**Material Transfer Agreement for Deposit of Biological Material**

This document (hereinafter referred to as “MTA-deposit”) sets forth the terms and conditions between NITE Biological Resource Center (hereinafter referred to as “NBRC”) and the DEPOSITOR on the deposit of the BIOLOGICAL MATERIAL stated in the attached “Accession Form for Deposit” (hereinafter referred to as “AF”).

**Article 1 (Definitions)**

Definitions of the terms used in this MTA-deposit shall be as follows.

* 1. “**BIOLOGICAL MATERIAL**” means microorganisms (bacteria, actinomycetes, archaea, filamentous fungi, yeasts, microalgae, or viruses (including bacteriophages)) or DNA.
	2. “**COLLECTION**” means a culture collection registered with the World Federation for Culture Collections (WFCC) or a member institution of the Japan Society for Microbial Resources and Systematics
	3. “**COMMERCIAL USE**” means the utilization of RESOURCES other than Article 1.12 and that are for profit purposes such as manufacture of products and examination activities. It includes applications for intellectual property rights based on the results obtained from utilizing the RESOURCES.
	4. “**COUNTRY OF ORIGIN**” means the country which possesses the BIOLOGICAL MATERIAL in *in-situ* condition.
	5. “**DEPOSITOR**” means a natural or legal person who deposits BIOLOGICAL MATERIAL with NBRC.
	6. “**DERIVATIVES**” means biochemical compounds resulting from the gene expression or metabolism of BIOLOGICAL MATERIAL or REPLICATES, even if they do not contain functional units of heredity.
	7. “**IRCC**” refers to Internationally Recognized Certificate of Compliance and means a PERMIT OR ITS EQUIVALENT made available to the Access and Benefit-sharing Clearing House as an internationally recognized certificate of compliance as provided for in Article 17.2 of the Nagoya Protocol.
	8. “**LIVING MODIFIED ORGANISMS**” means microorganisms having a nucleic acid or a copy thereof obtained using a technique which processes the nucleic acid outside the cell for the purpose of transformation of a microorganism, and it is treated as a microorganism.
	9. “**MODIFICATIONS**” means substances obtained by utilizing BIOLOGICAL MATERIAL, REPLICATES, or DERIVATIVES. MODIFICATIONS have different characteristics from their originals.
	10. “**NBRC NUMBER**” means the unique number assigned by NBRC to identify the Biological Material deposited with NBRC.
	11. “**NITE**” means the National Institute of Technology and Evaluation, the parent body of NBRC.
	12. “**NON-COMMERCIAL USE**” means the utilization of RESOURCES without producing any monetary profit at the stage of the utilization. This includes research and development based on RESOURCES.
	13. “**PERMIT OR ITS EQUIVALENT**” means a permit or a document equivalent thereto issued by the PROVIDER COUNTRY as evidence of the decision to grant prior informed consent and of the establishment of mutually agreed terms as provided for in Article 6.3(e) of the Nagoya Protocol on Access to Genetic RESOURCES and the Fair and Equitable Sharing of Benefits Arising from Their Utilization to the Convention on Biological Diversity (hereinafter referred to as the “Nagoya Protocol”).
	14. “**PROVIDER COUNTRY**” means the country that supplies the BIOLOGICAL MATERIAL (irrespective of whether the country is the COUNTRY OF ORIGIN or not).
	15. “**REPLICATES**” means cultured or amplified substances of BIOLOGICAL MATERIAL.
	16. “**RESOURCES**” means BIOLOGICAL MATERIAL, REPLICATES, DERIVATIVES and MODIFICATIONS.
	17. “**SPECIMEN**” means REPLICATES and Genome DNA (whole DNA extracted from microorganisms) that is prepared by NBRC for the purpose of storage or distribution of the BIOLOGICAL MATERIAL deposited with NBRC.
	18. “**USER**” means a natural or legal person that receives BIOLOGICAL MATERIAL from NBRC and/or that utilizes such BIOLOGICAL MATERIAL pursuant to “Agreement of Biological Resource Transfer and Treatment” (hereinafter referred to as the “MTA-utilization”).

**Article 2 (Deposit of BIOLOGICAL MATERIAL)**

* 1. The DEPOSITOR shall agree to the terms and conditions set forth in the MTA-deposit and AF upon deposit of the BIOLOGICAL MATERIAL described in the AF to NBRC.
	2. The DEPOSITOR shall warrant the following at the time of making the deposit.
1. The act of making a “Deposit of BIOLOGICAL MATERIAL” is not prohibited or restricted by any treaty and convention (including international agreements and protocols), law and regulation of the COUNTRY OF ORIGIN or the PROVIDER COUNTRY or other relevant agreement (except the agreements made between NITE and the DEPOSITOR or NBRC and the DEPOSITOR).
2. The distribution and utilization of BIOLOGICAL MATERIAL by NBRC, as provided for in Article 6 and 7, do not cause damage to any third party or NITE. The damage may include, but is not limited to, violation of the intellectual property rights or any other right owned by a third party.
3. The BIOLOGICAL MATERIAL does not fall under any of the following, provided, however, that it does not apply to the DEPOSITOR who lives outside of Japan.
4. “Class I Pathogens, etc.”, “Class II Pathogens, etc.”, “Class III Pathogens, etc.”, or “Class IV Pathogens, etc.” stipulated in the article 6 (20), (21), (22), and (23), respectively in the *Act on the Prevention of Infectious Diseases and Medical Care for Patients with Infectious Diseases* of Japan.
5. “Domestic animal infectious disease pathogen” stipulated in the article 46-5 or “pathogens of notifiable infectious diseases, etc.” stipulated in the article 46-19 in the *Act on Domestic Animal Infectious Diseases Control* of Japan
6. LIVING MODIFIED ORGANISMS which require containment measures of P3, P3A, or P3P Level or above as stated in the article 4 in *The Ministerial Ordinance Providing Containment Measures to be Taken in Type 2 Use of Living Modified Organisms for Research and Development* of Japan(Ordinance of the Ministry of Education, Culture, Sports, Science and Technology, and the Ministry of Environment No. 1 of 2004. When this ordinance is amended, the revised ministerial ordinance shall be referred to)
7. Microorganisms that require handling at biosafety level 3 or above or their DNA
	1. When an IRCC number has been assigned to the BIOLOGICAL MATERIAL to be deposited, the DEPOSITOR shall state the IRCC number in the AF.
	2. Upon making the deposit, the DEPOSITOR shall specify one condition for the utilization of the deposited BIOLOGICAL MATERIAL from the following. The specified condition is presented by NBRC to the USER at the time of distribution (see AF Section 4 “Conditions stipulated in the article 2.4 of MTA-deposit for utilization of the strain”).

(1) No specific conditions for utilization

The USER may conduct both NON-COMMERCIAL USE and COMMERCIAL USE on the RESOURCES.

(2) The purpose of utilization is limited to NON-COMMERCIAL USE. If the USER wishes to conduct COMMERCIAL USE on the RESOURCES, prior notification to the DEPOSITOR is required.

The USER may conduct NON-COMMERCIAL USE on the RESOURCES. When the USER wishes to make COMMERCIAL USE of the RESOURCES, including the applications for intellectual property rights, the USER shall notify the DEPOSITOR in advance. The DEPOSITOR, upon receipt of the notification, shall not place any restriction on the COMMERCIAL USE. The USER includes an organization or individual that engages in business activities for the purpose of making a financial profit, such as a company or enterprise.

(3) The purpose of utilization is limited to NON-COMMERCIAL USE. If the USER wishes to conduct COMMERCIAL USE on the RESOURCES, prior agreement with the DEPOSITOR is required.

The USER may conduct NON-COMMERCIAL USE on the RESOURCES. When the USER wishes to make COMMERCIAL USE of the RESOURCES, including the applications for intellectual property rights, the USER shall discuss the matter with the DEPOSITOR and reach an agreement before the COMMERCIAL USE takes place. The USER includes an organization or individual that engages in business activities for the purpose of making a financial profit, such as a company or enterprise.

(4) The purpose of utilization is limited to NON-COMMERCIAL USE. COMMERCIAL USE is not allowed in any case.

The USER may only conduct NON-COMMERCIAL USE on the RESOURCES. Applications for intellectual property rights may not be filed. The DEPOSITOR may choose this condition only when COMMERCIAL USE of the BIOLOGICAL MATERIAL to be deposited is prohibited by the laws of the COUNTRY OF ORIGIN, etc. The USER includes an organization or individual that engages in business activities for the purpose of making a financial profit, such as a company or enterprise.

(5) The conditions for utilization are specified by the DEPOSITOR

The USER shall abide by the conditions for utilization specified by the DEPOSITOR, provided, however, that the DEPOSITOR shall not specify the following conditions.

(a) Permission from the DEPOSITOR or a third party designated by the DEPOSITOR is required upon distribution from NBRC

(b) The DEPOSITOR claims sharing of profits against NBRC

(c) The DEPOSITOR limits the parties to which the distribution is made

(d) Other conditions for utilization that are determined as unacceptable by NBRC

* 1. Irrespective of the circumstances, after making the deposit, the DEPOSITOR shall not request NBRC and the USER to add any other conditions, such as suspension of the utilization of the RESOURCES by the USER, or monetary payment.
	2. The DEPOSITOR may change the conditions for utilization provided for in Article 2.4 (2), 2.4 (3), 2.4 (4) or 2.4 (5) to Article 2.4 (1) only when the request from the DEPOSITOR is made prior to the issuance of the certificate of deposit as provided for in 4.1 or the notification of the NBRC NUMBER as provided for in 4.2.
	3. As soon as NBRC receives the MTA-deposit and the BIOLOGICAL MATERIAL, the ownership of the BIOLOGICAL MATERIAL received shall be transferred to NBRC. In this case, the intellectual property rights and ownership of the original BIOLOGICAL MATERIAL remaining in possession of the DEPOSITOR shall not be transferred to NBRC.

**Article 3 (Assignment of contractual status and rights of the DEPOSITOR)**

* 1. The DEPOSITOR shall not assign its contractual status, rights, and obligations as the DEPOSITOR that arise from making the deposit to any third party. However, it shall not apply in the case of comprehensive assignment to a third party under the provisions of laws and regulations.
	2. When the DEPOSITOR makes the comprehensive assignment based on Article 3.1, the DEPOSITOR shall promptly notify NBRC in writing.

**Article 4 (Certificate of deposit of the BIOLOGICAL MATERIAL)**

* 1. When NBRC accepts a deposit based on Article 2, NBRC may preserve the BIOLOGICAL MATERIAL and issue to the DEPOSITOR the certificate of deposit that indicates the name of the BIOLOGICAL MATERIAL, NBRC NUMBER, date of registration, and conditions for utilization. In some cases, documents stating the conditions for utilization accompany the certificate of deposit as an attachment.
	2. When the DEPOSITOR desires, the DEPOSITOR may receive notification of the NBRC NUMBER from NBRC prior to the issuance of the certificate of deposit as provided for in Article 4.1,

**Article 5 (Cancellation of deposit by the DEPOSITOR)**

* 1. The DEPOSITOR may request for cancellation of deposit even after NBRC has received the BIOLOGICAL MATERIAL to be deposited, provided, however, that the request shall be made before receiving the certificate of deposit based on Article 4.1 or receiving the notification of NBRC NUMBER based on Article 4.2.
	2. When cancelling a deposit, shipment and other costs pertaining to returning the documents and the BIOLOGICAL MATERIAL shall be borne by the DEPOSITOR.

**Article 6 (Publication of information on the BIOLOGICAL MATERIAL)**

* 1. For distribution of the BIOLOGICAL MATERIAL as provided for in Article 7, NBRC may make the information on the BIOLOGICAL MATERIAL deposited along with the NBRC NUMBER publicly available. In addition, NBRC may further examine the BIOLOGICAL MATERIAL deposited and make updated and/or new information obtained through such examination publicly available.
	2. The DEPOSITOR shall agree that the BIOLOGICAL MATERIAL and related information may be made available to the public as provided for in Article 6.1, provided, however, that when DEPOSITOR desires, NBRC may keep the information confidential for three (3) years at the most from the date NBRC issues the certificate of deposit.
	3. Notwithstanding the provision of Article 6.2, after confirming that the NBRC NUMBER has been publicly known, NBRC may publish the information on BIOLOGICAL MATERIAL along with the NBRC NUMBER and make the BIOLOGICAL MATERIAL available for distribution without obtaining the DEPOSITOR’s consent and without notifying the DEPOSITOR.
	4. With regard to the BIOLOGICAL MATERIAL made publicly available by NBRC, in the event of any of the following, NBRC may discontinue or suspend its distribution without notifying the DEPOSITOR.
1. In the event provided for in Article 9.1
2. In the event provided for in Article 9.2
3. When anomalies such as contamination are found as a result of quality control testing etc.
4. When NBRC decides it is necessary to discontinue and/or suspend its distribution

**Article 7 (Distribution and deposit of the BIOLOGICAL MATERIAL)**

* 1. For the BIOLOGICAL MATERIAL deposited, NBRC may prepare the SPECIMEN for distribution, and upon request from the USER, may distribute the SPECIMEN under the provisions of the MTA-utilization and the conditions for utilization specified by the DEPOSITOR.
	2. Fees earned through distribution shall be treated as NBRC’s income.
	3. When the DEPOSITOR makes a request for the distribution of the BIOLOGICAL MATERIAL deposited by the DEPOSITOR itself, NBRC may distribute the BIOLOGICAL MATERIAL without any charge under the conditions set forth below:

(1) The recipient of the BIOLOGICAL MATERIAL shall be the DEPOSITOR itself

(2) The distribution shall be limited to one time per fiscal year (from April to end of March next year).

(3) The period for which the DEPOSITOR is entitled to reception of the BIOLOGICAL MATERIAL without charge shall be five (5) years after including the fiscal year that the deposit is made.

(4) Shipment costs to an overseas address and packaging fee shall be borne by the DEPOSITOR.

* 1. With regard to the BIOLOGICAL MATERIAL deposited with the conditions for utilization as provided for in Article 2.4 (1)or 2.4 (4), NBRC may deposit the BIOLOGICAL MATERIAL to COLLECTION, provided, however, that such deposit shall only be made if distribution from the Collection can be made under the original conditions for utilization specified by the DEPOSITOR upon depositing the BIOLOGICAL MATERIAL with NBRC.

**Article 8 (Utilization of the RESOURCES by a third party other than the USER)**

* 1. NBRC prohibits the USER from conducting the following acts on the BIOLOGICAL MATERIAL distributed from NBRC based on Article 7 as well as on the RESOURCES derived from such BIOLOGICAL MATERIAL.
1. Allowing any third party to utilize the BIOLOGICAL MATERIAL and RESOURCES
2. Distributing or allocating the RESOURCES

Notwithstanding the preceding paragraph, only in the case of the following, NBRC may allow the USER to let a third party utilize the same RESOURCES that are utilized by the USER itself, provided that the third party is made to strictly adhere to the provisions of the MTA-utilization and the conditions for utilization specified by the DEPOSITOR, and is made to dispose of or return the RESOURCES as soon as the utilization is completed.

(a) Outsourcing for analysis, cultivation, etc.

(b) Joint research conducted between the USER and the third party. The scope and purpose of the utilization under the joint research shall not exceed or deviate from the one described in the Order Sheet

(c) Other than Article 8.1 (1) and 8.1 (2) and when permitted by NBRC

* 1. When the condition for utilization specified by the DEPOSITOR is Article 2.4 (1), DERIVATIVES and MODIFICATIONS shall not be subject to Article 8.1.

**Article 9 (Return and disposal of the BIOLOGICAL MATERIAL)**

In any of the following cases, NBRC may return the REPLICATES of the deposited BIOLOGICAL MATERIAL to the DEPOSITOR, or dispose of them with the DEPOSITOR’s consent, provided, however, that in the case of Article 9 (2) and when urgent disposal is necessary, NBRC may dispose of them without obtaining the DEPOSITOR’s consent. In this case, NBRC should inform the DEPOSITOR after disposal.

(1) When it is difficult to maintain and manage the BIOLOGICAL MATERIAL, or it is inappropriate to handle the BIOLOGICAL MATERIAL at NBRC

(2) When possession of the BIOLOGICAL MATERIAL violates any treaty and convention (including international agreements and protocols), law and regulation, or contractual agreement etc., or when its possession may have adverse impact on human life, body, or properties due to public health or other factors

**Article 10 (Handling of information)**

* 1. NBRC does not use the information described in the MTA-deposit and AF outside the work pertaining to deposit, publication, and distribution of the BIOLOGICAL MATERIAL without the DEPOSITOR’s consent.
	2. Notwithstanding Article 10.1, when a request for disclosure of information is made or a need of mandatory reporting arises based on treaties, conventions, laws and regulations, rules, ordinances etc. or when there are other reasons where disclosure is deemed necessary by NBRC, NBRC may disclose the details of the deposit, including personal information, to a third party.
	3. When providing the detail information of the deposit under Article 10.2, NBRC only provides information described in the MTA-deposit, AF and the certificate of deposit in principle.

**Article 11 (Discussion on conditions for further utilization)**

* 1. With regard to the BIOLOGICAL MATERIAL that was deposited with the conditions for utilization provided for in Article 2.4 (2), 2.4(3) or 2.4 (5) in which a discussion with or notification to the DEPOSITOR is required for further utilization, the DEPOSITOR shall agree that NBRC may disclose the name or title, address, telephone number, and e-mail address of the DEPOSITOR to the USER when the USER informs NBRC of the need of a discussion or notification regarding the further utilization of the BIOLOGICAL MATERIAL distributed based on Article 7.1.
	2. When the DEPOSITOR receives a request from the USER for prior discussion regarding the further utilization of the BIOLOGICAL MATERIAL, the DEPOSITOR shall not decline such request without justifiable reasons. The DEPOSITOR shall also inform NBRC about the outcome of the discussion.
	3. In the discussion provided for in Article 11.2, without justifiable reasons, the DEPOSITOR shall not set any condition that would put the USER at a disadvantage especially in relation to COMMERCIAL USE.

**Article 12 (Assignment and transfer of distribution service of the BIOLOGICAL MATERIAL)**

NBRC may exclusively assign to a third party the distribution service and utilization right of BIOLOGICAL MATERIAL, as provided for in Article 6 and 7 without the DEPOSITOR’s consent, and assign all or a part of its contractual status, rights and obligations NBRC has as the depositary with respect to the DEPOSITOR.

**Article 13 (Notification from NBRC)**

* 1. When NBRC gives a notification to the DEPOSITOR, in principle, the notification shall be sent to the contact address of the DEPOSITOR mentioned in the AF. In the case where the DEPOSITOR has separately informed the contact address, notification shall be sent to such address.
	2. When there is a change in the contact address, the DEPOSITOR shall promptly inform the new address to NBRC.
	3. For the damages suffered by the DEPOSITOR in relation to or due to circumstances in which NBRC is unable to contact the DEPOSITOR, NBRC shall not assume any responsibility whatsoever.

**Article 14 (NBRC’s exclusion of liability)**

* 1. Irrespective of the reasons, NBRC shall not be liable for the death, alteration, or dissipation etc. of the BIOLOGICAL MATERIAL or its REPLICATES due to natural disasters or any other cause that are beyond reasonable control of NBRC.
	2. Except when it is because of NBRC’s willful intentions or gross negligence, NBRC shall not have any obligation of getting involved in any dispute arising between the DEPOSITOR and any third party (including the USER), and NBRC shall not assume any responsibility whatsoever.

**Article 15 (Expiry of MTA and handling after expiry of MTA)**

* 1. The contractual relationship between the DEPOSITOR and NBRC concerning the deposit under the MTA-deposit shall expire in the following events:

(1) When the BIOLOGICAL MATERIAL preserved by NBRC under Article 4 dies, alters, or dissipates

(2) When the deposit is canceled under Article 5

(3) When the BIOLOGICAL MATERIAL is returned to the DEPOSITOR or disposed of under Article 9

(4) When NBRC is unable to contact the DEPOSITOR for more than six (6) months

* 1. Notwithstanding Article 15.1, if expiration should occur due to events other than Article 15.1(2), and when there is a USER utilizing the BIOLOGICAL MATERIAL at the time of expiration, the DEPOSITOR shall continue to have rights and obligations to the USER until the utilization of the BIOLOGICAL MATERIAL by the USER is completed.
	2. When the contractual relationship expires due to Article 15.1(4), NBRC may continue to possess, make publicly available, and distribute the BIOLOGICAL MATERIAL. In this case, regardless of the conditions for utilization specified in the MTA-deposit and AF, NBRC may change the conditions for utilization to Article 2.4(1), which shall be presented to the USER when distribution of the BIOLOGICAL MATERIAL takes place.
	3. Provisions of Article 2.5 and Article 14 shall remain in effect even after expiry of the contractual relationship between the DEPOSITOR and NBRC concerning the deposit under the MTA-deposit.

**Article 16 (Governing law and the court of agreed jurisdiction)**

* 1. The MTA-deposit shall be governed by the laws of Japan.
	2. NBRC and the DEPOSITOR hereby agree that the Tokyo District Court shall have exclusive jurisdiction in the first instance to adjudicate any dispute arising out of or relating to the MTA-deposit.

**Article 17 (Discussion)**

NBRC and the DEPOSITOR shall discuss in sincere faith for the matters not set forth in the MTA-deposit and for any ambiguity that arise in the interpretation of the MTA-deposit.

to the Director General,

Biological Resource Center,

National Institute of Technology and Evaluation

We hereby agree to make the deposit under the terms and conditions of the MTA-deposit.

DEPOSITOR

|  |  |
| --- | --- |
| Contact person  | Representative (Exp.: Institution representative) |
| Name:  | Name:  |
| Signature:  | Signature:  |
| Title:  | Title:  |
| Organization: | Organization: |
| Address: Telephone: E-mail:  | Address: Telephone: E-mail:  |
| Date: / /  | Date: / /  |

（March, 2018）

Depositor’s strain No. (strain label)

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| 1. |   | 11. |   | 21. |   |
| 2. |   | 12. |   | 22. |   |
| 3. |   | 13. |   | 23. |   |
| 4. |   | 14. |   | 24. |   |
| 5. |   | 15. |   | 25. |   |
| 6. |   | 16. |   | 26. |   |
| 7. |   | 17. |   | 27. |   |
| 8. |   | 18. |   | 28. |   |
| 9. |   | 19. |   | 29. |   |
| 10. |   | 20. |   | 30. |   |