

**CORBEL Core template tool for Material Transfer Agreements**

**Scope and purpose**

This tool was developed to support those who need to assemble a material transfer agreement (MTA). It was designed from a background of biomedical and microbial sciences, and provides exemplar clauses which may be suited for agreements in these domains.

The Core tool was based on template MTAs that are used by the CORBEL partner RIs and input and experiences that were provided during WP8 activities by technical and legal experts and users of these templates. The tool helps to identify the main components of an MTA, which generally apply to any category of material, be they non-biological, human or other biological material. CORBEL intends to supplement this tool with modules that will provide more support specific for transfer hazardous materials (Supplement I), of human material and other biological materials.

Each section addresses important issues, provides some general guidance, a set of options, and example clauses, followed by the source MTA template between parentheses (if unchanged, the examples clauses are in *italic*).

**Core**

**Content**

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1. **Title of the agreement**

Besides the title of the agreement, it is useful (specifically during the negotiations and multiple exchange of different versions of the draft proposal of the agreement) to provide a version number and date with each revision version of the agreement. This way parties to the agreement are always aware which version is the last one and which version they are signing at the end. The version number(s) and associated date(s) can be noted down in the *footer* (bottom of the page) and then revised there each time needed.

It is useful to include key information on the scope/restrictions in the subtitle, e.g., “for Non-commercial Recipients only”.

If needed, a summary of the purpose of the MTA can be given.

1. **Parties to the agreement and Preamble**
	1. Full name of the Provider/Donor Organisation/Entity and its address (registered office /principal place of business), and the person acting as duly authorized signatory (Provider/Donor scientist, or other natural person);
	2. Full name of the Recipient Organisation/Entity and its address (registered office /principal place of business), the person acting on behalf of that organization as duly authorized signatory, and/or the Recipient Scientist (include the Recipient Scientist address if different);
	3. If considered relevant to the agreement, a concise description or statement on the nature, mission, or other general information of the Organisations which are party could be added and expressed in the preamble of the Agreement.

Example:

**WHEREAS:**

1. Party 1 is a…………………………………;
2. Party 2 is a…………………………………;
3. Parties wish to establish..................under the terms of this Agreement and more specifically ............................;
4. This MTA will serve as an agreement under which Parties………………………………………………

**3. Materials transferred**Material must be listed as text in the agreement or appended in annex – required are:

* 1. (Unique) Identifiers, if applicable;
	2. Names or circumscription of materials (substance name, taxonomic designation, etc.);
	3. Additional information as required by applicable legislation or regulatory requirements (e.g. Access and Benefit Sharing, see modules);
	4. Other information which is considered appropriate.

**4. Definitions**Depending on the context of an agreement a list of definitions can be inserted to avoid any misunderstanding about the meaning of these terms. Below, examples are given of definitions for frequently found terms in MTAs. These definitions should not be used uncritically – make sure that definitions you adopt are applicable and fit for purpose and that you use terms in a consistent way throughout the MTA. Where in/out of scope with respect to certain terms may be unclear, provide examples of well-known situations that would be in or outside scope.

* 1. **Provider**
1. *Organisation providing the Original Material* (CORBEL MTA).

	1. **Recipient**
2. *Organisation receiving the Original Material* (CORBEL MTA).
	1. **Recipient Scientist**
3. *The party requesting the Material* (MTA INSTRUCT);
4. *The scientific employee of Recipient performing the intended experiments with Material* (HMGU SMTA EMMA).
	1. **Depositor**
5. *Person(s) or entity that provided a public repository/collection (acting as Provider) with the Original Material* (ECCO Core MTA).

	1. **Original Material**
6. *The description of the material being transferred will be specified in XX* (CORBEL MTA);
7. That which was originally supplied to the Provider (typically a public repository/collection keeping and supplying materials) by the Depositor.

	1. **Material**
8. *Original Material, (Unmodified) Progeny and Unmodified Derivatives. The Material shall not include:
(a) Modifications* (CORBEL MTA , ECCO Core MTA*), or (b) other substances created by the Recipient through the use of the Material which are not Modifications, Progeny or Unmodified Derivatives* (CORBEL MTA);
9. *The Material includes 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* (MTA INSTRUCT);
10. *The "Material" which, regarding the inherent intellectual property rights, is and remains the exclusive property of the Provider, comprises the Original Material, any Progeny, Unmodified Derivatives, the Original Material contained in Modifications and proprietary information concerning the Original Material* (HMGU SMTA EMMA);
11. *personal data, screening results, biological specimens, images, research tools or other \_\_\_\_\_\_\_\_\_\_\_ that the Cohort (Provider) transfers to Recipient for the research purposes as specified (in Appendix X)* (BBMRI LPC MTA).

Note: Data associated with Material may be included in the definition of Material, or explicitly mentioned where relevant.

* 1. **Progeny (sometimes ‘Unmodified Progeny’)**
1. *Unmodified descendants from the Material, such as a virus from a virus, cell from cell, or organism from organism* (CORBEL MTA, HMGU SMTA EMMA);
2. *Unmodified descendant (e.g. sub-culture or replicate) from the Original Material* (ECCO Core MTA).

	1. **Unmodified****Derivatives**
3. *Substances created by the Recipient which constitute an unmodified functional subunit or product expressed by the Original Material* (CORBEL MTA, HMGU SMTA EMMA);
4. *Replicates or substances which constitute an unmodified functional subunit or product expressed by the Material* (ECCO Core MTA);
Examples descriptions/explanations (“such as, but not limited to”):
5. *Subclones or 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* (CORBEL MTA, HMGU SMTA EMMA);
6. *Purified or fractionated subsets of the Material, including expressed proteins or extracted or amplified DNA/RNA* (ECCO Core MTA).

	1. **Modifications**
7. *Substances created by the Recipient which contain/incorporate the Material* (CORBEL MTA, HMGU SMTA EMMA);
8. *Substances produced by the Recipient by using the Material, which are not the Original Material, Progeny, or Unmodified Derivatives, and which have new properties* (ECCO Core MTA).

Examples descriptions/explanations (“such as, but not limited to”):

1. *e.g. crosses, breeding varieties, cell fusions, subcloning etc.* (HMGU SMTA EMMA);
2. *Recombinant DNA clones* (ECCO Core MTA).
	1. **Project**

The proposed research that will be performed using the Material (referring to a description in Annex usually suffices).

* 1. **Commercial Purposes**The definition may imply, or explicitly include, any use by a Recipient which is a for-profit body. It is good to clarify the issue, as certain types of use by for example companies may be regarded as not-for-commercial purposes per se, e.g., use of material solely as a reference tool for testing (and the Material is not the object of the research in itself but only serves to confirm or verify certain features).
1. *The sale, lease, license, or other transfer of the Material or Modifications to a for-profit organisation. Commercial Purposes shall also include uses of the Material or Modifications by any organisation, 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 organisation. 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* (CORBEL MTA);
2. *The use of the Material for the purpose of profit* (ECCO Core MTA).
	1. **Transfer involving an intermediary**

Sometimes the Provider cannot transfer the Material directly to an End-user, because an intermediary must be involved in the transfer of the Material. Then, the Intermediary and End-user act consecutively as Recipients of the Material. In such cases, the following definitions can be relevant (examples from ECCO Core MTA):

**Recipient**

*The party to whom the Provider sends the Material. In case this is not the End-User but an Intermediary, this Intermediary agrees (i) to forward to the End-User the present MTA and the Material in unchanged form and quantity as received from the Provider, and (ii) to use for this further shipping the proper packaging, a trained shipper, and an authorized carrier, according to the applicable laws and regulations.*

**End-User***Scientist working with the supplied Material.*

**Intermediary***Third party, different and independent from the End-User, that makes an order on behalf of the End-User, and to which the collection addresses the Material. These can be wholesalers, importers, or other type of intermediary agents, unrelated to the End-User ‘s institution.*

*Note*: the Provider needs to decide if the Intermediary should also sign the agreement (besides the End-user).

**4.13 Prohibited use**

Purposes outside the scope of the Research Purpose as described under “Project description” (in attachment / annex) (ESGI D5.2 MTA).

**5. Ownership rights**Ownership rights held by Provider and Recipient to Material, its components and Modifications can be addressed in the agreement; think also about forseeable scenario’s for joint ownership rights to Modifications. In many situations Ownership rights to biological material can be very complex, and for certain categories of material it is subject to conventions, national legislation, or regulatory requirements. Especially in older public collections or repositories the ownership rights to many materials are actually unsettled, in which case transfer agreements do not deal with ownership rights, but could address other rights over material such as user rights which are acquired by the Recipient and those (also) retained by the Provider (see option 3 below, and the concept of “bundle of rights”). In this regard it might be relevant that Provider delivers the Material to the Recipient cost-free, or against a ‘handling fee’, or (rarely) the transfer is qualified as a purchase.

The options given below for transfer of materials are not suited for human or other biological material (for those see the appropriate module), and are not exhaustive.

* 1. **Ownership rights to Material and Modifications reside fully and solely with the Provider**
1. *The Material, and any Modifications are and shall remain the sole property of the Provider* (ESGI D5.2 MTA);
2. *Nothing in this Agreement grants the Recipient Organisation any rights over the Material (other than as specifically granted by this Agreement)*(MTA INSTRUCT).
	1. **Ownership rights to Material reside with Provider, ownership rights to Modifications will reside with Recipient (with exception of any Material contained in Modifications)**
3. *The Recipient must not transfer the requested Material, which is owned by the Provider and shall comprise any progeny, unmodified derivatives or original material contained in modifications thereof derived by inbreeding or crossbreeding, to any third party* (EMMA INFRAFRONTIER OUT);
4. The Provider retains ownership of the Material, including any Material contained or incorporated in Modifications;
5. *The Recipient retains ownership of* (CORBEL MTA):
6. *Modifications (except that, the Provider retains ownership rights to the Material included therein), and*
7. *those substances created through the use of the Material or Modifications, but which are not Progeny, Unmodified Derivatives or Modifications (i.e., do not contain the Original Material, Progeny, Unmodified Derivatives).*

If either (i) or (ii) results from the collaborative efforts of the Provider and the Recipient, joint ownership may be negotiated.

* 1. **Ownership rights to Material resides with Provider, Recipient will share ownership rights to Modifications with the Provider**
	2. **Ownership rights to Material are unsettled (or not addressed), but certain rights are transferred along with the Material to the Recipient**Considerthe possibilities and conditions of supply of material to other requestors (under comparable terms), who for example wish to replicate Recipient scientist’s research.

**6. Third party transfer**Conditions for transfer of Material to subsequent users can be lenient to highly restrictive. It is advisable to clearly define who will be regarded as a Third Party, for example will it be anyone not employed by the Recipient Organization, or also include anyone working within the Recipient organization but not under direct supervision of the Recipient scientist, or working in another location, etc. It is important that conditions for transfer are made very clear in the agreement (see 6.2). Furthermore, if Third party transfer will happen it must generally be under provisions or conditions equal or at least not less strict than to the Recipient. To avoid breaches, options 6.1 or 6.2 may be the safest for most situations.

* 1. **Third party transfer is not allowed**
1. *The Recipient must not transfer the requested Material, which is owned by the Provider and shall comprise any progeny, unmodified derivatives or original material contained in modifications thereof derived by inbreeding or crossbreeding, to any third party* (EMMA INFRAFRONTIER OUT).
	1. **Third party transfer requires Provider’s and/or other right holder’s consent**
2. *Material will not be transferred to anyone else within [/ outside] the Recipient Organisation without the prior written consent of the Provider* (CORBEL MTA);
3. *The Recipient and the Recipient Scientist agree to refer to the Provider any request for the Material from anyone other than those persons working under the Recipient Scientist's direct supervision* (ESGI D5.2 MTA, CORBEL MTA). *To the extent supplies are available, the Provider or the Provider Scientist agrees to make the Material available, under a separate implementing letter to this Agreement or other agreement having terms consistent with the terms of this Agreement, to other scientists (at least those at Non-profit Organisation(s)) who wish to replicate the Recipient Scientist's research; provided that such other scientists reimburse the Provider for any costs relating to the preparation and distribution of the Material* (CORBEL MTA);
4. *The Recipient agrees that the Material is to be used only at the Recipient’s organization and only by the Recipient’s investigator and staff under his/her direct supervision who are bound by obligations not less strict than those set out herein* (ESGI D5.2 MTA);
5. *The Recipient shall not distribute the Material and its Modifications to any other person, entity outside the Recipient´s Facility to use them without prior written permission from the Provider* (ESGI D5.2 MTA);
6. *Notwithstanding the preceding clause* [(d) above] *the Recipient shall have the right, without restriction, to distribute substances created by the Recipient through the use of the Material, only if those substances are not Progeny, Unmodified Derivatives, or Modifications* (ESGI D5.2 MTA);
7. *The Material shall be used exclusively for the purposes described in Annex X (project description). It must not be released to any person other than the Recipient's Scientist/s and staff under the Recipient's Scientist/s direct supervision who are bound by obligations not less strict than those set out herein. It shall be handled confidentially and forwarded to third parties only to the extent of Provider's prior written approval* (HMGU SMTA EMMA);
8. *Unless agreed in writing with the Collection* [Provider]*, Recipient shall not sell, distribute or propagate for distribution, lend, or otherwise transfer the Material to any others, except those Recipient that acts as Intermediary and those Recipient involved in Legitimate Exchanges* (see below, ECCO Core MTA).

	1. **Third party transfer requires Provider’s and/or other right holder’s consent and may be under additional conditions of interest to the Recipient** (to protect Recipient’s “first user rights”)
	2. **Third party transfer is allowed under pre-defined conditions** (and without Provider’s or other right holder’s involvement, although they may be informed if the Provider so desires), for example only to not-for-profit entities, or only for use for non-commercial purposes.
	3. **Substances which are *not* Material** (depending on the definition but typically not including Modifications), may be transferred to others than the Recipient or Recipient Organisation and this transfer subject to conditions laid down in the MTA (for example, only to non-commercial Recipients). Below an example is given (from CORBEL MTA):
9. *The Recipient and/or the Recipient Scientist shall have the right, without restriction, to distribute substances created by the Recipient through the use of the Original Material only if those substances are not Progeny, Unmodified Derivatives, or Modifications*;
10. *Under a separate implementing letter to this Agreement (or an agreement at least as protective of the Provider's rights), the Recipient may distribute Modifications to Non-profit Organisation(s) for research and teaching purposes only*.
	1. **Other transfer**

Certain transfers may not be regarded as Third Party Transfer, for example the ‘Legitimate exchange’ as defined in the ECCO Core MTA of microbial culture collections:

1. *The transfer of Material between scientists working in the same Laboratory, or between partners in different Institutions collaborating on a defined joint project, for non-commercial purposes. This also includes the transfer of MATERIAL between public service culture collections/BRCs for accession purposes, provided the further distribution by the receiving collection/BRC is under MTA conditions equivalent and compatible to those in place at the supplying collection.*

**7. Use conditions**

Depending on the scenario and needs of the Parties, the use conditions can be described in general terms or in more detail. The points below would typically be useful in many scenarios, e.g., where use of Material for non-commercial versus commercial purposes is addressed (which often is incorporated in the (sub)title of the MTA).

* 1. **Use restricted to the work described in the research project by the Recipient** – the description of the work and the purpose of the project should be included in text of the agreement or in Annex (MTA INSTRUCT). If Recipient wishes to use the Material in other work than described there, or outside the project, prior consent of the Provider will be required.
	2. **Use conditions are described in more general terms,** **e.g.** **research for non-commercial purposes and commercial purposes (which must be defined) are allowed, subject to pre-defined conditions** (investigational limitations, etc.)**, or prior consent of the Provider**
1. *The Recipient agrees that the Material is to be used solely for the Research Purpose, in teaching and academic research, being expressly prohibited any kind of commercial or profit-making purposes without an appropriate license or other permission from the Provider* (ESGI D5.2 MTA);
2. *The Material may not be used by the Recipient Scientist in research which is subject to the provision of any rights to a commercial third party without prior written consent* (MTA INSTRUCT).
	1. **Modes of use which are explicitly excluded (in addition to those prohibited under applicable law) can also be listed in MTA.** For example use of the material in human subjects or clinical trials (see also Prohibited Use, 4.13).
	2. **Sanctional clauses for putting Material to prohibited use (or other violation of the use conditions) may be included**
3. *If Material is put to a Prohibited Use, all information, Results, Developments and the like arising from the Prohibited Use shall be the property of the Provider and shall be treated in all respects as Provider’s Information* (ESGI D5.2 MTA).
	1. **Benefit sharing arrangements**When use of the Material could lead to benefits of which the Provider (or another right holder) wants a fair share, benefit sharing arrangements can be settled in MTA. For non-human biological material that is regarded as genetic resources in scope of the CBD and Nagoya Protocol, and subject to active Access and Benefits Sharing (ABS) legislation, benefit sharing arrangements will be settled in Mutually Agreed Terms (MAT). Benefits may be monetary (use for commercial purposes of material or modifications) or non-monetary. Detailed arrangements could be included in MTA, but partners can also negotiate at a later stage (when a commercial application has been developed successfully).
	2. **Compliance – general clauses**A general clause that the Recipient will use the material in compliance with all applicable (national and international) law and regulations and/or generally accepted guidelines (reference to best practices or codes of conduct specified), is useful for any scenario. Below some examples are given. However, in case of material where particular risks or liabilities are involved it is always better to include more detailed clauses to promote awareness and compliance, for which examples can be found in the modules for (hazardous) biological and human materials.
4. *The Recipient agrees to use the Material in compliance with all applicable statutes and regulations, including …* (CORBEL MTA);
5. *The Recipient shall use the Material in compliance with all laws and regulations applicable to such Material in the Recipient's place and country, including*… (ESGI D5.2 MTA, HMGU SMTA EMMA);
6. *Recipient agrees that any handling or other activity undertaken in their laboratory with the Material will be conducted under their responsibility and in compliance with all applicable laws and regulations* (ECCO Core MTA);
7. *The Recipient shall comply with all applicable laws, the terms of this Agreement, and relevant existing or future decisions or statements by authorities (e.g., data protection) or research ethics boards* (BBMRI LPC MTA);
8. *The Material may only be used by those under the Recipient Scientist’s direct supervision in the Recipient Organisation’s laboratories under suitable containment conditions, and in compliance with all applicable statutes and regulations* (MTA INSTRUCT).

**8. Intellectual Property and licensing**Provider may only allow use of Material for non-commercial research and education, and seeking protection of any invention under patent law, or use for commercial purposes in general, would require a license from Provider or a new agreement between Provider and Recipient (see Section 7).

* 1. **Provider’s or Third Party’s Intellectual property rights on the Material.**

Certain intellectual property (patents, trade secrets) or other proprietary rights may exist and be “attached” to the (Original) Material which may be known or unknown to Provider or Recipient. For avoidance of any doubt, it is useful to express in the MTA agreements that MTA does not provide for a license/right to intellectual property rights to Material. Here are some examples how this is clarified:

1. *Nothing in this Agreement shall be deemed to grant the Recipient any rights under any intellectual property rights* *owned or controlled by the Provider, nor any rights to use the Material for any products, processes or services for profit-making or other commercial purposes other than the Research Purpose. The Recipient furthermore ensures that the Material will not be used in research that is subject to consulting or licensing obligations to another institution, corporation or business entity* (ESGI D5.2 MTA);
2. *Nothing in this Agreement grants the Recipient Organisation any rights over the Material (other than as specifically granted by this Agreement) or under any patents, nor any right to use, or permit the use of, any products or processes containing, using, or directly derived from the Material for profit-making or commercial purposes (“Commercial Use”). If the Recipient Organisation wishes to make Commercial Use of the Material or a product directly derived from the Material it agrees to negotiate in good faith with the Donor Organisation representative for the grant of an appropriate licence or the conclusion of a revenue sharing agreement, if justified. The Donor Organisation will have no obligation to grant a licence* (MTA INSTRUCT);
3. *Nothing in this Agreement grants Recipient any rights under any patents, propriety, intellectual property, or other rights with respect to the Material* (ECCO Core MTA).

	1. **Intellectual property developed by Recipient when using the Material.**

If Provider allows use of Material under the MTA for research and development which could lead to inventions and patentable applications, the MTA should address conditions for the steps to be taken towards application for protection of IP. The clauses could address how Parties to the agreement (Provider, and possible other parties having ownership rights or other rights to the Material), will inform each other of inventions, how they will settle on the inventorship, and who is entitled to apply for intellectual property protection.

* + 1. **Recipient Informs Provider of developments, any invention or patentable modification, to agree on contributions to the inventorship by each Party, before taking further steps to file for intellectual property protection.**
1. *Where the research involving the Material or a Modification results in an invention or a patentable Modification of the Material, the Recipient and its Recipient Scientist/s shall promptly disclose this development to the Provider. Recipient and Provider shall decide in common about the inventorship, taking in due consideration the Provider's contribution to the invention through its Material. Decisions about all further proceedings, such as filing of a patent application or exploitation, shall be made after inventorship is determined* (HMGU SMTA EMMA)*.*
	* 1. **Recipient may take steps to file for intellectual property protection but will inform Provider upon filing**
2. *The Recipient is free to file patent application(s) claiming inventions made by the Recipient through the use of the Material but agrees to notify the Provider upon filing a patent application claiming Modifications or method(s) of manufacture of the Material* (CORBEL MTA);
3. *The Ownership of the Material remains at the Cohort* [Provider]*, and it claims no ownership to new intellectual property invented or developed solely by or for the Recipient in connection with the project* (BBMRI LPC MTA)*.*

**9. Reporting and publication**Parties may set conditions concerning reporting to Provider and publication of any results (see also confidentiality). To protect interests of IP or (material source) confidentiality, reviewing of Recipient’s manuscripts by Provider prior to publication may be made compulsory. Concerning citation of certain categories of materials, reference can be given to guidelines or best practice.

* 1. **Periodical reporting on results or reporting at end of project by Recipient to Provider, and in what form (e.g., raw data)**
	2. **Conditions for presentations at meetings or publication of results, including agreement on authorships, citations and acknowledgments of the source of material (including appropriate identifiers)**
1. *The Recipient agrees to acknowledge the Provider and EMMA as Distributor in any publication or presentation reporting on research involving an EMMA strain* (EMMA INFRAFRONTIER OUT);
2. *RECIPIENT agrees to acknowledge the COLLECTION* [Provider] *as the source of the MATERIAL in any and all publications that reference the MATERIAL* (ECCO Core MTA);
3. *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 acknowledgment of the source of the Material in all publications. The bioresource from which the material is originating* [Name Provider] *requires to be cited according to the CoBRA (Citation of BioResource in journal Articles) guideline in any publication referring to it. [Here the Provider could specify what would be this citation format for the specific resource object of the MTA, i.e. which name, which ID etc.]*(CORBEL MTA);
4. *The Recipient shall have the right to publish its findings and results related to the Material, provided that the Provider Scientist/s are either named as co-authors of the publication or cited as the source of the Material, according the respective contribution of the Material to the publication* (HMGU SMTA EMMA);
5. *This Agreement shall not prevent or delay the publication of Results, provided that the RECIPIENT does not include in any oral presentation or written publication, any information identified as confidential by the Provider without its prior written consent. The source of the Material shall be acknowledged by the Recipient, either naming the Recipient ´s Investigator as co-authors or citing them as the source of the Material, in any publication or presentation* (ESGI D5.2 MTA);
6. *If the Recipient Scientist wishes to include in a publication any information which has been provided by the Donor Organisation with the Material and which was clearly marked as “confidential” and “proprietary” at the point of disclosure (“Confidential information”), the Recipient Scientist will request permission from the Donor Organisation, providing a copy of the text before publication takes place* (MTA INSTRUCT).
	1. **Submit to the Provider all publications a certain time before public disclosure**
7. *The Recipient shall submit all publications four weeks prior to their public disclosure to the Provider. Provider agrees to keep Recipient’s publication confidential until published by Recipient* (HMGU SMTA EMMA).
	1. **Providing open access to research data at agreed time after start or end of the project**
8. *The Provider /Recipient will provide open access to any published results and data in accordance with the Berlin declaration (2003)* (ESGI D5.2 MTA).
	1. **Where the possibility for access to the material cited in manuscripts is a condition for publication, the issue may be discussed in advance with the Provider** (BBMRI LPC MTA)

**10. Confidentiality**In cases Parties have not settled confidentiality clauses in a separate Confidential Disclosure Agreement (CDA), such clauses can be included in MTA. Below example clauses are provided that may suit various scenario’s .

Recipient shall keep confidential any and all of the information received and relating to the Material, and shall not disclose it to any Third Party, unless with the prior and written consent of the Provider.

Recipient warrants that all its employees shall be obliged to maintain the confidentiality of such information received and relating to the Material and to use it only in accordance with the provisions of this Agreement, and shall use all reasonable endeavours to avoid and act against non-compliance by its employees.

Confidentiality obligations hereinabove mentioned shall not apply to any information that:

1. can be demonstrated to have been in the public domain as of the effective date of this Agreement, or legitimately comes into the public domain through no fault of the Recipient;
2. can be demonstrated to have been known to the Recipient prior to execution of this Agreement and was not acquired, directly or indirectly, from Provider or from a third party under a continuing obligation of confidentiality;
3. can be demonstrated to have been rightfully received by the Recipient after disclosure under this Agreement from a third party who did not require same to hold it in confidence or limit its use, and who did not acquire it, directly or indirectly, from Provider under a continuing obligation of confidentiality;
4. can be demonstrated to have been independently developed by personnel of the Recipient who had no substantive knowledge of any information provided by Provider; or
5. is required to be disclosed pursuant to law or court order, provided that Recipient provides prior notice to Provider and provides sufficient time to Provider to assert any exclusions or privileges that may be available by law.

 The obligations assumed under this clause shall remain in full force and effect not only during the Term of this Agreement, but also for as long as the confidential information is confidential.

**11. Warranties, liabilities and indemnification**

Depending on the category of material that is transferred and the nature of the Provider’s organisation, e.g., a scientific consortium, cohort, or a public service repository with a policy for customer complaints, clauses may vary considerably. In case Providers would make effort to send a replacement when there is a quality issue with material provided, this could be included in the MTA. Here, some examples are provided of the clauses that typically appear in MTA of consortia (10.1 a), public repositories (b), or cohort (c).

**11.1 Representations and warranties (Provider) and liabilities for use (Provider and Recipient)**

1. *Any Material delivered pursuant to this Agreement is understood to be experimental in nature and may have hazardous properties. The Provider makes no representations and extends no warranties of any kind, either expressed or implied. There are no express or implied warranties of merchantability or fitness for a particular purpose, or that the use of the material will not infringe any patent, copyright, trademark or other proprietary rights. Except to the extent prohibited by law, the Recipient assumes all liability for damages which may arise from its use, storage or disposal of the Material*  (CORBEL MTA, HMGU SMTA EMMA, EMMA INFRAFRONTIER OUT, MTA INSTRUCT);
2. *Except as expressly provided in this Agreement and within the limits of the scope of the Collection’s quality system, there are no representations or warranties by the Collection with respect to the Material, express or implied, including without limitation, any implied warranty of authenticity, typicality, safety, fitness for a particular purpose, or of the accuracy or completeness of the data* (ECCO Core MTA);
3. *The Cohort provides the Material on an “as is” basis, without any representations and warranties, whether express or implied. However, if the Material sent is not exploitable for quality reasons, the Cohort should be in measure to proceed to a new shipping* (BBMRI LPC MTA).
4. The Material is provided hereunder "as is", and it is understood to be experimental in nature and may have hazardous properties. The Provider makes no representations and extends no warranties of any kind, express or implied, as to the fitness of the Material for a particular purpose, and the absence of any legal or actual defects, whether or not discoverable or that the use of the Material will not pose a health safety risk (ESGI D5.2 MTA).

**11.2 Indemnification by the Recipient of the Provider from third-party claims, liability etc. arising from use of the material by Recipient**

1. *The Provider will not be liable to the Recipient (or the Recipients’Scientist) for any loss, claim or demand made by the Recipient, or made against the Recipient by any other party, due to or arising from the use of the Material by the Recipient, except to the extent permitted by law when caused by the gross negligence or willful misconduct of the Provider* (CORBEL MTA, ESGI D5.2 MTA, HMGU SMTA EMMA, EMMA INFRAFRONTIER OUT, MTA INSTRUCT);
2. *The liability of either party for any breach of this Agreement, or arising in any other way out of the subject matter of this Agreement, will not extend to loss of business or profit, or to any indirect or consequential damages or losses* (MTA INSTRUCT).

**12. Miscellaneous**

**12.1 Entering into force of the agreement (the effective date)**

Entering into force or Effective Date of the agreement can be either specified as a precise date in the agreement or referenced to be considered a date when the last party to the agreement signed the agreement (in this case it is important to remember to insert the dates with the signatures).

1. *This agreement will become effective when signed by all parties* (CORBEL MTA);
2. *This SMTA shall enter into force on the date of the last signature to it* (HMGU SMTA EMMA, ESGI D5.2 MTA);
3. *This Agreement is valid from the signature date until the end date defined in Appendix X* (BBMRI LPC MTA).
Special clause on retro-activity:
4. *In the event the Material or part of it should be under physical control of the Recipient before this Agreement is signed, the terms and provisions shall apply for this Material retroactively* (ESGI D5.2 MTA).

**12.2. Termination of the agreement**

Depending on the scenario, agreement with definite term (i.e. 2 years from the Effective Date/ entry into force) or agreement with indefinite term – expiration date will be known either by expiration of time or in case of indefinite term of the agreement - agreement will terminate by notice of a one party to another party.

Besides above, an expiration date (end date) can be associated with, and/or a number of possible events can be described upon which the agreement would terminate.

If there are conditions in the agreement that will survive expiry, these should be explicitly mentioned.

Events upon which the agreement would terminate are for example:

1. Reaching the preset expiration date;
2. Recipient's research with the Material or the project is completed (and without written notion);
3. written notice of ending the agreement is given by either party to the other, to be effective on a set number of days thereafter;
4. the Material is no longer exclusive as it becomes generally available from third parties, while such exclusiveness was a primary reason for setting the conditions under the agreement in the first place (this typically does not apply to replicable material in public repositories such as culture collections).

Renewal of the agreement term

If an expiry date is pre-set, the Provider may consider a clause that mentions possibilities for the renewal of the agreement term.

1. *At the Recipient’s request, Cohort may, at its discretion, extend the term and timelines by a new decision sent to the Recipient* (BBMRI LPC MTA);
2. *In any other case it will terminate upon completion of Provider’s Research Purpose, two (2) years after the Effective Date or upon expiry or non renewal of the Ethical Approval, whichever is earlier* (ESGI D5.2 MTA).

**12.3 Termination for a breach of term(s)**

1. *The Provider is entitled to request the immediate return or the immediate destruction of the MATERIAL, in case the Recipient does not comply with its obligations under this Agreement with thirty (30) days’ written notice by the Provider to the Recipient* (ESGI D5.2 MTA)*.*

**12.4 Rights upon expiration/termination of the agreement -additional conditions concerning fate of Material and data upon termination**

Several conditions might be added, depending among other on ownership arrangements of material and/or data. For example, upon termination what is to be done with the material and/or data provided to Recipient, e.g., discontinue use, audit of remaining material, destroy material, delete data, and notify the provider accordingly, or return material/data to the provider etc.

1. *Upon the effective date of termination, or if requested, the deferred effective date of termination, Recipient will discontinue its use of the Material and will, upon direction of the Provider, return or destroy any remaining Material. The Recipient, at its discretion, will also either destroy the Modifications or remain bound by the terms of this agreement as they apply to Modifications* (CORBEL MTA);
2. *On completion of the Project, the Recipient must return any remaining usable samples to the Cohort, unless otherwise agreed. Unusable samples must be destroyed, and the Cohort must be notified of destruction. The data and other Material provided by the Cohort must not be used anymore. All electronic copies of the data must be deleted; excluding copies that are needed for backing up the results. The Recipient shall notify which copies it maintains, and for how long* (BBMRI LPC MTA);
3. *After conclusion of the studies related to the Research Purpose, or at the expiry/termination of this Agreement, whichever occurs first, the Recipient shall, at the discretion of the Provider, either destroy or return to the Provider the remaining Material. Upon request, the Recipient shall also inform the Provider in written on the status of its research* (ESGI D5.2 MTA);
4. *Upon termination, the Recipient will (a) undertake an audit of the remaining Material and within 60 days provide the Provider with a complete list of all Materials which remain in existence at the date of termination (“Extant Material”); and (b) discontinue its use of the extant Material and either return to the Recipient or, at the option of the Provider, destroy any extant Material and certify that destruction to the Provider; and (c) either destroy any Modifications or remain bound by the terms of clause X as they apply to Modifications* (ESGI D5.2 MTA).

**12.5 Additional conditions concerning results upon termination**Depending on what is written down elsewhere in the agreement about ownership of results obtained by research of the Material, ownership of Modifications etc., a clause could be inserted here dealing with the fate of results and raw data obtained while using the Material.

1. *The Recipient must offer to the Cohort all research project results, such as assay and analysis data (“raw data”), supplied with appropriate documentation. These research results will be available from the Cohort also for other researchers according to the Cohort’s general access policy after a 12 months after the termination of the project as specified in the Appendix X. A certain embargo regarding this obligation can be negotiated on a case-by-case basis* (BBMRI LPC MTA).

**12.6 Payments for costs involved in the transfer, if any**

**12.7 Governing law and jurisdiction**

This clause is intended for the parties to the MTA to negotiate in advance which jurisdiction and law shall be applicable in case of disputes between the Parties in case such disputes arise under the MTA**.** It is always recommended to negotiate this under the MTA already. In case of both parties existing and incorporated under the law of the same country this is fairly easy as there is only one law and system in question. In case of parties incorporated in different countries and legal regimes, there will be negotiations about the governing law and each party will lobby for the law of its own country.

In these cases, it might be useful to agree on a ***law of a third/neutral country*** (i.e. German provider and Dutch Recipient agreeing on a law of Belgium as governing law).

In choosing third/neutral country law, it is advisable to agree on a law and a system which is fairly similar to the party’s own law.

Other possibility is choosing a ***law of the defendant party*** as governing law in which case the party which is in breach of the agreement and sued by the other party is able to defend itself under its own legal system.

As for the jurisdiction- there are few options, but the two most common ones are choosing either courts or arbitration.

Below are some examples:

(a) This Agreement is subject to ………. law excluding its conflict of law provisions. The Parties shall attempt in good faith to resolve promptly any dispute, arising out of or relating to this Agreement by negotiation.

Any dispute that cannot be settled through negotiations shall be exclusively decided by the competent court in ……….. (place). The proceedings shall be conducted in ............ (language).

(b) Should disputes arise over the interpretation or execution of this Agreement, the Parties will try to obtain amicable reconciliation leading to a transaction. Any claim, controversy or dispute arising under this Agreement that cannot be amicably settled shall be governed by and construed in accordance with the laws of the defending Party. Jurisdiction and venue for any dispute arising shall be exclusively in the city where the defending Party is registered/has its statutory seat.

(c) The Parties shall endeavour to resolve all disagreements or difficulties that may arise concerning the implementation of this Agreement without appealing to courts. In case an amicable settlement cannot be reached despite all efforts, the dispute shall be finally settled by arbitration in accordance with the Rules of Arbitration of the International Chamber of Commerce by one or more arbitrators appointed in accordance with the said Rules. The place of arbitration shall be ……….. (place/city), …………….(country).

**13 Annexes**

1. List of the material transferred;
2. Description of the research project or programme and its aims;
3. Other directly relevant agreements, and their priority;
4. Ethical approval.

**Supplement I: Hazardous material**

**Transport arrangements**

In case of transfer of material with known hazardous properties, the Recipient is responsible for assuring that the material may be legally imported and received, and that the appropriate permits or other documents required for transit have been obtained. The Provider will comply with all applicable national and international rules for biosafety and biosecurity, and strictly follow applicable transport safety regulations (dangerous goods). Provider is also responsible for checking information provided by the Recipient as far as can be reasonably expected.

1. *Recipient agrees that all information provided to the Collection in connection with any order for Material is accurate and complete, and otherwise complying with applicable laws and regulations* (ECCO Core MTA).
2. *Recipient declares that all information provided to Provider in connection with the transfer of Material by the Provider to Recipient is true, correct and complete, including any information provided for use in obtaining any license, permit or other authorization with respect to orders placed by Recipient* (Westerdijk Institute MTA).

**Use conditions**The Recipient should be fully aware of the known hazardous properties of material received, have the appropriate containment level in place in the laboratory and storage facilities according to applicable national and international law and regulations, taken measures for physical security to prevent unauthorized access to lab and storage facilities, and have personnel trained and qualified to safely handle such material.

1. *The Material is understood to be experimental in nature and may have hazardous properties* (CORBEL MTA, HMGU SMTA EMMA, ESGI D5.2 MTA)*;*
2. *Recipient agrees that Material designated Risk Group 2 or above (as defined by the national regulations of the country where the Collection is located) may cause human disease, and that Modifications, or other Material, not so designated, may cause human disease under certain conditions* (ECCO Core MTA);
3. Material transferred by the Provider may have hazardous properties. Recipient recognizes the potential hazard of utilizing the Material and understands that the taking of appropriate precautions to minimize any health risk becomes fully their responsibility upon receipt of the Material;
4. *Recipient (therefore) assures that within their laboratory (i) access to the Material* *will be restricted to personnel capable and qualified to safely handle said Material* *and (ii) Recipient shall exercise the necessary care, taking into account the specific characteristics of the Material, to maintain and use it with appropriate precautions to minimize any risk of harm to persons, property, and the environment, and to safeguard it from theft or misuse* (ECCO Core MTA);
5. Recipient warrants that it is capable and qualified to safely handle and store the Material and to safeguard it from theft and misuse, in compliance with all applicable laws and regulations. This includes provision of appropriate containment for its safe handling, as determined by any risks known to be associated with the Material*.*

**Supplement II: : List of MTA template used as input for this tool**

For template documents that are public a link to access them is provided.

1. CORBEL MTA: Biological Material Transfer Agreement
<http://www.corbel-project.eu/innovation-helpdesk/templates.html>
2. MTA INSTRUCT: Material Transfer Agreement Outgoing
<https://www.structuralbiology.eu/documents/list/85/>
3. HMGU SMTA EMMA: “Filling instructions for Standard Material Transfer Agreements (SMTAs) for academic centres (non-profit)” including two templates, INFRAFRONTIER/EMMA (HelmholtzZentrum München), v.27062014
<https://www.helmholtz-muenchen.de/en/innovations/technology-transfer/material-transfer-agreement-mta/index.html>
4. EMMA INFRAFRONTIER OUT: Legally binding General Conditions concerning the Request and Transfer of Mutant Mouse Lines from the European Mouse Mutant Archive
<https://www.infrafrontier.eu/procedures/legal-issues/emma-repository-conditions-and-mtas>
5. ECCO Core MTA: ECCO Core Material Transfer Agreement for the supply of samples of biological material from the collection. European Culture Collections’ Organisation, version 1.0 February 2009.
<https://www.eccosite.org/ecco-core-mta/>
6. BBMRI LPC MTA: BBMRI-LPC Material Transfer Agreement, Biobanking and Biomolecular Resources Research Infrastructure – Large Prospective Cohorts, January 4th 2016 final version.
<http://www.bbmri-eric.eu/publications/>
7. ESGI D5.2 MTA: Material Transfer Agreement Consensus ESGI version 1.0