GUIDELINES FOR REVIEWING MTAs

GENERAL PRINCIPLES
- MTA-OUT: Ensure that K.U.Leuven material is fully protected & freedom-to-operate for K.U.Leuven Providing Scientist (in current & future research with material) is not compromised
- MTA-IN: Limit restrictions and hindrances on exploitation of IP generated by K.U.Leuven Recipient Scientist during research and on publications
- Preferred clauses for the different sections of the MTA can be found in the template agreements or UBMTA

1. PARTIES (MTA-IN & OUT)
- Ensure that correct legal name & address is used (Katholieke Universiteit Leuven + K.U.Leuven R&D (including VAT number BE419.052.173 in case MTA has financial aspects); also identify K.U.Leuven’s Research Group/Dept/scientist involved
- Recommended: other Party’s scientist signs for approval

2. RECITALS (MTA-IN & OUT)
- Refer to specific situation of the material transfer (if applicable): e.g. refer to other agreements with the other Party if applicable or describe the intended research
- If the materials are supplied for use in a collaboration or if the materials are subject to another agreement (e.g. with a third party), check the terms of the other agreement to ensure there are no conflicts or provide the materials under a collaboration agreement instead of an MTA.
- Check if there is anything in the Recitals that should really be in the body of the contract (Recitals may not be legally binding).

3. DEFINITIONS

Effective Date (MTA-IN & OUT)
- Usually date of last signing Party is sufficient. If another date is needed (e.g. transfer of material already took place), agree upon an effective date with the other Party.

Material - Modifications
- Ensure that Original Material is correctly identified and described (e.g. in Annex, cite publication); Modifications are all materials incorporating or containing the Material

1 A more in dept discussion of MTAs can be found in the UNICO Practical Guides MTAs
- Inventions are (patentable or non-patentable) results obtained by using the Material, including Modifications

MTA-in:
- check if the materials listed are what the K.U.Leuven scientist expects
- Assess definition of Material, Modifications & Derivatives in light of relevant IP clauses – to what extent does the definition of Materials cover materials generated by the Recipient using the Original Materials? Attempt to narrow or broaden definition as appropriate:
  * preferred (for biological material): Material = Original Material + Progeny + Unmodified Derivatives (+part thereof)
  * Avoid: Material includes Modifications and/or Modified Derivatives (and/or any material that could not have been made but for the Material).
  * Avoid using undefined terms in definition (e.g. derivatives, improvements, … without further clarification)
  * If (definition of) Material includes confidential information/documents: check relevant Publication and Confidentiality clauses.

- in case material is a transgenic animal - assess how crossbreeds are treated in light of relevant IP clauses. Option: treat crossbreeds as Modifications.

- (MTA-OUT) in case of Human Tissue: watch out
  → transfer should be conform the Biobank Board form (when available).
  → other issues:
  * has patient consent been obtained?
  *has ethical approval been obtained?
  *data protection/privacy - data and materials should be anonymised/coded?

Inventions vs Developments
MTA-IN: It may be preferred to distinguish “Inventions” (= inventions, knowhow, research results,… conceived or developed by using the Material or incorporating the Material) and “Developments” (= inventions, knowhow, research results … conceived or developed by using the Material, where the Material itself is not necessarily incorporated or future use of the Material is not necessary). “Developments” can often be linked to a larger scientific program: limit reach-through of provider. See also IP issues.
Commercial Purposes
- Ensure that definition is clear; in general: commercial purposes = generating revenues +
rights/licenses to commercial (non-academic) third parties -> commercial license should be
subject to (license) agreement or other (IP+royalty) provisions.
- Check that there are no conflicts with other agreements.
- UBMTA is somewhat less strict: “However, industrially sponsored/funded academic
research shall not be considered a use of the MATERIAL or MODIFICATIONS for
COMMERCIAL PURPOSES per se,…”.
- (MTA-IN) ensure & check that definition corresponds to use by K.U.Leuven Scientist.
- (MTA-OUT) A stricter definition is usually preferred.

4. USE OF THE MATERIAL

Research – Purpose for which Materials are provided (MTA-IN & OUT)
- Ensure that Research is correctly described (e.g. in Annex) and that it adequately explains
what the researcher intends to do with the materials.
- Depending on the Material and in light of the relevant IP clauses, the Research can be
more or less strictly formulated.

Restrictions on Use
- Since generally, Modifications (by definition) include the Material, restrictions on use of the
Material should be valid for use of the Modifications as well.

Security & Safety measurements
- (MTA IN) if necessary check with K.U.Leuven Recipient scientist if he can comply to
relevant (safety) regulations.

Use only by specified persons
- Use is usually restricted to persons under direct supervision at laboratory of Recipient
scientist.
- (particularly for MTA-IN) Remember: non-staff members (students, visiting scientist,
emeritus) are not included if the wording just refers to employees. sometimes additional
declaration of/agreement with non-K.U.Leuven personnel may be required (outside the MTA)
to comply with such provisions.

Use only for the Research
Sometimes onerous provisions can be associated with use outside the Research (e.g. use outside the defined Research means the Provider owns all arising IP). This is usually to be avoided (particularly for MTA-IN, may be useful in MTA-OUT in particular cases).

*Use only for non-commercial use*
- see comments in Section 3 (Definition Commercial Purposes)

*Non-use in animals and/or humans*
- MTA-IN: check with K.U.Leuven Recipient scientist if the Research does not involve these.

*Method of transport, handling & delivery*
- (MTA-IN) Sometimes special provisions are required for particular Materials (e.g. transgenic animals). This is usually taken care of by the scientists, when arranging transfer of the Material. If necessary, check with K.U.Leuven Recipient scientist.

*In case of chemicals or pharmaceuticals (MTA-IN & OUT)*
- Usually not allowed to make derivatives or to analyze the Materials (except as agreed upon in the Research)

5. **Intellectual Property**

Usually, Provider and Recipient have different, sometimes opposite, view points on IP issues. Many factors play a role: nature/uniqueness of the Material; broad or narrow definition of Research; definitions of Material-Modifications-Inventions-Developments, FTO and/or contamination of IP position….

5.1 **MTA-OUT**
- ensure that Material & Material included in Modifications remains property of Provider.
- recommended: Recipient may not apply for any patent which would claim Material or its use without permission (→ safeguard FTO of KUL Scientist) + Recipient has the obligation to report any patentable or commercially useful results
- ownership of Inventions:
  → try to balance KUL’s interest & investment in the Material with the research efforts of the Recipient Scientist (“equitable share of revenue”-clause, license back for research purposes (important for FTO of KUL Scientist)).
  → Recommended: “inventions are jointly owned” or “co-ownership will be negotiated between the parties based on the contribution of each Party” (+ optionally: ownership is
determined in accordance with applicable law -> note: claiming co-ownership based on only providing the material may be difficult!

5.2 MTA-IN
- reporting:
* check with KUL scientist.
* Preferably: (i) limit to Inventions only (& not results of the Research as such) or (ii) by providing a (draft of a) publication directly related to the Research.

- ownership of Inventions:
Limit restrictions and hindrances on generation & exploitation of IP generated by K.U.Leuven Recipient scientist during research with material. Some of these terms may prejudice K.U.Leuven’s ability to exploit its own IP (eg by contaminating K.U.Leuven’s ownership position with regard to the results of its research).

→ Avoid: ownership rights at least partially with Provider because of “providing the material” to Recipient.

→ Modifications vs Developments. Recommended: limit ownership rights to Inventions (directly related to the Research). Avoid reach-through claims on Developments (and thus usually the wider research project or results/inventions whereby no IPR directly relating to the material are needed) – check definition of Research if necessary.

→ Inventions vs Improvements of K.U.Leuven Background. In case of far reaching ownership claims and/or access rights to Inventions and/or results of the Research by Provider (usually in MTA with pharma company), stress this with Researcher. Exclude Improvements from definition of Inventions and include definition of K.U.Leuven Background & improvements thereof:

e.g. Notwithstanding the foregoing, PROVIDER acknowledges that RECIPIENT possesses certain inventions, processes, know-how, trade secrets, improvements, other intellectual properties and other assets, including but not limited to analytical methods, procedures and techniques, procedure manuals, personnel data, financial information, computer technical expertise and software, biological and other materials and information related thereto, which have been independently developed by RECIPIENT and which relate to its education, research and/or services activities (collectively “RECIPIENT Background”). PROVIDER and RECIPIENT agree that any RECIPIENT Background or improvements thereto which are used, improved, modified or developed by RECIPIENT under or during the term of this Agreement (but that are not related to the Material) are the sole and exclusive property of RECIPIENT.

→ If options have been granted – cap the time period for exercise; and cap the time period for license negotiations if the option is exercised.
6. PUBLICATIONS
* check with K.U.Leuven scientist if co-authorship is acceptable (MTA-in) or needed (MTA-out). Similar for citing a particular publication reference in any publication by the recipient.
* It is recommended to remind K.U.Leuven Recipient scientists to the publication procedure to be followed (and possible delays), acknowledgment/co-authorship of Provider scientist, etc.

- MTA-IN:
* Restrictions on publications of K.U.Leuven Recipient Scientists are to be limited (only for protection of IP or confidential information)!
* Acceptable timeframes for review of publications: submission to Provider for review 30 days prior to submission; modifications only for removal of Confidential Information + 30-60 days for delays for patenting IP in Provider’s Material. Recommended: If Provider does not react within the review period, he implicitly agrees with publication.
* If Provider has the right to delete its own confidential information from any draft publication, ensure that definition of Confidential Information does not include the Results of the Research.

- MTA-OUT:
* min. 90 days delay to assess patent applications

7. CONFIDENTIALITY (MTA-IN & OUT)
- (MTA-IN) Do not accept that “Confidential Information” includes the results of the Research
  → check Publication provisions
- Limit/define/clarify the scope of confidential information, in particular if KUL intends to publish
- General guidelines for NDAs apply:
  - Check interests of both Parties: do both Parties disclose confidential information?
    yes → confidential information = information which is identified/marked “confidential”
    + “information which is obviously confidential in nature”
    no (only info from other Party) → confidential information = information which is identified/marked “confidential” (optionally: “information which is obviously confidential in nature”)
    no (only KUL)
    → option 1: confidential information = information which is identified/marked “confidential” + “information which is obviously confidential in nature”
    → option 2: confidential information = any information disclosed by KUL
- Stress to internal researchers the importance of marking their confidential information or the necessity to write meeting minutes identifying the confidential information.

- **Very important!!! Exceptions** to the confidentiality obligations should be listed (see our template for specific provisions)

- Do not accept definition of confidential information as being "any and all information disclosed" unless alternative clauses are refused by counterparty and only KUL discloses confidential information.

- However (especially MTA-IN): advisable to limit confidential information to information related to the Material and disclosed at time of transfer of Material

- Assess if specific confidentiality provisions are required. If too elaborate, perhaps a separate NDA may be preferable.

- Recommended: Providing Party keeps invention disclosures and/or reports of Receiving Party confidential.

- Recommended: confidentiality obligations survive termination of MTA for a limited number of years \( \rightarrow \) default 5 yrs after termination date (but this depends on the nature of the confidential information).

### 8. WARRANTIES & LIMITATION OF LIABILITY

**Notes for MTA-IN and -OUT:**

- liability of a party under Belgian law: only when party has caused damages by wrongful act or negligence + real damage has been caused by such wrongful act or negligence

- you cannot exclude liability for own essential obligations, for willful misconduct or for liability under mandatory law; add the following clause after limitations of liability (if you do not add this, limitations of liability may be deemed null and void before a court of law):

  "**Notwithstanding the foregoing, a Party’s liability shall not be excluded or limited in the event and to the extent damages are caused by the willful misconduct of such a Party and any limitations or exclusions of liability under this Agreement shall not apply to the extent such liability cannot be limited or excluded by applicable law.**"

**MTA-out:**

\( \rightarrow \) no warranties

\( \rightarrow \) counterparty is liable for all use, storage, disposal of material by counterparty or any third party

\( \rightarrow \) exclude KUL liability for damages caused by material
limit (if provisions are required by the recipient) KUL’s liability for breach of the agreement to duly evidenced damages to the extent caused by the material breach of KUL’s obligations under the MTA

→ exclude indirect/consequential damages: “The liability of KUL for any breach of KUL’s obligations under this Agreement will not extend to any indirect damages or losses, or to any loss of profits, loss of revenue, loss of data, loss of contracts or opportunity (whether direct or indirect), even if the Recipient has advised KUL of the possibility of those losses, or even if they were within the Recipient's contemplation.”

MTA-in:
- Check if Provider requests KUL to indemnify Provider outside scope of KUL’s liability under applicable law (e.g. indemnification for acts not attributable to KUL) → avoid indemnification procedures and limit KUL’s liability to “duly evidenced damages to the extent directly caused by the use, storage, disposal of the material by KUL, except in the event of willful misconduct by the other Party”

- Exclude KUL’s liability for indirect/consequential damages (third party damages, loss of profits, etc…) caused by breach of KUL’s obligations under the MTA: “The liability of KUL for any breach of KUL’s obligations under this Agreement will not extend to any indirect damages or losses, or to any loss of profits, loss of revenue, loss of data, loss of contracts or opportunity (whether direct or indirect), even if the Provider has advised KUL of the possibility of those losses, or even if they were within the Provider's contemplation.”

- Optionally: insert financial cap on liability: “liability of KUL is limited to […]” / if agreement has financial aspects: “liability of KUL is limited to the amounts invoiced under this Agreement”

- Do not accept penalty clauses (no prove is necessary of fault by KUL / actual damages could be lower than penalty / not covered by insurance)

- Discuss issues regarding these provisions with LRD legal counsel.

9. TERM & TERMINATION (MTA-IN & OUT)
- Effective Date: see above under ‘Definitions’
- Include possibility to terminate MTA for breach of the agreement
- Termination date:
  → Default: termination of MTA: (i) upon completion of research, unless research scope is vague: fixed termination date (e.g. 1-2 years after effective date) or (ii) date of termination for breach
  → return of Materials or their destruction.
- Pay attention to clauses/obligations extending beyond term of the MTA (confidentiality, IP, publications)
- MTA provisions stay valid after termination in case of Modification (& Provider retains ownership of Material incorporated in Modifications)

10. GOVERNING LAW & JURISDICTION
- Recommended: Belgian law & Jurisdiction, particularly if KUL is provider
- Other law systems may be acceptable (if Belgian law is not acceptable for counterparty):
  (i) law of the defending party
  (ii) other European continental (not UK) law ('neutral' for KUL)
- if above is not acceptable by other Party, the alternative is to remain silent.
- if further negotiations are still needed, discuss issue with LRD legal counsel
- Exception: MTA-out (short) → silent on governing law & jurisdiction is OK, as risk is minimal and to speed up administrative approval.
- Applicability of Belgian law, excluding its conflict of law provisions

- Insert escalation procedure
“All disputes between the Parties in connection to this Agreement shall first be discussed in good faith between the Parties in order to try to find an amicable solution. If no solution can be found to settle the dispute within forty-five (45) days after giving notice of the dispute to the other Party, then the Parties will refer the matter to their higher management (executive level: CEO, President, Rector,...) who are at least authorized representatives for the Parties and who will meet and negotiate in good faith in an effort to resolve the dispute within thirty (30) calendar days after the referral. If the matter has not been resolved within such period, each Party is entitled to submit the dispute to the sole competent courts of Belgium”.
- Arbitration vs court -> preferred for MTA: court proceedings
- Arbitration should be quicker and secrecy can be maintained, but it is more expensive than court proceedings → when secrecy is a major concern, arbitration is usually preferred.
However, this is usually less crucial for K.U.Leuven

11. MISCELLANEOUS CLAUSES
Fee (MTA-in & out)
- Usually Materials are supplied free of charge or with a small fee to cover costs of shipping & handling. Sometimes a particular (commercial) price is stated. If a price is stated, adjust authorized persons according to “volmachtenregeling”!
**Other provisions (MTA-in & out)**
- sometimes other provisions can be included, e.g. entire agreement, force majeure, Notices,…

**12. Annexes (MTA-in & out)**
- ensure that Material and/or Research is specified in Annex

**13. Signatures (MTA-in & out)**
In accordance with "volmachtenregeling" for LRD + KUL scientist (ZAP) signs “for approval”

- Recommendation (for MTA-out): remind (in accompanying mail) the other Party about their authorized signatory