

Неофициальный перевод выполнен в
**Национальном координационном центре по
вопросам доступа к генетическим ресурсам и
совместному использованию выгод
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APPROVED

Deputy Chairperson of the
Presidium of the National
Academy of Sciences of Belarus

_____ A.V. Sukalo
«25» May 2013

AFFIRM

Director of the State Scientific Institution
“Institute of Genetics and Cytology of
the National Academy of Sciences of
Belarus”

_____ A.V.Kilchecky
«25» May 2013

PROVISION

25.05.2013 № 16-0-2013

on

**the Republican DNA Bank of a
Human, Animals, Plants and
Microorganisms**

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CHAPTER 1

GENERAL PROVISIONS

1. This Provision defines a structure and operation procedures for the Republican DNA Bank of a Human, Animals, Plants and Microorganisms (hereinafter referred to as “the DNA Bank”), including objections, functions, rights and liabilities of the Laboratory for Genetic Resources Cryopreservation (hereinafter referred to as “the Laboratory”) of the State Scientific Institution “Institute of Genetics and Cytology of the National Academy of Sciences of Belarus” (hereinafter referred to as “the Institute”) to ensure the DNA Bank operation and shall apply to the activity of this Laboratory.

2. The DNA Bank was established by order of the Director of the State Scientific Institution “Institute of Genetics and Cytology of the National Academy of Sciences of Belarus” of 25 May 2013 № 16-o and is located at this Scientific Establishment with an address at: 27, Akademicheskaya Street, room 002, 220072 Minsk

3. The DNA Bank includes the following thematic sections:

DNA Bank of a Human;

DNA Bank of Animals;

DNA Bank of Plants;

DNA Bank of Microorganisms.

Each section stores DNA samples and the original biological material used for DNA samples extraction.

4. The DNA Bank is represented (for each thematic section) by:

4.1. DNA samples collection for long-term storage;

4.2. DNA samples collection for scientific purposes. This collection includes samples, which are of interest for scientific research and is used by legal entities engaged in molecular genetic research, for scientific work within the framework of all program types, innovation projects and grants;

4.3. DNA samples collection for commercial storage. This collection includes samples accepted for storage on a paid basis from legal entities and individuals subject of interest for a depositor.

5. Deposit and organization of DNA samples storage and the original biological material used for DNA sample extraction shall be exercised according to the Rules set in Annex A to this Provision.

6. DNA Bank operation is ensured by the Laboratory. The overall direction of the DNA Bank operation shall be exercised by Head of the DNA Bank appointed by the Institute Director. Operational supervision of the indicated process shall be carried out by Head of the Laboratory.

7. The Laboratory belongs to the Structural Division of the Institute. The structure and authorized personnel complement of the Laboratory shall be defined by necessity of tasks and functions execution assigned to it and shall be approved by the Institute Director.

8. To ensure the DNA Bank operation, the Laboratory shall use premises and facilities provided by the Institute. The equipment obtained to ensure the DNA Bank operation shall be retained by the Laboratory according to the procedures laid down.

9. In its operations the Laboratory shall be governed by:
normative legal acts of the Republic of Belarus;
provisions of the Presidium and the Bureau of the Presidium of the National Academy of Sciences of Belarus, orders and instructions of the Presidium Chairperson of the National Academy of Sciences of Belarus;
Statute of the Institute, orders and instructions of the Institute Director;
this Provision.

CHAPTER 2

LABORATORY OBJECTIVES TO ENSURE THE DNA BANK OPERATION

10. Laboratory priority objectives with a view of ensuring of the DNA Bank operation are the following:

10.1. development and implementation of coordinated and scientifically grounded measures for long-term high quality storage and efficient use of DNA sample collections of a human, animals, plants and microorganisms and the original biological material used for DNA samples extraction;

10.2. collection, storage and systematization of information on DNA sample collections and the biological material;

10.3. establishment of effective cooperation procedures with other DNA Banks and genetic material collections to join the International DNA Bank Network with a view of technology, information and sample* exchange in compliance with legal provisions of the National and International legislation.

CHAPTER 3

LABORATORY FUNCTIONS TO ENSURE THE DNA BANK OPERATION

11.1. creation of conditions for long-term storage of DNA samples and the original biological material used for DNA samples extraction;

11.2. ensuring that proper quality DNA samples are allocated into the collection;

11.3. regular replenishment of existing DNA sample collections and the biological material;

* excluding DNA samples of a human

11.4. creation and support of Databases on the stored DNA samples and the biological material of a human, plants, animals and microorganisms;

11.5. strengthening of material and technical facilities and the procedural framework with a view of the DNA Bank prospective development;

11.6. development of international cooperation within the scope of its competence and in line with the existing legislation of the Republic of Belarus;

11.7. rendering of counseling and other services in arrangement of DNA sample and biological material storage;

11.9. training of scientific personnel within the scope of its competence.

CHAPTER 4

LABORATORY RIGHTS AND LIABILITIES FOR THE PURPOSES OF THE DNA BANK OPERATION

12. Within the scope of its competence and in the performance of its functions to ensure the DNA Bank operation, the Laboratory shall have the right to:

12.1. examine draft decisions of the Institute Directorship with regard to the DNA Bank operation;

12.2. attract specialists of other Structural Divisions of the Institute to handle objections and functions laid on the Laboratory (by agreement with the Institute Director);

12.3. be involved in conclusion of cooperation agreements with legal entities of the Republic of Belarus and other countries in accordance with the existing legislation of the Republic of Belarus;

12.4. exercise corresponding works (render services) on the basis of relevant contracts concluded with legal entities and individuals within the limits of existing legislation of the Republic of Belarus;

12.5. improve personnel qualification by means of training courses and staff professional retraining within the scope of its competence;

13. The Laboratory is entrusted with the following functions:

13.1. fulfill to the fullest extent its functions with regard to the DNA Bank operation assigned to it by this Provision;

13.2. provide proper registration (documentation) and guaranteed storage of DNA samples and the original biological material;

13.3. determine the prospects for DNA Bank development;

13.4. provide the interested organizations with DNA samples to be used for research purposes in accordance with the existing legislation of the Republic of Belarus and international norms;

13.5. ensure safety in performance of works, compliance with Norms and Regulations of Labor and Fire Safety;

13.6. ensure the observance of labor and operational discipline by the

Laboratory staff;

13.7. provide in due course reports on the DNA Bank operation to the Director of the Institute.

CHAPTER 5 INTELLECTUAL PROPERTY RIGHTS

14. Transfer of a sample to the DNA Bank for storage shall entail no transfer of proprietary rights to the subject of intellectual property;

15. Samples subject to legal protection as intellectual property items may be used with the written consent of their rightsholder.

Annex A
to the Provision on the Republican
DNA Bank of a Human, Animals,
Plants and Microorganisms

Rules for samples deposit into the
Republican DNA Bank of a
Human, Animals, Plants and
Microorganisms

The Republican DNA Bank of a Human, Animals, Plants and Microorganisms is based at the State Scientific Institution “Institute of Genetics and Cytology of the National Academy of Sciences of Belarus” with an address at: 27, Akademicheskaya Street, 220072 Minsk, office 002.

The DNA Bank operation is ensured by the Laboratory for Genetic Resources Cryopreservation of the Institute.

The DNA Bank provides storage for DNA samples and the original biological material used for the DNA sample extraction.

The DNA Bank includes four thematic sections:

DNA Bank of a Human;

DNA Bank of Animals;

DNA Bank of Plants;

DNA Bank of Microorganisms.

1. FORMS OF SAMPLES DEPOSIT

1.1. Long-term storage. Samples which are of special scientific interest are accepted for storage. Samples are not subject* to withdrawal. A depositor retains a right to use not more than 25% of quantity of the transferred DNA samples for their own scientific research*.

1.2. Storage for scientific purposes. Samples which are of special scientific interest are accepted for storage. Sample collections are used for scientific work within the framework of all programs, innovative programs and grants and exchange among institutions involved in molecular genetic research. Samples shall be handed out from the collection only with consent of a depositor (s) and by their written authorization. Collection samples shall be furnished only to legal entities that have requisite conditions to carry out works with them (on the basis of corresponding written confirmation).

* excluding DNA samples of a human

1.3. **Storage for commercial purposes** is carried out to ensure the preservation of samples, which are of special interest for a depositor. The collection allocates DNA samples and the original biological material from legal entities and individuals accepted for paid storage. The amount of payment collected for commercial storage shall be defined by order of the Institute Director. Commercial storage shall be provided for a term specified at a time of deposit submission. At the discretion of a depositor, and provided that a corresponding payment has been made, the storage period may be extended. If within 6 months upon expiry of the established storage term a depositor does not submit an application for samples withdrawal or any other direction, the samples shall be subject to utilization upon written notification of a depositor.

2. PROCEDURE FOR SAMPLES DEPOSIT

2.1. Deposit into the DNA Bank may be carried out by both legal entities and individuals.

2.2. At a time of deposit a depositor shall submit:

DNA sample (s) and the original biological material used for DNA sample (s) extraction that conform to the requirements set in Annex B to this Provision;

Certificate for a sample collection (DNA, biological material) drawn up in line with Annex C to this Provision on the transferred sample (s), signed by a depositor (s) and certified by the seal (if a depositor is not a legal entity) (two hard copies and an electronic copy);

electrophoretogram of a DNA sample (s) and literature references to scientific publications on research and development works with the use of this DNA samples collection (to a maximum of 5) attached to the Certificate for DNA samples (DNA, biological material).

2.3. A depositor is obliged to maintain the deposited DNA sample (s) and original biological material in proper conditions prior to its transfer to the DNA Bank and placement for deposit.

2.4. The Institute has a right not to accept the sample deposit, provided that its quality does not correspond to the requirements specified in Annex B to this Provision.

2.5. A depositor bears responsibility for correspondence of the deposited DNA sample real properties and the original biological material specified in a Certificate.

2.6. The procedure shall be deemed completed from the moment of issuance to the depositor of a signed Act on the sample (s) transfer (DNA, biological material) drawn up in line with Annex D to this Provision.

2.7. DNA Bank identification number shall be attributed to the deposited sample and used subsequently.

2.8. Information on DNA samples, the original biological material and form of deposit (“long-term storage” and “storage for scientific purposes”) shall be placed in the open catalogue of a DNA Bank.

3. CHANGE IN THE DEPOSIT PROCEDURE, RELEASE OF SAMPLES

3.1. Changes in form of deposit may be carried out upon a written statement of a depositor.

3.2. Handing out of samples shall be carried out on the basis of an official written inquiry. The inquiry shall indicate a sample reference number, as well as address, telephone, fax and e-mail of the contracting authority. Depositor’s written authorization shall be attached to the inquiry (a signature shall be certified by the seal). Response to the inquiry shall be provided within 20 days upon its receipt.

3.3. Cost of samples deposit and the requested samples price shall be defined by order of the Institute Director.

3.4. Samples shall be handed out to the ordering customer or their representative (upon presentation of power of attorney for their receipt). An Act on sample (s) (DNA, biological material) (Annex E to this Provision) handing out and a Certificate for this (these) sample (s), drawn up in line with Annex F to this Provision, shall be issued in addition to a sample.

3.5. Claims relating to the sample quality shall be accepted within one week by the Institute.

3.6. DNA Bank collection samples shall be provided with no right of transfer to third parties.

Annex B

to the Provision on the Republican
DNA Bank of a Human, Animals,
Plants and Microorganisms

Requirements for DNA samples
and biological material for storage
at the Republican DNA Bank of
a Human, Animals, Plants and
Microorganisms

DNA sample collection for long-term storage

Every sample should:

- have volume not less than 20 μ l;
- have purity not less than 1,8;
- have concentration in aqueous solution not less than 100 mcg/ml;
- DNA extraction should be carried out by standard phenol-chloroform technique according to the standard protocol;
- DNA sample should be placed into the special tube (NUNC) for storage at low temperatures;
- be attended with the DNA sample electrophoregramme.

Every DNA sample should be attended with biological material used for the DNA sample extraction. The biological material should be placed into the tube for storage in liquid nitrogen. Its quantity should be sufficient for DNA extraction as required.

DNA sample collection for scientific purposes

Every sample should:

- have volume as per laboratory capacity;
- have purity not less than 1,6;
- have concentration in aqueous solution not less than 100 mcg/ml;
- DNA sample should be placed into the special tube (NUNC) for storage at low temperatures;
- be attended with the DNA sample electrophoregramme.

Full information on the extracted sample, including data on the original biological material origin and the used extraction technique shall be provided.

Annex C
to the Provision on the Republican
DNA Bank of a Human, Animals,
Plants and Microorganisms

Republican DNA Bank
of a Human, Animals, Plants
and Microorganisms

State Scientific Institution
“Institute of Genetics and Cytology
of the National Academy of Sciences
of Belarus”

27, Akademicheskaya Street, 220072 Minsk
Tel.: 284 19 18
Fax: 284 19 17
E-mail: office@igc.bas-net.by

27, Akademicheskaya Street, 220072 Minsk
Tel.: 284 19 18
Fax: 284 19 17
E-mail: office@igc.bas-net.by

SAMPLE COLLECTION CERTIFICATE (DNA, biological material)

Deposit date _____

Depositor (s) (<i>full name of the organization, address, tel/fax, e-mail</i>):	
Sample (s) creator (s):	
Program name, a task reference number for the collection development:	
Sample collection profile:	
Genetic traits:	

List of DNA samples and biological material

№	Sample reference number	DNA characteristics *					DNA Bank Identification Number **
		Biological material for DNA extraction	Extraction technique	Purity	Concentration (mcg/ml)	Quantity (mcl)	
1	2	3	4	5	6	7	8
Bank profile:							

***The following attached to the chart:**

- 1) DNA samples electrophoregramme;
- 2) literature references (scientific publications related to samples collection use, to a maximum of 5).

**** Column to be completed by the Republican DNA Bank personnel**

Form of deposit (*long-term storage; storage for scientific purposes; commercial storage*):

The Director is familiar with the Rules for samples deposit into the Republican DNA Bank of a Human, Animals, Plants and Microorganisms. Responsibility for the correspondence of real properties of the deposited DNA sample and biological material specified in the Certificate lies on the depositor.

Depositor assumes obligations to:

1. transfer proper quality DNA samples (Annex B to this Provision).
2. maintain a DNA sample and biological material subject to deposit till its transfer to the DNA Bank and allocation for depositing, as well as to renew DNA samples in a collection in the event of their degradation.

With regard to such forms of deposit as “long-term storage” and “storage for scientific purposes”, a depositor has been informed that information on DNA samples and the biological material shall be placed in the DNA Bank open catalogue.

Signatures _____

(Head (s) of a depositor organization (s)

« _____ » _____ 20_____

Creators: (full name, signature) _____

Annex D

to the Provision on the Republican DNA Bank of a Human, Animals, Plants and Microorganisms

AUTHORIZE
Head of
depositor
organization*

AUTHORIZE
Head of
depositor
organization*

AUTHORIZE
Director of the State
Scientific Institution
“Institute of Genetics and
Cytology of the National
Academy of Sciences of
Belarus”

_____ Full name
_____ 201__

_____ Full name
_____ 201__

_____ Full name
_____ 201__

ACT

on the sample transfer (DNA, biological material)

to the Republican DNA Bank of a Human, Animals, Plants and Microorganisms of the State Scientific Institution “Institute of Genetics and Cytology of the National Academy of Sciences of Belarus”

This Act is to certify that _____

_____ (organization, structural division, etc.)

transferred to the DNA Bank _____ samples _____
(indicate quantity) (DNA, biological material)

by profile:

form of deposit (*long-term storage, for scientific purposes, commercial storage*) _____

on the subject (*program, task code*) _____

Samples transferred by:
(*signatures of creators*)

Head of the Laboratory for Genetic Resources

Cryopreservation _____

Samples received by:

(*signature of collection supervisor*)

«____» _____ 201__

«____» _____ 201__

Contact details:

* in the event of a few depositor organizations

Annex E

to the Provision on the Republican
DNA Bank of a Human, Animals,
Plants and Microorganisms

STATE SCIENTIFIC INSTITUTION “INSTITUTE OF GENETICS AND
CYTOLOGY OF THE NATIONAL ACADEMY OF SCIENCES OF BELARUS”
Republican DNA Bank of a Human, Animals, Plants and Microorganisms

AUTHORIZE

Director of the State Scientific
Institution “Institute of Genetics and
Cytology of the National Academy of
Sciences of Belarus”

_____ 201__

ACT

**on the samples handing out (DNA, biological material)
from storages of the Republican DNA Bank of a Human, Animals, Plants and
Microorganisms**

This is to certify that from the storages of the Republican DNA Bank of a Human,
Animals, Plants and Microorganisms, DNA / biological material samples are handed
out to/ exchanged with

(organization, structural division, etc.)

(indicate DNA samples quality)

by profile:

deposit form (*long-term storage, for scientific purposes, for commercial
purposes*)_____

on the subject (program, task)_____

Head of the Laboratory for
Genetic Resources Cryopreservation _____

Samples handed out by:

Samples received by:

« _____ » 201__

« _____ » 201__

Contact telephone number.:

Contact telephone number:

Annex F
to the Provision on the Republican
DNA Bank of a Human, Animals,
Plants and Microorganisms

Republican DNA Bank
of a Human, Animals, Plants
and Microorganisms

State Scientific Institution
“Institute of Genetics and Cytology
of the National Academy of Sciences
of Belarus”

27, Akademicheskaya Street, 220072 Minsk
Tel.: 284 19 18
Fax: 284 19 17
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Fax: 284 19 17
E-mail: office@igc.bas-net.by

**Certificate for sample (s) handing out from a collection of the Republican DNA Bank
of a Human, Animals, Plants and Microorganisms**

Date of sample deposit _____

Name of an organization the sample (s) handed out to

Sample (s) creator (s):

Collection profile a sample to be handed out from

Purpose of handing out / exchange:

Data on DNA samples

№	DNA Bank identification number	Biological material used for DNA extraction	Extraction technique	Purity	Concentration (mcg/ml)	Quantity (mcl)	Storage conditions
1	2	3	4	5	6	7	8

Samples transferred by:

Samples received by:

«____» _____ 201__

«____» _____ 201__

The sample is provided with no right of its transfer to third parties
Claims relating to sample quality are accepted within one week