

Magdalena del Mar, June 28, 2023
RD-000099-2023-MIDAGRI-SERFOR-DGGSPFFS-DGSPF

SEEN:

The application for authorization of access to genetic resources and their derivatives for non-commercial purposes of wild flora, registered with file No. 2023-0004254 dated February 2, 2023, as requested by the company Neural Therapeutics Inc. identified with registration of the Canadian Revenue Agency (CRA) No. 731730677, (hereinafter, the user), through its legal representative, Mr. Ian Campbell, identified with Canadian identification document No. [REDACTED], for the development of the project entitled "Evaluation of the Peruvian cactus (*Echinopsis*) for possible medicinal purposes"; as well as, Technical Report No. D00006-2023-MIDAGRI-SERFOR-DGGSPFFS-DGSPFS-IAC dated June 27, 2023, and,

CONSIDERING:

That, Article 66 of the Political Constitution of Peru, states that natural resources, renewable and non-renewable, are the patrimony of the Nation, being the State sovereign in its use; Article 68 also provides that it is the obligation of the State to promote the conservation of biological diversity;

That in virtue of Decision 391, adopted on July 2, 1996, by the member countries of the Commission of the Cartagena Agreement, currently: Andean Community of Nations, composed of Peru, Colombia, Bolivia, and Ecuador; established the Common Regime on Access to Genetic Resources, which aims to regulate access to genetic resources of member countries and their by-products;

That article 1 of the aforementioned standard, referring to the Competent National Authority, establishes that it is the state public entity or agency designated by each Member Country authorized to provide the genetic resource or its by-products and therefore to sign or supervise access contracts, carry out the actions provided for in this common regime and ensure compliance;

That article 16 of the aforementioned norm, indicates that any access procedure will require the presentation, admission, publication and approval of an application, as well as the signing of a contract, issuance and publication of the corresponding resolution, together with the declarative registration of the acts related to said access;

That, for its part, in accordance with 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 (Nagoya Protocol)¹, recognizes the important contribution of technology transfer and cooperation to ~~sustainable development in-~~

¹ Signed by Peru on May 4, 2011, and approved by Legislative Resolution No. 30217 of July 3, 2014, and ratified by Supreme Decree No. 029-2014-RE on July 4, 2014.

building research and innovation capacity that adds value to genetic resources in developing countries, in accordance with Articles 16 and 19 of the Convention on Biological Diversity;

That, by means of Article 13 of Law No. 29763 "Forestry and Wildlife Law", the creation of the National Forestry and Wildlife Service (SERFOR) was provided as a specialized technical public body, with legal personality under domestic public law, as a budget attached to the Ministry of Agriculture, constituting the National Forestry and Wildlife Authority;

That, paragraph c) of Article 4 of the aforementioned Law, establishes that the forest and wildlife heritage of the Nation is constituted, among others, by forest and wildlife biological diversity, including its associated genetic resources;

That, through paragraph j) of Article 14 of the Forestry and Wildlife Law, it establishes that the functions of SERFOR, among others, are to manage, promote and administer the common regime on access to genetic resources of forest resources and wildlife within the framework of Decision 391 of the Cartagena Agreement and other related national regulations;

That, in accordance with the provisions of Article 154 of the Regulations for Forest Management, approved by Supreme Decree No. 018-2015-MINAGRI, establishes that when scientific research of forest heritage involves access to genetic resources, the researcher must sign an access contract with SERFOR;

That, by means of Supreme Decree No. 019-2021-MINAM, the Regulation on Access to Genetic Resources and their derivatives was approved, which aims to regulate the provisions related to access to genetic resources and their derivatives established in Decision 391, in accordance with the provisions of the Nagoya Protocol, identifying itself as the competent national authority, among others, the SERFOR of the Ministry of Agrarian Development and Irrigation, for Forest Heritage and Wildlife, including wild relatives of cultivated species; as well as the microorganisms associated with said Heritage, which are found in the national territory, which includes regional conservation areas and private conservation areas;

That, in accordance with paragraph 31.1 of Article 31 of the aforementioned regulations, it establishes that the Competent National Authorities authorize the collection or extraction of the biological resource containing the genetic resources in the same administrative procedure of access to genetic resources and their derivatives without commercial purposes;

That, in accordance with Article 35² of the Regulations on Access to Genetic Resources and Derivatives, which states that the effectiveness of authorizations for access to

² Regulation on Access to Genetic and Derived Resources, approved by Supreme Decree No. 019-2021-MINAM. "Article 35.- Effectiveness of authorizations for access to genetic resources and their derivatives for non-commercial purposes. The effectiveness of authorizations for access to genetic resources and their derivatives for non-commercial purposes is subject to the signing of a contract between the applicant and the Competent National Authority. Once the respective authorization has been issued, the Competent National Authority signs the access contract with the applicant, according to the approved simplified format".

genetic resources and their derivatives without commercial purposes are subject to the signing of a contract, according to the simplified format approved by Ministerial Resolution No. 006-2022-MINAM;

That Article 52 of the aforementioned regulation indicates that the user may sign an ancillary contract with a) the National Support Institution³, in accordance with article 43⁴ of the regulations;

That, in application of paragraph g) of Article 55 of the Regulations on Organization and Functions of SERFOR, approved by Supreme Decree No. 007-2013-MINAGRI and amended by Supreme Decree No. 016-2014-MINAGRI; the Directorate of Sustainable Management of Forest Heritage (DGSPF), among others, is responsible for developing, approving and signing contracts for activities for access to genetic resources of wild flora species;

That, in this context, through the application registered with file No. 2023-0004254 dated February 2, 2023, the user requested access to genetic resources and their derivatives for non-commercial purposes of species of wild flora, corresponding to the Cactaceae family of the department of Ancash, Lima, Junín and Piura, as well as the artificial propagation center "Vivero Knize" registered in SERFOR within the framework of the project "Evaluation of the Peruvian cactus (*Echinopsis*) for possible medicinal purposes"; for a period of nine (09) months;

That, the development of the project "Evaluation of the Peruvian cactus (*Echinopsis*) for possible medicinal purposes", is part of a non-commercial scientific research study related to the identification and quantification of compounds that occur naturally since they can obtain a significant medicinal value to treat many mental illnesses and provide access to new treatments;

That, the user maintains that for research purposes they will work with mature and healthy stems of cactus species of the genus *Echinopsis* spp., for which they will collect samples for herbarium and to carry out the studies of DNA identification and sequencing, chemical profiling and extraction of potentially key alkaloids and sampling for herbarium. The herbarium samples will be deposited in the ICNDMB "Magdalena Pavlich Herbarium". The purified and quantified products by spectrophotometry will be sent for sequencing to Macrogen Korea (<https://dna.macrogen.com/>) who will participate in the form of service. The sequences obtained will be analyzed using Sequencher Software 5.4.6 (GenCodes) and evaluated using the GenBank gene database;

That, the user has signed an accessory contract with the Universidad Peruana Cayetano Heredia, identified with RUC N° 20110768151 with address at Av. Honorio Delgado Nro.

³ Paragraph (o) Article 3 on definitions of the Regulations on Access to Genetic Resources and their Derivatives. **National Support Institution:** national legal entity, dedicated to biological research of a scientific or technical nature, which accompanies the foreign applicant and participates together with him in the access activities, being able to participate through a direction, area, or unit.

⁴ National Support Institution 43.1 Access requests submitted by foreign users must attach the ancillary contract with a National Support Institution. 43.2 The users and the National Support Institution are jointly and severally liable for the damage caused, by the researchers who are part of the project, to the genetic material contained in the biological material, if this is derived from the breach of any obligation provided for in the authorization or the contract granted.

430 Urb. Engineering - San Martin De Porres, Lima - Lima, duly represented by Mr. [REDACTED], identified with DNI N° [REDACTED], in his capacity as National Support Institution;

That, the collection of biological resources contained in genetic resources and their derivatives of wild flora species of the Cactaceae family is requested, within the framework of the provisions of Article 31 of the Regulations on Access to Genetic Resources;

That, considering that several species of the genus *Echinopsis* of the family Cactaceae are included in Appendix II of the CITES Convention, it was requested by Official Letter No. D000062-2023-MIDAGRI-SERFOR-DGGSPFFS-DGSPF, opinion to the MINAM in its capacity as the CITES⁵ Scientific Authority, *in order to determine if the collection would not harm the survival of the natural populations of the species of the genus Echinopsis involved in this project.* In view of this, the MINAM through Official Letter No. 00082-2023-MINAM/VMDERN/DGDB, concludes among others that, *"The collection requested before SERFOR and channeled for the opinion of MINAM as CITES Scientific Authority will not cause detriment to the natural populations of the species requested within the framework of the extraction plan, as long as the numbers of each of the specimens to be extracted are not increased";*

That, in the current Single Text of Administrative Procedures - TUPA of SERFOR, approved by Supreme Decree No. 001-2016-MINAGRI and amended by Ministerial Resolution No. 613-2016-MINAGRI, Ministerial Resolution No. 026-2019-MINAGRI, Executive Directorate Resolution No. D000103-2020-MINAGRI-SERFOR-DE and Executive Directorate Resolution No. D000099-2021-MIDAGRI-SERFOR-DE; there is no authorization procedure for access to genetic resources and their derivatives for non-commercial purposes;

That, in observance of the principle of ex officio impulse, provided for in numeral 1.3 of Article IV of the Preliminary Title of the TUO of Law No. 27444, Law of General Administrative Procedure; It follows that the authorities must direct and promote the procedure ex officio and order the performance or practice of the acts that are convenient for the clarification and resolution of the necessary issues;

That, therefore, the application in question has been evaluated in application of the requirements of paragraph 27.1 of Article 27 of the Regulations on Access to Genetic Resources and their Derivatives;

That, the file submitted by the user, is made up of the request for authorization of access to genetic resources and their derivatives for non-commercial purposes of wild flora species, which is accompanied by the documents that support the requirements presented, and the collection of biological material of wild flora, which are in accordance with article 27 of the Regulations on Access to Genetic Resources and their derivatives, and numeral 31.1 of article 31 of the aforementioned regulation, which establishes that

⁵ Article 18 of Supreme Decree No. 030-2005-AG, which approves the "Regulations for the Implementation of the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES) in Peru".

the Competent National Authorities authorize the collection or extraction of the biological resource containing the genetic resources in the same administrative procedure of access to genetic resources and their derivatives without commercial purposes and within the framework of General Directorate Resolution No. D000627-2021-MIDAGRI-SERFOR-DGGSPFFS;

That, in this regard, through Technical Report No. D00006-2023-MIDAGRI-SERFOR-DGGSPFFS-DGSPFS-IAC, issued on June 27, 2023, the actions taken during the development of the procedure for attention to the aforementioned request, as well as its evaluation, are exposed; report that is in conformity and the contents of which form an integral part of this resolution;

That, after the analysis of the conclusions and recommendations set out in the aforementioned technical report, it is clear, among others, the following: i) the application registered with file No. 2023-0004254 dated February 2, 2023, the company Neural Therapeutics Inc. identified with registration of the Canadian Revenue Agency (CRA) No. 731730677, through its legal representative, Mr. Ian Campbell, identified with Canadian identification document No. [REDACTED], meets the minimum conditions and meets all the requirements for granting the required authorization, so it is appropriate to grant authorization for access to genetic resources and their derivatives without commercial purposes of wild flora for the development of the Project entitled "Evaluation of the Peruvian cactus (Echinopsis) for possible medicinal purposes" for the period of nine (09) months, according to the work schedule of the research project presented; and consequently for its formalization the subscription of the access contract; (ii) The biological resources containing genetic resources and their derivatives correspond to species of wild flora belonging to the genus Echinopsis spp. of the family Cactaceae, from in situ conditions of the departments of Junín, Lima, Piura and Ancash, as well as ex situ conditions of the artificial propagation center "Knize Nursery "; (iii) it is recommended that the collection of wild flora samples be authorized for the implementation of this project; (iv) The user has complied in submitting the proposal for the distribution of non-monetary benefits; (v) It has an ancillary contract with a National Support Institution; (vi) Does not submit confidentiality petition; (vii) the research project has not required the collection of the collective or traditional knowledge of any community because it is not part of the objectives of the project;

That, in accordance with Decision 391 "Common Regime on Access to Genetic Resources"; the Regulation on Access to Genetic Resources and their Derivatives, approved by Supreme Decree No. 019-2021-MINAM; in the exercise of the delegated function through article 2 of the Resolution of General Directorate No. D000627-2021-MIDAGRI-SERFOR-DGGSPFFS; Ministerial Resolution No. 006-2022-MINAM, within the framework of the provisions of the Seventeenth Final Complementary Provision of the Regulations on Access to Genetic Resources and their Derivatives; Law No. 29763, Forestry and Wildlife Law; the Regulations for Forest Management, approved by Supreme Decree No. 018-2015-MINAGRI; the TUO of Law No. 27444, Law on General Administrative Procedure, approved by Supreme Decree No. 004-2019-JUS; as well as, in exercise of the powers conferred by Article 56 of the Regulations on Organization and

Functions of SERFOR, approved by Supreme Decree No. 007-2013-MINAGRI and amended by Supreme Decree No. 016-2014-MINAGRI;

RESOLVED:

Article 1.- AUTHORIZE the collection of biological material of wild flora species subject to research and access to genetic resources and their derivatives for non-commercial purposes of wild flora, in favor of the company Neural Therapeutics Inc. identified with registration of the Canadian Revenue Agency (CRA) No. 731730677, and legally represented by, Mr. Ian Campbell, identified with Canadian identification document No. [REDACTED], for the period of nine (09) months, by virtue of the considerations set forth in this resolution, corresponding to the **Authorization Code No. CTO-ARG-2023-002**.

Article 2.- AUTHORIZE the signing of the Contract between the company Neural Therapeutics Inc. and the Directorate of Sustainable Management of Forest Heritage of the General Directorate of Sustainable Management of Forest Heritage and Wildlife of SERFOR, by virtue of the considerations set forth in this resolution.

Article 3.- To authorize the collection of biological samples of wild flora, from *in situ conditions of the departments of Junín, Lima, Piura and Ancash*, as well as *ex situ conditions of the artificial propagation center "Vivero Knize" as detailed in Table 1, for the development of the research project "Evaluation of the Peruvian cactus (Echinopsis) for possible medicinal purposes"*.

Table 1. Area or places of collection of biological material for access

Species	Department	Province	Locality/ District	UTM Coordinates		
				Zone	East	North
Echinopsis spp	Piura	Huancabamba	Huancabamba	17 M	667745.16	9438962.05
	Lima	Huarocharí	Huarocharí	18 L	311582.00	8668394.00
	Lima	Huarocharí	Langa	18 L	345797.30	8659752.86
	Ancash	Huari	Chavín de Huántar	18 L	264373.38	8937200.65
	Ancash	Huari	San Marcos	18 L	257996.78	8950102.06
	Junín	Tarma	Tarma	18 L	422013.00	8739129.00
	Lima	Lima	Matucana	18 L	346666.85	8692254.08

Source: Prepared by DGSPF-SERFOR

This authorization does not authorize the export of samples of wild flora of the genus *Echinopsis* spp. If it is necessary to export the samples obtained, the user and the research team identified in this resolution may apply for the corresponding Export Permit before SERFOR through the Request desk for Foreign Trade - VUCE. The unique specimens of the collected taxonomic groups and holotypes can only be exported as a loan, having the document that proves the receipt of the samples in the corresponding country, the export permit and pass the respective control.

Article 4.- Authorize the participation of the specialists proposed to integrate the research team, as detailed below:

Table 2. List of specialists who will participate in the Project

Names and Surnames	Nationality	ID Document	Team Position	Stages in which he participates	Functions to be performed within each stage	Institution of Origin
					DNA Identification and Genetics	Universidad Peruana Cayetano Heredia-UPCH
					Chemical Identification	UPCH
					Sample extraction	Knize Nursery

Source: Prepared by DGSPF-SERFOR

Article 5.- For this project there is the participation of the user, as well as different areas of the Universidad Peruana Cayetano Heredia, as a National Support Institution, whose participation is detailed below:

Table 3. List of scientific institutions that will participate in the Research Project

Name of Institution	Address	Participation in the Project
"Magdalena Pavlich Herbarium" of the Universidad Peruana Cayetano Heredia - UPCH	Av. Honorio Delgado N° 430, San Martín de Porres, Lima	Sample processing, taxonomic identification of collected species, organization, and conditioning of specimens.
Science and Technology Research and Development Laboratory of the Natural Products Research Unit of the UPCH		Chemical identification processes
Genomics Unit Research and Development Laboratory of Science and Technology of the UPCH		Genetic work: description of the molecular identification of the collected plants of <i>Echinopsis</i> spp.

Products purified and quantified by spectrophotometry will be sent for sequencing to Macrogen Korea (<https://dna.macrogen.com/>) who will participate as a service party.

Article 6.- The Peruvian origin of the authorized genetic resources is recognized, the Peruvian State is the owner of the biological resources and the genetic resources contained, object of the authorized research project, obtained through the samples collected, regardless of whether they are conserved in *ex situ conditions*, inside or outside the country.

Article 7.- The company Neural Therapeutics Inc. shall share in a fair and equitable manner the benefits derived from the utilization of genetic resources and derivatives, with mutually agreed conditions, according to the following detail:

Type	Proposed benefits	Proposal for implementation
Mandatory	Dissemination of research results to relevant actors, including suppliers of the biological resource, in accordance with the provisions of authorizations and contracts.	<ul style="list-style-type: none"> – Dissemination of research results to communities near collection sites via virtual means. – Dissemination of the results to students or science technicians coordinating with the UPCH.
	Collaboration, cooperation and/or contribution to the education and training of relevant actors, specialists and/or technicians.	<ul style="list-style-type: none"> – UPCH researchers will become specialists in the identification of <i>Echinopsis</i> by DNA and alkaloid analysis, further enhancing their research skills and knowledge. – Local and interested people will be invited to participate in demonstrations of cuttings transplants to ensure the continuity of local species. –
Optional	Transfer of knowledge and technology to the provider of biological resources or to the inhabitants of the locality of origin of the biological resources on fair and more favorable terms.	Face-to-face or virtual talks or conferences will be given to any interested person such as students, members of the scientific community, members of related entities such as SERFOR, MINSA, etc., which will be given by the scientists who participated in the project.

Article 8.- Any intellectual property rights derived from the present research project for which access to genetic resources and their derivatives is authorized, will be the right of the user to process such intellectual property rights that will correspond to her and must be recognized.

Article 9.- In accordance with the considerations set forth in this resolution, the company Neural Therapeutics Inc. has the right to access genetic resources and their derivatives, through their collection, use, conservation in *ex situ* and *in situ* conditions, for research purposes, without commercial purposes.

Article 10.- Within the framework of the authorization, the rights of the company Neural Therapeutics Inc. are the following:

- a) Access to the genetic resources contained in the biological material of the species authorized to collect and use, for the fulfillment of the objectives presented in the research project, within the framework of the conditions and terms of the authorization or contract.
- b) To be assisted by SERFOR, for the fulfillment of its obligations.

Article 11.- Within the framework of the authorization, the rights and obligations of the Universidad Peruana Cayetano Heredia-UPCH, as a National Support Institution, are the following:

- a) Promote joint actions with the user to strengthen their capacities in research, management and technology transfer related to genetic resources and their derivatives.
- b) Negotiate with the user its benefits, within the framework of the accessory contract signed with the user.

- c) Maintain the confidentiality of the activities and results involved in the scientific research, technological development and / or innovation project.
- d) Comply with the commitments agreed in the accessory contract.

Article 12.- The company Neural Therapeutics Inc. and the National Support Institution are jointly and severally liable for the damages caused, by the researchers who are part of the project, to the genetic material contained in the biological material, if this is derived from the breach of any obligation provided for in the authorization or the contract granted.

Article 13.- In accordance with the considerations set forth in this resolution, the company Neural Therapeutics Inc. has the following obligations:

- a) Implement security measures and elimination of impacts that may occur due to the development of research activities, such as those related to data collection, treatment and transportation of samples, equipment transportation, personnel, among others that could mean a risk to the samples.
- b) Submit to SERFOR annual reports of progress and/or results, as well as publications generated from the research carried out, within the framework of the obligations contained in the access authorization.
- c) Provide the non-monetary benefits established in this authorization.
- d) Inform SERFOR of any change or modification to the provisions of the access authorization.
- e) Include in publications, research and results the origin of the genetic resources and their derivatives accessed, as well as the reference to the corresponding authorization or contract.
- f) Provide SERFOR the integrity of the information in Spanish regarding the purposes, risks, or implications of access, including possible uses of genetic resources; as well as information relating to the background, state of science or otherwise, which contributes to a better knowledge of the situation regarding genetic resources, inside and outside the national territory.
- g) To patent only products or processes that have been obtained or developed from Genetic Resources or their by-products.
- h) Deliver to SERFOR, at the end of the investigation, the Final Report with the results obtained and possible scientific developments and future application, within a period not exceeding two (02) months from its completion with respect to the authorized scientific research project, according to the terms indicated in Annex 1. This Final Report must contain the publications made based on the genetic resources accessed; in the case of publications, these will be made with prior knowledge of SERFOR and, in this case, the origin of the genetic resources accessed must be expressly recognized, as well as deliver together with the Final Report, the fulfillment of the non-monetary benefits.

Article 14.- In the development of the authorization of access to genetic resources and their derivatives without commercial purposes, granted by this resolution, it is prohibited to:

- a) Assign or transfer to third parties, without authorization from SERFOR, access, management, or use of authorized genetic resources.
- b) Claim any type of ownership over the genetic resource per se or its derivatives.
- c) Use the genetic resources accessed for purposes other than those established in the authorization or access contract.

Article 15.- If during the execution of the authorization granted data, information, or a discovery with commercial or industrial potential that is required to be used is generated or produced, the user must request SERFOR to sign an access contract for commercial purposes in accordance with the procedure established in the Regulations on Access to Genetic Resources and their Derivatives, which shall set out mutually agreed terms and benefit-sharing.

Article 16.- Once the activities of access to genetic resources and their derivatives have been completed, the user shall be responsible for the final destination of the genetic material used, in accordance with the provisions of Article 3 of this resolution.

Article 17.- Contravention of the obligations and/or conditions established in this resolution may be subject to determination of administrative responsibilities in accordance with the provisions of Exhibit 5 of the Regulations on Access to Genetic Resources and their Derivatives, approved by Supreme Decree No. 019-2021-MINAM.

Article 18.- Notify this resolution to the company Neural Therapeutics Inc. for its knowledge and purposes.

Article 19.- Notify this resolution to the Universidad Peruana Cayetano Heredia-UPCH, in its capacity as National Support Institution, for its knowledge and purposes.

Article 20.- To send this resolution to the Directorate of Information and Registration of SERFOR, for its corresponding registration; as well as, to the Directorate of Control of the Management of Forest Heritage and Wildlife, for the supervision of its compliance, if applicable.

Article 21.- Send a copy of this Resolution to the Office of User Services and Documentary Processing, for custody and archiving in the digital repository.

Article 22.- To arrange for the publication of this resolution on the SERFOR website: www.gob.pe/serfor.

Register, communicate and publish,
Digitally Signed Document
WILLIAMS ARELLANO OLANO
Director
Directorate of Sustainable Management of the
Forest Heritage
National Forest and Wildlife Service - SERFOR

DIRECTORIAL RESOLUTION

EXHIBIT 1

ANNUAL REPORT OF PROGRESS FORMAT AND/OR RESULTS OF THE AUTHORIZATION OF ACCESS WITHOUT COMMERCIAL PURPOSES

In order to comply with the commitments assumed in the Authorization of access to genetic resources and / or their derivatives without commercial purposes, the user must present the results of the authorized research, taking into account the following:

Submit to the Directorate of Sustainable Management of Forest Heritage of SERFOR the annual reports of progress and / or results in Spanish as a result of access to genetic resources and their derivatives. This information may be delivered in digital format through the application of the virtual parts table of SERFOR (<https://apps.serfor.gob.pe/mesadepartesvirtual/#/>) or physical in printed format at the face-to-face parts table of SERFOR (Av. Javier Prado Oeste 2442, Magdalena del Mar). To this end, the report to be submitted must have the following format:

- a) Contract number for access to genetic resources.
- b) If applicable, indicate the **Addendum** number that accredits the modifications made to the contract.
- c) Indicate the resolution number authorizing the investigation involving the collection and/or the export permit number (if applicable)
- d) General description of the methodology approved under the access contract and the places where access to the genetic resources of the authorized species was made.
- e) Results or progress of the project within the framework of the proposed objectives.
- f) Details of the benefits generated by access to genetic resources within the framework of the authorization of non-commercial access.