2

THE PRAXISUNICO PRACTICAL GUIDES SERIES

MATERIAL TRANSFER AGREEMENTS

PraxisUnico.
Impact through innovation

FOREWORD

PraxisUnico is a world-leading membership organisation for Knowledge and Technology Transfer Practitioners. PraxisUnico's mission is to develop, promote and connect an internationally recognised community of professional excellence – sharing and promoting best practice at the interface between academia and industry. PraxisUnico is led by a team of expert volunteers and is a not-for-profit organisation.

PraxisUnico is renowned around the world for its professional training courses, conferences, networking and industry engagement events. We provide consultation responses, surveys and opinion pieces on behalf of the sector, as well as information and practical tools, including this Practical Guides series.

The highly successful and popular set of Practical Guides was first produced in 2005 and funded by the UK Government. In 2014, PraxisUnico has invested its own reserves in a series of updates to the Practical Guides, to ensure that the community continues to have access to this valuable specialist resource. The updated guides have been produced in electronic format only, both for ease of use and for cost effectiveness.

This new and revised edition is a resource for Knowledge Commercialisation professionals in the UK and overseas. The set brings together, in one concise location, practical support materials for anyone dealing with commercialisation or other Knowledge Transfer contracts. Many thousands of practitioners from the UK and beyond have regularly used the guides and the draft template agreements, citing them as an invaluable source of practical information and guidance.

Acknowledgements

The PraxisUnico Practical Guides on Confidentiality Agreements, Material Transfer Agreements, Options, Licence Agreements, and General Legal Issues have been updated to take account of changes in the legal landscape that have occurred since their first publication. The updating has been carried out by Mark Anderson and his team at Anderson Law LLP: Lisa Allebone, Stephen Brett, Mario Subramaniam, and AnnMarie Humphries.

CONTENTS

Chapter

Appendix

CHAPTER 1
General introduction

Of the many kinds of contract that universities encounter, material transfer agreements ("MTAs") can be the most frustrating: often quite small documents, they can raise big issues in areas as diverse as intellectual property ownership, commercialisation strategy and liability. It may be difficult to justify spending much time on negotiating them, but the consequences of 'allowing an MTA through' with inappropriate terms might – just might – be a major problem for the university. The various commercial and administration departments (e.g. Research Contracts, Technology Transfer, Business Services) responsible for MTAs are increasingly finding that they are devoting large amounts of time and resource on them. For ease of reference throughout this Practical Guide it is intended that the terms "contracts executives" or "contracts department" encompass all workers in the variously named commercial and administrative functions referred to above.

The purpose of this Practical Guide is three fold:

1. to provide an introduction to MTAs and their terms, including discussion of legal, practical and negotiating issues;
2. to provide some suggested templates together with guidelines concerning their completion; and
3. to consider and discuss some underlying issues which are problematic or of particular concern for universities.

This Practical Guide attempts to provide information that is useful for both the beginner and the more experienced research contracts or technology transfer professional. The breadth of material covered may give the misleading impression that university contracts are fraught with legal and commercial difficulties. Usually, this is not the case. But sometimes differences of expectation, practice or legal culture can arise between the parties negotiating an agreement, particularly in international transactions. The beginner may wish to focus on the earlier chapters and to use the detailed discussion that appears in later chapters as a reference source if a specific question or problem arises.

Except where otherwise stated, this Practical Guide discusses English law, the approach of the English courts, and the author's experience of the approach taken by English universities.

CHAPTER 2
Introduction to MTAs

What is an MTA?

A Material Transfer Agreement ("MTA") is a contract governing the transfer of materials between researchers. The researchers might be employed by universities, research institutions or commercial companies or be private individuals. The supplier/provider (called the "Provider" in this Practical Guide) of the materials is usually the institution owning the materials but may sometimes be an authorised licensee.

In a large research institution the range of materials transferred under MTAs may be diverse, although they generally fall within the biological/chemical category. Familiar examples include transgenic animals, cell lines, cultures, antibodies, vectors (e.g. plasmids, baculoviruses), antibodies, nucleotides and chemicals (including drugs/pharmaceuticals). MTAs may also be used for equipment fabricated in-house, blueprints, integrated circuit designs and even some types of software (although software is more commonly transferred under an evaluation agreement or licence agreement).

The Provider may be willing to provide the materials for altruistic reasons (e.g. to assist others to conduct research) or to obtain a benefit (sometimes a fee for supply, but more usually with a view to generating data on the materials or to obtain longer-term rights, as discussed below). The recipient of the materials (the "Recipient") may want to use them for a variety of purposes, including:

a to carry out research with them (either on its own account or on behalf of the Provider); or

b to create intellectual property with them or from them; or

c to evaluate them to determine whether to enter into further agreements (such as further research or licensing arrangements); or

d to test them either alone or with other materials (e.g. for safety or efficacy purposes).

Is the 'material transfer' really a disguised research agreement?

A preliminary question, before reviewing the detailed terms of a proposed MTA, is whether the relationship between the Provider and the Recipient is limited to the transfer of materials. Sometimes, MTAs are proposed when, in reality, the work to be undertaken is sponsored research without payment. This may raise policy issues for the university, as well as affecting the contract terms that may be thought acceptable – the university may wish to propose the terms

of a research agreement rather than an MTA. The remainder of this Practical Guide assumes that the transaction under consideration is a material transfer rather than any other kind of relationship between the parties.

Why do I need an MTA?

In some institutions, "incoming" MTAs (i.e. where the institution is the Recipient of the materials) are more often encountered than "outgoing" MTAs (i.e. where the institution is supplying materials). A practical reason for this may be that the scientists in academic institutions are more "relaxed" than those in commercial companies regarding the supply of materials to (as they see it) fellow researchers and, perhaps, "by-pass" the contracts department.

In relation to incoming materials, the reason for having a written MTA in place may be simple: the Provider will not supply the materials unless the parties first enter into a written MTA on terms that are acceptable to it.

Where your institution is supplying materials to another organisation, there may be a variety of reasons why you (or any academic involved in creating the materials) would consider a written MTA to be essential. In particular, you may wish to have a legally-binding contract in place to ensure that your institution has some or all of the following rights:

- *permitted use of materials:* to control or limit the use that the Recipient is permitted to make of the materials in research
- *prohibited use of materials:* to prohibit the Recipient from using the materials for non-research purposes, e.g. using the Provider's cell line to generate antibodies for sale to third parties. (If the Provider is willing to allow this activity, it should generally be under a separate licence agreement rather than an MTA.)
- *access to results:* to obtain access to any results and data obtained from the Recipient's use of the materials
- *confidentiality:* to prevent public disclosure of the Provider's confidential information
- *publications:* to ensure that the academic provider is given appropriate recognition (or direct involvement, e.g. as a co-author) in any publication of those results
- *use of results:* to obtain a legal right (e.g. a licence or option to take a licence) to use those results and data (e.g. in further research or commercialisation – this is often a core requirement for commercial Providers)
- *ownership of resulting IP:* to obtain ownership rights in respect of (some or all of) those results and any patents or other intellectual property generated from them
- *royalties, etc:* to receive a share of any commercial revenues (e.g. licensing income) generated by the Recipient through use of inventions made using the materials (this is often a priority for Providers that are research institutions)

In addition, the Provider may wish to include in the MTA some other provisions of a more 'legal' nature. For example, particularly where the materials are being provided on a non-commercial basis, it may be appropriate to include provisions such as:

- *no implied warranties:* to clarify that the materials are not being 'sold' to the Recipient and therefore the Provider does not have the legal obligations that come with the sale of goods (e.g. the implied contract terms under the Sale of Goods Act 1979)
- *exclusion of liability:* to exclude legal obligations generally, as the materials are often research materials with unknown toxicity or other properties and the Provider does not wish to find itself liable for any injury or damage caused to the Recipient or others
- *indemnities:* to require the Recipient to indemnify the Provider against any legal liabilities that may arise from the Recipient's use of the materials (i.e. going one stage further than the exclusion of liability referred to above)
- *regulations:* to clarify that the Recipient, rather than the Provider, is responsible for dealing with any regulatory requirements (e.g. if applicable, the regulations on transportation and use of genetically modified organisms)
- *risk, etc:* to clarify other legal responsibilities, e.g. who bears the risk of loss of the materials in transit from the Provider to the Recipient, and who must pay for carriage and insurance (sometimes addressed by including in the MTA a reference to one of the 'Incoterms' – standard contract terms for the delivery of goods, issued by the International Chamber of Commerce – see Appendix C)

If on the other hand materials are provided without a written MTA being entered into by the Provider and the Recipient, it does not necessarily follow that the provision will not be subject to any contractual terms. It is impossible to say in this Practical Guide with any certainty what terms would apply to the provision in such circumstances, as the specific context would need to be analysed in order to determine this. However, as a starting point, the Provider and the Recipient may find that the contractual terms of their arrangement are to be inferred e.g. from their email correspondence, conversations, conduct, and/or any past dealings that they may have had, etc. Accordingly, not entering into a written MTA prior to the provision of materials may make the arrangements more uncertain and unclear for both parties and may therefore lead to more disputes. For further information, see the section in Chapter 1 of the Legal Issues Practical Guide entitled "Must it be in writing".

In summary, therefore, written MTAs can be viewed as a means of protecting the parties' research and commercial interests in valuable property. All too often, however, they are prepared as a kind of insurance policy in case materials which initially seem to be of low value or low risk, subsequently turn out to have unexpected benefits or liabilities associated with them.

Legal relationship between Provider and Recipient

The supply of materials, particularly living materials such as cell lines, may raise complex legal issues, including those referred to in the previous section. These issues can, to a large extent, be addressed by:

1. including appropriate contract terms in a written MTA;
2. having procedures in place to ensure that the institution complies with its regulatory obligations (e.g. use of genetically modified organisms); and
3. maintaining appropriate insurance cover.

Different areas of law may be involved, as will be explained further in Appendices C and D. The areas of law include:

- *regulations* on the transportation and use of research materials
- *intellectual property law*, including rights of ownership in respect of inventions made using the materials
- *contract law* generally (and specific laws on the sale or supply of goods)
- *legal restrictions* on the contract terms that certain US institutions can accept (particularly State universities, and organisations that have received US government funding for research)
- the law relating to the use of property owned by another person, e.g. under a contract of hire or loan (an ancient area of law known as *bailment*)
- liability in *tort*, e.g. for injury, loss or damage caused by negligent supply or use of materials (see legal glossary (Appendix E) for an explanation of "tort")

Some of the complexities of the contract terms of MTAs (and therefore the length of this Practical Guide) derive from the fact that so many areas of law are potentially involved in what, at first sight, appears to be a simple transaction – the supply of a small quantity of research materials! Although these legal issues lurk in the background and affect the standard wording of many MTAs, in most cases the negotiations will be concerned with more routine issues, such as ownership and use of the results obtained with the supplied materials.

Why are MTAs seen as problematic?

Although many different areas of law are involved, as described above, the difficulties that are encountered in dealing with MTAs tend to be of a more practical nature, and include the need to educate (some) academics and departmental administrators in the use of MTAs, establishing what terms are acceptable in an individual case, and efficiently processing the document through to signature by the appropriate people.

The contracts department can play a valuable role in educating/persuading its academics in the use of MTAs. In this increasingly litigious society, the academics are usually open to persuasive reasoning that, at a minimum, where the university is providing the materials it is only right that the recipients use the materials at their own risk. Another powerful argument is to explain to the academics that inappropriate terms in an MTA may prevent them from publishing their research. In addition, it is understood that in some cases, granting an exclusive licence to a commercial company could prejudice future research funding from certain UK charity funders. See below under "Waiver letters".

Many research institutions that deal with MTAs on a regular basis find that negotiating and entering into such agreements can be difficult and time consuming. This is even so where the routine supply or receipt of materials is involved. The following is an outline of why MTAs are seen as a problem:

For in-coming materials - requirement to use the Provider's agreement

For the routine supply of materials the Provider will normally require that the supply be made on its terms and conditions. This is because:

- it is customary practice, or the Provider is in a strong enough bargaining position to insist, that the Provider's terms and conditions of supply should apply;
- the Provider is required by law only to provide materials or enter into contracts on some terms and conditions (e.g. public bodies in some US States);
- the Provider is supplying the materials on a non-commercial basis and thus argues that since it is not receiving any benefit it should be able to specify the terms and conditions of supply. "Non-commercial" may have different meanings, e.g. that the materials are:
    - used only for non-commercial research purposes;
    - used only for internal research purposes;
    - not provided to a commercial organisation;
    - not used to generate data for a commercial organisation.

There is no standard definition of what counts as "commercial use"; if a dispute were to arise over its meaning, it would be for the court to interpret how the phrase was used in the specific contract. See further the discussion of this topic in Appendix C, and the discussion of how the courts interpret contracts generally, in the Practical Guide entitled General Legal Issues in University Contracts. In the case of particularly valuable materials it may be advisable to state explicitly what is, or is not, permitted under "non-commercial" use.

Time taken - resource intensive

The time taken to negotiate and enter into an MTA can be disproportionate to:

- the value of the materials themselves;
- their value to the Provider and/or Recipient of the materials; or
- the research, evaluation or testing for which the materials are necessary.

This may be due to some or all of the following factors:

- the academic recipient requires the materials and is unable/unwilling to obtain them from another source
- the Provider is required by law only to enter into contracts on some terms and conditions and it takes time to elucidate this and agree a compromise
- agreeing the exact definition of the materials / derivatives together with intellectual property and publication provisions
- the need to cross-check the provisions of other relevant MTAs or agreements
- the need to involve senior colleagues or other departments/specialisations (e.g. legal, insurers) where particular clauses are contentious (and the ensuing delays)

In addition, there is often a substantial amount of "hidden time" involved in processing in-coming MTAs which are often presented, already signed by the originating party, to a departmental secretary. Sometimes these are forwarded to the contracts department with a request to countersign and return. Time is then spent (i) explaining that just because one party has signed an agreement, it doesn't follow that it will be acceptable to the other and (ii) obtaining contact details for the Provider in order to obtain an electronic version. Additional time is spent logging the MTA and tracking it either manually or on a database.

Hard to determine the value of materials and outcome of the research

Since the materials are most often supplied for research purposes, it follows that it is difficult to predict whether any commercially useful application, product or discovery will arise. However, even if the academic is persuasive regarding (i) the unavailability of the materials from another source and (ii) the likelihood that intellectual property will arise is slight, there may still be other clauses (e.g. publication) that require attention in order not to prejudice the charitable objectives of the academic institution.

Academic perceptions/requirements

Academics are inevitably concerned about delays and the negative impact on their research that any delays may cause. News of a difficult negotiation over an MTA, and consequent delays, seems to travel fast on the academic grapevine. Sometimes the perception that a delay will be inevitable leads some academics to sign their own MTAs. Unfortunately:

- Such MTAs will not have been scrutinised by someone familiar with acceptable provisions. Valuable intellectual property may well be lost to the academic's institution.
- Even if a person signing the MTA is not an authorised signatory of your institution, under the laws of agency s/he may have 'apparent authority' to sign an MTA on the institution's behalf. If the other party relies on the apparent authority, then the contract will probably be binding on the institution. This subject is discussed further in Appendices C and D and also in the Practical Guide entitled General Legal Issues in University Contracts.

In order to expedite an MTA it is not unknown for an academic to argue, "it's very unlikely any IP will arise, so let's just sign." This may be true where the material is to be used as a research tool or as a positive/negative control. Even then, it is wise to check that the MTA isn't drafted broadly enough so that the other party owns all IP that results from "the use of" the materials or that "relates to" the materials. Where a pharmaceutical is involved, one should always be aware that occasionally a second medical use patent could arise from the research. If the MTA was signed on the basis that no IP would arise (and the other party owned the IP) then a potentially valuable commercial opportunity will have been lost.

Waiver letters

Where the terms of an MTA are judged unacceptable by the contracts department and the academic insists on receiving the materials, it is sensible to ask the academic to sign a waiver letter. In some Institutions, obtaining a waiver letter is standard policy if the academic insists on receiving the materials under an onerous MTA against advice from the contracts department.

The waiver letter should set out clearly which clauses are unacceptable and point out the consequences should any IP arise under the MTA – i.e. the Institution and the academic inventor would receive nothing from any commercialisation. It may also be useful to set out in the waiver letter that certain charities are unlikely to fund ongoing research using the materials, since future arising IP will be subject to the encumbering provisions of the MTA. An example of a waiver letter is included with the other precedents in Appendix A.

CHAPTER 3
Summary of best practice

The following points are put forward for your consideration as possible 'best practice' (on some points, readers may feel they are 'ideal practice') in relation to the preparation of MTAs.

- *Policy*. Have in place an institutional policy for MTAs, covering such matters as:
    - Whether to enter into them at all, for (a) incoming and (b) outgoing materials
    - What 'due diligence' should be done to ensure that obligations under an MTA do not conflict with obligations under other agreements, and to ensure that the terms of each MTA do not conflict with or prejudice an IP commercialisation strategy
    - Procedures to be followed to ensure that your institution complies with the terms of incoming MTAs, including security measures, agreements with academics and students, restrictions on who may receive the materials, etc.
    - Procedures to be followed to ensure that your institution protects its own materials, including procedures governing the provision of materials to third parties
    - Use of questionnaires / waiver letters, to be completed by the academic, to provide information relevant to the MTA and/or surrounding IP and liability issues
    - Who has authority to sign the MTA for the institution?
    - Whether individual academics should [also] sign and/or approve the terms of MTAs
- *Templates*. Have in place template MTAs (for both incoming and outgoing materials, respectively) ready for use in individual transactions.
- *Negotiation*. Who has responsibility for negotiating the terms of MTAs? Do they have the required level of training and skill? Is there a procedure for referring difficult issues to a more specialist adviser (e.g. an in-house lawyer)?
- *Terms*. Have in place clear 'bottom lines' as to terms that must, or cannot, be accepted in MTAs. Possible key issues might include:
    - Law and jurisdiction (is it covered by relevant insurance policies?)

- Ownership of IP in the 'results' obtained using the materials
- Rights of use of such IP by each party
- Obligations to share revenues arising from the commercialisation of such IP
- What restrictions on publications are acceptable
- Obligations to share results, provide reports, etc.
- Whether the Recipient must give an indemnity against any liabilities arising from use of the materials
- Whether the Provider should give any warranties

- *Monitoring*. Implementing procedures to monitor MTA obligations, including maintaining a database of MTAs (and other agreements)

CHAPTER 4
Key commercial issues:

Introduction to frequently-encountered negotiating issues in MTAs

The following paragraphs provide a brief explanation of issues that are often encountered when negotiating an MTA, and possible solutions. For further detailed discussion, the reader is referred to Appendices C and D. In this section "Provider" refers to the party supplying the Materials and "Recipient" refers to the party that is using the Materials under the MTA.

Defining the Materials

Some MTAs include broad definitions of the Materials being provided. If the definition refers to derivative materials, it may include materials generated by the Recipient. It is important to scrutinise the definition carefully, as the MTA will probably provide that the Materials, and associated intellectual property rights, are the property of the Provider.

Use of Materials

The key issue is to ensure that the MTA is clear on the use that the Recipient can make of the Materials. Usually the MTA provides that the Materials may be used in a defined programme of research. Watch out for clauses that prohibit the use of Materials in "commercial" research, as there may be some ambiguity as to whether this allows use in research with a commercial sponsor or research with a commercial objective. If such a clause has been included, it may be desirable to give details, in the MTA, of any particular commercial relationship in which the Materials will be used. (See further the discussion of this issue in Appendix C, and the discussion of how the courts interpret contract language generally, in the Practical Guide entitled General Legal Issues in University Contracts.)

Compliance with regulatory obligations

Some MTAs include provisions that clarify the parties' respective obligations to comply with regulations governing the use of the Materials and the conduct of research. For example, there are complex regulations governing the use of human tissue, as well as guidelines published by the Human Tissue Authority and the Medical Research Council. Sometimes these provisions are very specific, e.g. requiring a recognised safety officer to countersign the MTA. You may need to work with the academic department to ensure that they understand their regulatory obligations under the MTA and are able to comply with them.

Ownership of, and access to, results

In some cases, the Provider's reason for providing the Materials may be in order to obtain access to the results of the Recipient's work using the Materials. For example, a pharmaceutical company may be willing to provide access to its compounds in development, but on condition that it owns to any data generated using those compounds. In other cases, the Materials may be provided for entirely altruistic reasons. Meanwhile, the Recipient may be happy to share the results, or it may be concerned not to allow the results of its potentially valuable research to be disseminated or used.

'Access to results' is one of a number of issues that arise with MTAs, where the parties' objectives may differ. Other examples where the parties may often approach the MTA from differing perspectives involve publications, ownership of results, patenting, licensing and revenue sharing. To negotiate these issues, it is important to understand why each party is entering into the MTA. If the material transfer forms part of a drug development programme, for example, the party developing the drug is likely to be very sensitive about these issues, and will wish to avoid contaminating its intellectual property portfolio in respect of that programme – not least because it will have already committed considerable resources to developing the drug.

It is not always easy to find a mutually acceptable solution. Many US universities seem to be taking a hard line on ownership of results generated within their institutions, even if the results relate to a commercial company's drug in development. Anecdotal evidence suggests that this has made some companies unwilling to collaborate with US universities. Various compromise solutions are discussed in Appendix C. For example, one solution is to state that the Provider will own any 'new use' discovered for its Materials, but other inventions will belong to the Recipient.

Sometimes, it has to be recognised that the parties' commercial objectives are not easily reconcilable, and that the material transfer will not take place without one party backing down. Unfortunately, it can take some time in negotiations before realising that this is the case, particularly if the parties are exchanging drafts by email and offering subtly-different wording in each round of negotiation.

Publications

The right to publish research results is usually of primary concern to an academic institution. Thus the relevant clause in the MTA should be considered very carefully. Clauses that allow for a delay in publishing whilst patent applications are filed are usually acceptable, provided there is a reasonable time limit on the delay (typically up to six months). If your institution is the Provider, your academic may wish to be recognised in any publications, e.g. as having supplied the Materials, or sometimes as a co-author. There are some important points of detail on the wording of these clauses, which are discussed in Appendix C.

Patenting

Sometimes a Provider will wish to be involved in the filing of any patents that make claims concerning the Materials. Similar issues arise here as with ownership of results, discussed above. A key issue for the contracts department is whether any patents or other valuable intellectual property are likely to result from using the Materials. Sometimes this may be so remote that the institution may decide not to spend undue time in negotiating IP provisions and concede the point. Or it may decide that it is not prepared to spend time negotiating this issue and, if the other party won't accept the institution's terms, decline the material transfer.

Licences and revenue sharing

When deciding whether a Provider should obtain a licence to use any results generated by the Recipient using the Materials, the Provider's rationale for providing the Materials needs to be considered. Often, commercial Providers will require a licence (or at least an option to acquire a licence), and this will be of greater concern than obtaining a share of any revenues generated by the Recipient with those results. Academic Providers, by contrast, may be more concerned to share in any downstream revenues generated through use of their Materials.

Delivery, insurance and risk

Delivery, insurance and risk are usually issues of minor importance with typical material transfers. However, readers need to be aware that some MTAs may include provisions that address these issues. For example, the MTA may refer to 'Incoterms', which are a set of alternative, standard terms published by the International Chamber of Commerce that cover these issues, and are more often seen in international contracts for the sale of goods. See further Appendix C.

Parties

Usually, an academic's institution, rather than the academic personally, will sign the MTA. However, practice varies between countries and institutions, and where the MTA involves another institution to your own, it may be desirable to check on their approach to this issue. Sometimes, as with confidentiality agreements, the academic is asked to countersign the MTA, not as a party but as having "read and understood" the agreement which is being signed by his or her institution. See further Appendix C and D.

Warranties, liability and indemnities

Typically, MTAs provide that the Recipient will indemnify the Provider against any liability that may arise from the Recipient's use of the Materials. The MTA may also provide that the Provider doesn't give any warranties as to the condition of the Materials. This is understandable in the situation where Materials are provided as unproven research reagents, usually without charge, and where the Provider has no control over the use to which the Materials are put.

Occasionally, MTAs include some warranties to be given by the Provider that the use of the Materials will not infringe third party rights. Such warranties need to be considered carefully and will often be unacceptable to a Provider.

Law and jurisdiction

In international contracts, whether MTAs or any other type of agreement, there is often an issue as to which law the agreement will be governed by, and in which country any litigation, arbitration, ADR or other procedures will be conducted. Some UK institutions have insurance policies that exclude North American jurisdiction. See further Appendix C and D.

CHAPTER 5
Checklist

The checklist provided below lists (i) some preliminary points that may need consideration and (ii) the main clauses usually found in an MTA together with the main issues that should be addressed regarding each provision. Most of these points are discussed further in the Appendices and another Practical Guide, particularly:

Appendix B – notes on completion of template agreements

Appendix C – in-depth discussion of commercial issues

Appendix D – Special legal issues in MTAs

and in the Practical Guide entitled General Legal Issues in University Contracts

Preliminary	
Parties	• Should these be the employing institutions of the Recipient and Provider scientists? • Have the correct legal names and addresses been included? • Should the scientists sign – as a party or to state they have "read and understood" the terms of the MTA?
Authorised Signatory	• Does the MTA need to be signed by a central part of the organisation, e.g. a Technology Transfer Office? • Do you need to remind the 'other side' regarding their authorised signatory?

Materials	• Have the Materials and their intended use been correctly identified? • Is there a reference to the Materials being described in a Schedule? Is it attached? • Are there any regulations governing use of the Materials (e.g. the regulations governing the use of genetically modified organisms)? • Can the recipient comply? • Does the MTA require a Health & Safety Officer to countersign? • Are the Materials of human origin?
Human Tissue	• Has it been obtained from a reputable source and with patient consent? • Should you obtain a (blank) copy of the patient consent form used for your records? • Has ethical approval been obtained? • Is it your department's policy to file a copy of the ethical approval or ask your academic for the approval reference number? • Data Protection compliance: will the data and Materials be provided in an anonymised/coded form such that it will not be possible to identify the individual from whom the Materials were collected? • Does the MTA specify particular published guidelines to be followed (e.g. MRC guidelines)?
Recitals	• Is it useful/appropriate to cross-refer to a parallel agreement (e.g. a confidentiality agreement or a research collaboration agreement for which the Materials are supplied)? • If the Materials are supplied for use in a collaboration agreement check the terms of the collaboration agreement to ensure there are no conflicts • By referring to the terms of the collaboration agreement you may be able to edit the MTA significantly • Is there anything in the recitals that should really be in the body of the contract? (Remember – recitals may not be legally binding)

Contract Terms	
Date of the Agreement	• This is the date when the MTA is signed. The 'official' / 'legal' date will be the date when the last party signs and this should be the date entered onto any MTA database. • Is there a reason why the parties may wish that the MTA is effective as from a particular date (e.g. the materials were transferred 2 months ago?!) • If so, agree an "Effective Date" and draft this into the MTA • It is bad practice to try to backdate an agreement by entering a prior date in the signature block
Definitions	
Meaning of Materials	• Can the Materials be described easily in a sentence? • If there are several Materials, or where complicated nomenclature is involved, consider listing them in a Schedule to be attached to the MTA • Check the Materials listed are what the academic expects! • How broad is the definition of Materials? In conjunction with the IP clauses, should you attempt to narrow/broaden the definition? • Does the definition of Materials include confidential information/documents? If so check relevant IP, Publication and Confidentiality clauses.
Meaning of Derivatives	• Is this an unacceptably broad definition? • If the Provider is to own the IP in all Derivatives consider narrowing the definition.

Purpose for which the Materials are provided	• The purpose may be defined as the Research or the Project • Does this adequately explain what the academic intends to do with the Materials? • Would it be more appropriate for the Research to be described in a Schedule to be attached to the MTA? • Should the purpose be broader/narrower (taking into account the IP clauses)?
Term	• Usual time periods tend to be 1-2 years • Does the MTA specify a time period? Should it? • Are there any obligations (e.g. return of Materials) when the term ends? • Any obligation to seek to renew (e.g. 3 months) prior to expiry? • Are there any confidentiality obligations that extend beyond the term? • Should you include early termination provisions?
Meaning of Recipient	• Is the MTA drafted so that Recipient means the recipient scientist or the recipient institution – or both? • Should any changes be made so that the recipient scientist does not give personal warranties? • Should the recipient scientist sign as having "read and understood" the terms of the MTA?
Meaning of Provider	• Does this definition specify the correct legal name and official address of the institution providing the Materials? • Where Provider Scientist is defined – are there any obligations on the recipient to cite the Provider Scientist in any publications? • Does your academic know this?

Common restrictions:	
Security and safety measures by Recipient	• Does the MTA specify that Materials will be kept secure / in a particular location? • In compliance with certain safety regulations? • Can the academic comply / have you procedures in place to ensure s/he understands the obligations?
Use only by specified persons	• Does the academic know / is this practical? • Will students or other non-staff members (e.g. Visiting Fellows or Emeritus Professors) be working on the Materials (if so – would the definition of researchers include students or do you need to modify)? • Remember non-staff members would not be included if the wording just refers to employees.
Use only in a particular project	• Are there any onerous provisions associated with this (e.g. use outside the defined Research means the Provider owns all Arising IP)?
Only for non-commercial use	• Do the parties have the same understanding of "non-commercial use"? • Can the Materials be used in research funded by an industrial sponsor (provided that the other sponsor isn't granted any rights to the Arising IP)?
No use in projects where third party has an interest	• If this is explicitly stated, have you checked that the academic knows this and can/ will comply?
Non-use in animals / humans	• Have you checked with the academic that the research does not involve these?
Method of transport, handling, delivery	• Are there any special provisions required for the particular Materials? • Is there someone in your organisation with responsibility for this?

Charges for Materials	• Is it specified whether Materials are supplied free of charge, at cost or at a particular commercial price? • If the latter, then should the Materials be supplied under an MTA at all? • Is the responsibility for shipping, packaging and insurance allocated? • Who is responsible for the above costs if Materials are to be returned when the term ends?
Publication	• Does the Recipient have a right to publish? • Does the Provider have a right to delete its own confidential information from any draft publication? If so, have you checked that the definition of Confidential Information does not include the results of the research (or Arising IP)? • Are any delays to publication reasonable and do they fall within your institution's policy/guidelines? • Is there an obligation to acknowledge the Provider in any publication by the Recipient? • Is there an obligation to (i) quote the Provider Scientist by name and/or (ii) cite a particular publication reference in any publication by the Recipient? Is your academic aware of this?
Reporting obligations	• Does the MTA contain any unusual reporting obligations? • Is there a particular reason for this? Can/should the academic comply? • Any obligation to inform the Provider of data indicating that the materials may be toxic?
Confidentiality Provisions	• Are there any? Should there be? • Is it more appropriate to have a separate confidentiality agreement (which could be cross-referenced)? • Check what is covered by the definition Confidential Information

	• Does Confidential Information include the results of the Research? If so – check publication clauses (see above). • Should there be an obligation on the receiving party to keep invention disclosures confidential? • How long do any confidentiality obligations extend? Is this appropriate? • Are there provisions to reduce oral disclosures to writing or store documents in locked cabinets? Can/should your institution comply? • Is there an obligation that any new researcher working on the Research signs a confidentiality agreement? How does your department/institution 'police' this?
Intellectual Property	• Who will own the Arising IP from the Recipient's use of the Materials? • How wide is the ownership position? For example, does it just cover inventions relating to the Materials alone or does it extend to IP arising from the Recipient's wider research project? • Are there any options or licences back to the Provider in respect of such IP? • Could these IP terms prejudice the Recipient's ability to exploit its own IP (e.g. by contaminating the Recipient's ownership position with regard to the results of its research)? • Are there any provisions regarding Background IP (e.g. does the Provider expect a free licence to Background to enable it to exploit Arising IP)? • In an MTA with BigPharma, is there a provision for an exclusive licence? Could this prejudice the academic's future funding position (e.g. if s/he routinely relies on funding from certain charities)? • Are licences granted automatically in the MTA – or is there a provision for future negotiations?

	• Should there be any provision for revenue share terms? • If options have been granted – have you (i) capped the time period for exercise; (ii) capped the time period for licence negotiations if the option is exercised? • Is there a requirement on the Recipient to notify the Provider if an invention is made? • Who is responsible for patent costs (during the time periods for an option)? • Is there a clause giving the Provider automatic rights to Arising IP if the researcher uses the Materials outside the defined Research?
Warranties	• Should the Provider give any warranties regarding the condition of the Materials, e.g. that it has provided accurate information concerning the safety or use of the Materials? • Should the Provider warrant that the use of the Materials by the Recipient will not infringe third party IP? • Should the Recipient give any warranties, e.g.: • that s/he has had suitable training to handle the Material? • that ownership of arising IP will vest in the Provider (i.e. all those working on the Research are employees of the Recipient)? (Care should be taken if any students / consultants / Visiting Fellows, etc. will use the Materials). • Does the warranty cover something which (i) is not really your institution's responsibility; or (ii) something the other party can/should check for itself (i.e. can you agree to delete it)?! • Should the warranty be limited to matters within particular knowledge? (A 'best of knowledge' warranty will probably be too onerous for a university in most circumstances).

Liability and Indemnity	• Does the Provider exclude all liability incurred by the Recipient in relation to the Materials? • Is this appropriate? • If reference is made to "applicable law" – which country's law is applicable? • Are any indemnities being given? If so are they (i) appropriate, and (ii) covered by your institution's insurance policies? • Where your institution is giving an indemnity – should you insist on having control of any proceedings brought by a third party (against the other (indemnified) party)? • Should indemnities just be restricted to third party claims?
Law and Jurisdiction	• Has the law governing the MTA been stated? • Has jurisdiction also been specified (i.e. which party's courts would hear any dispute)? • Is it appropriate to specify exclusive or non-exclusive jurisdiction? • If confidentiality provisions are important consider whether to include a right to obtain an injunction in any jurisdiction?
Contracts (Rights of Third Parties) Act 1999	• Is it appropriate that any third parties should be given benefits under the MTA? (Usually, parties prefer to exclude third party rights – in cases of doubt, legal advice should be sought)
'Boilerplate' provisions	• Should any other provisions be included? For example: • Entire Agreement • Force Majeure • Use of the institution's name and logo • Notices (may be useful if option notices should go to the Technology Transfer Office rather than address of legal entity)

Schedules	• Is a Schedule appropriate for either a description of the Materials or the Research? • Have the contents been agreed / checked with the academic? • Is it attached?!

CHAPTER 6
Administration of MTAs

It is important to keep track of MTAs – both during the review and negotiation period and once they have been signed. This should be administered centrally, in order to check existing MTAs and other agreements for potential conflicts with an incoming MTA under review. Various practical aspects are considered below.

Having a Standard Operating Procedure (SOP)

It is extremely helpful to the contracts executive or the person negotiating the MTA if their institution has an established policy for dealing with MTAs that includes guidelines regarding particular clauses / issues. If written guidance is also issued on non-negotiable provisions, it enables the negotiator to take a more confident stance. It goes without saying that the guidance should be updated regularly and honed in light of practical issues experienced by those at the sharp end of the negotiations!

In addition to aiding the negotiators, having an SOP is also in the institution's interest as it should minimise disparities that may arise if various individuals grant different rights to similar institutions. An SOP should also reduce the chance of conflicts arising under co-existing agreements. A checklist of provisions that should (or should not) be included is a useful starting point for any SOP, together with guidance on when to refer particular issues to a more senior member of the department or to ask for legal advice. The SOP may also contain reminders to send an initial questionnaire to the appropriate academic and later, to enter certain details of the finalised MTA on the relevant database. The academic should also be sent a copy of the signed MTA and their attention drawn to obligations relevant to them (e.g. confidentiality). Finally, in any SOP it is also useful to have a list of authorised signatories and the relevant procedure for holiday cover.

Getting all the essential information for a new MTA

The academic requesting or receiving the Materials holds the key information that will enable the negotiator to understand the relevant issues and establish a position that will best protect the interests of the institution (and the academic). Many institutions find that it is useful to ask the academic to complete a questionnaire regarding the Materials and the research project. It is understood that some institutions even have a policy of refusing to deal with a request for a MTA unless the relevant form has been completed. Having a standard form questionnaire has several advantages:

- the negotiator does not need to rely on memory for the appropriate questions to ask

- it saves time
- the elicited information is contained in one document (rather than extracted over a course of emails)
- it helps to facilitate the relationship between the negotiators and the academics.

Regarding the latter point, the academics realise that there is a rationale to the questions; they may not themselves have appreciated some of the aspects of a MTA; and maybe they shouldn't be signing them off after all! There is also a useful training aspect regarding forms and accompanying institutional guidelines – latest editions can be used along with a presentation to publicise the work of the contracts department.

Whilst tick-boxes may reduce the input effort, certain questions may be more suitable for tick-boxes than others. Obviously a balance needs to be struck between seeking the relevant information and introducing another layer of bureaucracy by way of a lengthy form. An example questionnaire is set out in Appendix A.

Who should deal with new MTAs?

The flippant answer is: not a new recruit who has never seen one before! At least not without some training since, as discussed in previous sections, a MTA is often a chimaeric beast incorporating aspects of a variety of other agreements such as IP licences and confidentiality.

Obviously in-coming MTAs are more complicated to deal with than outgoing MTAs, as contracts executives should be familiar with their own institution's standard terms. For this reason, it may be possible for outgoing MTAs to be dealt with by more junior or administrative staff. It may also be possible to split up the various stages of processing an in-coming MTA so that the routine parts are done by a departmental administrator rather than the paralegal or contracts executive who handles the negotiations. For example, it may be departmental policy that all in-coming MTAs are logged by the administrator on a central database. The administrator may also be able to determine which executive should deal with a particular MTA – based either on the department of the originating academic or whether the MTA is a biological or chemical material, etc. Once the MTA is completed, certain other tasks may also be done by an administrator to ease the burden on the contracts executive, e.g.:

- logging the date of the agreement
- logging other relevant provisions, e.g. term; whether an option has been granted; reporting obligations; confidentiality provisions
- sending a copy of the signed MTA to the academic together with a covering letter highlighting particular obligations.
- allocating the original signed MTA a reference number for storing in a safe or other designated storage system.

Who should decide whether to enter into a new MTA

Where all the provisions in an in-coming MTA meet the receiving institution's acceptability criteria and/or may be ticked off according to a check-list or SOP, then more junior members of staff may be given the authority to decide that the MTA can be approved for signature. Where the incoming MTA is in a recognised format (e.g. the UBMTA – see Appendix C for further information) with no significant (adverse) amendments, this may also be a routine decision. Another example of a standardised, recognisable format may be where the receiving institution has negotiated a standard MTA with e.g., BigPharma to be used for certain "standard" reagents or a series of chemical compounds.

For "non-standard" terms, various provisions such as frequency of any reports, record-keeping and ability to comply with certain confidentiality obligations should always be discussed with the relevant academic. Since the academic will be using the Materials in their research, they will be best placed to determine the value of the Materials to their overall research programme and any potential commercial value of the results. The academic should always be informed of progress and whether particular problems have been encountered. Sometimes if a providing institution is unwilling to negotiate a provision that the academic finds unacceptable, the academic will volunteer the suggestion to abandon the MTA. More frequently, they are keen to obtain the Materials under any circumstances – in which case referring the matter to a senior colleague/ departmental head is advisable. Asking the academic to sign a waiver letter is also good practice (see the template at Appendix A).

Occasionally, if some terms are onerous or disadvantageous in combination with an unacceptable jurisdiction clause, a senior manager or head of the contracts department will need to tell the academic that they cannot advise that the institution enter into the MTA at all.

Some institutions have a policy that all non-standard MTAs are passed for a final legal review prior to signature. In addition to having a MTA questionnaire and SOP it is also good practice to have a signature sheet indicating which contracts executive has negotiated/approved the agreement for signing and whether the MTA was also sent for legal review. Alternatively, this information may be tracked on the MTA database.

How far should the academic using the Materials be involved in the negotiations

The contracts executive and/or the legal team are best placed to handle negotiations over such provisions as law and jurisdiction, and the subtleties of liabilities and indemnities. Academics do not normally have the time or the inclination to become involved in the negotiations. However, in instances where the other side is being particularly intransigent, it may help to facilitate the issue if the academic contacts their opposite number. This is another reason for regularly updating the academic regarding progress.

When to involve the lawyers

Most contracts executives are either familiar with, or can be trained regarding the institution's policy regarding acceptable IP provisions. Where necessary, a set of guidelines of potential clauses (on a sliding scale of most favourable through to least favourable to the institution) can be circulated. Institutions may also wish to decide their own policy regarding who in the management hierarchy can take commercial decisions regarding whether or not to accept various foreign jurisdictions and law. Lawyers are often asked to advise on law and jurisdiction, but ultimately the decision whether to enter into a particular MTA may be a commercial decision in consultation with the institution's insurance advisers. As discussed previously, the importance/rarity of the Materials may also be a factor.

Liability and indemnity provisions are probably the main areas where more specialist legal advice is sought. However, unfamiliar phrasing within any clause is often worth checking. As mentioned above, some institutions have a set policy that certain BigPharma and non-standard MTAs are all passed for a final legal review prior to signature. A legal review of a random selection of non-standard MTAs every so often may also be useful as part of a due diligence exercise (or good practice).

Making employees and others aware of their obligations

It is good practice to ensure that employees are aware of their obligations in respect of MTAs. This has been mentioned above in conjunction with having an SOP. Usually, the contracts executive has ensured that any academic does not have any personal liability; however there may be obligations on the Recipient that are to be performed by the academic, particularly in regards to confidentiality and/or reporting and publications. With regard to confidentiality, all third-party confidential information should be clearly identified – perhaps labelling it clearly as confidential. Any employee who receives third-party information should be informed that it must be kept confidential and not used except as permitted under the MTA (or parallel CDA) with the third-party. For further advice on CDAs you may wish to consult the Practical Guide on CDAs published as part of the PraxisUnico series.

Maintaining effective security measures for confidential information

Sometimes universities can be rather casual in their treatment of confidential information. For example, it may be kept in a lockable cupboard – but the cupboard is not always locked. Or too many people have access to the key. Sometimes, materials are lost when there is an office move. It may be important to devise appropriate security procedures and then make sure, by instruction and periodic checks that people are actually complying with the procedures.

MTA database – for conflicts and due diligence searches

Every year large institutions enter into many hundreds of IP-related agreements such as research contracts and confidentiality agreements in addition to MTAs. As the numbers grow it becomes increasingly important to keep track of what has been agreed and with whom. Although it is possible to keep manual records by filing MTAs

under the name of a particular academic or department, it is obviously far easier (and efficient) to use an electronic database where a variety of fields can be searched. Useful fields to include are: academic's name; Provider; whether Provider is also sponsoring the research; date and term; name of materials; licence/option details; confidentiality provisions/time period; any unusual provisions. Where several hundred MTAs alone are agreed every year, it may be preferable to have a separate MTA database otherwise the agreement type should also be a searchable field.

APPENDICES

APPENDIX A
Templates

The two MTA templates provided below are suitable for use between non-commercial institutions. They are designed as one-page forms that would have the terms and conditions printed on the reverse.

Template 1 is for use where the institution is the Provider of the Materials.

In the rare instances where the institution supplying the Materials does not have their own standard template, the Recipient could propose the use of Template 2.

In some areas (e.g. intellectual property ownership), the templates, particularly the one for outgoing materials, take a more 'protective' position than, for example, the UBMTA does. On other topics (particularly the question of revenue sharing) the template does no more than establish a principle and deliberately avoids a more detailed and possible controversial (but also more legally binding) approach. The approach taken in these documents has been developed in discussion with a couple of specific universities, and reflects their stages of thinking on MTAs at the time the documents were drafted. Before using these templates, readers should consider their suitability for their own institutions and take legal advice.

Notes to assist you with the completion of the template MTAs are set out in Appendix B.

MATERIAL TRANSFER AGREEMENT

([Institution name], the receiver of the Material)

1. *Insert name and address of supplier* _____

(the "Supplier"), has collected and/or developed the materials known as

2. *Insert description of materials* _____

and includes any constructs, strains, progeny and unmodified derivatives (as the case may be) obtained from or as a direct result of the use of the materials (together, the "Materials")

3. *Insert name of Scientist* _____

_____

(the "Recipient") who is an employee of

4. *Insert name and address of Scientist's Institution* _____

("Institution")

and wishes to acquire a sample of the Materials for academic research relating to:

5. *Insert description of academic research for which Materials are to be used* _____

_____

(the "Research Programme")

6.	*Insert quantity of Materials to be supplied and period for which they are to be provided for*	The Supplier is willing to provide a sample of _____ of the Materials for a period of _____ years (the "Term") on the Terms and Conditions shown overleaf, and the Recipient and the Institution agree to comply with those Terms and Conditions

AGREED by the parties through their authorised signatories:-

For and on behalf of Supplier	**For and on behalf of Institution**	**Acknowledged by the Recipient (who is not a party to this Agreement)**
signed	signed	signed
print name	print name	print name
title	title	title
date	date	date

Standard terms and conditions for release of materials

1 The Recipient and the Institution shall keep the Materials secure at the Recipient's laboratory and ensure that no-one other than the Recipient and authorised co-workers ("Co-workers") have access to them. In this Agreement the "Materials" shall include any and all materials, documents and information that the Supplier may provide to the Recipient under or in connection with this Agreement, and including any constructs, strains, progeny, derivatives, portions, improvements and components obtained from or as a result of using any item provided by the Supplier.

2 The Recipient and the Institution shall use the Materials only for the Research Programme and not for any commercial purpose or commercially-sponsored research without the prior written consent of the Supplier even if those purposes are being pursued in the Recipient's laboratory.

3 The Recipient and the Institution shall not supply the Materials to any other party. The Materials shall under no circumstances be used in humans.

4 The Term may be extended with the written agreement of the Supplier. Permission to extend the term of this Agreement must be sought by the Recipient three (3) months before the expiry of the Term.

5 The Recipient and the Institution shall acknowledge the Supplier as the source of the Materials in any publication which mentions them. The Recipient shall send the Supplier a copy of any reports or publications which describe work carried out using the Materials, and shall make available on request any raw data and the Supplier shall be entitled to use all such data, reports and publications and make them available to third parties.

6 The Materials (and any copies thereof made by or in possession of or under the control of the Recipient pursuant to this Agreement) shall be and remain the property of the Supplier and shall be immediately returned (or if the Supplier so requires, destroyed) (i) on termination of this Agreement, or (ii) in the event that the Recipient or Institution is in breach of any of the conditions of this Agreement, and (iii) at any other time on request of the Supplier.

7 The Materials shall at all times remain the property of the Supplier and will not be removed from the Recipient's address. No licence under any Supplier intellectual property is granted or implied by this Agreement.

8 In the event that the Recipient or Co-workers make or observe any new discovery, improvement or invention ("Invention") relating to the Materials or as a direct result of the Research Programme then the Recipient will bring this to the attention of the Supplier. The Recipient and the Institution shall not make or seek to make actual commercial gain from such an Invention, nor make any patent application

or secure any other proprietary rights to legally protect any such Invention except with the prior written consent of the Supplier. The Supplier will, at all times, retain the right to use an Invention for non-commercial research purposes.

9 If any commercial revenues result from the Recipient's or the Institution's use of the Materials, the Supplier shall be entitled to an equitable share of any such revenues that accrue to the Institution or the Recipient.

10 The Recipient and Co-workers shall use the Materials in accordance with good laboratory practice and the highest standards of skill and care and shall ensure compliance with any applicable laws and regulations governing the transportation, keeping or use of the Materials.

11 The Materials are supplied without cost but the Recipient/Institution shall reimburse the Supplier for any reasonable shipping and related costs that may be incurred when preparing and sending the Materials to the Recipient.

12 The Materials are experimental in nature and the Supplier makes no representation and gives no warranty or undertaking, in relation to them. As examples, but without limiting the foregoing, the Supplier gives no warranty:- (i) that it owns all necessary property and other rights in the Materials and that their use will not infringe any patent, copyright, trade mark or other right owned by any third party; or (ii) that the Materials are of merchantable or satisfactory quality or fit for any particular purpose, have been developed with reasonable care and skill or tested, for the presence of pathogens or otherwise, or are viable, safe, or non-toxic.

13 The Supplier shall have no liability to the Recipient or Institution, whether in contract, tort (including negligence) or otherwise, in relation to the supply of the Materials to the Recipient and/or Institution or their use or keeping by the Recipient and/or Institution or by any other person, or the consequences of their use, to the maximum extent permitted under applicable law. The Recipient and Institution shall indemnify the Indemnified Parties from and against all Claims and Losses arising from such supply, use or keeping, including without limitation Claims and Losses arising from:- (i) injury to the Institution's employees and third parties; (ii) infringement of third party intellectual property rights; and (iii) use of the Materials within or outside the scope of this Agreement.

14 For the purposes of this Agreement:- (i) "Indemnified Parties" shall mean the Supplier and its associated undertakings and their respective directors, officers, employees and representatives; (ii) "Claims" shall mean all demands, claims, proceedings, penalties, fines and liability (whether criminal or civil, in contract, tort or otherwise); and (iii) "Losses" shall mean all losses including without limitation financial losses, damages, legal costs and other expenses of any nature whatsoever.

15 The Recipient and the Institution agree to be bound by this Agreement in consideration of the Supplier making the Materials available to the Recipient.

16 English law shall apply to this Agreement, and the English courts shall have [non-]exclusive jurisdiction. This Agreement does not create any right enforceable by any person that is not a party to it.

MATERIAL TRANSFER AGREEMENT

([Institution name], the receiver of the Material)

1. *Insert supplier's name and address* _____

(the "Supplier"), has collected and/or developed the materials known as

2. *Insert description of materials* _____

and includes any constructs, strains, progeny and unmodified derivatives (as the case may be) obtained from or as a direct result of the use of the materials (together, the "Materials")

3. *Insert name of Scientist* _____

_____

(the "Recipient") who is an employee of

4. *Insert name and address of Scientist's Institution* _____

("Institution")

and wishes to acquire a sample of the Materials for academic research relating to:

5. *Insert description of academic research for which Materials are to be used* _____

_____

(the "Research Programme")

6.	*Insert quantity of Materials to be supplied and period for which they are to be provided for*	The Supplier is willing to provide a sample of _____ of the Materials for a period of _____ years (the "Term") on the Terms and Conditions shown overleaf, and the Recipient and the Institution agree to comply with those Terms and Conditions

AGREED by the parties through their authorised signatories:-

For and on behalf of Supplier	**For and on behalf of Institution**	**Acknowledged by the Recipient (who is not a party to this Agreement)**
signed	signed	signed
print name	print name	print name
title	title	title
date	date	date

Standard terms and conditions for the receipt of materials

1 The [Recipient and the] Institution shall keep the Materials secure at the Recipient's laboratory and ensure that no-one other than the Recipient and authorised co-workers have access to them.

2 The [Recipient and the] Institution shall use the Materials only for the Research Programme, subject to the following sentences of this clause. Any intellectual property generated in the course of the use of the Materials by the Recipient and/or the Institution shall belong to the [Institution] (the "Resulting IP"). The [Institution] shall be entitled to commercialise any Resulting IP so generated without restriction, subject to Clause 5.

3 The Institution shall ensure that the Recipient acknowledges the Supplier as the source of the Materials in any publication which mentions them.

4 The Materials shall remain the property of the Supplier and shall be returned on request, except for those Materials used in the creation of the Resulting IP as described in Clause 2. No licence under any Supplier intellectual property is granted or implied by this Agreement, except that the Institution shall have a non-exclusive licence to use any Supplier intellectual property which is reasonably necessary for the commercialisation of the Resulting IP. Such licence shall be irrevocable, royalty-free, world-wide, without limit of time and with the right to sub-licence.

5 If any commercial revenues result from the Institution's or the Recipient's use of the Materials, the Supplier shall be entitled to an equitable share of any such revenues that accrue to the Institution or the Recipient.

6 The [Recipient and the] Institution shall use the Materials in accordance with good laboratory practice and the highest standards of skill and care and shall ensure compliance with any applicable laws and regulations governing the transportation, keeping or use of the Materials.

7 The Institution shall reimburse the Supplier for any reasonable shipping and related costs that may be incurred when preparing and sending the Materials to the Recipient.

8 The Institution agrees to be bound by this Agreement in consideration of the Supplier making the Materials available to the Recipient.

9 English law shall apply to this Agreement, and the English courts shall have [non]-exclusive jurisdiction over any matter relating to it.

10 This Agreement does not create any right enforceable by any person that is not a Party to it.

Waiver letter

[Institution's headed paper. Contracts/Technology Transfer Office]

Dear [Prof/Dr]

MTA [reference] [name of Institution]

You recently requested that the above agreement be signed on your behalf by [Institution]. Unfortunately, as we have discussed, the terms of the MTA are not acceptable to [Institution] as the organisation providing the Materials will own all rights to any intellectual property resulting from your research using the materials. In addition, they would have the right to use and commercialise such intellectual property without any equitable return to either [Institution] or yourself. Please see clause(s) [*insert*] of the MTA.

[In addition, I should also point out that certain funding charities are increasingly reluctant to award grants for research that is dependent on the use of materials thus encumbered].

You have indicated that you understand the position but still wish to proceed with the MTA since the research will not result in any inventions [and/or you require the materials urgently].

In order to proceed with the signature of the MTA on behalf of [Institution], I should be grateful if you would countersign and return this letter confirming that you wish [Institution] to do so. A copy of this letter will be held on file to show that you understand that in the event of an invention arising from your research using these materials, [Institution] will not be in a position to commercialise it and you will not receive any financial recompense.

Please do not hesitate to contact me if you have any further queries.

With kind regards.

Yours sincerely,

Confirmed and agreed:

_____ _____

[name] *[Prof/Dr]*

[Contracts Executive] _____

On behalf of [Institution] *date*

MATERIAL TRANSFER AGREEMENT (MTA) INFORMATION SHEET

Please complete the following details and answer the following questions, so that [Research Contracts Department] may determine whether the proposed MTA is acceptable to the [Institution], and arrange for signature of the MTA, if appropriate.

1. Please state below the name of the principal investigator, any co-investigator(s), and in each case his/her department or faculty.

2. Please state the name of the institution providing the materials and a description of the materials.

3. What do you intend to use the materials for? (Please give a brief 2 or 3 sentence synopsis of the research).

4. Please give details of any non-commercial funding for the research in which you will be using the materials (e.g. EPSRC grant; Wellcome Trust etc,).

5. Will any industrial or commercial funding (including "in kind" contributions) be used for your research using the materials, or is the research otherwise conducted under any written agreement? If yes – please specify the name of the Sponsor organisation and the nature of the funding, support or agreement.

6. Will any students or visiting fellows be working on the research using the materials? Or anyone

who would not be classed as an employee of [Institution]? If so – please identify them and give details of the funding sources for such persons.

7. If students will be using the materials, will their research using the materials form part of a thesis?

☐ Yes ☐ No

8. Do you intend to modify the material in any way?

☐ Yes ☐ No (If yes – please give details):

9. Do you intend to incorporate the material into something else or combine it with other material?

☐ Yes ☐ No (If yes – please give details):

10. Will the materials be used <u>together with other materials provided by a third party</u>?

☐ Yes ☐ No

If yes – please give details of the other materials and which organisation provided them. (If you are aware of an MTA for the other materials please specify the date of signing and any reference number you may have for that MTA):

11. Is the material:

	Yes	No
of human origin?	☐	☐
to be used in humans (in your research)?	☐	☐
known to be toxic?	☐	☐
readily available from another source?	☐	☐

available commercially? ☐ ☐

If so, please indicate cost: £ ……

12. In your opinion, how likely is it that your research with the materials will generate any invention or significant intellectual property?

Extremely unlikely ☐

Unlikely ☐

Possible ☐

Difficult to say ☐

Please don't hesitate to add any further information that you think may be relevant or helpful. Once you have completed the form, please sign it and return to this department.

Depending on your responses to the above questions, the proposed MTA may require amendments in order to (i) protect your/[Institution's] intellectual property and (ii) to ensure that it does not conflict with existing research contracts with other sponsors.

We will endeavour to negotiate any amendments as quickly as possible and appreciate your cooperation during this process.

…….. ……..

Principal Investigator Date

APPENDIX B

Notes for the completion of the template MTAs set out in Appendix A

The text below summarises briefly the main points that should be considered when completing the Template MTAs provided in Appendix A, or similar agreements. Some other issues that may arise are included for completeness.

1. Parties to the MTA

The main point here is to include the full, legal title and appropriate address of the "other" party. The legal title should include any abbreviations such as 'limited' or 'plc'. In the usual situation where one's own institution is the Supplier, the other party will be described as the Institution (as in Template 1). In the case of universities or research institutions, the appropriate "main" body should be named as the party – i.e. the university/institution itself and **not** a particular department or faculty.

For a UK company, it is good practice to check both the name, address and registration number using the free service available on the Companies House website (www.companieshouse.gov.uk). Where possible, insert the company's registered address and refer to it as such. Where the company prefers to use another address, reference should be made to, e.g. "Megapharmacom, a company incorporated in [England] under registration number [*insert*], whose principal place of business at [*insert address*]." In all cases, it would be useful to refer to the company's registered number given to it by Companies House as this never changes and it will be possible to trace the company at a later date, if required.

For charities registered in England and Wales it is possible to confirm their name, address and registration number using the register of charities available on the website for the Charity Commission for England and Wales (www.charitycommission.gov.uk).

To check the details of non-UK companies, try a Google search or try using the links to other company registers available on the Companies House website. If this fails to unearth the relevant details, the contact at the company should be asked to confirm that the name of the company stated in the draft MTA is its correct, legal title and that its registration number and address stated are also correct. As with English companies, the full legal title will include relevant abbreviations (e.g. Inc. (USA companies) or GmbH (German companies), etc.). The county of incorporation should generally be stated. For US companies it is good practice to include the particular State of incorporation.

2. Materials

Since the Materials are the vital component to the MTA, it is essential that they are adequately described! Beware of wording that says the Materials are "as described in an email to Professor Fumble." There should be no other descriptions other than in the MTA. If the Materials really cannot be described simply, or there are many components, then the appropriate wording should be cut and pasted into a schedule to the agreement. There should be a clear reference to the schedule in the MTA, e.g.:

"….. the materials known as the translocation plasmids, as detailed further in the Schedule to this Agreement."

Where the Materials comprise several, similar plasmids, care should be taken with their nomenclature (particularly if a combination of Greek symbols is used) and any list provided should be checked with the relevant academic. The same applies equally to nucleotide or protein sequences (where a typo could make a difference). If a schedule has been used to describe the Materials, make sure this is attached to the MTA.

3. Amount

Both Templates 1 and 2 make a provision for the amount of Materials to be stated. This may be of more relevance in some instances than others. Where the Materials are self-replicating, the Recipient will probably not be too concerned to receive a small amount. On the other hand, where one's Institution is supplying a small amount of a scarce chemical then 10 mg may be more appropriate than 10 g. Again, this should be checked with the relevant academic.

4. Research Programme

A short description should be provided of the research programme or project in which the Materials are to be used. This description will set the limits on what the Recipient can do with the Materials, and is therefore important.

Where the Supplier of the Materials will own all arising IP, it is important (from the Recipient's point of view) to define the Research Programme as narrowly and precisely as possible.

5. Term

In both the Template agreements there is a space provided to insert the length of time that the Materials are to be supplied. Generally this is for 1 or 2 years. It would be unusual for this to be more than 3 years and if this is the case, thought should be given to whether there is (or should be) a collaboration agreement between the parties.

6. Signature block

This raises two issues: (i) who should sign and (ii) what should be the date of the agreement.

Who should sign

Both Templates state above the signature blocks: "Agreed by the parties through *their authorised signatories*." The italicised text should act (but usually doesn't) as a prompt to the party signing regarding whether he does in fact have the authority to sign on behalf of the institution. As discussed previously, many academics believe (erroneously) that they do have the authority to sign on behalf of their institution.

When dealing with another university's contracts department, one's opposite number is usually well aware of the problem. However, persons dealing with MTAs in small companies may not have the same familiarity with the problem - so when the MTA has been finally negotiated, it is helpful to emphasise in an email that you would be grateful if they could arrange to have the agreement signed by an authorised signatory of the company.

Date of the Agreement

Both templates have a space to indicate the date on which the parties sign. By convention, the date of the Agreement (and the date which should be logged on any MTA database) is the date when the last party signed – unless agreed otherwise by the parties. They may wish to agree otherwise where:

- the institutions are attempting to formalise an informal supply, e.g. where the academics involved have already exchanged the Materials;
- in addition to Materials, confidential information has already been provided or will be provided in advance of the Materials.

If either of the above situations apply, the signature blocks should be left the same but an additional clause will need to be inserted earlier in the MTA making clear when it is to take effect. Wording such as "This agreement shall be effective from [1 January 20[ ]]" should be used. On no account should an attempt be made to back-date the agreement by inserting a date in the signature block that predates the date when the MTA is actually signed. (This could amount to a forgery – see further, Appendices C and D and the Practical Guide on General Legal Issues).

7. Law and Jurisdiction

This does not, strictly, need completing in the same sense as the headings above. The standard provision in both template agreements is for English law and jurisdiction. However, it has been included again here (i) for completeness (related to confidentiality raised in point 6 above) and (ii) because since it is a frequently changed clause it is worth emphasising that it always merits one last check!

Always consider:

i who the parties are; relevant affiliates/ subsidiaries

ii where the main work is to be performed

iii are there any confidentiality provisions.

Particularly if there are confidentiality provisions, make sure that there is a provision stating that "Nothing in this Agreement shall prevent any party from seeking an interim injunction in any court of competent jurisdiction".

APPENDIX C
In-depth discussion of commercial issues in an MTA

Discussion of Provider's & Recipient's perspectives

Introduction

This Appendix will focus on some detailed drafting and negotiation issues in MTAs. The main topics to be covered will be:

- Defining the materials
- Restrictions on use of the materials
- Compliance with regulatory obligations
- Access to results
- Publications
- Ownership of results
- Patenting
- Licences
- Revenue sharing
- Delivery obligations
- Insurance and risk (including Incoterms)

Drafting and negotiating issues on 'legal' clauses are discussed in the Practical Guide entitled General Legal Issues in University Contracts. In particular, that Practical Guide provides commentary on:

- Dating the agreement
- Parties, including third party rights

- Warranties, liability and indemnities
- Law and jurisdiction
- Avoiding unintended legal consequences (e.g. sale of goods)

During the discussion in this Appendix, examples will be taken from the Template Agreement (outgoing materials) included in Appendix A, together with various MTAs that the author has encountered. References to specific Providers have been anonymised but in order to give an idea of the origin of certain clauses, references to "BigPharma" mean major, multinational pharmaceutical companies, and "BioTech" indicates one of the smaller biotechnology or biopharmaceutical companies.

In the USA much effort was expended in the 1990s on the production of a Uniform Biological Transfer Agreement (UBMTA). This was the result of a collaboration between the (US) Association of University Technology Managers (AUTM) and the National Institutes of Health (NIH). It stemmed from the increasing awareness by technology managers that negotiating MTAs was very time-consuming and there ought to be a simpler (standardised) way of transferring materials between non-profit institutions – who, after all, share the same ideals! Clauses from the UBMTA will also be considered as it is often sent to UK institutions. Note – all defined terms in the UBMTA appear in upper case lettering. Further details regarding the UBMTA may be found at www.autm.net

In the UK, the Brunswick Group has developed an MTA for use between two universities to facilitate routine transfers of materials between academic institutions. Further details regarding the Brunswick Group MTA template can be found at www.praxisunico.org.uk/news/detail.asp?ItemID=473 That website states that the Brunswick Group MTA template is available for all universities and other public sector to use, not just those in the Brunswick Group and lists a number of UK universities that have signed up for its use.

Definition(s) of "materials", "derivatives" and "modifications"

The definitions of materials, derivatives, and other materials-related terms in an MTA are significant as in most cases they will determine the carve-out of intellectual property ("IP") rights arising from the use of the materials, as between the Provider and Recipient. A key point to watch out for is whether the definition covers materials generated by the Recipient using the original materials. Sometimes, as in the UBMTA, a distinction is made between unmodified derivatives (owned by the Provider) and modified derivatives (owned by the Recipient).

There is no standard or one-size-fits-all definition of materials, derivatives, or any other of the materials-related terms. In each case, the reader needs to consider their appropriateness in the specific circumstances, particularly in view of the fact that these definitions are likely to carve out the ownership of IP rights arising from the use of the materials as mentioned above.

The Materials originally provided by the Provider might typically include proteins, cell-lines, plasmids, DNA, RNA, bacterial strains, yeast strains, hybridomas, antibodies, transgenic plants, transgenic animals, cultures and pharmaceuticals (whether chemical or biological).

The further materials generated by the Recipient might typically include constructs, improvements, components, progeny, clones, sub-clones, modified derivatives, or unmodified derivatives.

Examples of unmodified derivatives might include:

- Sub-clones of unmodified cell lines,
- purified or fractionated subsets of the original material,
- proteins expressed by DNA/RNA supplied by the Provider, or
- monoclonal antibodies.

In a few cases (notably specialist chemicals or pharmaceuticals) the Materials may be defined simply as the substance itself. If this is the case, there will normally be additional provisions in the MTA where the Recipient agrees not to attempt to make derivatives and, often, not to analyse the Materials.

Therefore, what is caught by the various materials-related definitions needs to be considered on a case-by-case basis in light of the specifics of the circumstances, including for example the nature of the materials in question, whether the materials are proprietary or are particularly important to the Provider, what the Recipient intends to do with the materials, what is likely to arise out of the Recipient's use of the materials, etc., etc.

Although there is no standard or one-size-fits-all definition of the various materials-related terms used in MTAs, some examples are set out below for the reader's consideration. In addition, the author understands that certain universities in the United Kingdom (known as the "Brunswick Group") have developed their own equivalent of the UBMTA for exchanges of non-proprietary materials between academic organisations for non-commerical purposes. At the time of writing, the Brunswick MTA defines the materials as including "all unmodified progeny generated from the material supplied and that part of all derivatives and the derivative's progeny which contains any of the material supplied or its progeny".

Examples of definitions of Materials

Template Agreement: ….the materials known as [description] and including any constructs, strains, progeny, derivatives, portions, improvements and components (as the case may be) obtained from or as a result of the use of the materials (the "Materials").

UBMTA: MATERIAL: ORIGINAL MATERIAL, PROGENY, and UNMODIFIED DERIVATIVES. The MATERIAL shall not include: (a) MODIFICATIONS, or (b) other substances created by the RECIPIENT through the use of the MATERIAL which are not MODIFICATIONS, PROGENY, or UNMODIFIED DERIVATIVES.

In the Template Agreement the definition of Materials is quite wide. This is due to:

- encompassing the (undefined) terms constructs, derivatives, improvements within the definition; and
- using the wording "obtained from or as a result of the use of" [the Materials]

In contrast, the UBMTA specifically defines Modifications as "substances created by the Recipient which contain/incorporate the Material". Under the UBMTA the Recipient retains ownership of Modifications (with the proviso that the Provider retains ownership of the Material therein). Furthermore, the UBMTA definition of Materials does not include substances created by the Recipient "through the use of the Materials" (**provided** that these are not Modifications, Progeny or Unmodified Derivatives).

Unmodified Derivatives are defined in the UBMTA as:

"Substances created by the Recipient which constitute an unmodified functional subunit or product expressed by the ORIGINAL MATERIAL. Some examples include: subclones of unmodified cell lines, purified or fractionated subsets of the ORIGINAL MATERIAL, proteins expressed by DNA/RNA supplied by the PROVIDER, or monoclonal antibodies secreted by a hybridoma cell line."

Negotiation Point

A Provider will usually seek to maintain a definition of Materials that is as broad as possible whilst a Recipient will seek to narrow it. However, other factors will influence this such as the value/availability/novelty of the Materials. The use of the defined term in the MTA also needs to be considered. Clearly if the Provider has a very broad definition of Materials and seeks to own all IP arising from use of such Materials, this is a less equitable position than a broad definition of Materials together with a provision for fair division of any proceeds of commercialisation.

In the wording of some MTAs it may be helpful to consider adding the word "unmodified" before the word "derivatives" or request that in any wording where Derivatives are defined as "substances derived from the Materials" then it is modified to: "substances derived ***directly*** from the Materials."

Further information on biological terms

Glossaries of biological terms can be found at a variety of websites including:

http://users.rcn.com/jkimball.ma.ultranet/BiologyPages/W/Welcome.html

Restrictions on use of the Materials; meaning of non-commercial and commercial use

The MTA will usually provide that the Materials may only be used in a defined programme of research, details of which are set out in the MTA itself or in a schedule attached to it. Often, the MTA will additionally include some "belt and braces" wording stating that the Materials may not be used in humans, and may not be used in any commercial research activities.

Fifteen or twenty years ago it was more readily assumed that any research undertaken in a UK university would be regarded as having a non-commercial purpose. Furthermore, the terms "commercial" and "non-commercial" were considered as opposites (and mutually exclusive). Today the distinction is not quite so simple, and this issue comes up in MTAs and in licence agreements, where the university will generally wish to reserve to itself a right to conduct non-commercial research. Unfortunately, there is no clear, universally-understood meaning of the term "non-commercial". It may be uncontroversial that "blue skies" research, funded by, say, a Research Council, will be regarded as academic and non-commercial. The main grey area is whether or not commercially-sponsored research is considered to be commercial use. A further issue that sometimes arises is whether research that is directed to an eventual commercial product, however it is funded, should be considered as commercial. In the absence of a substantial body of case law that establishes boundaries to the term "non-commercial", the best way to proceed *may* be to define the term clearly in the contract. For example, in a patent licence agreement, a university licensor may wish to state explicitly that it reserves the right to use the licensed inventions in teaching and research, including commercially-sponsored research. Whilst this may achieve greater clarity, it may also 'flag up' the issue in the negotiations and meet resistance from the licensee.

The specimen wording below indicates that:

- the Template Agreement takes the "for the avoidance of doubt" approach in that it prohibits use of the Materials for (a) any commercial purpose and (b) commercially sponsored research
- the UBMTA approaches the issue from the other perspective stating that industrially sponsored academic research shall not be considered a use of the Material or Modifications for Commercial Purposes *per se* (unless other conditions are met).

Relevant wording:

Template Agreement: The Recipient shall use the Materials only for the Research Programme and not for any commercial purpose or commercially-sponsored research without the prior written consent of the Supplier even if those purposes are being pursued in the Recipient's laboratory.

UBMTA (from the Definitions section): COMMERCIAL PURPOSES: The sale, lease, license, or other transfer of the MATERIAL or MODIFICATIONS to a for-profit organization. COMMERCIAL PURPOSES shall also include uses of the MATERIAL or MODIFICATIONS by any organization, including RECIPIENT, to perform contract research, to screen

compound libraries, to produce or manufacture products for general sale, or to conduct research activities that result in any sale, lease, license or transfer of the MATERIAL or MODIFICATIONS to a for-profit organization. However, industrially sponsored academic research shall not be considered a use of the MATERIAL or MODIFICATIONS for COMMERCIAL PURPOSES per se, unless any of the above conditions of this definition are met.

Practical tips:

- Check whether commercially sponsored research **is** allowed under the specific terms of the MTA. Even if it is not, a check with the relevant Recipient academic will establish whether this is still an issue.
- Remember – commercially *sponsored* research could have a broader meaning than commercially *funded* research. (Sometimes sponsors may provide non-monetary support, e.g. equipment, reagents or culture media).
- Look out for any notes/modifications/attachments to the UBMTA. If Materials are "Patent Pending" there may be additional provisions appended to the UBMTA – e.g. that the Material will not be used in a research project involving ***collaboration*** with a for-profit organisation (emphasis added).

Unapproved (or 'off piste') Research

Occasionally one encounters a provision whereby any IP arising from the use of the Materials in an experiment that is outside the defined research project vests automatically in the Provider. It is a moot point whether such clauses are unfair. On the one hand, academics are by their very nature keen to investigate new avenues and one could argue that they should have freedom to pursue their ideas. After all – this is why companies are keen to fund innovative research. If the academic discovers something with potential whilst venturing "off piste" why should both parties not benefit? Conversely, a pharmaceutical company may have invested considerable resources in some novel compounds that may have development potential and they are keen to guard against any unapproved use.

Realistically, the answer probably depends on what the Materials are. Where the Materials are routine, the Recipient should probably seek to delete such clauses where possible.

Example clause: While the Provider in no way condones the use of the Material for purposes outside the Research, if such work is performed, or upon the failure by the Recipient to comply with any obligation as set forth in [*insert relevant clause numbers*], all information, developments, discoveries, technologies, inventions and the like arising therefrom, whether patentable or not shall be treated in all respects as [Provider IP] in accordance with the terms of this Agreement.

Compliance with regulatory obligations

MTAs sometimes include provisions that clarify the parties' (usually the Recipient's) obligations to comply with regulations governing the use of materials and the conduct of research.

Various legal provisions cover health and safety at work, including:

- *EPA*. The Environmental Protection Act 1990 covers such things as disposal of waste and control of dangerous substances as well as any release (or escape) of genetically modified organisms.
- *GMOs*. The holding, use or transportation of genetically modified organisms (GMOs) are separately covered by both EC Directives and UK legislation.
- *COSHH*. The health and safety of an institution's employees is governed by the Health and Safety at Work, etc. Act 1974 and various legislation derived from it – the most well known of which is probably the Control of Substances Hazardous to Health Regulations 2002, known as the COSHH Regulations.
- *Others*. Additional legislation governs such matters as flammable substances and radioactive substances.

Most institutions will have a well-documented safety policy together with various committees and/or safety officers overseeing compliance. Occasionally, the authors have encountered MTAs specifying that the materials require a certain level of laboratory containment facilities and requesting (in addition to an authorised signature) that a recognised safety officer should also countersign the MTA. Obviously, the MTA and its provisions should then be discussed with the relevant safety officer to ensure that the institution can comply with any obligations specified in the MTA. Even where no countersignature is requested, if any containment provisions look onerous, it is useful to contact the relevant safety officer.

Human Tissue

The regulations governing the use of human tissue are complex. A few brief comments are made here. First, as to legislation and best practice, which includes the following:

- The Human Tissue Act 2004 – governs the use of human tissue.
- The EU Tissue and Cells Directive sets out legal requirements for all units involved in the donation and procurement of human tissues. The Directive was published on 7 April 2004 and EU countries are obliged to comply by 7 April 2006. Further details can be obtained from the department of health website (www.dh.gov.uk) and the Medical Research Council (www.mrc.ac.uk)
- The MRC and the Human Tissue Authority has published various guidelines regarding working with human tissue and best practice (including patient consent, anonymising samples, etc.).

Scientists working in this field should be fully aware of their obligations in relation to the use of materials. Some of the practical steps that are taken include the following:

- In some institutions, it is departmental policy to keep a copy of the relevant Ethics Committee approval for the research project of the requesting (Recipient) academic on file.
- Other considerations may include a check that the Provider can supply a template of the relevant form, indicating that the tissue was originally obtained with patient consent

GMOs

Where the Materials consist of GMOs, wording such as the following might be encountered:

Example wording: The Material is a Genetically Modified Micro-organism (GMO) and thus the Recipient shall comply with the related applicable law. Without limiting the scope of the preceding sentence, the Recipient shall preserve the GMO in a contained environment and shall not release the GMO without the relevant authorisations.

Access to results

From a Provider's perspective, it may be part of the rationale for allowing the Materials to be used in research, that the Provider should have access to the results of the research. The Recipient may have different views, particularly:

a if an academic Recipient does not wish to "write up" detailed reports that would not otherwise have been written; or

b if a Recipient wishes to keep a tight control over the dissemination of research results that have commercial value, e.g. concerning a drug in development.

The appropriate terms will therefore depend on the individual circumstances. Some MTAs specify that the Recipient shall submit periodic reports, often in addition to any final report. This raises two points: (a) confidentiality and (b) is this reasonable in the circumstances and/or is the academic willing? In relation to confidentiality, it is a simple matter to insert that the Provider shall treat the reports as confidential. This can be done routinely by the contracts executive. It is worth stressing that it is important not to overlook this, since any reports could potentially count as a premature disclosure that might bar subsequent patentability.

Frequency of reports should be discussed with the relevant academic(s) before any commitment is made – since they will have to produce the reports!

As well as establishing the rights of the Provider to obtain copies of reports, the MTA may also address the question of the Provider's rights to use those results (or, in some cases, ownership of the results). These topics are discussed further in the section on IP rights, below.

Publications

Agreements with academic research organisations or non-profit institutions such as universities or research-based charities will normally require that the results of any research can be published. This is usually due to the fact that the organisation must comply with charity law (which requires publication) to retain its charitable status. In addition, most funding bodies have a publication/dissemination requirement and this is made clear in the terms and conditions of the grant award.

In addition to the need to maintain charitable status, universities generally have a policy regarding the publication of their research efforts. Indeed, the correlation of academic career progression with publications is well recognised.

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.

Most MTAs require a draft of any publication or proposed oral/poster presentation to be submitted to the Provider of the Materials for review. From a Recipient's perspective, it may be important to check that the review clause does not give a right of veto to publishing the results. The Recipient will probably seek to ensure that any review periods are time-capped.

Example from a US university: Recipient will provide Provider with a copy of any manuscript or abstract disclosing [Results] prior to submission thereof to a publisher or to any third party, and in any case, not less than forty-five (45) days prior to any public disclosure, for the purpose of protecting the Material and any proprietary and intellectual property of Supplier that might be disclosed by such publication.

Time allowed for review

There are several variations on time periods for review:

a draft is submitted [30] [45] [60] days prior to publication

b as above, and Provider may delay publication for an additional [60] [90] days in order to protect intellectual property / remove Provider's confidential information if such is found when reviewing

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

Academic institutions understand the issues and are usually fairly flexible. In the author's experience, even BigPharma are becoming more willing to negotiate. The formula of initial review ([30] [60]) plus additional delay ([60] [30]) should not exceed 90 days. Whilst it is rare to agree on less than 30 days for the initial review, it is often possible to compromise on 45 days for the additional delay period.

From a Recipient's perspective, care should be taken with version (a) above. A potential disagreement could arise in the event that the Provider does not respond to the submitted draft. Is the Recipient free to publish? Even if the

MTA is worded so that it appears that the Provider should respond within 30 days – what if they don't? It is probably best to take the "for the avoidance of doubt approach" and insert the appropriate clarification (see words in bold in the following example). It is also advisable to "nip in the bud" any possible suggestion that the Provider is being given a right of pre-approval prior to publication. This is addressed by the italicised wording in the same example.

Publications example 1: [Subject to confidentiality provisions in clause x], Investigator may make presentations and/or publish scientific papers relating to the Results provided, however, that prior to submitting such papers for publication, such papers are first submitted to BigPharma for review and comment. BigPharma will provide the Recipient with comments on such papers within thirty (30) days of their receipt by BigPharma**. A lack of response by BigPharma within thirty (30) days shall be taken as approval for the Recipient to disclose the Results.** The Recipient agrees to take into account recommendations and comments provided by BigPharma *but shall otherwise be free to publish provided that BigPharma has had the opportunity to identify patentable material and BigPharma's confidential information.*

UBMTA: The wording in the UBMTA is fairly neutral: This agreement shall not be interpreted to prevent or delay publication of research findings resulting from the use of the MATERIAL or the MODIFICATIONS. The RECIPIENT SCIENTIST agrees to provide appropriate acknowledgement of the source of the MATERIAL in all publications.

Acknowledging provider

Some institutions specify that the Provider scientist should be acknowledged using wording such as:

- Recipient agrees to acknowledge Provider scientists, as academically and scientifically appropriate, in its publications; or
- Recipient shall acknowledge Provider scientist, according to scientific custom, in all publications resulting from the use of Materials.

In the author's view, the latter example is more open to the interpretation that the providing scientist expects to get his/her name on any resulting publication 'for free'. In the former example the wording "as…. scientifically appropriate" at least suggests that the scientist may have contributed some work/discussions. From a Recipient's perspective (and subject to discussion with the appropriate academic – who (i) may not be particularly bothered or (ii) may have already agreed that the Provider scientist will get his/her name on any publication) tighter/more explicit wording could be:

Acknowledging Provider Example 1: If a publication results from work using the Materials, Recipient agrees to acknowledge Provider and/or give credit to Provider scientists, as scientifically appropriate, based on any direct contribution they may have made to the work.

Practical Tip

Care should be taken if the Materials are to be used in collaborative research or research sponsored by a commercial company. In either case there may be pre-existing agreements where other parties have a right to pre-publication reviews. If the MTA Provider is also to have this right, a potential conflict could occur in regard to proprietary confidential information of the various parties. Possible solutions (including a specially drafted confidentiality agreement) will need to be considered on a case-by-case basis.

Creation, ownership, protection, licensing and exploitation of intellectual property created during the existence of an MTA

Different ways of carving-up the IP

Where the Provider of the materials is a commercial company, the main area of contention in negotiations will often be the question of rights to resulting IP. Even between non-profit institutions this section of an MTA often requires some discussion. Many different solutions can be agreed, depending on the nature of the materials and what they are to be used for by the Recipient. For example, if the material is a compound in development by a commercial Provider, the Provider is likely to want to own the resulting IP concerning that compound. If the materials are routine research materials, the Provider may be less concerned about owning the resulting IP. Possible variations include, in summary:

- Recipient owns resulting IP; Provider receives non-exclusive licence to use such IP in its own R&D; Recipient pays Provider a royalty on exploitation of resulting IP
- Provider owns resulting IP; Recipient receives non-exclusive licence
- Recipient owns resulting IP; Provider receives option to negotiate an assignment or exclusive/non-exclusive licence
- Ownership of resulting IP is split, e.g. patents claiming the materials themselves or their use belong to the Provider, all other IP belongs to the Recipient
- Resulting IP is jointly owned, with provisions for the Provider to have an exclusive licence in a defined field.

In the authors' experience, US universities have in recent years tended to offer similar terms in MTAs to those offered in their research contracts, i.e. the university will own all resulting IP and grant a limited, non-exclusive licence to the Provider for non-commercial research, combined with an option to negotiate an exclusive licence. In the authors' view this hard-line approach is not always appropriate, particularly where the MTA concerns use of a commercial company's compound in development. For further commentary, see also the Practical Guides on Option and Licence Agreements.

In practice, clauses covering IP range from the relatively neutral to the extreme "Provider owns everything" variety. Examples of each are illustrated below.

Template Agreement: In the event that the Recipient or the Institution makes or observes any new discovery, improvement or invention ("Invention") relating to the Materials or as a direct result of the Research Programme then:

- The Recipient will bring this to the attention of the Supplier.
- The Recipient shall not make or seek to make actual commercial gain from such an Invention, nor make any patent application or secure any other proprietary rights to legally protect any such Invention except with the prior written consent of the Supplier.
- The Supplier will, at all times, retain the right to use such Inventions for non-commercial research purposes.
- If any commercial revenues result from the Recipient's or the Institution's use of the Materials, the Supplier shall be entitled to an equitable share of any such revenues that accrue to the Institution or the Recipient.

Provider owns all (example 1): BigPharma will own all rights to any and all patentable and non-patentable inventions, improvements, know-how and/or other intellectual property rights, data, findings and results arising from the use of the Materials and/or generated in the course of the Studies ("Developments"). Recipient will take, at BigPharma's cost, all steps necessary for the Recipient to assign and/or transfer such Developments to BigPharma and will reasonably assist BigPharma in the preparation of any patent applications on such inventions.

Provider owns all (example 2): Recipient hereby grants to BioTech an exclusive, irrevocable, worldwide, royalty-free commercial licence, with the right to sublicense, to make, have made, use, sell, have sold, import and otherwise exploit in all fields of use any and all inventions and discoveries, conceived or made by Recipient utilising the BioTech materials and all corresponding patents and patent applications.

Non-exclusive licence back plus option and right of first refusal: Recipient hereby grants to BioTech a fully paid-up, irrevocable, non-exclusive, worldwide license to make, use, sell, offer to sell and import Material and BioTech's derivatives of Materials under any patent applications and patents claiming [Recipient's] Sole Inventions.

Recipient also grants BioTech an exclusive option to obtain an exclusive, worldwide license, with a right to sublicense, to make, use, sell, offer to sell and import products under any patent applications and patents claiming [Recipient's] Sole Inventions and Recipient's interest in any patent applications and patents claiming Joint Inventions. The terms of the exclusive license shall be negotiated in good faith by the parties and provide for commercially reasonable compensation to the Recipient.

In the event the parties fail to reach a mutually acceptable licensing arrangement within 6 months after commencing negotiations, Recipient shall be entitled to negotiate with a third party for a license to any patent application or patent on [Recipient's] Sole Inventions or Recipient's interest in Joint Inventions. Prior to granting a license to a third party, however, Recipient shall offer to BioTech a license on the same terms offered to the third party, and if BioTech requests a license on those terms, Recipient shall grant the license to BioTech.Revenue sharing: rights sof Provider to share in any revenues generated by the Recipient

Some MTAs include wording indicating that the Provider will be entitled to a share of any revenues generated by the Recipient from use of the Materials, e.g. if a patent is filed claiming any aspect of the Materials. In the authors' experience such provisions tend to be found more in MTAs drafted by academic Providers. Commercial Providers tend to be more concerned to protect their ownership position with respect to inventions made using the Materials. Most MTAs do not include detailed financial provisions regarding revenue-sharing, but if such terms are included they are probably best set out in a schedule to the MTA. The detailed terms of royalty agreements (i.e. clauses providing for the payment of lump sums and/or running royalties for use of IP) are beyond the scope of this Practical Guide, but similar issues should be addressed as in licence agreements, i.e. definitions of net sales/net receipts and milestone events, duration, frequency and dates of payment, accounts, statements, auditing, withholding taxes, VAT, etc.

The following example shows wording that has found favour with certain UK universities. It is designed to "set down a marker", with a very light touch, that may or may not be legally enforceable, but has been thought sufficient to establish a principle that will be accepted in negotiations between UK universities.

Template Agreement: If any commercial revenues result from the Recipient's or the Institution's use of the Materials, the Supplier shall be entitled to an equitable share of any such revenues that accrue to the Institution or the Recipient.

Who will file any patents?

Occasionally, Providers will include provisions giving them the right to file, or to comment on, patent applications.

Is any IP likely to arise?

Before becoming too bogged down in any negotiations it is useful to discuss with the relevant academic whether any IP is likely to arise at all. Sometimes the Materials may just be provided as a standard or control in a particular assay.

Depending on the provisions of the MTA, where IP is unlikely to arise, it may be acceptable to leave ownership of any IP arising ***directly*** from the use of the Materials with the Provider. However, even in cases where the academic suggests that no IP will arise, beware of broad wording vesting ownership in the Provider such as "….results arising from the *use of the Materials* and/or generated *in the course of the Studies*". Even if the Materials are provided just as controls, such broad drafting (unless "Studies" are tightly defined) can be very onerous "reach through" provisions.

Obtaining a balance between Provider's and Recipient's interests

Occasionally, an academic MTA will surface that fits on half an A4 page and contains very few provisions at all other than providing that Recipient is liable for the use, handling, storage etc of the Materials. The Recipient may wonder whether to include provisions from his own "standard" MTA and flesh out IP ownership issues "for the avoidance of doubt". Sometimes, the Recipient may feel that it is best to "let sleeping dogs lie" rather than raise potentially difficult negotiation issues. The approach taken may depend partly on an assessment of the important of any resulting IP and whether the Provider is likely to have any interest in that IP in the absence of specific terms in an MTA, e.g. entitlement to be named as a joint inventor?

Often, it will be the Provider who has most to lose from the absence of IP terms in the MTA. If the Provider wishes to acquire any rights in the Recipient's work, it would be advisable to include appropriate terms in the MTA. However, faced with a "skeleton" MTA, the Recipient should also be aware that "his" arising IP may be subject to patent applications regarding the Materials that the Provider may have already filed or is considering.

Other than a simple option to negotiate a commercial licence, the other provisions outlined above such as a right of first refusal all have potential disadvantages. The Recipient (academic and contracts executive) may wish to consider the following:

- Are the Materials available elsewhere?
- Is it appropriate for the Provider to obtain rights to research devised and realised by the Recipient's academic (and/or his team)?
- Who is funding the research? Could the rights granted under the MTA be greater than any rights granted to the funder? Is this equitable in the circumstances?
- Depending on the source of funding (research council / commercial company), could the proposed MTA either (i) prevent the Recipient from controlling the commercialisation of the research for public benefit and/or prejudice future funding or (ii) result in a breach of an existing agreement?

Conflicts/avoiding contamination of an IP portfolio will be considered further below.

Some of the arguments raised in negotiation include the following:

- A Provider will doubtless argue that since the research could not proceed without the (freely provided) Materials, this justifies their position – e.g. ownership or an automatic grant of a licence. In limited instances (such as a cell line; highly specialised Materials of limited availability; or Materials that are difficult and costly to isolate) this may be true.

- For more routine Materials the Recipient might argue that it is providing the intellectual input involved in devising the experiments and undertaking the research.
- Other arguments could centre on whether or not the Provider is also funding/sponsoring the research.
- It may be reasonable for a Provider to expect a non-exclusive licence for its non-commercial use. This may extend to teaching if the Provider is an academic institution.
- In addition (and provided that there are no conflicting obligations or plans for the results) a Recipient may also be willing to include an option for the Provider to negotiate a commercial licence. Even if there are conflicting obligations, depending on their extent, it may be possible to incorporate wording referencing "subject to existing obligations" (see below).

Options to acquire a licence

Sometimes, it is agreed that the MTA will include an option to acquire a licence or assignment of IP. Option clauses should be carefully drafted (see the separate Practical Guide on Option Agreements). Among the points to consider are the following:

- An option clause should specify a finite period for the run of the option – e.g. for the period of the research programme (and possibly a specified number of months thereafter). Arguably, a better alternative is to express the option as available for a period of 6 months following notification to the Provider that the Recipient has either made an invention or filed a patent application.
- Failure to define the period available for exercising the option leads to uncertainty and is a potential cause of a dispute. The Provider could reason that the option is still extant and seek to exercise it, whilst the Provider may have already found another licensee.
- In addition to limiting the period for the exercise of an option, the time available for negotiating any licence should also be capped. In the absence of a specified period, then the Provider might argue that the timeframe is unlimited. Again, capping gives certainty to the IP owner and doesn't hinder the commercialisation process by delaying alternative negotiations with other interested parties.
- Spell out what will happen if the parties are unable to reach agreement at the end of the negotiation period. Wording that the option will lapse or that the IP owner will be free to offer the rights to third parties may be better for the IP owner than a provision for expert adjudication which will involve expense and may delay the commercialisation process.

Contaminating your intellectual property portfolio

For reasons that have been outlined above, a Recipient may wish to make sure that the IP terms of the MTA do not "contaminate" its IP position with regard to the area of research in which it wishes to use the Materials, e.g. by requiring the Recipient to grant rights to the Provider. The same issue can arise in the other direction, i.e. a Provider, who requires rights to IP generated in research that made use of its Materials, will wish to avoid a situation where third parties (e.g. a funder of the research) have competing rights in that IP. Some Providers seek to address this point by including detailed provisions in the MTA that prohibit the Recipient from using the Materials in circumstances where third party IP rights might arise. For example, the MTA might provide as follows:

- The Material will not be used in research that is subject to consulting or licensing obligations to another institution, company or business entity unless prior written permission is obtained from Provider.
- No outside funds or materials will be used to support the Research Programme which will result in obligations inconsistent with the terms of this Agreement.

References are sometimes made in such clauses to co-mingling (without any further explanation). This probably means that the Materials should not be mixed / used in experiments using other materials which would themselves be subject to third party rights. A more explicit example is:

- The Materials shall not be used in any research that is subject to any consulting or license agreement with or sponsored by any third party without the prior written consent of the Provider. The Materials shall not be co-mingled with any biological material(s), sponsored or funded by any third party without the prior written consent of the Provider.

Insurance and delivery obligations

There are three occasions when insurance may be considered with respect to MTAs:

- Is the Provider or Recipient responsible for arranging and paying for, carriage and insurance of the materials during transport to the Recipient?
- Are any obligations in the MTA with regard to liability (e.g. warranties and indemnities) covered by your institution's insurance policies?
- Where a foreign law and/or jurisdiction is agreed – is this covered by the institution's insurance policies?

General questions of liability, and law and jurisdiction are discussed in the Practical Guide entitled General Legal Issues in University Contracts. The following section will discuss obligations to deliver the Materials and associated insurance issues.

It is usually accepted that since the Materials will (normally) be supplied free of charge, it is reasonable to expect the Recipient to pay shipping costs. It appears to be standard practice that the Provider organises packaging and a suitable courier, and invoices the Recipient later. Often, MTAs include a provision to this effect. Unless the Materials are particularly valuable, it is unusual for the contracts department to become further involved.

Such an arrangement begs the question of who is liable if the Materials are lost in transit. Generally, any cost of production of the Materials is relatively small, so in the event of loss in transit another sample could be supplied. However, if the Materials are particularly valuable, further questions would need to be asked regarding the courier's insurance provisions and any relevant limits.

Incoterms

Occasionally, MTAs refer to Incoterms. This is an abbreviation of **In**ternational **Co**mmercial Terms, which is a set of standard contract terms dealing with delivery, insurance and risk that is published by the International Chamber of Commerce (ICC). Incoterms are used mainly in international contracts for the sale of goods. The rationale for their introduction was to reduce confusion over the interpretation of shipping terms in commercial contracts, by outlining the obligations of the parties in respect of risk and insurance at various stages of transit.

A selection of alternative terms, with different names (such as "FOB", "CIF", etc.) is provided, from which the draftsman can select the most appropriate term for his or her contract. At one end of the spectrum of risk and obligation is the term called "ex works", which places all obligations on the purchaser from the time the goods leave the supplier's premises. A Provider of Materials will usually prefer this Incoterm, and may argue that, as the Materials are being provided free of charge, any other allocation of risk and responsibility is inappropriate. At the other end of the spectrum is "DDP" (Delivery Duty Paid), which places all obligations on the Provider until the goods reach the purchaser's premises. There are intermediate Incoterms which allocate different levels of responsibility between the parties. An advantage of referring to an Incoterm by name in your contract, is that it avoids the need to include detailed wording setting out the parties' responsibilities for carriage, insurance, import dutes, etc. But obviously the contract negotiator needs to be familiar with those obligations before he or she can accept the reference to a particular Incoterm.

If Incoterms are referenced, then the agreement should also specify which version of the Incoterms is being used. The current version is Incoterms 2010 (although it is still possible to use and refer to a previous edition – e.g. Incoterms 2000). Further details concerning Incoterms may be found at the ICC website: www.iccwbo.org/incoterms/understanding.asp

Export control laws

Sometimes, research agreements, MTAs or CDAs, particularly those prepared by US organisations, include provisions that refer to export control legislation. Some organisations seem to include a clause of this kind in all of their contracts as a matter of course, and it is often considered not to be negotiable.

The wording usually places an obligation on both parties not to breach US export control laws. Such laws prevent the export of sensitive materials and information, usually those that might have a military application, to certain, specified countries. The laws have a long reach: they seek to regulate the further exporting of such materials and information outside the US (e.g. if materials are exported to the UK then re-exported to another country). In this context, US claims to have jurisdiction over the activities of non-US nationals (e.g. a UK research institution) are controversial, to say the least.

The UK has adopted its own export control laws (remember the Matrix-Churchill affair) but they tend not to be mentioned in most research agreements. By way of example, the authors have been involved in assisting a UK research institution to apply for UK export licences for ship design software, which although not intended for use in a military context could possibly be used for warships. The need to obtain an export licence will depend partly on the nature of the materials and their possible application, as well as the country to which the materials are to be exported. One might speculate, for example, that materials that could be used in chemical warfare would require an export licence.

Clearly, a UK research institution is unlikely to know what obligations might arise under US export control laws in respect of another organisation's materials. If an export control clause is of concern, one approach might be to include wording requiring the Provider to inform the Recipient of any particular requirements with respect to the Provider's materials.

In most cases, one suspects that these clauses are included as boilerplate language, and "for the avoidance of doubt", rather than because of a specific concern about the materials. If the question of compliance with US export control laws is genuinely an issue, this might make one pause to consider whether there are also any UK export control laws that need to be considered. For example, if a UK Recipient modifies a US Provider's materials and supplies the modified materials back to the Provider, should advice be taken on compliance with UK export control laws? And should wording be included in the MTA to deal with this issue? For further information on UK export control laws, see the Export Control Organisation Compliance Code of Practice dated March 2010 issued by the Department for Business Innovation & Skills

A few examples of export control clauses follow.

Example US clause 1: If the U.S. Export Administration Act (or any equivalent law) applies to the Confidential Information, the Recipient shall not disclose it nor export products produced with the benefit of the Confidential Information to or in any country to which restrictions are applied from time to time by the Office of Export Licensing of the U.S. Department of Commerce (or any equivalent body).

Example US clause 2: Each Party acknowledges its obligation to control access to and/or exportation of technical data under the applicable export laws and regulations of the United States, and each Party agrees to adhere to and comply, to the best of its knowledge, with such laws and regulations with respect to any technical data received under this Agreement

Example US clause 3: Notwithstanding any other restrictions in this Licence, Licensee will comply with all applicable laws, rules, and regulations governing the export, import, or re-import of the Source Code or any products or work deriving from the Source Code ("Export Controls") and will obtain all necessary licenses, permits or similar. Licensee will, if reasonably requested by Licensor, provide all necessary or appropriate assistance and information to Licensor at all relevant times to enable Licensor to comply with its Export Controls obligations.

Example UK clause 1: The Parties acknowledge that the export of [Goods and Technology] under this Agreement may be subject to the export control regulations ("Export Controls") of the United Kingdom and other countries.. As a condition of acceptance of this quotation/contract and issuance of any subsequent order or contract, the [Company] [Parties] agree not to knowingly export, re-export or transfer the [Goods and Technology] without first obtaining all applicable authorisations or licences. In the event that any requisite government licence or other authorisation cannot be obtained in fulfilment of any subsequent order or contract, [ ] shall not be liable to [Company] in respect of any bond or guarantee or for any loss, damage or other resultant financial penalty [or loss].

Other legal issues

Please refer to Appendix D for a discussion of certain legal issues affecting the wording of the MTA, including the need to avoid having the supply of materials treated as a "sale of goods".

APPENDIX D
Special legal issues in MTAs

Detailed legal issues in the drafting of MTAs

Date of the agreement

This is the date when the MTA is executed (i.e. signed). For logistical reasons, the parties often sign on different dates. The 'legal' date will be the date when the last party signs and this should be the date entered onto any MTA database (and at the head of the agreement if there is a space allocated for this purpose).

Provision in Standard Agreement: The standard agreement has the signature blocks at the bottom of the front page, with a date to be entered for each signatory.

Drafting issue: Occasionally one of the parties may suggest backdating the MTA or that it only comes into effect on a certain (future) date. The former situation may occur where the Materials have already been supplied by an academic (maybe several months previously)! In neither case should an attempt be made to 'misdate' the MTA by entering the wrong date in the signature block – e.g. attempting to backdate by actually signing on 29 August but entering the date as 1 June. The correct way to do this is to agree an "Effective/Commencement Date" and draft accordingly. See general legal commentary on dating agreements, above.

Parties to the MTA

The main point to emphasise is to include the full, legal title and appropriate address of the "other" party. The legal title includes any abbreviations such as 'limited' or 'plc'. Note that in the case of universities or research institutions the appropriate "main" body should be named as the party – i.e. the university/institution itself and **not** a particular department or faculty. For further information, see the commentary under the heading "Parties to the MTA" in Appendix B.

Drafting point

Should the Recipient Scientist be a party to the MTA?

Where a research institution enters into an agreement, the individual academic(s) are sometimes expected to sign as well. This is quite often experienced with MTAs. The academic could be signing in one of two capacities:

- As a party to the agreement, and therefore legally liable if he breaches his obligations under the agreement; or
- (Merely) by way of acknowledgement that the institution is entering into the agreement and that he is aware of the obligations set out in the agreement.

Sometimes it is not easy to establish whether a particular institution has a set policy on this issue. Some organisations may organise their 'MTA-Out' template so that a recipient scientist is a party to the agreement whereas when dealing with in-coming MTAs they try and ensure that their own academic only signs on a "read and understood" basis. Always check the definition of the "Recipient" included in the MTA to see whether this covers just the Institution or also includes the recipient scientist.

When reviewing an incoming MTA prepared by the Provider, it may be necessary to check each clause of the MTA to see whether it states that the scientist has obligations under the clause (this may depend partly on any definition of Recipient – does it include the academic?). Depending on your Institution's policy, some obligations on the academic may be acceptable (e.g. confidentiality; requirement to acknowledge the Provider scientist/quote a specific citation in any publication, etc.) but always check that the academic is aware of these and is willing to comply with them.

Usually, clauses where the academic has personal liabilities or gives warranties should be avoided other than in exceptional circumstances (e.g. where the academic warrants that s/he is aware of regulations for handling human tissue). In such cases it is good practice to ensure that your departmental SOPs have been followed, and there is a record that (i) the issues have been explained to the academic and (ii) the academic has acknowledged their obligations.

Warranties

As mentioned previously, an MTA may sometimes have elements of a development agreement, a licence and/or an option. Although English law is normally reluctant to imply terms into contracts unless this is necessary, (e.g. see section on warranties in the general legal discussion, above), it may be prudent for a Provider to specifically exclude any warranties concerning the materials, as in the following example:

Standard Agreement: The Materials are experimental in nature and the Provider makes no representation and gives no warranty or undertaking, in relation to them. As examples, but without limiting the foregoing, the Provider gives no warranty: (i) that it owns all necessary property and other rights in the Materials and that their use will not infringe any patent, copyright, trade mark or other right owned by any third party; or (ii) that the Materials are of

merchantable quality or fit for any particular purpose, have been developed with reasonable care and skill or tested, for the presence of pathogens or otherwise, or are viable, safe or non-toxic.

Limiting liability

It is unusual to see a limit set on liabilities in an MTA. This is in contrast to a research agreement where a non-profit institution may seek to limit its direct losses to a set sum, e.g. the contract price (or a specific multiple of that price) or a particular amount (e.g. £250,000).

Very occasionally an MTA may contain a provision whereby the Recipient is asked to warrant that it has adequate insurance cover in place and that it will maintain the cover. An example is given below. Obviously, from a Provider's perspective it is useful to have such a warranty. A Recipient will prefer to remove it as it is usually prudent to warrant as little as possible! Certainly it is easy to see that provisions (ii) and (iii) could well be resisted – in which case it is arguable that there is little point in retaining provision (i).

Example wording 1: The Recipient hereby warrants to the Provider that it has (i) at the date hereof, effected adequate insurance to cover its liability to the Provider under clause above, (ii) shall at all times maintain such insurance on such terms as the Provider may reasonably require, and (iii) shall produce to the Provider when requested to do so proof that any such insurance is in force.

Law and jurisdiction

It is always advisable to include a law and jurisdiction clause in any contract that has an international element. If the MTA is between English parties and the obligations arise only in England then, strictly, the clause will be unnecessary under normal circumstances. However, it is probably easier to include one in any standard template for MTAs as inevitably materials will be transferred to academics overseas at some stage and the clause will (or should!) serve as an *aide memoire*. See further the general legal commentary on law and jurisdiction, above.

Standard Agreement: English law shall apply to this Agreement, and the English courts shall have [non]-exclusive jurisdiction.

Insurance and foreign jurisdiction

As with any other contracts, liabilities arising under MTAs between EC institutions (or the European Economic Area (EEA) countries) are usually covered by the institution's insurance policy. (The EEA covers Iceland, Liechtenstein and Norway in addition to EC member states). Where the other party is located in the USA or somewhere more unusual, a check should be made with the institution's insurers to determine whether the particular MTA would be covered before agreeing to the other party's jurisdiction/law in the event of a dispute/problem. If the country is not covered, various options may be considered. For example:

a check with the academic if the Materials are available elsewhere

b does your institution have a policy where the MTA may not go ahead in the event the other party won't agree to your jurisdiction?

c agree to remain silent on the subject of law/jurisdiction

d accept the foreign law/jurisdiction

For further information, see the commentary included in the Practical Guide on General Legal Issues on this topic.

Other legal issues in MTAs

The following paragraphs mention some legal issues that sometimes affect the drafting of MTAs.

Is the supply of materials a "sale of goods"?

Sometimes, a Provider will wish to make clear that the Materials are not being "sold" as this would result in the Provider having certain implied contractual obligations under the (UK) Sale of Goods Act 1979 or other laws. One way that this is done, is to state that property in the Materials remains with the Provider. Sometimes, MTAs are more explicit and state that the Materials are not being sold. At the same time, the Provider may wish to include wording stating that its expenses of providing (or generating) the Materials are to be borne by the Recipient, as in the following examples:

Example wording 1: Provider hereby grants to Recipient a non-exclusive license to use the Materials solely for research, non-commercial purposes under the terms of this Agreement. This Agreement does not result in title to the Materials being transferred to the Recipient. Title to the Materials shall remain with the Provider and transfer of said Materials is to be considered a bailment for the purposes of this license and not a conditional or unconditional sale.

Example wording 2: In consideration of the right to use the Material, Recipient agrees to pay the Provider a total of [£ *insert*] for offsetting expenses incurred in connection with the generation of the Materials for the Recipient.

Reference to "Title to the Materials" is essentially referring to ownership – which usually happens in a sale situation. Note that the above clause also refers to no sale having taken place.

Should the recipient pay for the materials?

Whether or not the Recipient should pay for the Materials (in addition to reimbursing the Provider its expenses of providing or generating the Materials) largely depends on what the commercial deal is between the parties. In the author's experience, however, it would be unusual for the Recipient to pay the Provider for the Materials as

part of an MTA-type arrangement. The template MTAs included in this Practical Guide have been drafted on this assumption – i.e. that no money would change hands between the Recipient and the Provider as part of the deal, except perhaps for the reimbursement of expenses as mentioned above.

If the reader intends to use any of the template MTAs included in this Practical Guide as a starting point for his/her preparation of an agreement, and payment for the Materials is one aspect of the reader's commercial deal, then the template in question could be adapted for this purpose. However, the reader needs to think through the terms of the template very carefully and be aware that the terms are likely to require significant revision. This is because the templates have been drafted as non-commercial agreements and the terms reflect this – e.g. in particular in relation to warranties and limitation of liability, etc.

As discussed in more detail in the Legal Issues Practical Guide, under English law, each party to a contract under hand (i.e. a contract not executed as a deed) must provide some "consideration" in order for the contract to be binding. In view of this the author sometimes gets asked how this requirement is satisfied by an MTA if no money changes hands between the parties. The answer to this is that, under English law, "consideration" needs to be something of value, but consideration does not need to be money and the consideration provided by one party does not necessarily have to be of comparable value to the consideration provided by the other party. In the case of an MTA, therefore, the consideration provided by the Provider could be the provision of the Materials and the consideration provided by the Recipient could be the various promises it makes in the MTA (e.g. to restrict its use of the Materials to the Research Programme, to indemnify the Provider, etc.).

However, if the reader is concerned that the requirement for consideration may not be satisfied in the particular circumstances of the commercial deal he/she is facing, one solution may be to execute the MTA as a deed, as the requirement for consideration does not apply to contracts that are executed as deeds. For further information, the reader should consult the Legal Issues Practical Guide.

Bailment

Occasionally, MTAs include specific references to bailment, as in the first example of MTA wording included under the heading "Is the supply of Materials a sale of goods", above.

Bailment is an old area of law that concerns the duties that a person has to look after another person's property, and associated rights and obligations. This area of law is relevant, for example, to the obligations of a hotel to keep its guests' property safe, the obligations of a dry-cleaner not to destroy your clothes, or your obligations to a car hire company, if you hire a car. Such obligations may arise in the absence of any contract between the parties, although it is more usual to find the obligations set out in a contract.

There is not, as far as the authors are aware, any English case law applying the law of bailment to transfers of biological or chemical material. However, various legal commentators have suggested that the law of bailment is applicable to material transfers.

Bailment arises where one person (the bailee) is voluntarily in possession of goods belonging to another person (the bailor). The relationship between the bailor and bailee is different from a contractual relationship and may give both the bailor and bailee rights against third parties. The element common to all types of bailment is the imposition of an obligation. This arises when the bailee takes goods into his possession and thereby assumes responsibility for their safe-keeping.

Principal duties of the bailee

The following paragraphs summarise the main duties of a bailee, and consider how these duties might apply in the circumstances of a material transfer. In the absence of case law on these matters, the following comments are to some extent speculative.

Take care of the materials

This includes protecting the materials from third parties. Legal opinion is that this duty may go further than under the general law of negligence. There is also the statutory duty on the Provider (deriving from the Supply of Goods and Services Act 1982) to carry out the service with reasonable care. (This is the reason why a Provider will seek to disclaim warranties).

Exercise skills

If the bailee states or makes known (known legally as 'holding himself out') that he possesses particular skills he will be liable if he fails to exercise those skills. On the other hand, where a bailor knows that a bailee is inexperienced then a lower standard of care may be expected.

BigPharma are often fond of including clauses at the start of an MTA such as "the Recipient is skilled in… [in vitro / in vivo techniques]." Recipients may wish to consider removing such clauses where possible.

Duty not to convert

This effectively means that the bailee should not appropriate the materials for himself – or sell them on! Conversion effectively means depriving someone of their property by:

- wrongly taking it
- wrongly detaining it
- wrongly disposing of it.

Duty not to deviate

'Deviation' from the bailment is considered a serious breach for which the bailor has an immediate right for the materials to be returned. Deviation includes all failures to comply with the conditions imposed by the bailor which would include:

- keeping the materials for longer than agreed
- keeping the materials in a different laboratory/site
- providing the materials to third party's without the bailor's express permission.

Duty to redeliver

The bailee should generally redeliver the goods – either to the bailor or as instructed by the bailor. However, unless otherwise agreed, the bailee only has to make the materials available (at his own premises) for collection. Thus, it is far better (and in the interests of both parties) to clearly state in the MTA what the arrangements will be when the MTA terminates.

Where materials are provided in circumstances in which there are no intellectual property rights protecting them and they can't be protected as confidential information, then (in the absence of a contractual arrangement / signed MTA), the law of bailment may be the only way the Provider can protect the materials and prevent their use by third parties.

APPENDIX E

MTAs in practice (survey results)

MTA drafted by your organisation:

1. Do you have a standard MTA?

All the institutions that responded said yes. One organisation has 4 different templates and another has 2.

2. Is it only for outgoing material?

Everyone said yes!

3. Are you ever able to use it for incoming materials – if so, when?

The consensus was rarely. However, most institutions said that they would do so occasionally if the supplier was an academic organisation or start-up that did not have its own standard MTA.

4. Are any of the provisions negotiable?

Yes – but generally the language not the principles. One university commented that they felt their MTA was fair (based on the UBMTA MTA), so in general the provisions were not negotiable although they would listen to sensible issues raised by the other party.

5. Which provisions are negotiable?

The answers to this varied – including:

- governing law
- ownership of results/ability to use results
- definition of materials
- definition of progeny/derivatives (depending on work planned)

6. Which ones do you never negotiate over?

Again, the answers varied. There was a suggestion of none! However, the majority of replies indicated:

- ownership of the Materials
- non-commercial use
- freedom to publish
- Materials provided "as is"
- Liability and its limitation
- Grant of a licence back to the IP generated by the Recipient

7. Which ones are you reluctant to negotiate over?

Again, the replies varied but the most frequent answers were:

- liability / indemnity from Recipient for claims arising from the research
- publication
- law and jurisdiction
- obligation on Recipient to share commercialisation revenue

8. Do you have different versions for different types of materials (e.g. a different version for more valuable or sensitive materials such as human tissue)?

The majority of respondents said no, with one comment that this was under review. One institution said they had separate versions for each of human tissues, animal models and hybridoma cell lines. Another distinguished their versions for biologicals vs computer software. Human tissue was also dealt with by inserting further provisions into the standard MTA.

9. Are there provisions in your standard MTA which routinely are found to be unacceptable to the other party?

The responses were split with approximately 60% saying no. However, some of the respondents who said no qualified their answer by saying that they had not used the MTA enough to form an opinion.

Of those who said yes, the most frequent problem was encountered with US academic institutions especially:

- law & jurisdiction
- liability/indemnity.

Other comments were that intellectual property was frequently discussed. Where an MTA asks the Recipient to obtain the Provider's consent prior to patenting/commercialising IP arising from the use of Materials, this was often unacceptable to Recipients.

10. Do particular types of organisations more often than not have objections to your precedent or particular issues or clauses in the precedent?

Comments were that large companies preferred to use their own standard MTA and it seemed to be that US institutions had objections most frequently. It was observed that in the latter case many of the objections resulted from restrictions imposed by NIH funding. Pharmaceutical companies and US biotech companies were also mentioned.

11. Is it persons at a particular level who raise the (most) objections?

Responses indicated that it was rare that the scientists involved raised any objections although there was one comment that it depended on the issues. Most objections were from lawyers and contracts staff.

12. When an MTA is proposed do you have a standard form or other document which is completed to set out the main points in relation to the transaction?

The majority of respondents did not have a standard form although one commented that they would like one! In general, the required information was obtained from the relevant academic by e-mail and telephone. Other institutions used a form (but only for in-coming MTAs); made use of a general contract review form; had the relevant form on their website.

13. What details does this form contain?

- contact details of the other party
- legal status of other party
- description of the Materials / Research*
- use of Materials (commercial/non-commercial)*
- details of the academic

* these were flagged as important.

Other points raised regarding the Materials themselves were to consider export controls and requesting a copy of a [template] patient consent form if the Materials derive from humans.

14. Signature of the academic's head of department; agreeing that the Materials can be provided/accepted?

A third of the responses said no. Positive replies included "important" and some suggested that a senior administrator within the appropriate department could sign. Others indicated that the recipient academic would also sign to say that they will abide by the terms of the in-coming MTA.

15. Who completes this form initially – the academic, you or a designated person in your department (whose role is to deal with MTAs)?

Responses were split between the academic and the contracts department.

16. Do you have a standard operating procedure (SOP) for the negotiation & signing of MTAs?

Responses were split approximately 50:50. Some "no" answers were qualified by stating that although there is no written SOP, a standard/agreed process is in place. Others indicated that they have a "sign-off" form that must be completed before the MTA is formally signed.

Whether your organisation has or does not have a SOP, what is the position concerning the following:

17. Who in your organisation negotiates and signs off on MTAs (job title)?

It was rare that the same person negotiated and signed off MTAs. In general it was a business development manager/contracts executive/technology transfer executive that negotiated the MTA (calling on a senior manager or lawyer for support, as required).

Sign-off was generally by a senior business manager/ head (or Director) of the contracts department. Some organisations mentioned that the official signatory had been formally delegated with authority to sign. [At the other extreme, one organisation responded that Heads of Schools (who are part of the University's management team) sign off on MTAs (but often without consulting central authority).]

18. Why were they chosen for this role? (e.g. because most senior person/ most appropriate person; this role has always done this).

The most frequent response was "most appropriate person". Comments relating to signatory reflected seniority/ appropriateness and/or experience of dealing with legal issues.

Comments relating to negotiations suggested that contracts executives were the most appropriate for the negotiations due to their familiarity with the academics and their areas of work. In addition, many contracts executives had higher degrees in life sciences and it was the nature of the job to be familiar with issues surrounding IP. In some cases both junior and senior contracts executives worked on MTAs. A couple of institutions said that MTA/CDA negotiation was established as a separate role (junior to technology transfer) and that post holders were chosen for their legal background.

19. Is the authority to agree to particular types of clauses or issues reserved to a particular person (e.g. a (senior) manager)?

There was a range of responses from no to yes; senior managers (plus or minus legal input). Other responses included comments that no formal policy was in place although clauses which extended the institution's liability outside the insurance policy were referred to senior managers for approval. Other comments were that there would be consultation with senior managers or head of contracts department, but subject to the wish of the relevant academic.

20. What clauses or issues are these?

There was general agreement that these were:

- law and jurisdiction (especially where Provider is in the USA or Canada) or where the other institution suggests silence.
- IP rights (including free licences to arising IP)
- Extended delays to publication
- Liabilities
- Use in humans / human materials.

Other comments were that any contentious issues were referred; the contracts executive will not sign if the academic is not in agreement (and can refuse to sign if the terms are unacceptable).

21. Do they take the decision themselves or do they discuss with others?

In some institutions the decisions were taken individually but the majority of responses indicated that there was usually discussion with senior colleagues or Director/Head. Others (such as lawyers; academic's head of department/ faculty) were involved where appropriate.

22. Are there particular types of MTAs where although there are unacceptable terms you do not resist them because you believe the risks are low for your organisation in accepting them?

Most responses indicated yes but on a case-by-case basis. In general, respondents felt more comfortable doing this if it was another academic MTA. Other comments indicated they would do so in cases where the academic particularly requires the materials. Sometimes where an MTA originated from a pharmaceutical company and the academic was particularly insistent that (i) they needed the material and (ii) no IP was likely to arise, then an otherwise unacceptable MTA would be signed (provided that there was no conflict with funders).

23. When would you involve a lawyer (internal/external) in the negotiation or drafting process concerning an MTA?

External lawyers were rarely used. However, in some institutions lawyers were involved in the negotiations or consultation with contracts executives. In one institution, the Head of IP and a senior IP manager are both lawyers. In-house lawyers were consulted most frequently regarding:

- warranties/liability clauses
- terms outside SOP's
- complex IP provisions / significant deviation from template
- significant risk (financial / reputation)
- high commercial value (Materials or arising IP).

24. Are there particular issues in relation to which you always involve a lawyer? Do the same issues keep re-occurring? What are they?

Just under half of the respondents indicated that there were no particular issues where they would involve a lawyer. Where the same issues re-occurred it was generally warranties and liabilities that were referred for legal advice. Other comments included:

- legal sign-off is required if an MTA is outside of the SOPs
- regularly consult lawyers re governing law (although we often ignore them and go silent on law).

25. When would you involve your organisation's insurers?

The responses were extremely varied. Some institutions replied 'almost never' or 'never to my knowledge'. Other respondents involved insurers only if the incoming MTA required an insurance warranty or if the warranties/liabilities clauses varied (in comparison to the institution's own standard MTA). Other responses included:

- if the Provider insists on any North American law
- check if there are terms relating to medical practitioners
- sent to in-house insurance manager routinely & uninsured risks are never agreed to.*

* Note – in this case the respondent referred to contracts generally.

26. Are there particular issues or areas that you commonly refer to the insurers?

The majority of respondents said no. Where the response was yes it was for situations where acceptance of the MTA's terms might place the institution at risk for which it is either uninsured or has minimal cover.

27. Are there issues where you always involve/ask your organisation's insurers (such as questions re governing law)?

In general, it was the legal team that dealt with issues of governing law. Other comments included:

- insurers have said that N. American law is specifically excluded from liability insurance
- university is not insured for US contracts – but tend to skirt this by being silent on law
- insurers consulted for non-English law and where genetic modification/clinical trials/restricted substances are involved
- N American law combined with a Provider which isn't regarded as low risk (e.g. a company).

28. If your organisation never involves its insurers, should they and why?

There were fewer responses to this question. Some respondents said that the in-house legal team dealt with most issues where some organisations might normally involve their insurers. Others indicated only where specific problems could be foreseen or if a risk was considered significant.

29. How far do you involve the academic in the negotiation process?

The answers to this question varied considerably from 'as little as possible' to 'as much as possible'! Others suggested 'according to their request'.

However, there was a general consensus that:

- it was rare to use the academic in the actual negotiations
- the academic would not be authorised to agree anything
- it was very important to consult with the academic to understand the background to the agreement/interests on both sides/research priorities/importance of Materials

Other issues raised were:

- check the academic understands and agrees to abide by the terms of the MTA
- the academic is often responsible for managing a long term relationship with a company and it is thus appropriate to involve them in discussions as much as possible (although they would not be present for negotiation of the actual terms)
- the contracts executive would involve the academic if acceptance of the MTA affected academic rights (e.g. publication rights; right for a PhD student to submit a thesis based on results; ability to use results in future research
- the academic would also be involved where the Provider claims rights in any 'downstream' results from the use of Materials

30. (a) Are academics or other departments or sections other than yours allowed to negotiate or sign off on MTAs? (b) When does this happen? (c) Why?

(a) Two thirds of respondents said no. Several commented that academics often sign (without authorisation).

(b) When it does happen: when the agreement is in the academic's name; a trial underway to allow some Heads of Department to sign specific (pre-agreed) MTAs that the contracts department has approved (eg AUTM MTA). Other comments regarding when this happens included: 'never'; 'often'; 'probably frequently'; 'ignorance of knowing they shouldn't or deliberately'.

(c) Why: academics receiving documents direct from companies (and not realising the significance of the documents); some academics not aware of central support function – or (if they are) a perception of delays in the contracts department; different employment status of charity funded researchers employed by universities.

31. How do you handle any objections or comments of the academic?

Most responses indicated by discussion / explanation. The contracts executives try and take account of the academic's comments and assess on a case-by-case basis, considering the importance of the materials and their general availability. Other common themes include a gradual process of education – trying to persuade the academics that any changes to MTAs are for the benefit of the academic community as a whole and that the contracts department is unwilling to set precedents regarding unacceptable terms. Attempts are also made to explain the risks that may be taken through "cutting corners".

Other comments included that frequently the academics are willing to sign up to anything to get the material – it is the contracts executive's role to ensure that the terms don't conflict with other agreements and that the university can abide by them. Some responses indicated that ultimately the wishes of the academics were deferred to.

32. To what extent when negotiating an MTA do you check that your organisation is not breaching other contracts/licenses or conditions of grant?

The responses were quite variable. Some institutions commented that checks were minimal or that they did not check as much as they should. Others responded that due diligence searches were done if there were warranties or an exclusive licence was granted under the MTA. Some responses indicated that general checks were done or that they always checked the background funding to ensure that there were no conflicts, and that other contracts relating to the particular academic would be checked.

Several respondents indicated that they relied mainly on the academic to provide the information. One indicated that it was a standard question where materials are 'out-going' – but did not indicate if this happened for 'in-coming' materials.

33. How do you do this (e.g. is there a central or local database (manual or electronic))?

Again, the answers varied – ranging from searching through paper files on a particular academic and their projects to using electronic databases. Some institutions relied on the academic supplying the information - either verbally, by email or responding to a questionnaire (if used). Some institutions also mentioned relying (to a greater/lesser extent) on the knowledge base of the contracts executive's dealing with particular academics over a period of time.

34. Who does this (e.g. there is standard procedure whereby a certain person is always asked to check this out before an MTA can go forward for approval)?

The responses varied, the most common being:

- a dedicated person
- a manager (senior to the person negotiating the MTA)

- the contracts executive negotiating the MTA
- no standard procedure. MTAs commonly referred to contracts executive most familiar with the particular academic's research.

35. (a) Is a log/database of all MTAs entered into kept? (b) If so who keeps it? (c) If not – why not?

a The majority (84%) of respondents said yes. Some replies were qualified by time limitations (eg only for the last 3 or 4 years).

b Tended to be organised by an administrator / coordinator but available to all staff in the contracts department.

c Where databases were not kept, respondents indicated that they relied on departmental records or it was not felt to be important by their organisation.

36. When is it used? (e.g. when spin-out transactions are being arranged as part of a due diligence process).

Responses varied, including:

- when commercialising IP
- due diligence and information gathering
- due diligence (spin-outs)
- when filing a new patent – check to see if external materials were used (due diligence)
- recording all the agreements the organisation has entered into
- when there are other MTAs relating to the same material
- to check activity of a particular academic for IP issues
- checking for precedents / suitable language
- when dealing with an MTA from the same organisation

Precedents provided by the other party (in-coming MTAs)

1. Do you have a standard precedent / template for in-coming materials

Most respondents (92%) said no. One institution said they would offer the UBMTA as a 'neutral' template.

2. Are you ever able to use it?

The institutions responding yes to the above question said 'occasionally'. The institution that would offer the UBMTA replied 'yes'.

3. If you are able to, in what circumstances can you do so?

Where the other party either does not have a standard MTA or it is inappropriate.

4. What are routinely the most unacceptable clauses most often found in agreements proposed by the other party?

The most common were:

- Arising IP – automatic free licences or ownership
- Arising IP – broad definition
- Agreeing who has rights to modifications of the Materials
- Law & Jurisdiction (especially US)
- Publication – delays/restrictions
- Liability
- Reporting requirements

5. Do particular types of organisations routinely propose unacceptable clauses? (eg commercial, pharmaceutical, research organisations).

Nearly all replies said commercial (especially pharmaceutical/biotech companies). Other comments included that these organisations nearly always expect automatic free licences / ownership of arising IP.

6. What do you do with such clauses as a first action?

In general, respondents did not reject clauses outright. Most respondents tried to work with what had been sent – modifying the other party's version or (less frequently) proposing their own wording for a particular contentious cause and emailing their response with the suggested alternative.

One respondent indicated that they discussed the proposed response with their academic (and gained approval) before contacting the other side with the proposed change.

7. If there is a deadlock over a particular issue or clause (or even a whole agreement) would you propose an alternative agreement (such as for the USA, the UBMTA)?

Some respondents had done so. Others commented that they would do so for other academic institutions but there was little point with companies as usually the UBMTA is not acceptable to them. If there was deadlock then an institution may take a view on whether to accept the risk or reject the MTA.

Another comment was that it would depend on the source and importance of the material. [One respondent was unaware of the UBMTA].

8. Are there particular types of MTAs where even though there are unacceptable provisions you do not resist them because you believe the risks are low for your organisation in accepting them?

The answers varied from no to yes – and 'it depends'! Where it depended – this would be on the terms proposed, taking into consideration what the material was and how it would be used. One organisation responded that they had not done enough MTAs to answer.

Where the materials are incoming?

The answers were mainly yes – with additional comments such that if the value of the materials was high (financial or academic), and/or the material was unavailable elsewhere then the institution would aim to be as flexible as possible re accommodating the academic's wishes.

The materials are harmless?

Most respondents said no.

The value of the materials is low?

Most respondents said no – if the value is low the preferred option would be not to proceed with the particular MTA but seek an alternative source.

The materials can only be used for non-commercial research purposes?

Most respondents said no.

The other party is a non-commercial research organisation (such as a university)?

Most respondents said yes. Additional comments were that an attempt would still be made first to try and change the unacceptable provision(s).

Other?

Comments included:

- particular MTAs where past experience has shown that the MTA is impossible to change
- where the academic is insistent
- sometimes accept 'unacceptable' IP terms if considered low risk in the context of the study

9. What risk/benefit analysis do you carry out in accepting MTAs which have unacceptable provisions?

The replies varied from none to no formal procedure but dealt with on a case by case basis, and the effects of the clauses on the researcher and their continued work in the area. Most respondents mentioned informal discussion (with academic and/or institution's authorised signatory). Generally dealt with on a case by case basis taking into account the academic justification for the materials.

10. Do you have set criteria (like those listed at number 8 above)?

All the respondents said no, with comments that it was usually done on a case by case basis.

11. Do you undertake a financial analysis of the benefits /dis-benefits/ financial consequences for your organisation?

All the respondents said no. One commented how does one measure the risk of a very unhappy academic?!

12. When negotiating an MTA do you sometimes / often find particular problems with representatives of the other party?

a) That the representative of the other side is a junior member of staff who cannot negotiate on or deal with any of your concerns relating to, particular causes or issues. Or they have a take it or leave it attitude or refuse to refer the issue or concern to a more senior representative?

Most of the respondents said yes – they had encountered all of the above problems. Other comments included:

- big companies often have a take it or leave it attitude
- junior staff don't have the authority to amend and are reluctant to refer on because company is unwilling to invest resources in negotiating MTAs
- MTAs (and CDAs) often seen as low priority for a company
- sometimes initial negotiations are with an academic – difficult to find the correct 'contracts' person

b) The length of time that it takes to resolve issues or concerns, i.e. that the issue or concern has to be referred on, e.g. to the legal department, sometimes in other countries.

Most respondents agreed that timeliness was a real problem. Again, companies were mentioned as a particular problem, especially ones using external lawyers where comments were passed back and forth. Other problems identified included:

- apparent lack of interest of the other party in amending their standard
- agreeing to change and then changing their mind maybe because someone more senior refuses
- initially saying they would respond with comments but then taking a lot of chasing before they do so

One respondent commented that timeliness was a particular issue as perceived delays can mean that a company is reluctant to consider the university for a research project if an MTA takes too long to negotiate.

One respondent was concerned that they were themselves 'slow' due to the heavy workload….

PraxisUnico.
Impact through innovation

Jeffreys Building
St John's Innovation Park
Cowley Road
Cambridge
CB4 0DS

T 01223 659950
E info@praxisunico.org.uk
www.praxisunico.org.uk