What is an MTA?

- Material Transfer Agreement
- Contract governing the **transfer of materials between researchers**
- Means of protecting parties' research and commercial interests in valuable property
- Supplier / provider of the materials is usually the organisation owning the materials but may sometimes be an authorised licensee
- Range of materials transferred may be diverse but generally fall within the biological / chemical category
- Common examples:
  - Transgenic animals
  - Cell lines
  - Cultures
  - Antibodies
  - Vectors
  - Chemicals (including drugs/pharmaceuticals)

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Reasons for Providing and Receiving Materials

PROVIDER

- May be willing to provide the materials for **altruistic reasons** (e.g. to assist others to conduct research); or
- Provides the materials to **obtain a benefit** (e.g. fee for supply, but more usually with a view to generating data on the materials or to obtain longer-term rights)
- Generally insists on use of its own Template MTA

RECIPIENT

- May want to use the materials for a **variety of purposes**, including:
  - To carry out research with them (either on its own accord or on behalf of the Provider)
  - To create IP with them or from them
  - To evaluate them to determine whether to enter into further agreements (such as further research or licensing arrangements)
  - To test them either alone or with other materials (e.g. for safety or efficacy purposes)

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Why do I need an MTA (Provider)?

Provider of the Materials generally requires a legally-binding contract to be put in place to ensure that it has some or all of the following rights:

- **Permit use of the materials:** to control or limit the use that the Recipient makes of the materials in research
- **Prohibit use of the materials:** to prohibit the Recipient from using the materials for non-research / commercial purposes (e.g. using the Provider's cell line to generate antibodies for sale to third parties)
- **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 associated with the materials
- **Publications:** to ensure that the Provider is given appropriate recognition (or direct involvement, e.g. as a co-author) in any publication of results arising from use of the materials
- **Use of results:** to obtain a legal right (e.g. a licence or an option to take a licence) to use the results and data (e.g. in further research or commercialisation). This is often a core requirement for commercial providers

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Why do I need an MTA (Provider)?

- **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
- **Exclusion of liability:** to exclude legal obligations generally (research materials often have unknown toxicity or other properties and Provider does not wish to find itself liable for any injury or damage caused to Recipient / others) and also ensure that the Recipient uses the materials at its own risk
- **Other legal terms**: to ensure appropriate terms are included, including:
  - **No implied warranties**: to clarify the materials are not being 'sold' and therefore the Provider does not have the legal obligations that come with the sale of goods;
  - **Indemnities**: to require the Recipient to indemnify the Provider against any legal liabilities that may arise from the Recipient's use of the materials (this goes one stage further than exclusion of liability, affording an additional protection to the Provider)
  - **Regulations**: to clarify that the Recipient, rather than the Provider, is responsible for dealing with any regulatory requirements (e.g. the regulations or transportation and use of genetically modified organisms)

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Considerations for Recipient of Materials

- **Ownership of IP:** Providers (particularly pharma companies) generally claim ownership of IP generated by Recipient from use of their materials. Grant of ownership may constitute breach of RCSI's contract with the funder of the research and must be carefully considered on a case by case basis
- **Publication:** To ensure the Recipient retains the right to publish the results of its research with the materials
- **Obligations to Funders:** As above, IP arrangements need to be carefully considered, particularly for MTAs with industry parties. It is important to cross-reference the MTA terms with the agreement between RCSI and the funder of the research to ensure the MTA terms are compatible / RCSI is not in breach of its contract with the funder

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Legal Implications – ORI Review

Although they may appear on their face to be relatively straightforward agreements, different areas of law need to be considered when drafting and negotiating MTAs, including:

- Regulations (on transportation and use of research materials)
- Data Protection law
- Intellectual Property Law
- Contract Law
- Tort Law
- Law relating to the use of property owned by another person

All MTAs must therefore be reviewed by the ORI prior to signature and signed by an authorised RCSI representative

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Common Issues with MTAs Received by RCSI

Provider's Terms and Conditions: Customary Practice (and Provider is generally in a strong enough bargaining position to insist) that Provider's terms and conditions of supply should apply. This results in negotiations which can be protracted and disproportionate to the value of the materials themselves and their value to the Provider and / or Recipient. In this scenario the materials should be obtained from an alternative source i.e. purchased, if possible

Most contentious issues tend to be:

- **Ownership of resulting IP:** MTAs from commercial organisations will often seek access (via a licence) to IP resulting from use of the materials. Grant of such licence would result in an inability to commercialise and commercialisation is a requirement of many funders. A generally acceptable compromise is grant of an option to obtain an exclusive licence to the IP at fair market rate
- **Publication:** MTAs, particularly from commercial organisations, often seek to put restrictions on the publication of results arising from use of the materials. It is reasonable for the Provider to have access to copies of proposed publications (or oral presentations) so as to afford them the opportunity to remove confidential information. However, a veto on publication is never acceptable.

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Other Issues requiring careful consideration

Materials:

- Have the materials and their intended use been correctly identified? Generally recommended to describe the materials, including the quantity to be provided, in a Schedule to the MTA
- Confirm the materials are what the academic expects
- Are there any regulations governing use of the materials and can the Recipient comply? (e.g. use of genetically modified organisms)
- Are the materials of human origin? If they are:
  - Has appropriate patient consent been obtained?
  - Has ethical approval been obtained?
  - Data Protection (GDPR) compliance: will the data and materials be provided in an anonymous / coded form?
  - Are their appropriate technical and organisation safeguards in place?

Permitted Use:

- Ensure the purpose is clearly defined i.e. 'Research' or 'Project'
- Ensure the purpose adequately explains what the researcher intends to do with the materials
- Ensure "Non-commercial" use is clearly defined and understood by Provider and Recipient
- Ensure non use in humans and animals
- Ensure provision for non-transfer of the materials to third parties

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Other Issues requiring careful consideration

Security and safety:

- The MTA should specify the materials will be kept secure / in a particular location
- If there are particular safety requirements (e.g. for hazardous materials) these must be specified
- Preferable to include provision restricting access to the materials to recipient scientist / employees of recipient
- Are there any regulations governing use of the materials and can the Recipient comply? (e.g. use of genetically modified organisms)

Confidential Information:

- Has confidential information been adequately protected? (information, data, material)

Warranties:

- The material should not come with any warranties. Important to specify the material is supplied “AS-IS” with no warranty as to merchantability, fitness for purpose, non-infringement of third party intellectual property rights

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Other Issues requiring careful consideration

Liability and Indemnities:

- The Recipient should assume responsibility for use of the materials and all liability for damages that may arise form their use, storage or disposal of the materials
- Preferable to secure a statement of no liability and an indemnity from the Recipient against any claims, losses, or other liabilities that may arise as a result of the Recipient's use, storage or disposal of the materials

Governing Law:

- Preferable to secure Irish law however this is not always achievable.

Termination:

- The MTA should specify a start (effective) and end date
- Should be provision for the parties to terminate the MTA by provision of advance written notice
- Should be provision for the Recipient to stop using the material in the event the MTA is terminated and to return or destroy any remaining material
- Any obligations intended to survive termination should be set out

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MTA Procedures (Incoming Materials)

Before requesting Materials from an external source contact the ORI to discuss

When the MTA is received from external party:

Forward to ORI for review (including contact details for the person or office to whom the MTA should be issued for review and signature) and also advise on the following:

1. Source(s) of funding for the research
2. Likelihood IP will be generated from use of the Materials

ORI will use these details to inform its review of the MTA

ORI will liaise with the Provider to negotiate and finalise the MTA

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MTA Procedures (Outgoing Materials)

Before providing Materials to an external party contact the ORI and provide the following details:

1. Details of Party to whom the Materials are being transferred
2. Description of the Materials to be transferred
3. Quantity of Materials to be transferred
4. Source of funding for the research from which the Materials arose
5. 'Value' of the Materials – are the materials novel and is there a plan to patent them?

ORI will use these details to inform an appropriate MTA and will issue this MTA to the Recipient's legal / technology transfer office for review

ORI will liaise with the Recipient to negotiate any requested amendments and finalise the MTA for signature

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MTA– Key Terms

1. Preamble
2. Definitions
3. Description of Materials & Permitted Use
4. Restrictions on Use of the Materials
5. Confidentiality
6. IP ownership
7. Publication
8. Warranties
9. Liability and Indemnities
10. Termination
11. Governing Law and General Provisions

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MTA Checklist (Outgoing Materials)

- What materials am I transferring? Does RCSI own the materials i.e. do I the have the right to transfer them?
- Are the materials novel? Have they been patented or is there a plan to do so? This is critical to informing appropriate IP provisions
- Who is funding the research? Are the materials subject to any restrictions under existing Agreement(s)?
- Are the materials human / biosamples? Is their valid patient consent for their transfer?
- Are the materials and their permitted use clearly and accurately detailed?
- What am I receiving in return and is it appropriate to the value of the materials? i.e. right to acknowledgement in publications v. right to co-authorship; reach through on royalties

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MTA Checklist (Incoming Materials)

- Who is funding the research?
- Is there likelihood of an invention?
- Are the materials human / biosamples? Is their valid patient consent for their transfer so that I am entitled to use them in the research?
- Is the Provider seeking ownership of or access to resulting IP? This may conflict with RCSI's IP Policy and funders' terms and conditions
- Do I retain the right to publish?
- Are there any unreasonable reporting requirements?

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Thank you…
Please feel free to contact:
researchcontracts@rcsi.ie;

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