable and/or which are not covered by the university's insurance policy, and a non-exhaustive list of types of liability (and extent of liability) which are covered by the university's insurance policy;
- *Clause requiring senior management approval*: Which clauses must be referred to more senior management for review. Some universities may take the view that any amendment or change of the standard liability clauses should always be referred to management or a legal adviser for consideration.

Indemnities

Readers should consult the relevant section of *Practical Guide to Legal Issues* for a brief discussion of the legal aspects of indemnities. A typical position for a UK university might be that it is not willing to give indemnities except in defined circumstances. Subject to the university obtaining legal advice and checking the insurance position, some of those circumstances might be:

- In an MTA, it may be acceptable for the recipient of materials to give the provider of materials an indemnity concerning those materials – see further the Practical Guide to MTAs]
- Some indemnities that seek to apportion third party liabilities may be acceptable, if 'balanced'. For example if a patient is injured in a clinical trial being conducted by the university, it may be acceptable for the university to indemnify the sponsor against claims arising from failure by the university to follow the protocol, as long as the sponsor gives an indemnity against all other claims, e.g. if the drug causes injury to the patient.
- A university may require an indemnity from a licensee against claims from purchasers of the licensed products.

It is worth noting that many US State universities claim that they are not able to give indemnities as a matter of State law. Usually this arises from an area of law known as “state immunity”, also known (in the UK at least) as sovereign immunity. Sometimes such universities are willing to give a watered-down promise that they will be ‘responsible’ for any claims arising from their breach of contract.

Relationship of liability clauses to other provisions

There are two other key clauses in contracts which need to be considered when considering the liability clauses:

- entire agreement provisions; and
- law and jurisdiction provisions.

Typically, the ‘entire agreement’ clause will seek to exclude any warranties or terms that are not set out in the contract document. If there is no such clause then the liability clauses may need to be adjusted to take account of these factors. For law and jurisdiction, particularly if a non-English law is chosen then the liability clauses will need to be reviewed to see whether they are effective under the law which is chosen to govern the contract.

Entire agreement and law and jurisdiction provisions are considered further in *Practical Guide to Legal Issues*.

Chapter 9

Conflicts of interest

What is a conflict of interest?

There are many kinds of conflict of interest, most of which are not relevant to university commercialisation agreements. For present purposes, we are concerned with a member of the academic staff of a university who has multiple relationships with an outside organisation, such as a spin-out company, research sponsor or licensee of intellectual property. To illustrate the problem, the following case example provides some particularly obvious instances of unacceptable conflicts of interest:

- An academic develops some technology concerning pharmaceutical drugs.
- A spin-out company is formed to commercialise this technology.
- The academic is given some shares in the company, he is a director of the company and has a personal consultancy agreement with it.
- The technology is used to develop a lead compound that may have utility as a pharmaceutical drug.
- The company sponsors the university, with the academic as principal investigator, to conduct some clinical trials at the university involving the company's lead compound.
- The company also sponsor the university to conduct some pre-clinical studies on some other lead compounds that it has developed. The academic engages one of his students to conduct these studies as part of his work towards a PhD.

When conducting the clinical trials and studies for the company, this academic has a number of potential conflicts of interest, some of which are described below. Some of these conflicts of interest may be perceived, rather than actual, but this does not make them any less important to address. Some of the conflicts might be better described as conflicts of duty, (e.g. his legal duties as a director to act in the best interests of the company vs. his duties as a

university employee and clinician). For convenience, all of these conflicts are simply described as conflicts of interest.

In this example, the academic has a number of roles, which may conflict with one another. This is not to say that they always or often will, but there is at least a risk of a conflict.

- Role as a director of the company, required by law to act in the best interests of the company.
- Role as a shareholder of the company, having a financial interest in the success of the company's products.
- Role as a consultant to the company, perhaps engaged to help make the company's products successful.
- Role as an academic, seeking to obtain research funding for the activities of his laboratory or department.
- Role as a clinician (sometimes such academics have an honorary appointment in a hospital that is linked to the university), acting in the best interests of the patient.
- Role as an academic and university employee, conducting research in an objective and unbiased manner and consistent with the charitable objectives of the university; not bringing the university into disrepute.
- Role as a supervisor of the student, providing the student with appropriate experience in the best interests of the student.

There are many other examples of situations where an academic may find that he has a conflict of interest. Not all of these are in the medical field, but there is an extra layer of potential conflicts in the medical field in relation to the interests of patients.

The conflicts of interest that arise from the above case example, and how they should be dealt with, are discussed further, below.

This chapter and the policy document in Appendix A4 are concerned with the personal interests of an academic in relation to outside commercial organisations. Other types of interest, not covered here, include:

- Any conflicts of interest of the *university*, e.g. as a shareholder in a spin-out company.

- Any conflicts of interest that may arise from the non-commercial interests of the academic, e.g. through membership of external committees, etc.

These other areas, although important, have not received the same degree of public attention as the conflicts of interest that arise from academics having interests in commercial organisations. In the authors' experience, TTEs may be more likely to encounter issues in the latter area, i.e. those discussed in this chapter.

Experience in the USA

Many universities and medical schools in the USA have written conflicts of interest policies that have been in place for many years. Several US institutions have included their policies on their websites. Some of these policies are very strict and provide for an absolute ban on certain types of activity. It is understood that clinical trials as described in the above example would be banned in many US universities and medical schools.

Experience in the UK

UK universities have started to grapple with conflicts of interest in recent years, and some have developed written policies. This has been prompted partly by the increasing use of spin-out companies as a route to commercialisation of university IP. The policy document included in Appendix A is adapted from the policy of University College London. Thanks are due to Jeff Skinner and UCL for permission to include this document.

It may be fair to say that there has been less experience of serious conflicts in the UK than in the USA, and that the approach of UK universities has been to take a more pragmatic approach to the issues that arise. Specifically, UK universities may be more inclined to the approach that potential conflicts must be notified to the university authorities, and if notified may be permitted, subject to supervision, rather than being automatically banned. However, this comment is based on the authors' experience, necessarily limited, which may not reflect the position throughout the UK. The authors would be interested to hear of UNICO members' experiences, which could be summarised in any update to this Practical Guide.

Which situations should be covered in a conflicts of interest policy

The policy document in Appendix A provided a detailed description of different types of conflict and how they should be managed. It also includes, in its Annexes:

- some examples of situations that are considered to be particularly problematic;
- the terms of reference of a university committee on conflicts of interest, which would have powers to approve or disapprove any cases brought to its attention;
- a form (and accompanying notes) for an academic to make an annual declaration of his interests, both commercial and non-commercial.

The policy document draws upon the experience of US universities in classifying four main categories of conflict of interest, namely:

- Educational Mission (especially in regard to supervision of students)
- Research Integrity
- Conflicts of Commitment and Loyalty
- Financial Conflicts

It can immediately be seen that the case example described earlier in this chapter gives rise to potential conflicts in all four of these categories, including:

- Educational Mission – with regard to the student who is engaged to do work for the benefit of the spin-out company and whose academic studies are being supervised by the academic.
- Research Integrity – because the academic has a financial interest in the success of the clinical trials.
- Conflicts of Commitment and Loyalty – because the academic has duties as a director of, and consultant to, the company that may conflict with his duties to the university.
- Financial Conflicts – because the academic is a shareholder in the spin-out company and receiving research funding from it.

As mentioned earlier, these situations present a risk of conflicts of interest; how those risks are dealt with is a matter for the university concerned.

The policy document in Appendix A deals with such risks in a number of ways, including:

- Requiring *disclosure* of all potential conflicts
- Requiring *approval* by superiors for certain types of activity
- Procedures for *review* of potential conflicts by a committee that has the power to veto activities
- Requiring that academics owe their *primary duties* and allegiance to the university
- Requiring that “conflicted” persons *not take part in negotiations* over certain types of agreement, e.g. the financial terms of a research contract
- Requiring that students be *supervised by a different supervisor* to the one that has a conflict of interest, in certain situations
- *Prohibiting investment* by supervising academics in student-run business, in certain situations
- Requiring that *co-investigators* be appointed to research projects, in certain situations

Some institutions have policies that are specific to their charitable mission, e.g. it is understood that Cancer Research UK requires in all of its contracts with outside organisations a clause allowing Cancer Research UK to terminate the contract if the outside organisation has any interest in a tobacco company.

Readers who wish to get a better understanding of the situations where potential conflicts may arise, and some of the ways in which these situations might be addressed, should study the policy document in Appendix A. It is assumed that each university will wish to adopt its own detailed rules on how conflicts are dealt with, perhaps using the general framework of that document.

Role of the TTE in relation to conflicts of interest

It is assumed that many TTEs will not be directly responsible for the adoption or implementation of the university’s conflicts of interest policy, but that they may have some input to the policy, given that much of it will be concerned with the university’s commercial activities.

The situations in which conflicts of interest may directly affect the TTE's activities may include the following:

- In the *structuring* of transactions – if it is known that an academic has, or would have, a conflict of interest, it may be possible to structure the deal differently so as to avoid such a conflict, e.g. sometimes, by making someone other than the conflicted academic the principal investigator under a research contract, or by limiting the PI's role in the spin-out company. Or, in extreme cases, it may be necessary to decline a contract where the conflict of interest is perceived to be too great.
- In the *drafting* of agreements – for example, in the case of a spin-out transaction where the lead academic is appointed as a consultant to the spin-out company, by ensuring that the terms of the consultancy agreement make clear that the academic's primary duties are to the university. Sometimes, these consultancy agreements are adapted from employment contracts and included wording indicating that the academic's primary duty is to the spin-out company, which would not usually be acceptable.
- By *advising* the academic and the university authorities where it appears to the TTE that a conflict of interest has arisen or might arise.
- In the *resolution* of any existing conflicts, e.g. by recommending that an academic give up either his directorship in a spin-out company or his research contract with that company, so as to remove the conflict in the future.
- Occasionally, in *dealing with* any conflicts that the TTE may have personally, e.g. if he is a director of a spin-out company and he becomes aware of information as a university employee that puts him into a conflicted position vis-à-vis the company. The question of who should be the university's nominated director of a spin-out company is discussed in the Practical Guide to Spin-out Transactions.

Chapter 10

Monitoring and management of existing agreements

Introduction

Historically, some universities have been better at negotiating new agreements than at managing existing agreements. The authors have encountered numerous examples of where universities have not given the management of existing agreements as much priority as it deserved. No doubt these examples are the exception rather than the rule. They include:

- Failing to invoice the commercial partner for payments due under the agreement, either on time or at all.
- Failing to follow up on late payment of invoices.
- Failing to react for several years if the commercial partner does not submit royalty statements or other reports (which are usually required to be sent in quarterly, every six months or annually).
- Failing to monitor the commercial partner's performance of its obligations, e.g. its diligence obligations under a licence agreement.
- Failing to exercise its powers of audit of the commercial partner's records, e.g. under a licence agreement.
- Failing to notice that an agreement has expired and needs to be renewed.

An interesting side-effect of these failings is the story, heard quite frequently, that when the university eventually does get around to conducting an audit, it is discovered that the licensee has been under-reporting sales income, and under-paying royalties, for many years. It seems that this is sometimes due to a misunderstanding (e.g. by the licensee's accounts department) of the types of products that are royalty-bearing, rather than any deliberate fraud.

The blame for some of these failings is sometimes passed to other departments of the university, e.g. "finance". In the authors' view, a TTE should be given responsibility for project managing each existing commercialisation agreement

and ensuring that these basic commercial activities are performed, even if a different department of the university is to perform them.

It seems that part of the reason why these types of activities have sometimes been overlooked is that TTEs are usually very busy people who have to prioritise their workloads. Their performance as employees may have been judged on their ability to bring in and close new deals, rather than their management of existing relationships. Temperamentally, some may have been more suited to doing deals than administering them. In such circumstances, it is understandable that an “old” deal may receive less attention than a new one. But this may be a misguided approach for the university to take in the longer term.

What should universities do?

It is suggested that universities should commit resources to the management of existing commercial relationships, including by taking the following steps:

- *Responsible person.* By making a TTE responsible for the project management of each existing commercial contract. This does not necessarily need to be the same person who negotiated the contract, although often it will be. In larger departments, it may be appropriate to recruit a dedicated administrator (although it should be emphasised that this is an executive, rather than a secretarial, role). Whoever has this role should be assessed on their ability to manage the ongoing aspects of the contract, including those areas highlighted in the bullet points in the introduction, above.
- *Record-keeping.* By maintaining records of existing agreements, including a summary of all significant obligations and dates, and implementing a diary system that prompts the project manager (or other relevant personnel) to check whether the obligation has been met.
- *Active management.* By actively managing existing contracts. Specific actions to be taken may include:
 - Initiating regular meetings with licensees and others to discuss performance.
 - Making it a matter of policy to audit licensees regularly, using the audit rights set out in the contract. By explaining at the outset that this is the

university's standard policy, this should significantly reduce the risk of a licensee being "offended" by the audit.

- Ongoing assessment of the market to establish whether the commercial partner's performance meets the university's expectations.
- Following up promptly and persistently where the commercial partner fails to send in a report or perform some other obligation. Sometimes, situations are allowed to drift for several years without resolution, because no-one at the university is actively managing the situation, or because the problem is allowed to take second-place to other, more exciting projects such as new business opportunities.
- In appropriate cases, exercising the university's rights of termination of the contract, if the commercial partner fails to perform its obligations.

Sometimes, universities are concerned that if they take some of these steps, the relationship with the commercial partner may suffer, because the university will come across as being too aggressive. In practice, this concern is usually misguided. Taking these steps should help to make the university appear professional and competent, and more in tune with normal business practice.

Appendices

Appendix A – Templates

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Key issues in managing technology transfer agreements

1. Due diligence questionnaire
2. Employee assignment and revenue sharing agreement
3. Publications clause
4. Conflicts of interest policy

Appendix A1 – Due diligence questionnaire

Title Of Invention: _____

Date: _____

Part A: Introduction

This form is designed to capture the initial details of inventions made at University. Information provided will be used by University TCo to assess the commercial potential and patentability of the invention. In order to assist University TCo with this assessment please complete the form as fully as possible.

If you would like to discuss your technology with a University TCo executive prior to completing this form, please telephone [].

Part B: The Invention:

(please attach further papers as required)

Background (why the invention is required)

Description (how, in laymean's terms, the invention works). To be patentable, inventive steps (i.e., non-obvious steps which are crucial in obtaining the benefits of the invention) must be clearly shown. Please highlight any such inventive steps in this section.

Advantages (what the invention does, over and above existing methods)

Development status (how much further development is required and why)

Is it a main project area of the group? Y ☐ N ☐

Is work in this area going to be performed in the next twelve months (as part of ongoing research activities)? Y ☐ N ☐

How far do the researchers estimate they will progress in this time?

Part C: Inventors' Details

	Name, department, and employment status	Inventive Contribution [%]
NAME: EMPLOYMENT DETAILS: DETAILS OF THIRD PARTY PAYMENTS COVERING EMPLOYMENT (e.g., whether Recharged To NHS Trust)		
NAME: EMPLOYMENT DETAILS: DETAILS OF THIRD PARTY PAYMENTS COVERING EMPLOYMENT (e.g., whether Recharged To NHS Trust)		
NAME: EMPLOYMENT DETAILS: DETAILS OF THIRD PARTY PAYMENTS COVERING EMPLOYMENT (e.g., whether recharged to NHS Trust)		

Continue on a separate sheet if necessary

Note: inventor(s) will be required to sign a form confirming the inventorship and inventive contributions if the invention is taken forward by university ttco.

Part D: Third Party Interests

Details of funding sources:

Research contract No/Reference	Details of funding
	Sponsor: IP Terms (if known):
	Sponsor: IP Terms (if known):
	Sponsor: IP Terms (if known):

Continue on a separate sheet if necessary.

Please forward any copies of contracts as may be required.

Details of Materials Transfer and other relevant Agreements:

In particular please give; (i) details of any agreements that have been executed which may give rise to restrictions on the commercial use of inventions arising, e.g., relating to materials or software provided under a transfer or license from a third party; and (ii) details of any rights to the invention that arise through industrial or third party support of the research that led to the invention, if not already listed above.

Part E: Disclosures:

Please list any previous or anticipated disclosure (i.e., any transfer of information to companies or individuals other than colleagues that was not imparted in confidence) of information that could be of relevance to the invention.

Date	Type of Disclosure (Tick as appropriate)						Description of disclosure e.g., title, reference etc
	Paper	Abstract	Conference	Poster	Meeting	Other e.g. database	

Continue on a separate sheet if necessary

PART F: Commercial Considerations

Please provide any details that may help University TCo to assess the commercial potential of the invention. In particular list any companies that you know use or exploit this type of technology and detail any interest they may have shown in your research.

Any thoughts you have had as to how the invention could be commercialised and an indication of your interest in being involved in that process should also be given.

Appendix A2.1 - Employee assignment of IP

Note: the following template includes some optional clauses. The relevance of most of these will depend on what types of IP are being assigned.

THIS ASSIGNMENT dated _____ 200[] is between:

1. whose home address is _____ (the "Inventor"); and
2. University of _____, [incorporated by Royal Charter in the United Kingdom], whose address is _____ (the "University").

WHEREAS:

- A. The Inventor is a full-time employee of University, [and is engaged to carry out research].
- B. The Inventor has made inventions and developed technology, materials and/or know-how relating to [relevant technology] as described in Part A of Schedule 1 (the "Technology").
- C. The University and the Inventor have agreed the terms of a revenue sharing agreement to be entered into by the parties on the same date as this Assignment (the "Revenue Sharing Agreement").
- D. The Inventor wishes to assign to the University all of his right, title and interest in the Technology, including all right, title and interest in the specific items of intellectual property and other property identified in Part B of Schedule 1 (the "Assigned Property") and the University wishes to take an assignment of the Technology and Assigned Property, subject to and in accordance with the terms of this Assignment.

THIS ASSIGNMENT WITNESSES AS FOLLOWS:

1. Assignment

- (a) [In consideration of the University executing the Revenue Sharing Agreement and the sum of £1 (one pound sterling) now paid by the University to the Inventor (receipt of which the Inventor acknowledges), the Inventor hereby assigns and transfers to the University absolutely

[and with full title guarantee], all [of his] right, title and interest in and to the Technology and the Assigned Property.

(b) The assignment effected by this clause 1 shall include, without limitation, the assignment and transfer of:

(i) all [patents and other] intellectual property listed, or that may be granted pursuant to any applications listed, in the attached Schedule, as well as all [patents or other] intellectual property that may derive priority from or have equivalent claims to [or be based upon] the Assigned Property in any country of the world [(and including supplementary protection certificates, divisions, continuations, continuations in part, reissues and extensions)], and the Assigned Property shall be deemed to include all such items of property; and

(ii) all [copyright or other] unregistered intellectual property listed in the attached Schedule; and

(iii) [all rights in respect of any know-how described in the attached Schedule;]

(iv) [all rights of ownership of any materials that form part of the Technology, including without limitation any cell-lines, antibodies or other materials; and]

(v) all rights of action, powers and benefits arising from ownership of the Technology and the Assigned Property, including without limitation the right to sue for damages and other legal and equitable remedies in respect of all causes of action arising prior to, on or after the date of this Assignment.

(c) [To the extent that the Technology and Assigned Property includes any know-how protected under the laws governing confidential information, references to the "assignment" of such know-how shall include the following obligations on the Inventor:

(i) the Inventor shall transfer to University such rights as he may have in law to prevent the unauthorised use or disclosure of such know-how;

(ii) to the extent that such rights cannot be, or are not transferred by virtue of the provisions of paragraph (a) above, the Inventor will agree

to be joined in any action (whether as claimant or otherwise) brought by the University or its assignee against any third party that is alleged to infringe such rights, subject to the University effectively indemnifying the Inventor against any damages, costs and expenses incurred in relation to any such action;

- (iii) the Inventor shall neither use nor disclose any such know-how without the prior written consent of the University; but these obligations of non-use and non-disclosure shall cease upon the know-how becoming publicly known (other than as a result of breach of this clause by the Inventor);
 - (iv) the Inventor warrants and represents that he is not aware of any disclosure of such know-how to any third party, prior to the date of this Assignment, except under written obligations of confidentiality; and
 - (v) if required to do so by the University, the Inventor will make such acknowledgements to third parties as the University may reasonably require stating that the University owns all such know-how and that the Inventor does not retain any ownership rights in such know-how.]
- (d) [To the extent that the Technology and Assigned Property includes any materials or other physical property, references to the "assignment" of such property shall include the following obligations on the Inventor:
- (i) The Inventor shall provide to the University the samples and other items of such property described [where? When? etc] and shall transfer to the University all [of his] right, title and interest in and to such property; and
 - (ii) The Inventor warrants and represents that [Schedule ?] sets out a full and accurate description of all other quantities of such property that, to the best of his knowledge, are in existence and are not being supplied to the University under this Assignment ("Retained Items"); and
 - (iii) The Inventor shall not provide the Retained Items to any other person [commercial organisation?] and shall not use the Retained Items for any purpose [other than teaching and research].]

(e) The Inventor shall execute such documents and give such assistance as the University may require:

- (i) to secure the vesting in the University of all rights in the Technology and the Assigned Property; and
- (ii) to uphold the University's rights in the Technology and the Assigned Property; and
- (iii) to defeat any challenge to the validity of, and resolve any questions concerning, the Technology and the Assigned Property.

2. Warranties, representations and undertakings

The Inventor warrants, represents and undertakes that:

- (a) immediately prior to the assignment in clause 1 above he had not been and he is not currently a party to any agreement or understanding, whether oral or written, which would in any manner be inconsistent with the assignment of rights provided for in this Assignment; and
- (b) during the term of this Assignment he shall not enter into any agreement or understanding, oral or written, nor engage in any activity, which would in any manner be inconsistent with the provisions of this Assignment; and
- (c) [Schedule ? sets out the names of all persons of whom he is aware who might have rights in the Technology, including any other persons who were involved in developing the Technology, and any organisations which funded the development of the Technology.]

3. General

- (a) The obligations on the Inventor under clauses 1.3, 1.4, 1.5, 2 and 3 shall continue in force without limit of time.
- (b) English Law shall govern the validity, construction and performance of this Assignment, and the parties submit to the jurisdiction of the English Courts in respect of any dispute arising in connection therewith.

AGREED by the parties:

By [name of inventor]

For and on behalf of

UNIVERSITY of []

Signed

Signed

Print Name

Print Name

Date

Title

Date

Schedule 1

Part A: General description of Technology

Part B: Identification of any specific items of intellectual property or other property including (a) any patents, patent applications, copyright works, design rights, etc; (b) any important know-how; and (c) any materials (e.g. cell lines) that are to be assigned.

Appendix A2.2 - Employee revenue sharing agreement

THIS AGREEMENT dated _____ 200[] is between:

_____ whose home address is

_____ (the "Inventor"); and

UNIVERSITY OF _____, [incorporated by Royal Charter in the United Kingdom,] whose address is ? (the "University").

WHEREAS:

The Inventor and the University are willing to enter into an assignment (the "Assignment") of intellectual property relating to [relevant technology] on the same date as this Agreement.

The University is willing to pay to the Inventor a percentage of Net Receipts (as defined below), subject to the provisions of this Agreement.

IT IS AGREED AS FOLLOWS:

1. Definitions

In this Agreement, the following words shall have the following meanings:

Assignment An assignment of intellectual property and other rights to be executed by the Parties on the same date as this Agreement.

Assigned Property Has the meaning given in the Assignment.

[Commercialisation Fee] [In any Payment Period, means ?% of the amount left after the Costs incurred during that Payment Period have been deducted from the Gross Receipts obtained in that Payment Period.]

Costs any costs, fees and expenses (whether internal or external) reasonably incurred by the University or by the Inventor at University's request in respect of:

(1) the preparation of this Agreement and the Assignment and any documents executed

pursuant thereto, as well as the registration of any document with any patent office or other institution, and the payment of any stamp duty or other tax or charge in connection with such documents;

- (2) seeking and maintaining patents or other intellectual property in respect of the Assigned Property, including defending any claims of opposition or for revocation of any intellectual property rights in respect of the Assigned Property and bringing claims against third parties [where the University is advised that the intellectual property of the third party constitutes an impediment to the exploitation of the Assigned Property] (and University's costs shall include any damages or other sums awarded against the University or agreed in settlement in respect of such claims);
- (3) the negotiation and execution of agreements with licensees and others in respect of the development or exploitation of the Assigned Property and the administration of such agreements, including any costs of dealing with claims or proceedings associated with such agreements; and
- (4) travel and other expenses incurred by the University or by University staff or the Inventor at the University's request and with the University's prior written approval in carrying out their obligations under this Agreement.

Gross Receipts

The actual sums received by the University from time to time from Third Parties in respect of the exploitation of the Assigned Property.

<i>Net Receipts</i>	The Gross Receipts less the Costs then less the Commercialisation Fee and less any Third Party Payments.
<i>Parties</i>	The Inventor and the University, and "Party" shall mean either of them.
<i>Payment Period</i>	[each six-monthly period ending on 30 June or 31 December in any year][each quarterly period ending on 31 March, 30 June, 30 September or 31 December in any year].
<i>Property Rights</i>	Shall include rights in respect of patents, copyright, database rights, designs, inventions, know-how, materials and other property and rights in any country of the world.
<i>Third Parties</i>	Any person(s) other than the Parties and their respective employees.
<i>Third Party Payments</i>	Any payments to Third Parties that (a) funded some or all of the research from which the Assigned Property arose and/or (b) are entitled to receive any payments from the University in respect of the exploitation of the Assigned Property.

2. Exploitation

Conditional upon the Inventor and University having executed the Assignment, and subject to the provisions of this Agreement, University shall use its reasonable endeavours, having regard to the circumstances prevailing from time to time, to secure the exploitation of the Assigned Property upon such terms as it shall, in its sole discretion, see fit.

3. Accounts and payment of royalty

(a) *Accounts.* The University shall keep accounts showing the amounts of each of the following in respect of each Payment Period, namely the Gross Receipts, the Costs, [the Commercialisation Fee,] any Third Party Payments, and the Net Receipts.

- (b) *Payments.* The Gross Receipts shall be the absolute property of the University but the University shall:
- (i) pay to the Inventor a royalty being the relevant percentage of Net Receipts stated in the attached Schedule 2; and
 - (ii) reimburse any Costs reasonably incurred by the Inventor at University's request and with University's prior written approval, and subject to submission of receipts for all such expenditure.
- (c) *Statements.* As soon as possible after the last day of each Payment Period in each year during the period of this Agreement, University shall prepare and send to the Inventor a cumulative statement showing the amount of Gross Receipts, Costs, [Commercialisation Fee,], Third Party Payments and Net Receipts up to that date. At the same time as sending such statement, University shall send to the Inventor a cheque for the amount of royalties due under clause (b)(i).
- (d) *Auditing.* The University shall make available its accounts, as referred to in clause (a), on reasonable notice for inspection during business hours by an independent chartered accountant nominated by the Inventor for the purpose of verifying the accuracy of any statement given by University to the Inventor under clause (c). The accountant shall be required to keep confidential all information learnt during any such inspection, and to disclose to the Inventor only such details as may be necessary to report on the accuracy of University's statement. The Inventor shall be liable for the accountant's charges unless the accountant certifies that there is an inaccuracy of more than 10 per cent in any royalty statement, in which case the University shall pay his charges in respect of that inspection.
- (e) *Shareholdings etc in lieu of royalties.* If the University assigns or licenses the Assigned Property to any company:
- (i) in which the Inventor is or will be a shareholder; or
 - (ii) which agrees to make payments or provide other benefits to the Inventor in respect of the exploitation of the Assigned Property;

then the University's obligations to pay royalties or other sums under this Agreement to the Inventor shall terminate as of the date of such assignment or licence.

(f) *Apportionment.* Where Gross Receipts are derived from the commercialisation of some or all of the Assigned Property in combination with other Property Rights that are not the subject of the Assignment, the Gross Receipts for the purposes of this Agreement shall be a proportion of the total sums received by University from the exploitation of the combined Property Rights. The University in its sole discretion shall decide the proportion.

(g) [*Hold-back.* If the University anticipates that, at a future date, the amount of any Costs and/or any Third Party Payments may exceed the amount of Gross Receipts, resulting in a negative amount of Net Receipts, the University may retain from any payment that would otherwise be due under Clause 3(b) such amount as it considers reasonable to cover such future Costs and/or Third Party Payments.]

4. General

(a) Nothing in this Agreement shall be deemed to constitute or evidence any partnership, agency, or employment relationship between the University and the Inventor.

(b) English Law shall govern the validity, construction and performance of this Agreement and the Parties submit to the jurisdiction of the English Courts in respect of any dispute connected with this Agreement.

(c) Any notice to be given under this Agreement shall be in writing and shall be sent by first class mail to the address of the relevant Party set out at the head of this Agreement, or such other address as a Party may from time to time notify to the other Party in accordance with this clause.

AGREED by the parties:

By [name of inventor]

For and on behalf of

UNIVERSITY of []

Signed

Signed

Print Name

Print Name

Date

Title

Date

SCHEDULE 1

Percentage of Net Receipts to be paid to the Inventor

Net Receipts up to £ _____

_____ % to Inventor

[where there is more than one inventor: _____ % to be shared between the inventors in proportions to be stated here]

Net Receipts above £ _____

_____ % to Inventor

[where there is more than one inventor: _____ % to be shared between the inventors in proportions to be stated here]

Appendix A3 – Publications clause

- 1.1 The Sponsors recognise that by charity law and under the University's policy, the results of the Project should be publishable.
- 1.2 The Sponsor agrees that researchers engaged in the Project shall be permitted to present at symposia, national, or regional professional meetings, and to publish in journals, theses or dissertations, or otherwise of their own choosing, methods and results of the Project; provided that the Sponsors shall have been furnished copies of any proposed publication or presentation at least [14 days][one month] in advance of the submission of such proposed publication or presentation to a journal, editor, or other third party.
- 1.3 The Sponsors shall have [14 days][one month], after receipt of said copies, to object to such proposed presentation or proposed publication on the grounds that there is patentable subject matter which needs protection or that it contains any of the Sponsors' confidential information.
- 1.4 If any Sponsor makes such objection, the said researcher(s) shall, as applicable, (a) delete the Sponsor's confidential information or (b) refrain from making such publication or presentation for a maximum of [30 days][6 months] from the date of receipt of such objection in order to file for UK and/or other patent application(s) to be directed to the patentable subject matter contained in the proposed publication or presentation.
- 1.5 In any permitted publication, the Sponsors and the University shall each record the active role of the other Parties' staff in the Project.

UNIVERSITY OF [_____]

POLICY AND GUIDELINES FOR CONFLICTS OF INTEREST

Executive Summary

Universities and their employees engage in a wide range of activities. The traditional academic roles, such as teaching and supervising students and conducting grant-funded academic research, are often supplemented by commercial collaborations including consultancy, commercial research and development, intellectual property licensing and involvement in 'spin-out' companies.

By and large, [University] leaves individual Departments and academic staff to develop their own balanced 'portfolio' of activity, including external collaborations of one kind or another. However, by engaging in such external activities, employees place themselves in a difficult position in which an outside interest may conflict, or appear to conflict, with their [University] duties. The employee may then be open to suspicion that decisions they take as a [University] employee are influenced by personal financial interest – even when, as is almost universally the case, the employee is acting with neutrality and complete professional integrity.

In the vast majority of cases simple disclosure of a potentially conflicting external activity is sufficient to absolve the employee of suspicion. Occasionally [University] may suggest a different way of managing an activity that avoids the conflict of interest. In extreme cases the conflict of interest may be so fundamental and unmanageable that it is necessary to restrict one or other of the employee's conflicting activities.

The purpose of the 'Policy and Guidelines for Conflict of Interest' is:

- To highlight and illustrate potential conflict situations, some of which are not obvious.
- To set out which activities can be managed (and how they can be managed), and which [University] considers unmanageable (and therefore cannot allow).

The most important message in the document is that you should always disclose an activity if you are in doubt about whether it represents a conflict of Interest. The Policy describes the way in which such disclosure should be made at the time (i.e. before you engage in the activity), and by completion of an Annual Return.

This Policy accords with the Seven Principles of Public Life established by the Nolan Committee and similar policies are common in most universities and other publicly-funded bodies. The fact that [University] has adopted such a Policy does not in any way cast doubt on the integrity of [University] employees. Rather it recognises that [University] wishes to give a great deal of freedom to employees to engage in external activities, but in so doing needs to put in place a mechanism to protect its employees, and itself, from reputational damage and other liabilities.

The authors are aware that the document is, in places, detailed and prescriptive. However this level of detail is necessary to provide clear and unambiguous guidance to employees facing specific conflict situations, and to be quite clear on [University]'s Policy. This document forms part of [University]'s Financial Regulations.

UNIVERSITY OF [_____]

POLICY AND GUIDELINES FOR CONFLICTS OF INTEREST

I. Background

Universities and their employees engage in a wide range of activities. The traditional academic roles, such as teaching and supervising students and conducting grant-funded academic research, are nowadays often supplemented by commercial collaborations including consultancy, commercial research and development, intellectual property licensing and involvement in 'spin-out' companies.

[University] recognises that involvement in such commercial activities carries many advantages, including the practical application of new technologies, the provision of an additional source of research funding and insights into commercial and societal needs and the receipt of royalty income for [University] and its departments. Contemporary attitudes are captured by the fact that the Government and HEFCE have created a permanent stream of funding to encourage and resource these 'third-leg' activities (complementing funding provided for teaching and research).

These activities can produce positive benefits, but they also have the potential for creating conflicts of interest. In particular, conflicts of interest can arise when the interests of a commercial venture, from which a [University] employee derives direct benefit, differ from the interests and primary obligations of [University] as a whole, or when the commercial venture consumes an undue share of the employee's attention. [University] believes it to be essential that its employees should manage or avoid, and be seen to manage or avoid, such conflicts. Moreover, many funding agencies, in the UK and elsewhere, are now seeking assurance that universities are properly managing conflicts as a condition of grant funding.

This document ("Conflicts Policy") sets out [University]'s policy and provides some practical guidelines to its employees on how they should manage potential or actual conflicts of interest. This Conflicts Policy takes effect from [tbd]. It supplements and expands upon the policy set out in [University]'s Financial Regulations and forms part of those Regulations.

Accordingly, it is a condition of their employment that [University] employees must comply with its requirements. The Policy applies to [state categories of staff], though the broad principles of the Policy apply to all staff.

The full prior disclosure of interests is clearly an important (and in many cases, sufficient) mechanism for the management of conflicts of interest. Employees are required to complete the 'Annual Declaration of Interests' return in August of each year. (Attached as Annex 3 of this document).

Whilst this document describes and provides guidelines for many of the situations in which conflicts occur, it is not meant to be exhaustive. The primary obligation rests with the employee to recognise situations in which he or she potentially has a conflict of interest and to disclose and discuss that conflict to their Head of Department. If you are uncertain how this Conflicts Policy might affect your activities, please contact your Head of Department or the Secretary of the 'Committee on Conflicts of Interest', whose contact details are given in Annex 2.

Within [University] there are two categories of conflict that may arise, personal (those faced by individuals) and institutional (those faced by [University] as an institution). This document addresses personal conflicts¹.

2. Types of Conflicts.

A working definition of "conflict of interest" is:

"A conflict between the private interests and the official responsibilities of a person in a position of trust".

The damage caused by such conflicts can be considerable. For example, should the press cast doubt on the validity of an academic's research findings due to the academic being discovered to have had a conflict of interest, there could be considerable reputational damage to the academic and [University].

¹. Excluding those covered in the separate document entitled, 'Code of conduct on personal relationships at work'.

This illustration highlights another important issue. The definition is not restricted to those cases in which an individual actually betrays that trust; it can be just as damaging for the conflict to exist or appear to exist. For this reason, an explicit conflict of interest policy does not infer any lack of trust in or loyalty of academic colleagues. Rather, it is a mechanism for protecting [University] employees against criticism or compromise by ensuring that they recognise and disclose such conflict situations and take steps to avoid and manage them.

Some of the principles set out in this Conflicts Policy relate to what might be better described as “conflicts of duty” (e.g. where one’s duty as a [University] employee conflicts with one’s duty as a director of a spin-out company). The term “conflicts of interest” as used in this document includes conflicts of duty, rights, obligations, interests and similar conflicts, whether as an individual or as a representative of [University].

The main categories of conflict of interest (discussed in more detail below) are:

- Educational Mission (especially in regard to supervision)
- Research Integrity
- Conflicts of Commitment and Loyalty
- Financial Conflicts

Some of the situations described in this Conflicts Policy concern spin-out companies. Employees often have multiple roles in such companies, for example as a Director, shareholder and consultant. Fulfilling these multiple roles in the company can create (or appear to create) a conflict with the employee’s primary obligations and allegiance to [University]. This Conflicts Policy addresses conflicts involving spin-out companies as well as many other situations where conflicts may arise. Other general examples include:

- (a) The use of the University’s research or administrative facilities to pursue personal business, commercial or consulting activities
- (b) Any attempt to restrict rights governing the timing and contents of publications, save in circumstances approved by the University to

protect privacy, commercially sensitive proprietary information and patentable inventions

- (c) Involvement in externally-funded activity that might infringe the right of a student engaged in the activity to complete the degree for which he or she is registered and/or to publish freely or seek patent protection for his or her findings (save in the circumstances referred to in (b) above).
- (d) A financial interest held by an individual in an external enterprise engaged in activities closely related to that individual's line of research in the university
- (e) A personal involvement in any company which is in, or in the process of negotiating, a contract with the university.
- (f) Over-dependence on a particular company for research funding – which may result in that company either formally or informally influencing the direction of the research or dissemination of results.

These categories are intended to be illustrative and not exhaustive. Similarly, any examples of conflicts of interest given below are illustrative only.

3. Principal Situations in which conflicts can arise.

Conflicts of interest, such as those described above, usually arise when an employee:

- Has a financial interest in an activity (e.g. research, consultancy or license income) that is dependent on particular research outcomes
- Has a financial interest in the sponsor of a research project or studentship (e.g. as a shareholder of the sponsoring body)

This Conflicts Policy addresses both financial and non-financial conflicts of interest. However, the risk of a conflict, or the perception of a conflict, may be greater where a [University] employee has a Significant Financial Interest in relation to that activity or participant.

Similar issues arise where a Significant Financial Interest (as defined below) is held by a close family member (e.g. spouse, partner, parent, or sibling of that [University] employee) or by an associated entity such as a company or trust established or controlled by the employee or close family member or a

trust from which any of them benefits or may be expected to benefit. Throughout this Conflicts Policy, references to an employee shall be understood as including, where the context permits, his or her close family members and such associated entities.

(i) Significant Financial Interests and exceptions

For the purposes of this Conflicts Policy, a Significant Financial Interest includes the following items received or held by the employee:

- Shares, share options, warrants and other securities and security interests (together referred to below as "Shares") in a company;.
- Payments for services, e.g. consulting fees, directors fees, stipends and honoraria or payments in kind (together referred to below as "Consultancy Fees"); and.
- Payments in respect of intellectual property, including licence fees, royalties and revenue-sharing arrangements, except those payments made under [University]'s royalty sharing scheme.

Certain minimum thresholds apply to the definition of Significant Financial Interests:

1. Where a financial interest consists of Shares, it will be treated as excluded from the definition of Significant Financial Interests where **all** the following conditions are met:
 - The Shares are held in a company that is listed on a recognised stock exchange.
 - The current value of the Shares does not exceed £10,000 at any time.
 - There is no relationship or connection, explicit or implicit, between the acquisition of the Shares and any research to be conducted for that company
2. Where a financial interest consists of *Consultancy Fees*, it will be treated as excluded from the definition if both of the following conditions are met:
 - The Consultancy Fees amount to less than £10,000 in any twelve month period.

- It can be reasonably demonstrated that payment of any fee is not related to or contingent on the award of the proposed relationship between [University] and the company (e.g. a research contract or sponsored studentship, as discussed later).

(ii) Directorships and other External Appointments

A Director (i.e. a member of the Board of Directors) of a company has fiduciary duties to the company (e.g. to act in the best interests of the company), which as a matter of law may go beyond the duties of an ordinary employee or consultant. Other appointments, for example, as a trustee of a charity or other trust, or membership of certain external committees, may create similar duties. These duties may arise without there being any formal contract in place. Other personal appointments, e.g. as a consultant, may give rise to onerous duties where these are included as a term of the consultancy or other agreement.

Whenever a [University] employee accepts an external position or appointment, the potential for conflicts of interest may arise. For example, where an employee is a Director of a company that sponsors research at [University], his or her legal duties as a Director may conflict with his or her duties as a [University] employee, regardless of whether the employee receives payment for services.

Directorships and other appointments outside [University] are referred to below as “External Appointments”. Certain restrictions in relation to the acceptance of External Appointments, and restrictions on a [University] employee engaging in activities where they have an External Appointment, are described later in this Conflicts Policy.

(iii) Other situations where conflicts may arise

The holding of a Significant Financial Interest or an External Appointment are specific examples of situations that increase the risk or perception of a conflict of interest. However, it is not possible to provide a comprehensive definition of circumstances that necessarily give rise to a conflict of interest. In any situation where the individual is uncertain as to the propriety of a given arrangement, advice should be sought from the

individual's Head of Department², who may refer to the Committee on Conflict of Interest.

The overall test is that the associations made, and actions permitted, could be successfully justified to a sceptical member of the public.

(iv). [University]'s policy

[University] is committed to the principle that its employees' activities should not give rise to situations in which employees have, or appear to have, harmful conflicts of interest. At the same time, [University] recognises that policies that seek to eliminate all potential conflicts could also prevent many of the activities (e.g. spin-out companies) that universities now wish to encourage. Accordingly, rather than seek to prohibit all activities that might give rise to a conflict of interest, this Conflicts Policy provides for a three-fold approach:

- Disclose always.
- Manage the conflict in most cases.
- Prohibit the activity when necessary to protect the public interest or the interest of [University].

The key goal is to segregate the decision-making about the *financial* activities and the *research/teaching* activities, so that they are separately and independently managed. [University] is particularly concerned to ensure that its employees' activities do not create conflicts in the areas of

². In several places, the Guidelines refer to a requirement on a [University] employee to consult with or obtain the permission of his or her Head of Department before conducting an activity. Where the employee concerned is a Head of Department, such references should be understood as referring to the relevant Dean. In the case of Deans, such references should be understood as referring to the appropriate Vice-[President] and in the case of Vice [President]s should be understood to refer to the [President] and in the case of the [President], should be understood as referring to the Chairman of Council.

[University]'s Educational Mission and Research Integrity, as these areas are considered to be of fundamental importance to [University] as an institution dedicated to teaching and research.

On occasions, [University] itself may be involved in an activity in which a [University] employee has a conflict of interest. For example, [University] may own shares in a spin-out company in which a [University] employee also owns shares. Depending on the circumstances, the [University] employee's shareholding may give rise to a conflict of interest. Employees should be aware that the fact that [University] may benefit from an activity (e.g. as a shareholder) does not in any way mitigate or reduce the employee's obligations under this Conflicts Policy.

[University] implements its policy by issuing this Conflicts Policy and by implementing the practical steps described below.

(i) Conflict of educational mission

Principles

[University]'s employees who are involved in educating, training, supervising or directing the work ("Education") of students, should ensure that the education they provide is appropriate to the Student.

[University] has a primary objective to educate and train students. Special care must be taken to assure that the choice of a student's research project, and the direction of that research is not, and does not appear to be influenced by, their supervisor's financial interest

While the following policy and guidelines refer to research students, many of the same points are also applicable to junior members of academic staff and research assistants.

Conflicts and their management.

As a general rule, [University] would prefer not to enrol a student where:

- The student receives support from (is sponsored by) a company in which the proposed academic supervisor has a Significant Financial Interest.

- Where the results arising from, or IP generated in the course of, the research project are related to the research activities of a company in which the supervisor has a Significant Financial Interest.

[University] believes that such situations are extremely difficult to monitor and that both the supervisor and the university are vulnerable to allegations that the student's research (and advice given on other issues, e.g. IP protection) was directed in a way that was not in the student's best interest.

One approach to the management of this conflict situation is to identify an alternative member of academic staff, with no Significant Financial Interest, to act as the supervisor for the student. In such cases the individual with a conflict of interest should not seek to direct the project except through the alternative supervisor.

However, [University] recognises that it is also to the student's advantage to be supervised by the member of staff with the greatest relevant expertise, and that, in a very few circumstances this may require that a student is supervised by a staff member with a Significant Financial Interest in the sponsoring organisation. In these circumstances permission must be sought by the Head of Department from the Committee on Conflicts of Interest. Where such permission is granted certain conditions will be imposed:

1. Before embarking on a research project, a student must be provided by the supervisor with a clear description of 1) the source of the sponsorship for the research to be undertaken, 2) any personal financial interest the supervisor has in a sponsor, 3) any restrictions that might be imposed on the scientific communication of the data by the sponsor, and, 4) any rights that the sponsor may have to any intellectual property generated in the course of the project.
2. The Second Supervisor may not have any connection with or interest in the sponsoring company (whether by way of Shares or Consulting Fees).

Increasingly, students themselves start businesses whilst still at university. No member of staff who is in a position to judge the quality of that student's work or to evaluate the student in any way, should take any Financial Stake or hold a Formal Position in such a student-run, owned or controlled venture

whilst the student is enrolled at [University]. Financial Stake means equity, option or any form of interest in such ventures. Formal Position means a member of the Board of Directors, acting as a paid consultant or employee or executive of the venture.

Conflict of research integrity

Principles

[University] employees should maintain the highest standards of scientific integrity in the conduct of research.

The complete, objective and timely dissemination of new findings through publications, is essential for research integrity. In this context, 'publication' means any means of dissemination of research findings, including publication in a journal, information placed on the web, conference presentations or any other kind of scientific communication.

The potential for personal gain must not jeopardise nor appear to jeopardise the integrity of research activities, including the choice of research, its design, the interpretation of results, or the reporting of such results.

Conflicts and their management

Conflicts of interest can arise in a number of situations, for example:

- The researcher has a Significant Financial Interest in the company sponsoring the research, this being exacerbated if the value of the researcher's Significant Financial Interest may be affected by the outcome of the research.
- The researcher is an inventor of patents whose value may be affected by the outcome of the research.
- The researcher holds a position in an enterprise (e.g. as Director) that may wish to restrict (or otherwise manage) adverse research findings for commercial reasons.

The preservation of research integrity must be largely dependent on self-regulation. The primary way to encourage appropriate conduct is to promote and maintain a climate consistent with high ethical standards. The

fundamental factor in ensuring the quality of research and research practices has to be the honesty of the individual investigator.

However, where a researcher has, or appears to have a conflict of interest (for example, because he or she has a Significant Financial Interest in a research sponsor), integrity in designing, conducting and reporting the research may be insufficient to protect the researcher and the university from suspicion and consequent reputational damage. In such cases researchers must take special measures to put themselves beyond suspicion.

The first step for managing such conflicts is disclosure. Where any member of staff has a conflict of interest, they should:

- *Before the research project is accepted* (i.e. a contractual arrangement agreed), disclose to and seek written consent from their Head of Department, who may refer to the Committee on Conflicts of Interest if he or she has any doubts. The disclosure should be in the form of a written memorandum that states the nature of the research, the staff and students who will be involved in conducting the research and the potential conflict and the method proposed to manage the conflict,
- Play no part whatsoever in the negotiation of the financial terms of the research contract, either as an agent of [University] or the sponsor,
- *At the time of submission* of a publication to a journal, comply with any conflict of interest policy of the relevant journal,

Make a similar form of disclosure on all other forms of publication³.

³. Most journals now have a Conflict of Interest policy. For example 'Nature' now invites authors to disclose competing financial interests. Should the author decline to do so then this fact will be published. Where the journal believes that trust has been significantly compromised by an author's actions, it will seek to redress the matter by 'an appropriate combination of sanctions and communications to readers and employers'. Nature suggests a practical definition of 'competing financial interest' as, "Any undeclared financial interests that could embarrass you were they to become publicly known after your work was published"

Conflicts of this kind should be managed or avoided in a number of ways:

- By declining the opportunity to conduct the research, instead arranging for the work to be carried out by an independent researcher, either in [University] or elsewhere.
- By appointing a co-investigator who has control over the design and analysis of the research and its results, or an oversight committee.

Clinical research is special case deserving of greater scrutiny, given the very significant financial consequences of research outcomes and the potential harm to members of the public engaged in clinical trials or under treatment. In some cases [University] may prohibit staff from acting as Principal Investigator. In addition to the guidelines laid out in this document, researchers should comply with any additional requirements as laid down by the appropriate (e.g. Hospital Trust) Ethics Committee.

Conflict of financial interest

Principles

[University] employees have a responsibility to respect and promote the financial interests of [University]. Staff should wherever possible ensure that [University] :

- receives appropriate financial benefits from the provision of research services, including consultancy and other services conducted through [University].
- receives appropriate financial benefits from the use or commercialisation of its intellectual property.
- receives appropriate financial benefits from the use of other resources and assets, including equipment, technical staff, facilities, and,
- makes responsible use of its financial resources in relation to the purchase of goods as specified in Paragraph [] of [University]'s Financial Regulations.

Conflicts and their management

A [University] employee's relationship with another organisation, e.g. as a share-holder of a spin-out company, may create financial responsibilities to

that organisation which conflict with his or her financial responsibilities to [University].

Such potential conflicts should be managed in a number of ways, including:

- Seeking formal permission from the Head of Department, describing the nature of the proposed relationship. If the Head of Department believes that the conflicts created by the proposed arrangement are manageable and that the use of any [University] resource will not conflict with academic priorities they may approve the arrangement in writing. If the Head of Department is in any doubt as to whether a conflict exists, he/she may refer the matter to the Committee on Conflicts of Interest. If such approval is given, either by the Committee or the Head of Department, then the arrangement will be formalised and an appropriate fee may be levied for the resource to be used.
- Contracts with external organisations, including their financial terms, being negotiated by the appropriate Administrative Department (e.g. Contract Research Office) with the employee playing no part whatsoever in such negotiations.
- Disclosing (if necessary under confidentiality) and seeking a waiver from [name relevant part of University] in respect of all inventions or other IP generated by the individual as part of (for example) a private consultancy.
- Where [University] employees provide consultancy services, by conducting that consultancy through [University]. Further guidance on consultancy are set out in [University]'s regulations on Private Consultancy Work.
- Where any goods or services are to be purchased from a business in which an employee has any Significant Financial Interest, then such interest should be declared to the Director of Finance .

Conflict of commitment/loyalty

Principles

[University] employees owe their primary commitment and allegiance to [University]. Membership of Committees, Boards, Advisory Groups etc (External Appointments) infers an obligation (and sometimes a statutory

duty) to act in the best interests of the external body. These duties may overlap with those duties and obligations as employees of [University]. Where an External Appointment is allowed under the Consultancy Guidelines or otherwise allowed by [University], this does not absolve the employee from ensuring that he or she continues to give their primary commitment and allegiance to [University].

Conflicts and their management

Rules applying to the acceptance of external appointments and the conduct of non-academic work, including limits on the amount of time that may be devoted to such activities, are set out in the [Consultancy Guidelines]. The scheduling of commitments to such external bodies should be such that they do not result in significant rescheduling of lectures, tutorials or other supervisory or management duties.

Where a [University] employee is involved in founding a new company, he or she may be induced to dedicate more time to it than is consistent with their duties to [University]. This risk can be reduced by ensuring that appropriate people are employed by the company to manage and direct both its business and scientific activities, with the [University] employee's role being limited to consultancy. Alternatively, the [University] employees may be able to arrange unpaid leave of absence from [University] for a period of time so that they can dedicate themselves full-time to the company.

In exceptional circumstances, it may be acceptable to [University] to permit academic staff to devote significant time (over and above that permitted under the Consultancy Guidelines) to an external appointment, for example where such absence can be shown to be short-term, non-disruptive to the employee's other duties and of clear benefit to [University]. Such cases should be put to the HoD in a timely fashion, giving full details of the nature of the activity and the timing and duration of the external commitment. The HoD will refer the matter to the Committee on Conflicts of Interest with a recommendation and the Committee will decide whether to grant such permission.

In all cases, the employee must disclose in writing and discuss any potential conflicts with their HoD:

- Prior to the commencement of such commitment,
- When circumstances change in a way that result in changes to that conflict (either as a result of changes to the employee's responsibilities in [University], changes in the nature of the relationship between the external company and [University], or changes in the commitment to the external body). This can present a significant challenge since circumstances often change gradually and with little formality. It is nevertheless important, for the staff member's own protection, that the HoD is informed, in advance, of any changes to the relationship.

Annex 1

Some examples of activities that are generally not allowable, or that require prior written approval (and may be subject to overview).

A. Activities that are generally not allowable.

- A1. A [University] employee⁴ acting as academic supervisor for an industry-funded student where the employee concerned has a Significant Financial Interest⁵ in the sponsoring company.
- A2. A [University] employee taking any financial stake or holding a formal position in a student-run, owned or controlled company while the student is enrolled at [University] the [University] employee is in a position to judge the quality of that student's work or to evaluate the student in any way.
- A3. A [University] employee taking any part in the negotiation of a contract between [University] and a company, where the employee has a Significant Financial Interest in the company.
- A4. A [University] employee publishing or formally presenting research results or providing expert commentary on a subject, without disclosing any Significant Financial Interest in a company that may benefit from the results being reported or opinions expressed.

B. Activities that may be allowable after disclosure, review and approval by the HoD⁶ (who may refer to the Committee on Conflicts of Interest).

- B1. A [University] employee acting as academic supervisor for a Student where the research results are related to the research or commercial activities of a company in which the Supervisor has a Significant Financial Interest.
- B2. A [University] employee acting as Principal Investigator on a project funded under contract by a company, where the

⁴. 4 Definition extends to certain family members as defined in Section III.

⁵ As Defined in III of the Document.

⁶ See Footnote 2.

- employee concerned has a Significant Financial Interest in the company.
- B3. A [University] employee carrying out research, the outcome of which may affect the value of patents or other intellectual property held by the employee concerned (except where [University] is owner such intellectual property).
- B3. A [University] employee holding a position in a Company (e.g. as Director) where the company may, for commercial reasons, wish to restrict (or otherwise manage) adverse research findings generated by the employee concerned.
- B4. A [University] employee conducting research externally that would normally be conducted by [University].
- B5. A [University] employee taking administrative action within [University] which is beneficial to a company in which he or she has a Significant Financial Interest.

Annex 2

Committee on Conflicts of Interest

Terms of Reference

1. To respond to requests from Heads of Departments for advice in relation a member of their staff as to whether a conflict of interest exists or may exist, as defined in the [University] Policy and Guidelines for Conflicts of Interest and/or how it might best be managed.
2. To consider, for approval, all cases referred by Heads of Departments involving the proposed supervision of a sponsored student by a staff member with a Significant Financial Interest in the sponsoring organisation. Any such approval will be granted in accordance with the conditions set out in the [University] Policy and Guidelines for Conflicts of Interest.
3. To consider, for approval, any cases referred by Heads of Departments in relation to a member of their staff involving conflicts of research integrity if a particular research project were to be accepted. The case should be submitted before a contractual arrangement is agreed.
4. To consider, for approval, any cases referred by Heads of Departments where a member of staff's proposed relationship with another organisation creates a conflict of interest.
5. To consider, for approval, all cases – to be submitted by Heads of Departments in relation to a member of their staff – of significant time (over and above that permitted under [University]'s Consultancy Guidelines) devoted to an external appointment.

The [University] Policy and Guidelines for Conflicts of Interest applies to all Academic, Honorary, Emeritus and Academic Related (AR5 or above) staff. However, if a Conflict of Interest applies in the case of a member of staff in another staff category, this should be referred to their Head of Department.

In accordance with the [University] Policy and Guidelines for Conflicts of Interest, the above references to Heads of Departments apply to the relevant

Dean for Heads of Departments, the relevant Vice-[President] for the Deans and Directors of the Postgraduate Institutes, the [President] for the Vice-[President]s, and the Chair of Council for the [President].

The Committee will report to the Council by means of submission of its Minutes to the Council's officers and by an annual report to the Council summarising, in general terms, the business which it has considered in the preceding year.

Constitution

- Academic Vice-[President]s (Arts, Biomedicine, Sciences)
- Commercial Director
- Director of Finance
- Director of Human Resources
- Lay member of Council

All enquiries should be directed to the Secretary, Committee on Conflicts of Interest. The Commercial Director will convene and service the Committee. The Chair will be one of the Vice-[President]s – normally Biomedicine or Sciences, to be agreed at the time of the meeting.

Annex 3:

REGISTER OF INTERESTS

of Directorships, Partnerships, Consultancies, Trusteeships, Trade Engagements, Other Remunerated Engagements and Membership of External Committees.

[University] Policy and Approval Procedures

Introduction

In keeping with its academic aims and purposes, [University] encourages close liaison between its staff and industry, commerce and Government departments through the acceptance by staff of personal Directorships, Partnerships, Consultancies (including Private Clinical Practice), Trusteeships, Trade Engagements and membership of official committees.

[University] encourages such interaction, but is mindful of its obligation to provide safeguards, wherever possible, against anything arising from these links which could be detrimental to [University] or to individual members of staff. One area of concern is that of potential conflicts of interest; another is legal liability and indemnity insurance cover.

Where the possibility of conflict of interests exists, it is universally accepted that prior declaration by all parties of their interests is essential. A Register of Interests is kept of the personal interests of staff, both full- and part time, which may overlap with the interests of [University]. Thus, members of staff, in addition to declaring their interests as Consultants etc, are asked to provide details of membership of external committees whose work may be related to that of [University], e.g. Research Councils, government departments, professional bodies, training organisations.

Members of staff could also be engaged in trading activities or other remunerated positions, without necessarily holding Consultancies etc, in which there could be deemed to be a conflict of interest with [University].

The Register is kept on computer under the highest security classification and is subject to the provisions of the Data Protection Act. Persons with

bona fide and substantial reasons to inspect declarations shall be allowed access at the discretion of the chairman of the Committee on Conflict of Interest.

Annual Return

All members of [state categories of staff] are required to complete and submit an Annual Return in August of each year.

Prior to submission the Return should be discussed with your Head of Department, who is best placed to understand how any external activities overlap with your [University] activities. Thereafter the Return should be sent to the Director of Finance, and a copy given to your Head of Department.

Staff are not required to submit a return if their answers to questions 1, 2 AND 3 are all 'No'. Staff are however reminded that failure to declare an interest is a disciplinary matter and therefore Staff are advised to declare such an interest if they are in any doubt about its relevance or materiality.

Form ***

IN CONFIDENCE**UNIVERSITY OF [_____] DECLARATION OF INTERESTS**

To be completed by each member of Academic and Related staff, whether full or part time.

PLEASE COMPLETE IN BLOCK CAPITALS

Full Name _____

Department/Division _____

1. Have you at any time over the last 12 months occupied a position of Director, Partner, Consultant, Trustee, Trader or Employee of any external organisation?

YES/NO If YES please detail on form EA/B (attached).

2. Have you at any time over the last 12 months been a member of an external committee?

YES/NO If YES please detail on form EA/C(attached).

Have you at any time over the last 12 months held any other remunerated engagements or and other Significant Financial Interests (e.g. shareholding) as defined in §3 of [University]'s Policy and Guidelines for Conflicts of Interest?

YES/NO If YES please detail below.

I certify that the information given above is, as far as I can recall, true and accurate. I have discussed this Declaration with, and will provide one copy to, my Head of Department.

Signed _____ Date _____

Signed (HoD) _____ Date _____

Please return your completed form to Director of Finance

IN CONFIDENCE

UNIVERSITY OF [_____] DECLARATION OF INTERESTS*

**DIRECTORSHIPS, PARTNERSHIPS, CONSULTANCIES, TRUSTEESHIPS,
TRADERSHIPS OR EMPLOYMENT (OTHER THAN [University]).**

PLEASE COMPLETE IN BLOCK CAPITALS

Your Full Name _____

Department/Division _____

Name of external organisation _____

Address _____

Position Held: _____

DIRECTOR/PARTNER/CONSULTANT/TRUSTEE/TRADER/EMPLOYEE

(Please delete as appropriate)

Dates of Appointment _____

Name of External organisation _____

Address _____

Position Held: _____

DIRECTOR/PARTNER/CONSULTANT/TRUSTEE/TRADER/EMPLOYEE

(Please delete as appropriate)

Dates of Appointment _____

*Please photocopy additional sheets if required.

Form ***

IN CONFIDENCE

UNIVERSITY OF [_____] DECLARATION OF INTERESTS*

MEMBERSHIP OF EXTERNAL COMMITTEES

(Only those committees where the work is related to or overlaps with the activities of [University] need to be declared)

PLEASE COMPLETE IN BLOCK CAPITALS

Your Full Name _____

Department/Division _____

Organisation Name _____

Address _____

Name of Committee, Board or Council _____

Dates of Appointment _____

Organisation Name _____

Address _____

Name of Committee, Board or Council _____

Dates of Appointment _____

* Please photocopy additional sheets if required.

Acknowledgements

Special thanks are due to the UNICO members who commented (including by participating in a lengthy teleconference) on various issues that are covered in this Practical Guide.

UNICO is based on, and thrives upon, the sharing of ideas within the profession. We believe that the UNICO Practical Guides are the latest tangible example of this. We thank everyone who has contributed to them, and we thank you for taking the time to read and use them.



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