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MATERIAL & DATA TRANSFER AGREEMENTS

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NOTE

THIS WEBINAR IS BEING RECORDED!

WHAT ARE MTA'S & DTA'S

- MTAs & DTA's (collectively called "Transfer Agreements") are bilateral agreements, between two organizations, legally binding for the signing Parties, the "Provider" and the "Recipient".
- Material can be bio-specimens but also other types of materials, such as chemical compounds.
- The aim is to set the frame for collaboration among research entities and PIs when data and material are being transferred and define the rights of the Provider and the Recipient.
- They are entered into force for countries within EU as well as with third countries. National legislation applies.
- Public and private entities.

WHO NEEDS MTA'S & DTA'S AND WHY?

- Transfer Agreements provide a mechanism to the data and material owners, (Research Institutions- Universities-Companies-Researchers) in order to protect their interests and rights when transferring their data.
- These agreements promote, inter alia, secure data and material sharing within the research community and promote transparent research especially for materials that will be used in clinical or commercial development.
- BUT an agreement itself, could never protect or guarantee by itself that contractual parties act bona fides and respect the signed terms.
- National legislation will apply for enforcement.
- EU countries GDPR applies.

NEGOTIATION & EXECUTION OF THE AGREEMENTS

- All the terms for each transfer are agreed upon between the parties before actual transfer takes place.
- These agreements should NOT be negotiated by the researchers themselves.
- Responsible for negotiating the terms is the legal or technology transfer offices.
- Cooperation with Principal Investigator (PI) for describing data and material is essential.
- Both Parties and PIs must be fully aware of their contractual obligations.
- In case of breach contractual terms apply.(if transfer between countries international private law is applicable).

IMPORTANT INFORMATION INCLUDED IN TRANSFER AGREEMENTS

- Name and full address of the providing and recipient institution.
- Name, title, date of signature of the legal representative and of the P.I, who are signing the agreement.
- Practicalities regarding the purpose for which the data/material are being transferred.

IMPORTANT INFORMATION INCLUDED IN TRANSFER AGREEMENTS

- Detailed description of the data/material that are transferred and the transfer process.(dedicated Annex should be included in the Transfer Agreement.)
- Whereas all Annexes and Appendices form an integral part of the Agreements and are legally binding between the Parties!
- Costs related to the data/material transfer and the party that bears these costs and payment conditions need to be specified

IMPORTANT INFORMATION INCLUDED IN TRANSFER AGREEMENTS

- Description of how and by whom data/material will be used.
- Recipient’s acknowledges that the material/data shall at all times belong to the Provider.
- Confidentiality term, binding involved in research persons who will make use of data/material.
- If the DTA involves transfer of personal data from the EU to the third countries, compliance with the GDPR rules, is essential.
- Warranties and liability for each of the parties, waivers of responsibility, and further use of data/material.
- Effective date of Transfer Agreement (usually date of last signature).

IMPORTANT INFORMATION INCLUDED IN TRANSFER AGREEMENTS

- Intellectual Property issues e.g. copyright issues, acknowledgments based on contribution, industrial property-patents etc.
- The publishing Party shall transmit any material intended for publication to the other Party for review prior to its submission for publication (usually 20-30 days). In case of objection, Parties must resolve disagreement before publishing.
- The New IP deriving from material, can be owned by both the Provider and the Recipient in shares proportionate to their contributions to the creation (Record keeping!).
- In the case new knowledge which is patentable is produced, then the details of shares of the patent among inventors are to be finalized at a separate intellectual property agreement AFTER the new knowledge is produced and BEFORE patent application.
- Negotiation phase NOT only by researchers.

IMPORTANT INFORMATION INCLUDED IN TRANSFER AGREEMENTS

- Termination of the Agreement.
- Dispute resolution use of mediation and/or arbitration.
- Jurisdiction – choose the country whose jurisdiction shall apply or choose “silence of law” (Remain silent on jurisdiction. In this case international private law applies).
- Term that the Agreement supersedes any prior agreements, written or verbal.
- Term that the Agreement may be executed in counterparts and may be exchanged by electronic mail but that All properly executed counterparts will constitute one document.

IMPORTANCE OF TRANSFER AGREEMENTS

- Criticized for being “too complex” and bureaucratic burden to research.
- In March 1995, NIH put in place a simplified MTA systems for sharing non proprietary materials: Uniform Biological Materials Transfer Agreement (UBMTA)
- e.g. Addgene (nonprofit plasmid repository) uses implementing letter & an MTA for research conducted by nonprofit or academic institutions (https://www.addgene.org/techtransfer/)
- Litigation on a European level just 23 cases, Bubela et al. Use and Misuse of Material Transfer Agreements: Lessons in Proportionality from Research, Repositories, and Litigation, PLOS Biology, DOI:10.1371, February 3, 2015 (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4315468/)

TEMPLATES

- These Templates where drafted within the framework of the EU funded Project “**B3Africa**, **Bridging Biobanking and Biomedical Research Across Europe and Africa**” , by Prof. Jane Reichell, Dr. Santa Slokenberga and Dr. Olga Tzortzatou. Any use of these templates is exclusive responsibility of the respective users.

(For more information on the project and guidance on tools for material and data sharing within and across continents please see also: http://biobanklearning.iarc.fr/ethical-and-legal-guidange-and-tools-for-sample-and-data-sharing-within-and-across-continents/)

MATERIAL TRANSFER AGREEMENT - MTA

MTA Reference Number:

THIS Material Transfer Agreement ("MTA") is made with an effective date of [INSERT DAY, MONTH, YEAR] ("Effective Date")

BETWEEN:

[INSERT NAME AND ADDRESS OF Providing INSTITUTION] ("Provider" with [Dr NAME OF THE INSTITUTION's PI] as INSTITUTION's Principal Investigator hereunder; and

[INSERT NAME AND ADDRESS OF RECEIVING INSTITUTION] (the "Recipient"), with [Dr NAME OF RECEIVING INSTITUTE PI] as Receiving Institute's Principal Investigator hereunder;

(each a "Party" and collectively the "Parties").

Both Parties Agree that:
Subject to the terms and conditions of this Agreement, the Provider hereby agrees to provide, and the Recipient hereby agrees to accept, the Materials and Information specified below for such Purposes of Use and subject to such Restrictions on Use as specified below.
This Agreement is not a contract for sale of goods and nothing in this Agreement shall be considered as granting any license or right under any intellectual property rights or as representing any commitment by either Party to enter into any further agreement, by implication or otherwise.
This Agreement constitutes the entire understanding of the Parties with respect to the matters contained herein; superseding all prior oral or written understandings or communications between the Parties, and it may be modified only by an amendment signed by both Parties.
The Material is not for use in human subjects and will be strictly used either for teaching or for "not – for – profit" research purposes only and is provided free of charge.

1.
•Confidential Information means all information exchanged between both Parties within this Agreement.
- Material means the Material listed in Appendix 1 of this Agreement.
- Purpose means the content of the Appendix 2 of this Agreement.

•Research Group means Dr. ……as the Recipient Scientist and the members of his/her research laboratory.
- Providing Scientist means Dr……. who provides the material to the recipient scientist.

•New IP means that the Recipient's use or possession of the Material or Confidential Information under this Agreement indicatively results from the following: inventions, discoveries, facts, data, ideas, manners, methods or processes of manufacture, methods or principles of construction, chemical compositions or formulations, techniques, products,

prototypes, processes, know how, routines, specifications, drawings, trade secrets, technology methods, works in respect to which copyright subsists and other knowledge.
•Third Party means any party, apart from the Recipient and the Provider, either a legal entity or a person.
•Common Knowledge means any novel knowledge, information and/or data generated as a result of the collaboration between both Parties.

2. Ownership of the Material

The Provider will provide a sample of the Material to the Recipient and may also disclose Confidential Information to the Recipient. The Recipient acknowledges that the Material shall at all times belong to the Provider. The Recipient also acknowledges that the Confidential Information, including any copyright that subsists in any part of the Confidential Information, shall at all time remain the absolute property of their holder.

3. Transfer to Third Parties

The Recipient must ensure that only the Research Group has access to the material. Both the Material as well as the Confidential Information cannot be transferred to any Third Party without the prior written approval on behalf of the Provider. The Provider retains the right to deny any such transfer for whatever reason appears to be infringing its rights.

4. Confidentiality

The Recipient must use the Material and the Confidential Information of the Provider only for the Purpose and must not use the Material or Confidential Information of the Provider for any other reason.

5. Publications an Dissemination

The results arising from the use of the Material within the Purpose of this MTA may be published by the Parties either jointly, or separately. In order to avoid prejudice to any proprietary rights, the publishing Party shall transmit any material intended for publication to the other Party for review at least thirty [INSERT NUMBER] days prior to its submission for publication.
In absence of any objection within that period, the publication may proceed. The Parties agree to solve amicably any disagreement regarding the publication. If a solution cannot be reached the Parties agree not to proceed with the intended publication.
In any such publications, or any other written or oral public disclosures concerning the Research Project, the Parties' respective contribution will be duly recognized by acknowledgment or co-authorship, as appropriate and agreed between the Principal Investigators of the Parties. Notwithstanding the foregoing, neither Party will make any communication orally or in writing, public announcements or press releases concerning the terms of this MTA, the Research Project or any related matter without the prior written agreement of the other Party. Further, neither Party may use the other Party's name and logo without the prior written approval of that Party.

6. Intellectual Property

The New IP in the Material shall be owned by the Recipient. The Recipient grants to the Provider a perpetual, non–exclusive, royalty free license to use the New IP in the Material. The

New IP in a Derivative will be owned by both the Provider and the Recipient in shares proportionate to their contributions to the creation of the Derivative and each party must sign all documents required to record such ownership under this clause. The Recipient shall promptly disclose the New IP to the Provider and must provide a written report to the Provider containing the data and conclusions generated within thirty (30) days of the completion of the testing Purposes.

7. Warranties and Liabilities

The Recipient is responsible for the safe handling and storage of the Material in order to ensure that the Material will not cause any harm to any person or property. The Recipient acknowledges that the Material may be toxic, may contain infectious agents or other substances that are hazardous or dangerous or harmful to persons or property. Recipient agrees to waive all claims against the Provider, the Researcher, and their respective employees, agents and trustees, and to defend, indemnify and hold harmless the Provider, the Researcher and the respective employees, agents and trustees from all claims and damages asserted by Recipient or third parties arising from the use, storage, handling or disposal of the Materials, progeny and mutants thereof, or of products or information derived from there.

The Provider makes no representations and extends no warranties of any kind, either expressed or implied. There are no expressed or implied warranties of merchantability or fitness for a particular purpose. Moreover there are no expressed or implied warranties that the use of the material will not infringe any patent, copyright, trademark, or other proprietary rights.

8. Term of the Agreement

The term of this Agreement is …… years starting from the Effective Date. Upon conclusion of the Purpose, or immediate termination of this Agreement by the Provider because of breach by the Recipient, or termination of this MTA for any reason by either Party, the Recipient agrees to discontinue all use of the Provider Material and return all remaining Material to the Provider, or destroy it, as well as provide written notice upon thirty days (30 days).

8. Legislation

The Parties agree that this Agreement shall be governed by and construed in accordance with …….. Legislation. Exclusive place of venue / jurisdiction are the Courts in …….. Each Party shall retain one copy signed by both Parties.

9. Settlement of disputes

All claims, disputes, and controversies arising out of or in relation to the performance, interpretation or enforcement of this agreement, including but not limited to breach thereof, unless amicably settled, shall be referred to mediation before, and as a condition precedent to, the initiation of any proceeding, including arbitration.

10. Miscellaneous

1.This MTA will in no way be construed as creating the relationship of principal and agent, of partnership in law or of joint venture as between the Parties or any other person involved in the Research Project.

2.This MTA may be executed in counterparts and may be exchanged by electronic mail in .pdf format. All properly executed counterparts will constitute one document.

3.This MTA may be amended only by written agreement duly signed by the authorized representatives of the Parties. This MTA is personal to the Parties and neither Party will assign, transfer, or deal in any other manner with its rights and obligations under this MTA without the express prior written consent of the other Party.

This Agreement is duly signed on behalf of the parties as follows:

Signed for and on behalf of the Provider: Signed for and on behalf of the Recipient:

_____

_____

Provider Principal Investigator Recipient Principal Investigator
Name: Name:
Title: Title:

_____

_____

Legal Representative of Provider Legal Representative of Recipient
Name: Name:
Title: Title:

_____

Date:

_____

Date:

ANNEX I – Material description
ANNEX II - Research Project

DISCLAIMER: This is a Sample Template. It has been prepared by Olga Tzortzatou, Santa Slokenberga, Jane Reichel for the purposes of B3Africa project. Any use of this Sample Template is exclusive responsibility of the respective users.

DATA TRANSFER AGREEMENT
(OUTGOING FOR DATA TRANSFER WITHIN THE EU)

DTA Reference Number: [TO BE INSERTED]

THIS Data Transfer Agreement ("**DTA**") is made **effective in …….as of / / ("Effective Date"),**

BETWEEN:

[INSERT NAME AND ADDRESS OF PROVIDER INSTITUTION] ("ProviderProvider"), with [Dr NAME OF THE INSTITUTION's PI] as INSTITUTION's Principal Investigator hereunder; and

[INSERT NAME AND ADDRESS OF RECEIVING INSTITUTION] (the "**Recipient**"), with [Dr NAME OF RECEIVING INSTITUTE PI] as Receiving Institute's Principal Investigator hereunder;

(each a "**Party**" and collectively the "**Parties**").

The Parties AGREE AS FOLLOWS:

1. This DTA will start on the Effective Date stated above.
2. The following data and all tangible representations thereof (which includes any written information identified to the Receiving Institute as "Confidential" and transferred by the ProviderProvider to the Recipient together with the data):

   [INSERT SHORT DESCRIPTION OF THE DATA TO BE TRANSFERRED],

   held by the Provider ("**Data**") will be made available to the Recipient for the purpose of the collaboration between the Parties in conducting the project entitled:

   [INSERT PROJECT TITLE] (the "**Research Project**");

   The Data and the Research Project are further described in **ANNEX II**.

3. The Provider will transfer the Data to the Recipient upon receipt of the fully-executed copy of this DTA acknowledging and agreeing to its terms.

4. **Annex I** of this DTA describes the obligations of the Recipient regarding the security it will apply to the Data it receives from the Provider under this DTA. ANNEX I and II 1 (*and any other annexes or appendices*) forms an integral part of this DTA and is legally binding between the Parties.

Authorized use of the Data:

5. The Data are made available to the Recipient under this DTA solely for non-profit research, and solely in connection with and for the purpose of the Research Project, free of charge.

Other than for and within the purpose of the Research Project, as described in Appendix 1, the Data will not be further transferred, distributed to third parties or otherwise used without the Provider's prior notice at least one (1) month before the indented transfer. A written approval or justified rejection shall be provided, to the Recipient by the Provider, within twenty (20) days from the request. Receiving Institution hereby agrees to quit from any right opposing against the Provider's final decision, which shall be binding for both Parties from the date it is issued.

6. The Data will be used only and solely by the Recipient and Recipient's authorized and trained personnel, under the responsibility and supervision of the Recipient's Principal Investigator, for the purposes hereof exclusively and under no less stringent obligations than as provided for in this DTA.

7. The Recipient will not seek to reverse engineer or de-anonymize the Data in any way whatsoever and will comply with all relevant and applicable legislation and ethical requirements. The Recipient further represents and warrants that the use of the Data will not violate any acts, laws, by-laws, rules and regulations applicable to the Data.

Confidentiality:

8. The Recipient agrees to keep the Data in confidence, except for Data that: (a) are publicly known, or available from other sources which are not under a confidentiality obligation to the source; (b) have been made available by its owners without a confidentiality obligation; (c) are otherwise already known by or available to the Recipient without a confidentiality obligation; or (d) are required to be disclosed by operation of law, provided that the Recipient immediately so notifies the Provider in writing and provides adequate opportunity for the Provider to object to, or restrict, such disclosure or request confidential treatment thereof.

Intellectual property rights and ownership:

9. Except for the rights explicitly granted hereunder, nothing contained in this DTA is construed as conveying any rights under any patents or other intellectual property which either Party may have or may hereafter obtain.

10. The Provider retains ownership and/or custody of the Data as applicable and has the unrestricted right to use, disclose or transfer the Data to any third parties for any other purposes. The Recipient acknowledges and agrees that nothing contained in this DTA is deemed to grant to the Recipient any intellectual property rights in any of the Data provided hereunder. The Recipient furthermore agrees to provide the Provider with a copy of any derived data/variables arising from the use of the Data.

11. The Parties agree that the ownership of any intellectual property rights in the results that may arise out of the Research Project will be owned by the Provider and the Recipient and they shall enter into a separate agreement in order to negotiate in good faith the terms and conditions under which they shall distribute their shares. The Parties will keep all results confidential, and shall only disclose them to third parties under obligations of confidentiality, unless or until the Parties agree that such confidentiality is no longer necessary. In case of disagreement regarding the disclosure or not of the results to third parties, the Parties agree herewith to refrain from disclosing them.

12. Subject to the above provision, the Parties may use the results arising out of the Research Project for their own research/academic purposes only. Any other use (e.g. for commercial use) will be subject to a separate agreement .

Publications:

13. The results arising from the use of the Data within the purpose of the Research Project may be published by the Parties either jointly or separately. In order to avoid prejudice to any proprietary rights, the publishing Party shall transmit any material intended for publication to the other Party for review at least thirty [INSERT NUMBER] days prior to its submission for publication. In absence of any objection within that period, the publication may proceed. In case of disagreement regarding the publication Parties agree to amicably reach a common decision otherwise abstain from publishing. In any such publications, or any other written or oral public disclosures concerning the Research Project, the Parties' respective contribution will be duly recognized by acknowledgment or co-authorship, as appropriate and agreed between the Principal Investigators of the Parties.

14. Notwithstanding the foregoing, neither Party will make any communication orally or in writing, public announcements or press releases concerning the terms of this DTA, the Research Project or any related matter without the prior written agreement of the other Party. Further, neither Party may use the other Party's name and logo without the prior written approval of that Party.

Warranties and liability:

15. The Provider makes no warranty of the fitness of the Data for any particular purpose or any other warranty, either express or implied.

16. The Recipient agrees that, except as may explicitly be provided in this DTA, the Provider has no control over the Receiving Institute's use of the Data hereunder. Consequently, the Recipientagrees that the Provider shall not be liable for such use, or any loss, claim or damages which may arise from or in connection with such use.

17. Each Party represents and warrants that: (a) it has the full corporate right, power and authority to enter into this DTA and to perform its obligations under this DTA; (b) the execution of this DTA and the performance of its obligations do not and will not conflict with or violate any agreement to which it is a party or by which it is bound; and (c) this DTA has been executed by a duly authorized representative.

18. The term of this Agreement is ……. ( ) years starting from the Effective Date. Upon conclusion of the Purpose, or immediate termination of this Agreement by the Provider because of breach by the Receiving Institution, or termination of this DTA for any reason by either Party, the Receiving Institution agrees to discontinue all use of the data, as well as provide written notice upon thirty days (30 days).

Miscellaneous:

19. This DTA is governed by (indicate the applicable law unless Parties agree silence of law).

20. All claims, disputes, and controversies arising out of or in relation to the performance, interpretation or enforcement of this agreement, including but not limited to breach thereof, unless amicably settled, shall be referred to mediation before, and as a condition precedent to, the initiation of any proceeding, including arbitration.

21. This DTA may be amended only by written agreement duly signed by the authorized representatives of the Parties. This DTA is personal to the Parties and neither Party will assign, transfer, or deal in any other manner with its rights and obligations under this DTA without the express prior written consent of the other Party.

22. Either Party may terminate this DTA upon giving the other Party 30 days written notice.

23. Upon expiry or earlier termination of this DTA, the Recipient will securely dispose of the Data or return and delete the Data to the Provider as agreed between the Parties.

24. This DTA will in no way be construed as creating the relationship of principal and agent, of partnership in law or of joint venture as between the Parties or any other person involved in the Research Project.

25. This Agreement sets forth the entire understanding between the parties and supersedes any prior agreements, written or verbal.

26. This DTA may be executed in counterparts and may be exchanged by electronic mail in .pdf format. All properly executed counterparts will constitute one document.

This DTA is duly signed on behalf of the Parties as follows:

Signed for and on behalf of the Receiving Institute:	Signed for and on behalf of the Provider:
_____	_____
The Receiving Institute's Authorized Official Name: Title: Date:	the Provider's Authorized Official Name: Title: Date:

Read and acknowledged by the Principal Investigator of the Receiving Institute:	Read and acknowledged by the Principal Investigator of the Provider:
Name:	Name:
Title:	Title:
Email:	Email:
Date:	Date:

DISCLAIMER: This is a Sample Template. This template is based the World Health Organization International Agency for research on cancer publicly available document NO. CIRC 72 (09/2017), as modified by Santa Slokenberga, Jane Reichel, and Olga Tzortzatou for the purposes of B3Africa project. Any use of this Sample Template is exclusive responsibility of the respective users.

On the importance of DTA/MTA and essential elements see Mascalzoni D. et al. “International Charter of Principles for Sharing Bio-Specimens and Data”, EJHG (2015) 23, 721-728.

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Q&A

ASK US WHAT YOU WANT TO KNOW…