B3Africa Webinar
Material Transfer Agreements/Data Transfer Agreements

Elodie Caboux, IARC

Jane Reichel, UU

B3 Africa
BRIDGING BIOBANKING AND BIOMEDICAL RESEARCH
ACROSS EUROPE AND AFRICA

MTA/DTA

Learning objectives. At the end of the training sessions, participants will be able to:

- Explain the purpose of a MTA/DTA;
- Determine when a MTA/DTA is necessary;
- Integrate the appropriate information into a MTA/DTA;
- Determine who signs the MTA/DTA;
- Assign references to MTA/DTA;
- Follow the progress/end of the MTA/DTA.

Target audience. Researcher, scientists, administrative personnel, biobank manager, laboratory technician, bioinformatician, ELSI specialist, IT manager, IT technician

To know you better

- Are you involved in preparing MTA/DTA for biological material/data transfers?

  Yes or No

- Do you have your own MTA/DTA template?

  Yes or No

1) Explain the purpose of a MTA/DTA

In your opinion, what is the purpose of a MTA/DTA?

(multiple answers)

1) Explain the purpose of a MTA/DTA

In your opinion, what is the purpose of a MTA/DTA?
(multiple answers)

A) It is a protocol for material/data transfer

B) It is a contract for material/data transfer

C) It is a document between individuals

D) It is a document between institutions

E) It defines the rights and responsibilities

Purpose of a MTA/DTA

An agreement or contract (legally binding document) that governs the transfer of research materials and/or data between two organizations, when the recipient intends to use them for research purposes. It defines the rights and obligations of the provider and the recipient with respect to the use of the materials and/or data.

2) Determine when a MTA/DTA is necessary;

In your opinion, when is a MTA/DTA necessary?

(multiple answers)

2) Determine when a MTA/DTA is necessary;

In your opinion, when is a MTA/DTA necessary? (multiple answers)

A) When access to samples and data is required

B) When sharing of samples and data

C) To define the policy on disclosing data

D) To define the policy on doing research

E) To define the policy on governing the biobank

A MTA/DTA is necessary

- For any access or sharing of samples/data
- To prevent disclosure of participant-identifiable data to researchers or any unauthorized person
- To include the obligations, rights and responsibilities of the researcher before receiving/sending the samples/data
- To define intellectual property
- Should be put in place before the transfer of samples/data

3) Integrate the appropriate information into a MTA/DTA;

In your opinion, what information should be integrated into a MTA/DTA?

(multiple answers)

3) Integrate the appropriate information into a MTA/DTA;

In your opinion, what information should be integrated into a MTA/DTA? (multiple answers)

A) Name of the participant(s)
B) Description of samples/data to be transfered
C) Information on the planned use of samples/data
D) Protocol used for processing samples or analysing data
E) Return of samples/data/results

Information to be integrated in a MTA/DTA

- description of samples and data to be transfered
- use the samples and data in line with the biobank access policy;
- adhere to applicable laws, regulations, and guidance;
- not to allow the further distribution of samples or data;
- dispose of, or return, the samples and data after use;
- guarantee confidentiality and data protection;
- not attempt to re-identify participants;

Information to be integrated in a MTA/DTA (cont'd)

- provide traceability of samples;
- inform the biobank of any issues with the data or samples.
- return research results in the form of individual results, raw data, an interim/final report, relevant publications, or patent applications;
- cite or acknowledge the biobank (or PIs responsible for the collection) in publications, patents, or other documents, or include a citation in any published work to a specific publication describing the biobank; and
- respect intellectual property terms;

4) Determine who signs the MTA/DTA

Within your institution/ team, who signs MTAs/ DTAs?

(multiple answers)

4) Determine who signs the MTA/DTA

Within your institution/ team, who signs MTAs/ DTAs? (multiple answers)

A) Human Resources Officer
B) Legal representative/Administrative Officer
C) Director of the Institution
D) Responsible of the biobank
E) Scientist in charge of the research project

Who signs the MTA/DTA

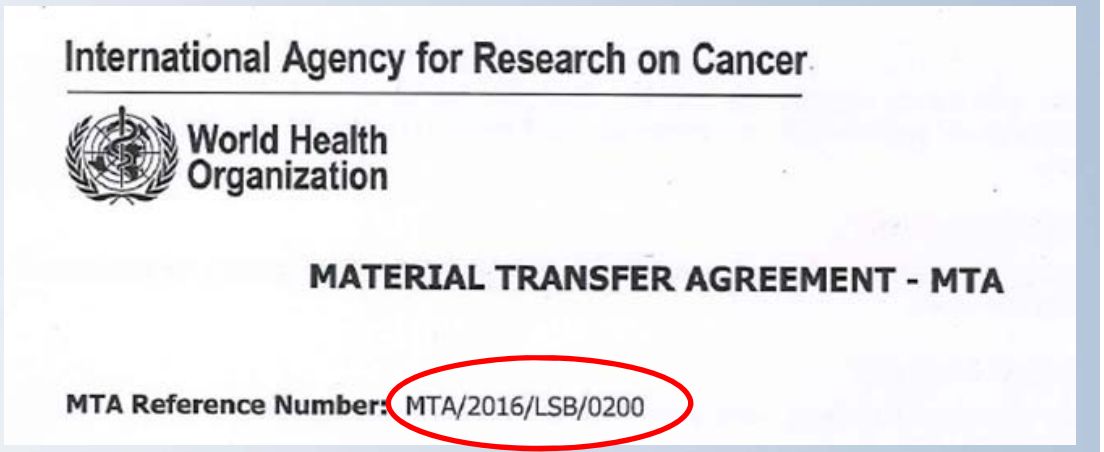
- The MTA must be signed by a person who is authorized to approve legal documents on behalf of the institution

- The scientist responsible of the research project

5) Assign references to MTA/DTA;

IARC model:

- Year when the MTA is established
- Group/department in charge of the project
- Import or export acronym
- Increment number



6) Follow the progress/end of the MTA/DTA

- Number of samples exchanged/shipped in line with what is agreed on the MTA
- Term of agreement: samples exchanged within the valid period
- Agreed purpose of use
- Return of samples at the end of the project
- Amendment if necessary to complete the project
- End or progress report

Management of IARC MTAs through a database for recording and follow-up

Year of creation	Type of MTA	MTA date	Project name	IARC contact name	Shipment date	SHIP reference	Number of samples sent (details)	Number of samples sent (total)	TOTALLY SENT	Sample type	Provider's name	Provider's institution	Provider's country	Recipient's name	Recipient's institution	Recipient's country	Third party	Duration of the Agreement	Estimated end of the Agreement	EXPIRED	Comments	Signed copy	Date of request	Date of creation	Operator
2017	Import	07-Mar-17	Influence of Metabolic Syndrome and Circulating Bile Acid Levels on the Development of Hepatocellular Carcinoma and Biliary Tract Cancers	M. Jenab	22/05/2017	SHIP/2017/DG/LSB/1212	242	242	YES	Citrated plasma and/or erythrocyte samples from a maximum total of 242 Danish subjects (cases of liver biliary tract cancers and their matched controls)	Anne Tjønneland	Danish Cancer Society Research Center	Denmark	M. Jenab	IARC	France	Yes	3 years	March 2020		4 sets of aliquots will be sent to RIVM, the Netherlands	Yes	22-Jan-17	24-Jan-17	E. Caboux
2017	Import	07-Mar-17	Influence of Metabolic Syndrome and Circulating Bile Acid Levels on the Development of Hepatocellular Carcinoma and Biliary Tract Cancers	M. Jenab	15/05/2017	SHIP/2017/DG/LSB/1212	242	242	YES	1ml of a maximum total of 242 citrated plasma of Danish cases of liver biliary tract cancers and their matched controls	Anne Tjønneland	Danish Cancer Society Research Center	Denmark	M. Jenab	IARC	France	Yes	3 years	January 2020		100µl of plasma will be sent to Instituto de Investigación Sanitaria La Fe, Valencia	Yes	22-Jan-17	24-Jan-17	E. Caboux
2017	Export		Advanced Glycation End Products: Are exposures associated with colorectal cancer risk and survival?	M. Jenab	30/05/2017	SHIP/2017/DG/LSB/1217	2088	2088	YES	70ul of citrated plasma from each of 2088 EPIC subjects (1044 colorectal cancer cases and 1044 matched control subjects)	M. Jenab	IARC	France	Casper Schalkwijk	Maastricht University Medical Center	The Netherlands	No	3 years	January 2020				22-Jan-17	25-Jan-17	E. Caboux
2017	Export	26-Feb-17	To investigate the role of DNA methylation in breast cancer development	Z. Herceg	22/02/2017	SHIP/2017/DG/EGE/1196	2	2	Yes	2 Vials of frozen human breast cancer cell line	Z. Herceg	IARC	France	Rabih Murr	University of Geneva Medical Center	Switzerland	No	6 months	August 2017			Yes	12-Feb-17	14-Feb-17	E. Caboux

IARC out-going MTA template

International Agency for Research on Cancer

World Health Organization

MATERIAL TRANSFER AGREEMENT - MTA

MTA Reference Number: [.....] [to be provided by LSB]

Subject to the terms and conditions of this Agreement, the IARC/WHO hereby agrees to provide, and the Institute 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.

In this Agreement, the following expressions shall have the following meanings:

1. "Providing Institute":

"IARC/WHO"
The International Agency for Research on Cancer (IARC) of the World Health Organization (WHO), 150 cours Albert Thomas, 69372 Lyon cedex 08, France.

Contact: [.....] [insert name and e-mail address of IARC PI or LSB contact details]

2. "Receiving Institute":

[.....] [insert name and full address of Institute]

Contact: [.....] [insert name and e-mail address of Institute's PI]

3. "Materials":

[.....] [insert precise description of Materials], held by IARC/WHO, and made available to the Receiving Institute hereunder in a quantity of [.....]. [insert quantity to be provided by IARC/WHO]

4. "Information":

Any information, unpublished or otherwise, owned by IARC/WHO and communicated to the Receiving Institute by IARC/WHO during the term of this Agreement relating to the Materials, their production, properties and/or experimental results observed using the Materials or any derivatives therefrom.

5. "Purposes of Use":

The Materials are provided for the following purposes, as more fully described in Annex 2 (the "Research Project"):

[.....] [insert a brief description of the purposes for which the Materials, and products incorporating or developed with the Materials, may be used] [Add reference to a specific grant, etc. when appropriate]

6. "Restrictions on Use":

The Materials shall not be used for any purpose other than the Purposes of Use. In particular, the Materials shall not be used for gain or commercial profit but for teaching or not-for-profit research purposes only.

7. "Term of Agreement":

This Agreement shall remain in full force and effect as from the date of its signature by both parties for a duration of [.....]. [specify duration/may be based on project duration]

8. "Materials Charges":

[Please keep an applicable clause and delete the rest]

<As per price list> The cost of sample retrieval, processing –including DNA extraction– packaging and shipment will be charged by IARC/WHO to the Receiving Institute at the latest rate posted on IARC/Biobank website (*http://ibb.iarc.fr/about/ibb_services.php*).

<As per agreed unit price> The cost of sample retrieval, processing –including DNA extraction– packaging and shipment will be charged by IARC/WHO to the Receiving Institute at the following agreed rate. [list unit price below]

<Lump sum amount> The cost of sample retrieval, processing –including DNA extraction– packaging and shipment will be charged by IARC/WHO to the Receiving Institute for the total lump sum amount of [.....]. [amount/currency in words].

<Free of charge> The sample retrieval, processing –including DNA extraction– packaging and shipment will be provided free of charge.

9. "General Conditions":

The General Conditions attached hereto under Annex 1 form an integral part of this Agreement.

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

Signed for and on behalf of IARC/WHO:	Signed for and on behalf of Receiving Institute:
_____	_____
IARC/WHO Responsible Scientist Name: Title:	Receiving Institute's Responsible Scientist Name: Title:
_____	_____
IARC/WHO Authorized Official Name: Tamas Landesz Title: Director of Administration and Finance	Receiving Institute's Authorized Official Name: Title:
_____	_____
Date:	Date:

CIRC 41 (01/2014)

IARC in-coming MTA template

INSERT LOGO HERE

MATERIAL TRANSFER AGREEMENT - MTA

MTA Reference Number: [...]

SCHEDULE OF PARTICULARS

Subject to the terms and conditions of this Agreement (which expression means this Schedule and the General Conditions attached hereto), the Institute hereby agrees to provide, and IARC/WHO 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.

In this Agreement, the following expressions shall have the following meanings:

1. "Providing Institute":
[.....] [insert name and full address of Institute].

2. "IARC/WHO":

The International Agency for Research on Cancer, World Health Organization, 150 cours Albert Thomas, 69372 Lyon cedex 08, France.

3. "Materials":

[.....][insert precise description of Materials], held by the Institute, and made available to IARC hereunder in a quantity of ..... [insert quantity to be provided to IARC].

4. "Information":

Any information, unpublished or otherwise, owned by the Institute and provided by the Institute to IARC during the term of this Agreement relating to the Materials, their production, properties and/or experimental results observed using the Materials or any derivatives therefrom.

5. "Purposes of Use":

The Materials are provided to [.....] [insert a detailed description of the purposes for which the Materials, and products incorporating or developed with the Materials, may be used].

6. "Restrictions on Use":

The Materials shall not be used for any purpose other than the Purposes of Use.

7. "Term of Agreement":

This Agreement shall remain in full force and effect as from the date of its signature by both parties for a duration of [.....][specify duration/or based on project duration].

8. "Materials Charges":

Materials will be provided free of charge.

9. "General Conditions":

The General Conditions attached hereto form an integral part of this Agreement.

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

Signed for and on behalf of IARC/WHO:	Signed for and on behalf of Providing Institute:
_____	_____
IARC/WHO Responsible Scientist Name: Title:	Providing Institute's Responsible Scientist Name: Title:
_____	_____
IARC/WHO Authorized Official Name: Tamas Landesz Title: Director of Administration and Finance	Providing Institute's Authorized Official Name: Title:
_____	_____
Date:	Date:

B3 Africa
BRIDGING BIOBANKING AND BIOMEDICAL RESEARCH ACROSS EUROPE AND AFRICA

International Agency for Research on Cancer

World Health Organization

MATERIAL TRANSFER AGREEMENT - MTA

MTA Reference Number: MTA/2016/LSB/0200

Subject to the terms and conditions of this Agreement, the IARC/WHO hereby agrees to provide, and the Institute 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.

In this Agreement, the following expressions shall have the following meanings:

1. "Providing Institute":

"IARC/WHO"
The International Agency for Research on Cancer (IARC) of the World Health Organization (WHO), 150 cours Albert Thomas, 69372 Lyon cedex 08, France.

Contact: Maimuna Mendy, mendym@iarc.fr

2. "Receiving Institute":

Imperial College London, St. Mary's Hospital Campus, South Wharf Street, London W2 1NY, UK
Contact: Simon D Taylor-Robinson, s.taylor-robinson@imperial.ac.uk

3. "Materials":

Urines from Prolifica project, held by IARC/WHO, and made available to the Receiving Institute hereunder in a quantity of 108 samples.

4. "Information":

Any information, unpublished or otherwise, owned by IARC/WHO and communicated to the Receiving Institute by IARC/WHO during the term of this Agreement relating to the Materials, their production, properties and/or experimental results observed using the Materials or any derivatives therefrom.

5. "Purposes of Use":

The Materials are provided for the following purposes, as more fully described in Annex 2 (the "Research Project"):

Urines will be used for Metabolic profiling experiments (reference: Prolifica Consortium Agreement, GR-IARC-2010-01-14-02 and MTA/2016/IMP/LSB/0199).

6. "Restrictions on Use":

The Materials shall not be used for any purpose other than the Purposes of Use. In particular, the Materials shall not be used for gain or commercial profit but for teaching or not-for-profit research purposes only.

7. "Term of Agreement":

This Agreement shall remain in full force and effect as from the date of its signature by both parties for a duration of 1 year.

8. "Materials Charges":

The sample retrieval, processing –including DNA extraction– packaging and shipment will be provided free of charge.

9. "General Conditions":

The General Conditions attached hereto under Annex 1 form an integral part of this Agreement.

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

Signed for and on behalf of IARC/WHO:	Signed for and on behalf of Receiving Institute:
IARC/WHO Responsible Scientist Name: Maimuna Mendy Title: Head of IARC Biobank	Receiving Institute's Responsible Scientist Name: Simon Taylor-Robinson Title: Professor
IARC/WHO Authorized Official Name: David Allen Title: Director of Administration and Finance	Receiving Institute's Authorized Official Name: Jonathan Weber Title: Professor
Date: 29.2.16	Date: 22/02/16

ANNEX 1 - GENERAL CONDITIONS

1. Use

1.1 The Materials and Information are supplied by IARC/WHO to the Receiving Institute solely for the Purposes of Use and subject to the Restrictions on Use as set out herein.

1.2 The Materials and Information shall not be used in human subjects, in clinical trials, or for diagnostic purposes involving human subjects without the written consent of IARC/WHO.

1.3 Other than for and within the Purposes of Use, and as specifically described in Annex 2, the Materials and Information shall not be transferred, offered for sale or otherwise used, without the prior written agreement of IARC/WHO.

1.4 The Receiving Institute shall allow only parties who have a need to know for the Purposes of Use and who are bound by similar obligations of confidentiality and Restrictions on Use as contained in this Agreement to have access to the Materials and Information.

1.5 The Receiving Institute shall require any party handling and/or using the Materials and Information to comply with all relevant laws, rules and regulations applicable to the use of such Materials and Information.

2. Confidentiality

2.1 The Information may incorporate confidential information of IARC/WHO. Accordingly, if and to the extent any such Information is clearly marked by IARC/WHO as "confidential", the Receiving Institute shall during the Term of this Agreement and for a period of three (3) years following its termination, treat such Information confidential and only disclose it under like obligations of confidentiality and Restrictions on Use as those contained herein. The Receiving Institute shall be deemed to have fulfilled its obligations, if it exercises at least the same degree of care in maintaining confidentiality as it would in protecting its own confidential information.

2.2 The above mentioned obligations of confidentiality shall not apply to Information which:

(i) can be shown to have been known to the Receiving Institute at the time of its acquisition from IARC/WHO; or

(ii) is acquired from a third party, not in breach of any confidentiality obligation to IARC/WHO; or

(iii) is independently devised or arrived at by, on behalf of, or for Receiving Institute without access to the Information; or

(iv) enters the public domain otherwise than by breach of the undertakings set out in this Agreement.

3. Rights

3.1 Except for the rights explicitly granted hereunder, nothing contained in this Agreement shall be construed as conveying any rights under any patents or other intellectual property which either party may have or may hereafter obtain.

3.2 IARC/WHO shall retain ownership of the Materials and Information and shall have the unrestricted right to use, assign or distribute the Materials and Information to any third parties for any other purposes. The Receiving Institute acknowledges and agrees that nothing contained in this Agreement shall be deemed to grant to the Receiving Institute any intellectual property rights in any of the Materials or Information provided hereunder.

4. Publications

4.1 Subject to IARC/WHO's proprietary rights, the results obtained through use of the Materials within the Purposes of Use may be published by the Receiving Institute. In order to avoid prejudice to IARC/WHO's proprietary rights, the Receiving Institute shall transmit any material intended to be published to the IARC/WHO for review at least thirty (30) days prior to its submission for publication. In absence of any objection by IARC/WHO within that thirty (30) days period concerning prejudice to its proprietary rights, the publication may proceed, provided, however, that IARC/WHO shall be duly acknowledged in such publication.

5. Warranties and Liabilities

5.1 IARC/WHO makes no warranty of the fitness of the Materials for any particular purpose or any other warranty, either express or implied. However, to the best of IARC/WHO's knowledge, the use of the Materials and/or Information within the Purposes of Use shall not infringe on the proprietary rights of any third party.

5.2 The Receiving Institute agrees that, except as may explicitly be provided in this Agreement, IARC/WHO has no control over the use that is made of the Materials or the Information by the Receiving Institute in accordance with the terms of this Agreement. Consequently, the Receiving Institute agrees that IARC/WHO shall not be liable for such use.

6. Amendment, Extension and Termination

6.1 Any amendment to this Agreement, including extension of the Term of Agreement, shall be valid only by written amendment executed by the duly authorized officers of both parties.

6.2 Notwithstanding the conditions set forth in this Agreement in particular the Purposes of Use, Restrictions on Use and Confidentiality obligations, either party may terminate this Agreement with sixty (60) days prior written notice to the other party.

6.3 When the Research Project is completed or this Agreement is terminated, whichever comes first, any unused Materials will either be destroyed in compliance with all applicable statutes and regulations or will be returned to IARC/WHO by the Receiving Institute upon IARC/WHO's request.

7. Miscellaneous

7.1 Nothing contained in this Agreement shall be construed as a waiver of any of the privileges and immunities enjoyed by IARC, as part of the World Health Organization (WHO) and the United Nations system, under national or international law, and/or as submitting IARC to any national court jurisdiction.

7.2 Nothing in this Agreement shall be interpreted as establishing a partnership between the parties or establishing one party as the agent of the other or conferring a right on one party to bind the other, except as may be specifically set out herein.

7.3 Any dispute relating to the interpretation or application of this Agreement shall, unless amicably settled, be subject to conciliation. In the event of failure of the latter, the dispute shall be settled by arbitration. The arbitration shall be conducted in accordance with the modalities to be agreed upon by the parties or, in the absence of agreement, with the rules of arbitration of the International Chamber of Commerce. The parties shall accept the arbitral award as final.

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

CIRC 41 (01/2014)

THANK YOU FOR YOUR ATTENTION

B3 Africa
BRIDGING BIOBANKING AND BIOMEDICAL RESEARCH
ACROSS EUROPE AND AFRICA