KTI
Knowledge Transfer Ireland
Where Research & Business Connect

# KTI Practical Guide

# Material Transfer Agreements

# Foreword

The KTI Practical Guides have been produced as a resource for those approaching transactions between Irish research performing organisations (RPOs)[1] and commercial companies. Each Practical Guide explains common terms in the agreements and describes the considerations that might apply.

The KTI Model Agreements contained in each Practical Guide take account of the legal constraints upon RPOs when entering into contracts, as well as the unique nature of RPOs, whose primary purpose is not-for-profit rather than commercial. At the same time, the terms of the agreements seek to address the typical commercial priorities of companies, e.g. to have access to intellectual property rights. The Guides are based on European best practice.

The Practical Guides are offered as a starting point for drafting and discussion, as required. Neither companies nor RPOs are mandated to use the Model Agreements.

The KTI Practical Guides and Model Agreements are available on the KTI website to download and use directly. www.knowledgetransferireland.com

### Disclaimer

*Parties should take their own legal advice on the suitability of any model agreement for their individual circumstances and on associated legal and commercial issues. None of Knowledge Transfer Ireland, Enterprise Ireland nor any of the individuals or organisations who have produced or commented on these documents assumes any legal responsibility or liability to any user of any of these model agreements or commentaries.*

The KTI Practical Guides and Model Agreements were prepared by Anderson Law LLP (Oxford, UK; www.andlaw.eu) with advice on certain Irish law issues from LK Shields Solicitors (Dublin, Ireland; www.lkshields.ie).

[1] RPOs are considered to be Higher Education Institutes (Universities and Institutes of Technology) or State research organisations

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# Introduction to Material Transfer Agreements

### 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 of the materials (the "Provider") is usually the organisation owning the materials but may sometimes be an authorised licensee.

In a large organisation, 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:

- to carry out research with them (either on its own account or on behalf of the Provider); or
- to create intellectual property with them or from them; or
- to evaluate them to determine whether to enter into further agreements (such as further research or licensing arrangements); or
- 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 RPO, as well as affecting the contract terms that may be thought acceptable – the RPO 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?

The reason for having a written MTA in place may be simple, namely the Provider will not supply the materials unless the parties first enter into a written MTA on terms that are acceptable to it. However, there are also a variety of other reasons why a written MTA might be considered essential when materials are to be supplied from one organisation to another. For example, the Provider may require a legally-binding contract to be put in place to ensure that the Provider has some or all of the following rights:

- *Permitted use of materials:* to control or limit the use that the Recipient makes 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 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 an 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 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 RPOs).

In addition the Provider may wish to include in the MTA some other provisions of a more 'legal' nature. For example, and 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.
- *Exclusion of liability:* to exclude legal obligations generally (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), and to ensure that the Recipient uses the materials at its own risk.
- *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. 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' – i.e. standard contract terms for the delivery of goods, issued by the International Chamber of Commerce).

In addition, the Recipient may also be keen to ensure that appropriate written terms are put in place with the Provider, e.g. to ensure that the Recipient retains the right to publish the results of its research with the materials and also to ensure that the terms of the supply of the materials are compatible with any funding terms and conditions that may be in place for the research in which the materials will be used.

In summary, therefore, 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:

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

Different areas of law may need to be considered when preparing an MTA, such as:

- *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);
- the *law relating to the use of property owned by another person*, e.g. under a contract of hire or loan; and/or
- liability in *tort*, e.g. for injury, loss or damage caused by negligent supply or use of materials.

Some of the complexities of the contract terms of MTAs 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 between companies and RPOs sometimes seen as problematic?

Many companies and RPOs 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 this may be the case:

*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 (although perhaps not directly relevant to the heading of "MTAs between companies and RPOs", an example of when this argument is sometimes encountered is when the arrangements involve 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; and/or
    - 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. 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; 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 (e.g. grant terms and conditions); and/or
- the need to involve senior colleagues or other departments/specializations (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 administrator or academic. Sometimes these are forwarded to the Technology Transfer Office (TTO) 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. It is therefore important that MTAs are handled through the TTO.

*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 researcher 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 RPO. Therefore, it is necessary for the terms of the MTA to be reviewed by the TTO and to keep in mind that the primary purpose of the MTA may not be financial.

*Academic perceptions/requirements*
Academic researchers are inevitably concerned about delays and the negative impact on their research that any delays may cause. Companies may also be frustrated. 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. This is to be avoided as:

- Such MTAs will not have been scrutinised by someone familiar with acceptable provisions. Valuable intellectual property may well be lost to the academic's RPO. This is particularly true if the MTA 'reaches through' into any of the research that the academic will undertake.
- Even if a person signing the MTA is not an authorised signatory of the RPO, under the laws of agency s/he may have 'ostensible authority' to sign an MTA on the RPO's behalf. If the other party relies on the ostensible authority then the contract will probably be binding on the RPO.

This may have significant implications for the RPO e.g. in respect of liability, pre-existing obligations, IP etc..

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.

### Issues to consider

The following is a list of some issues to consider when reviewing an MTA:

- *Templates.* Use of the appropriate Model MTA will speed up negotiation and allow an MTA to be concluded as swiftly as possible. For materials going out from the RPO, a company is advised to use the Model (outward) MTA to avoid delay.
- *Terms.* 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; and
    - Whether the Provider should give any warranties.
- *Monitoring.* The RPO will implement procedures to monitor MTA obligations, including maintaining a database of MTAs (and other agreements).

### Important points to note about the Model MTAs

The reader faced with drafting a material transfer agreement must always keep in mind that a template can only ever be a starting point. The specific circumstances of the particular arrangement must always be considered and the template tailored as appropriate. For example, a number of fact specific, complex issues may be raised when drafting a material transfer agreement, which by their nature cannot be dealt with in a template. Examples of these issues include the following:

- The Model MTAs have not been drafted to take account of the individual requirements of Irish RPOs which might apply. Readers are advised to seek out and address, by additional provisions, any peculiarities or requirements of a relevant RPO.
- The Model MTAs have not been drafted to be used by or in relation to consumers. Contracts concluded with consumers are obliged to include an additional layer of legal protections, to be written in plain-spoken language, and to contain other features imposed by consumer-specific laws which are beyond the scope of this Practical Guide.
- In addition, the reader should be aware that in some situations the law relating to 'state aid' might need to be considered (e.g. if an industrial party to the material transfer agreement does not pay market value for all of the benefits it receives). This is a complex area and there is no 'one-size-fits-all' way of dealing with it. Accordingly, the reader should seek specialist advice when required.

# Checklist of Preliminary Issues and Provisions Commonly Found in MTAs

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.

| **Preliminary** | |
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| **Parties** | • Should these be the employing organisations of the Recipient and Provider researchers?<br>• Have the correct legal names and addresses been included?<br>• Should the researchers 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. in an RPO, a Technology Transfer Office or in a company, perhaps a legal department?<br>• Do you need to remind the 'other side' regarding their authorised signatory? |
| **Materials** | • Have the materials and their intended use been correctly identified?<br>• Is there a reference to the materials being described in a schedule? Is it attached?<br>• Are there any regulations governing use of the materials (e.g. the regulations governing the use of genetically modified organisms)?<br>• Can the recipient comply?<br>• Does the MTA require a Health & Safety Officer to countersign?<br>• Are the materials of human origin? |
| **Human Tissue** | • Has the material been obtained from a reputable source and with patient consent?<br>• Should you obtain a (blank) copy of the patient consent form used for the collection of the materials for the RPO's records?<br>• Has ethics approval been obtained?<br>• Is it the RPO's policy to file a copy of the ethics approval or ask the researcher for the approval reference number?<br>• Data Protection compliance: will the data and materials be provided in an anonymous/coded form?<br>• Does the MTA specify particular published best practice guidelines to be followed? |
| **Recitals** | • Is it useful/appropriate to cross-refer to a parallel agreement between the Provider and the Recipient (e.g. a confidentiality agreement or a research collaboration agreement for which the materials are supplied)?<br>• If the materials are supplied for use in a collaboration agreement check the terms of the collaboration agreement to ensure there are no conflicts.<br>• By referring to the terms of the collaboration agreement you may be able to edit the MTA significantly.<br>• 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.<br>• 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 two months |

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| | ago?!)<br>• If so, agree an "Effective Date" and draft this into the agreement.<br>• 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?<br>• If there are several materials to be transferred, or where complicated nomenclature is involved, consider listing the materials in a schedule.<br>• Check the materials listed are what the academic expects!<br>• How broad is the definition of materials? In conjunction with the IP clauses, should you attempt to narrow/broaden the definition?<br>• Does the definition of the materials include confidential information/documents? If so check relevant IP, publication and confidentiality clauses. |
| **Meaning of Derivatives** | • Is this an unacceptably broad definition?<br>• If the Provider is to own the IP in all Derivatives consider whether it is appropriate to narrow the definition. |
| **Purpose for which the Materials are provided** | • The purpose may be defined as the Research or the Project.<br>• Does this adequately explain what the researcher intends to do with the materials?<br>• Would it be more appropriate for the research to be described in a Schedule attached to the MTA?<br>• Should the purpose be broader/narrower (taking into account the IP clauses)? |
| **Term** | • Usual time periods tend to be 1-2 years.<br>• Does the MTA specify a time period? Should it?<br>• Are there any obligations (e.g. return of any remaining materials) when the term ends?<br>• Any obligation to seek to renew (e.g. 3 months) prior to expiry?<br>• Are there any confidentiality obligations that extend beyond the term?<br>• Should you include termination provisions? |
| **Meaning of Recipient** | • Is the MTA drafted so that Recipient means the recipient researcher or the recipient institution – or both? Is this appropriate?<br>• Should any changes be made so that the recipient researcher does not give personal warranties?<br>• Should the recipient researcher sign the MTA as having "read and understood" its provisions? |
| **Meaning of Supplier** | • Does this definition specify the correct legal name and official address of the institution providing the materials?<br>• Where Provider Scientist is defined – are there any obligations on the Recipient to cite the Provider Scientist in any publications?<br>• Does the researcher know this? |
| **Common restrictions** | |
| **Security and safety measures by Recipient** | • Does the MTA specify that the materials will be kept secure/in a particular location?<br>• In compliance with certain safety regulations?<br>• Can the researcher comply/have you procedures in place to ensure s/he understands the obligations? |
| **Use only by specified persons** | • Does the researcher know/is this practical?<br>• Will students or other non-staff members (e.g. visiting fellows or emeritus professors) be working with the materials (if so – would the definition of researchers include students or do you need to modify)?<br>• Remember non-staff members would not be included if the wording just refers to employees. |

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| **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'?<br>• Can the materials be used in research funded by an industrial sponsor (provided that the other sponsor isn't granted any rights to the IP)? |
| **No use in projects where third party has an interest** | • If this is explicitly stated, have you checked that the researcher knows this and can/will comply? |
| **Non-use in animals/humans** | • Have you checked with the researcher that the research does not involve these? |
| **Method of transport, handling, delivery** | • Are there any special provisions required for the particular materials?<br>• Is there someone in the RPO 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?<br>• If the latter, then should the materials be supplied under an MTA at all?<br>• Is the responsibility for shipping, packaging and insurance allocated?<br>• 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?<br>• Does the Provider have a right to a pre-publication review? If so, is the researcher aware of this?<br>• 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)?<br>• Does the Provider have a right to delay publications (e.g. to allow time for a patent application to be filed)? If so, are any delays to publication reasonable and do they fall within the RPO's policy/guidelines?<br>• Is there an obligation to acknowledge the Provider in any publication by the Recipient?<br>• 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 the researcher aware of this? |
| **Reporting obligations** | • Does the MTA contain any unusual reporting obligations?<br>• Is there a particular reason for this? Can/should the researcher comply?<br>• Is there any obligation to inform the Provider of data indicating that the materials may be toxic? |
| **Confidentiality Provisions** | • Are there any? Should there be?<br>• Is it more appropriate to have a separate confidentiality agreement (which could be cross-referenced)?<br>• Check what is covered by the definition Confidential Information.<br>• Does Confidential Information include the results of the Research? If so – check publication clauses (see above).<br>• Should there be an obligation on the receiving party to keep invention disclosures confidential?<br>• How long do any confidentiality obligations extend? Is this appropriate?<br>• Are there provisions to reduce oral disclosures to writing or store documents in locked cabinets? Can/should the RPO comply?<br>• Is there an obligation that any new researcher working on the Research signs a confidentiality agreement? How does the RPO 'police' this? |
| **Intellectual Property** | • Who will own the arising IP from the Recipient's use of the materials?<br>• 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 |

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| | from the Recipient's wider research project?<br>• Are there any options or licences back to the Provider in respect of such IP?<br>• 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)?<br>• Are there any provisions regarding Background IP (e.g. does the Provider expect a free licence to Background IP to enable it to exploit arising IP)?<br>• In an MTA with industry – is there a provision for an exclusive licence? Could this prejudice the researcher's future funding position (e.g. if s/he routinely relies on funding from certain charities)?<br>• Are licences granted automatically in the MTA – or is there a provision for future negotiations?<br>• Should there be any provision for revenue sharing terms?<br>• If options have been granted – have you (i) capped the time period for exercise; and (ii) capped the time period for licence negotiations if the option is exercised? Is it clear what happens if the negotiation period expires, but agreement on licence terms has not been reached?<br>• Is there a requirement on the Recipient to notify the Provider if an invention is made?<br>• Who is responsible for patent costs (e.g. during the time periods for an option)?<br>• 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?<br>• Should the Provider warrant that the use of the materials by the Recipient will not infringe third party IP?<br>• Should the Recipient give any warranties, e.g.:<br>o that s/he has had suitable training to handle the material?<br>o that ownership of arising IP will vest in the Provider (i.e. all those working on the Research are employees of the Recipient)? (Take care in relation to students/consultants/visiting fellows, etc.).<br>• Does the warranty cover something which (i) is not really the RPO's responsibility; or (ii) something the other party can/should check for itself (i.e. can you agree to delete it)?!<br>• Should the warranty be limited to matters within particular knowledge? (A 'best of knowledge' warranty will probably be too onerous for an RPO in most circumstances). |
| **Liability and Indemnity** | • Does the Provider exclude all liability incurred by the Recipient in relation to the materials?<br>• Is this appropriate?<br>• If reference is made to "applicable law" – which country's law is applicable?<br>• Are any indemnities being given? If so are they (i) appropriate, and (ii) covered by the RPO's insurance policies?<br>• Where the RPO is giving an indemnity – should it insist on having control of any proceedings brought by a third party (against the other (indemnified) party)?<br>• Should indemnities just be restricted to third party claims? |
| **Law and Jurisdiction** | • Has the law governing the MTA been stated?<br>• Has jurisdiction also been specified (i.e. which party's courts would hear any dispute)? Or has an alternative dispute resolution procedure been specified (e.g. arbitration or mediation).<br>• Is it appropriate to specify exclusive or non-exclusive jurisdiction?<br>• If confidentiality provisions are important consider whether to include a |

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| | right to obtain an injunction in any jurisdiction? |
| **'Boilerplate' provisions** | • Should any other provisions be included? For example, provisions such as:<br>○ Entire Agreement;<br>○ Force Majeure;<br>○ No use of the RPO's name and logo without prior consent; and/or<br>○ Notices (may be useful if option notices should go to Technology Transfer Office rather than address of legal entity). |
| **Schedules** | • Is a schedule appropriate for either a description of the materials or the Research? If so, it is attached and have the contents been agreed/checked with the researcher? |

# Model MTA (OUTWARD: RPO to Academic Researcher) including drafting points

Dated _____20[●]

(1) [Full legal name of the RPO]

and

(2) [Full legal name of Institution]

# MODEL MATERIAL TRANSFER AGREEMENT

(OUTWARD: RPO to Academic Researcher)

# MATERIAL TRANSFER AGREEMENT[i] [ii] [iii] [iv]

**[[RPO name], the Provider of the Material]**

| | | |
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| **1.** | *Insert the RPO's name and address*[v] | _____ (the "**Provider**"), has collected and/or developed the materials known as |
| **2.** | *Insert description of materials*[vi] | _____ and includes 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 (together, the "**Materials**"). |
| **3.** | *Insert name of Researcher, the principal user of the materials* | _____ (the "**Researcher**"), who is an employee of |
| **4.** | *Insert name and address of Researcher's Institution, the recipient of the materials* | _____ (the "**Institution**") |
| | | and the Institution 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*[vii] | _____ (the "**Research Programme**") to be undertaken by the Researcher. |
| **6.** | *Insert quantity*[viii] *of Materials to be supplied and period*[ix] *for which they are to be provided* | The Provider is willing to provide a sample of _____ of the Materials for a period of _____ year(s) (the "**Term**") on the terms and conditions shown overleaf, and the Institution agrees to comply with those terms and conditions. |

**AGREED by the parties through their authorised signatories[x]:**

| **For and on behalf of [Provider]** | **For and on behalf of [Institution]** | **Acknowledged by the Researcher *(who is not a party to this Agreement)*** |
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| _____ 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 Institution shall keep the Materials secure at the Researcher's laboratory and ensure that no-one other than the Researcher and authorised co-workers ("**Co-workers**") has access to them.
2. The Institution shall ensure that the Materials are used only for the Research Programme and not for any commercial purpose or commercially-sponsored research without the prior written consent of the Provider even if those purposes are being pursued in the Researcher's laboratory.
3. 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 prior written agreement of the Provider. Permission to extend the term of this Agreement must be sought by the Institution three (3) months before the expiry of the Term.
5. The Institution shall ensure that the Researcher and the Co-workers acknowledge the Provider as the source of the Materials in any publication which mentions them[xi]. The Institution shall send the Provider 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 Provider 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 Institution) shall be and remain the property of the Provider and shall be immediately returned (or if the Provider so requires, destroyed) (i) on termination of this Agreement, or (ii) if the Institution is in breach of any provision of this Agreement, and (iii) at any other time on request of the Provider.
7. No licence under any Provider intellectual property is granted or implied by this Agreement.
8. In the event that the Institution, the Researcher or the 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, the Institution will promptly bring this to the attention of the Provider[xii]. The Institution shall not, and shall ensure that the Researcher and the Co-workers 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 Provider[xiii]. The Provider will, at all times, retain the right to use all Inventions for non-commercial research purposes[xiv].
9. If any revenues result from any use of the Materials by the Institution, the Researcher or the Co-workers, the Provider shall be entitled to a reasonable share of any such revenues[xv].
10. The Institution shall ensure that the Researcher and the Co-workers 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[xvi].
11. The Materials are supplied without cost but the Institution shall reimburse the Provider for any reasonable shipping and related costs that may be incurred when preparing and sending the Materials to the Researcher.
12. The Materials are experimental in nature and the Provider makes no representation and gives no warranty or undertaking, in relation to them[xvii]. As examples, but without limiting the foregoing, the Provider gives no warranty that (i) 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) 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 Provider shall have no liability to the Researcher, the Co-workers or the Institution, whether in contract, tort, negligence or otherwise, in relation to the supply of the Materials to the Researcher, the Co-workers or the Institution or their use or keeping by the Researcher, the Co-workers, or the Institution or by any other person, or the consequences of their use, to the maximum extent permitted under applicable law. The Institution shall indemnify[xviii] the Provider from and against all Claims and Losses arising from such supply, use or keeping, including 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) "**Claims**" shall mean all demands, claims, proceedings, penalties, fines and liability (whether criminal or civil, in contract, tort, negligence or otherwise); and (ii) "**Losses**" shall mean all losses including without limitation financial losses, damages, legal costs and other expenses of any nature whatsoever.
15. If the Provider seeks indemnification pursuant to Clause 1313, the Provider shall provide prompt written notice to the Institution of the initiation of any action or proceeding that may reasonably lead to a claim for indemnification. Upon receipt of such notice, the Institution shall have the right to assume the defence and settlement of such action or proceeding, provided that it shall not settle any action or proceeding without the Provider's prior written consent. The Provider and the Institution shall co-operate with each other in the defence of such claim.
16. The Institution agrees to be bound by this Agreement in consideration of the Provider making the Materials available to the Researcher.
17. The laws of the Republic of Ireland shall apply to this Agreement, and the courts of the Republic of Ireland shall have [non-]exclusive jurisdiction over any matter relating to it[xix.]

## Drafting Notes:

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[iii] Users of this Model Agreement are advised that the authors have not drafted it to be used by or in relation to consumers. Contracts concluded with consumers are obliged to include an additional layer of legal protections, to be written in plain-spoken language and to contain other features imposed by consumer specific laws which are not dealt with in this template.

[iv] Users of this Model Agreement should be aware that in some situations the law relating to 'state aid' might need to be considered (e.g. if an industrial party to the material transfer agreement does not pay market value for the benefits it receives). This is a complex area and there is no 'one-size-fits-all' way of dealing with it. Accordingly, the user should seek specialist advice when required.

[v] As with all agreements, the parties should be accurately identified. This is a particular issue in agreements with academic institutions, which sometimes have an obscure legal status or are known by a different name to their correct legal name. Care should also be taken not to enter into agreements with a "school" or "department" (or similar) that has no legal identity apart from its parent university; instead the university should be named. Individual RPOs will have their own legal formalities which will need to be completed to bind the RPO.

[vi] 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 which should be attached to the MTA. There should then be a clear reference to the schedule, e.g. "The materials known as the translocation plasmids, as detailed further in the Schedule attached to this MTA". 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 researcher. The same applies equally to nucleotide or protein sequences (where a typo could make a difference).

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 (i.e. the Institution). 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.

[vii] 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 Institution can do with the Materials, and is therefore important. A key issue is to ensure that the MTA is clear on the use that the Institution 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. Where the Provider of the Materials will own all arising IP, it is important (from the Institution's point of view) to define the Research Programme as narrowly and precisely as possible.

[viii] This template makes 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 Institution will probably not be too concerned to receive a small amount. On the other hand, where the Provider 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 researcher.

[ix] In this template 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.

[x] The signature block raises two issues, i.e. (i) who should sign and (ii) the date of the MTA.

Regarding who should sign the MTA, the template states 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 researchers believe (erroneously) that they do have the authority to sign on behalf of their RPO. When dealing with another RPO'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.

Regarding the date of the MTA, the template has a space to indicate the date on which the parties sign. By convention, the date of the MTA (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 organisations are attempting to formalise an informal supply, i.e. where the researchers 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 MTA 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.

[xi] 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. If the RPO is the Provider, the researcher may wish to be recognised in any publications, e.g. as having supplied the Materials, or sometimes as a co-author.

[xii] In some cases, the Provider's reason for providing the Materials may be in order to obtain access to the results of the Institution'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 Institution 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. 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.

[xiii] 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 RPO 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 RPO's terms, decline the material transfer.

[xiv] 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.

[xv] Ideally, and from the point of view of legal certainty, any revenue sharing arrangements (including specific royalty rates) would be agreed as part of this agreement. However, this will often be unrealistic, as the type and value of any inventions will not be known in advance of their being made. Many MTAs do not result in valuable inventions being made; it may be commercially unproductive to spend time negotiating such matters for every MTA. This clause takes a light-touch approach to the question of revenues, and simply provides that the Provider will receive a "reasonable share". This is probably most suited to MTAs between academic institutions or other parties that are likely to agree such matters without recourse to litigation.

As mentioned above, this template MTA has tried to strike a balance between simplicity/brevity and addressing the issues fully - and this clause is a prime example of this. The user should note that there is a risk that the wording of clause 9 would not be enforceable in the Irish courts for lack of certainty, as the parties have not set out the revenue sharing arrangements fully. To reduce this risk, the parties could consider including a mechanism in the MTA for calculating what would be a "reasonable share". Obviously, this would increase the length and complexity of the MTA and potentially the negotiations of it also.

[xvi] 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. Sometimes these provisions are very specific, e.g. requiring a recognised safety officer to countersign the MTA. You may need to work with the researcher to ensure that they understand their regulatory obligations under the MTA and are able to comply with them.

[xvii] The MTA may 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. Users should also be aware that, while wording of this kind will generally be considered useful, it cannot be guaranteed to exclude terms implied by law. As to which terms will be implied by law, the answer will depend on which country's laws govern the contract.

[xviii] Typically, MTAs provide that the Institution will indemnify the Provider against any liability that may arise from the Institution's use of the Materials.

[xix] 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.

Where this Model Agreement is adapted to be used to govern the performance of obligations in a jurisdiction outside of the Republic of Ireland, users should note that their ability to enforce the rights and obligations set out here may be subject to the law of that jurisdiction and that local legal advice may need to be sought.

# Model MTA (INWARD: Provider to RPO) including drafting points

Dated _____20[●]

(1) [Full legal name of the Provider]

and

(2) [Full legal name of the RPO]

# MODEL MATERIAL TRANSFER AGREEMENT

(INWARD: Provider to RPO)

# MATERIAL TRANSFER AGREEMENT[i] [ii] [iii] [iv]

**([RPO name], the recipient of the Material)**

| | | |
|---|---|---|
| **1.** | *Insert Provider's name and address*[v] | _____ (the "**Provider**"), has collected and/or developed the materials known as: |
| **2.** | *Insert description of materials*[vi] | _____ 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 Researcher, the principal user of the materials* | _____ (the "**Researcher**"), who is an employee of**:** |
| **4.** | *Insert name and address of the Researcher's institution (RPO), recipient of the materials* | _____ (the "**Institution**") |
| | | and the Institution 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*[vii] | _____ (the "**Research Programme**") to be undertaken by the Researcher. |
| **6.** | *Insert quantity*[viii] *of Materials to be supplied and period*[ix] *for which they are to be provided* | The Provider is willing to provide a sample of _____ of the Materials for a period of _____ year(s) (the "**Term**") on the terms and conditions shown overleaf, and the Institution agrees to comply with those terms and conditions. |

**AGREED by the parties through their authorised signatories[x]:-**

| **For and on behalf of [Provider]** | **For and on behalf of [Institution]** | **Acknowledged by the Researcher *(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 the Materials

1. The Institution shall keep the Materials secure at the Researcher's laboratory and ensure that no-one, other than the Researcher and authorised co-workers, has access to them.

2. The Institution shall ensure that the Materials are used only for the Research Programme, subject to the following sentences of this Clause. Any intellectual property generated by the Institution using the Materials shall belong to the Institution (the "**Resulting IP**")[xxx]. However, for the avoidance of doubt and notwithstanding the preceding sentence, any intellectual property that may subsist in the Materials or any copies of the Materials generated by the Institution shall belong to the Provider. The Institution may commercialise any Resulting IP so generated without restriction, subject to Clauses 4 and 5.

3. The Institution shall ensure that the Researcher and any authorised co-workers acknowledge the Provider as the source of the Materials in any publication which mentions them[xxxi].

4. The Materials shall remain the property of the Provider 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 to use any intellectual property provided to the Institution by the Provider ("**Provider IP**") is granted or implied by this Agreement[, except that the Institution shall have a non-exclusive licence to use any Provider IP which is reasonably necessary for the commercialisation of the Resulting IP. Such licence shall be irrevocable, royalty-free, worldwide, without limit of time and with the right to sub-licence.][xxxii]

5. If any revenues result from the Institution's use of the Materials, the Provider shall be entitled to a reasonable share of any such revenues that accrue to the Institution[xxxiii].

6. The Institution shall ensure that the Materials are used 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.

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