



PROJECT IDENTIFICATION FORM (PIF)

PROJECT TYPE: MEDIUM-SIZED PROJECT

TYPE OF TRUST FUND: NPIF

PART I: PROJECT IDENTIFICATION

Project Title:	Promoting the application of the Nagoya Protocol on ABS in Argentina		
Country(ies):	Argentina	GEF Project ID:	5820
GEF Agency(ies):	UNDP	GEF Agency Project ID:	5339
Other Executing Partner(s):	Secretary of Environment and Sustainable Development (SAyDS); National Institute of Agricultural Technology (INTA); and Chubut Province	Submission Date:	May 7, 2014
GEF Focal Area (s):	Biodiversity	Project Duration (Months):	36
Name of parent program (if applicable): ➤ For SFM/REDD+ <input type="checkbox"/>	N/A	Agency Fee (\$):	86,346

A. INDICATIVE FOCAL AREA STRATEGY FRAMEWORK:

Focal Area Objectives	Trust Fund	Indicative Grant Amount (\$)	Indicative Co-financing (\$)
BD-4: Build Capacity on Access to Genetic Resources and Benefit Sharing	NPIF	908,904	3,000,186
Total Project Cost		908,904	3,000,186

B. INDICATIVE PROJECT DESCRIPTION SUMMARY:

Project Objective: To contribute to the implementation of the Nagoya Protocol by strengthening the national access and benefit-sharing (ABS) framework and facilitating access to genetic resources of guanacos for the development of an anti-diarrheal treatment.

Project Component	Grant Type	Expected Outcomes	Expected Outputs	Trust Fund	Indicative Grant Amount (\$)	Indicative Co-financing (\$)
1. Strengthening the national ABS framework and building capacity to facilitate implementation of the Nagoya Protocol	TA	<ul style="list-style-type: none"> - Nagoya Protocol ratified - National framework for the protection of traditional knowledge in place - ABS regulation and administrative procedures of the Chubut province approved - The capacity of the indigenous affairs, protected areas, forests, fishing, and agricultural divisions of the Environment Ministry in Chubut province to implement the ABS framework improved by 	<ul style="list-style-type: none"> - Increased political support and knowledge by the Argentinean Congress related to the potential scientific, technological, and socioeconomic benefits for the country from ratification of the Nagoya Protocol - Draft proposals for a national framework for the protection of traditional knowledge and ABS regulations and administrative procedures of the Chubut province - 200 staff from the National or Federal Competent Authority 	NPIF	313,139	1,226,760

		<p>at least 35% as measured by the ABS Capacity Development Scorecard</p> <ul style="list-style-type: none"> - 60% of the population of researchers, local communities, indigenous peoples, and relevant industry targeted by the campaign is aware of the national law and Convention on Biological Diversity (CBD) and Nagoya Protocol provisions related to ABS and traditional knowledge 	<p>(NCA), institutions within the Chubut province and local communities trained in ABS rules and procedures, community protocols, and traditional registries including negotiation of ABS agreements and monitoring of bioprospecting projects</p> <ul style="list-style-type: none"> - Training programme and modules on bioprospecting, value chains, marketing, business planning, codes of conduct, and research procedures community protocols/ traditional knowledge registries developed and made available to relevant federal and state institutions - Integrated national information system for ABS projects on genetic resources and traditional knowledge linked to designated checkpoints - Campaign to raise awareness about the ABS law, the CBD, the Nagoya Protocol, and the scientific, technological, and socioeconomic benefits targeting researchers, local communities / indigenous peoples, industry, and relevant stakeholders - Knowledge, attitudes, and practices (KAP) assessment surveys targeting specific groups (e.g., researchers, local communities / indigenous peoples, industry, and relevant stakeholders) that may use or benefit from current or emerging ABS transactions are carried out to assess enhanced awareness about national ABS law, the CBD, and the Nagoya Protocol 			
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<p>2. Contributing to the conservation and sustainable use of genetic resources derived from the guanaco population</p>	<p>TA</p>	<ul style="list-style-type: none"> - Reduction by 20% to 25% (baseline and target to be confirmed during the PPG) of illegal hunting of guanacos in productive landscapes of Chubut province - 200 hectares (ha) of landscape management tools (e.g., live fences, agroforestry and/or silvopastoral systems, enrichment of existing forests, etc.) strategically placed in the production landscape improve the habitat of guanacos - Capacity of local communities and indigenous peoples who reside in the production landscapes of the Chubut province to mainstream principles for the conservation and sustainable use of guanacos into production practices improved by X% as measured by the UNDP's capacity development scorecard (baseline and target to be determined during the PPG) 	<ul style="list-style-type: none"> - National and provincial management plans for the conservation and sustainable use of guanacos between 2013 and 2018 strengthened - Landscape management tools protocol (e.g., live fences, agroforestry and/or silvopastoral systems, enrichment of existing forests, etc.) improves the quality of life for local communities and contributes to the conservation of guanacos and their habitat - Survey protocol for the study of the sanitary status of the guanaco population in Chubut province contributes to its conservation 	<p>NPIF</p>	<p>100,000</p>	<p>766,136</p>
<p>3. Pilot project uses genetic resources from guanacos to develop an anti-diarrheal product and demonstrates PIC and MAT, including fair and equitable sharing of benefits</p>	<p>TA</p>	<ul style="list-style-type: none"> - ABS agreement(s) negotiated between INTA and government representatives of the Chubut province - Anti-diarrheal product based on VHH as a treatment to prevent diarrhea caused by rotavirus and/or norovirus (model antigens) - State-of-the-art technology (hardware, software, and know-how) transferred from the Vrije Universiteit Brussel (VIB) to INTA 	<ul style="list-style-type: none"> - Monetary and non-monetary benefits derived from the use of genetic resources and their derivatives of guanacos are agreed to by INTA and government representatives of the Chubut province -Structural, biochemical, and functional properties of VHH nano-antibodies (nAb) from guanacos identified and compared with the properties of llamas - Pre-clinical studies using VHH expressed in baculovirus or E. coli to supplement the milk diet as a preventive strategy for 	<p>NPIF</p>	<p>413,138</p>	<p>734,545</p>

			diarrhea caused by RVA and/or norovirus			
			Subtotal		826,277	2,727,441
			Project Management Cost	NPIF	82,627	272,745
			Total Project Costs		908,904	3,000,186

C. INDICATIVE CO-FINANCING FOR THE PROJECT BY SOURCE AND BY NAME IF AVAILABLE, (\$)

Sources of Co-financing	Name of Co-financier	Type of Co-financing	Amount (\$)
National Government	SAyDS	Cash	1,309,811
National Government	SAyDS	In-kind	23,125
National Government	INTA	Cash	215,000
National Government	INTA	In-kind	500,000
Local Government	Chubut Province	Cash	826,250
Private Sector	ALGENEX Spain	In-kind	46,000
Private Sector	Vrije Universiteit Brussel	Cash	30,000
GEF Agency	UNDP	Cash	50,000
Total Co-financing			3,000,186

D. INDICATIVE TRUST FUND RESOURCES (\$) REQUESTED BY AGENCY, FOCAL AREA AND COUNTRY

GEF Agency	Type of Trust Fund	Focal Area	Country Name/Global	Grant Amount (a)	Agency Fee (b)	Total c=a+b
UNDP	NPIF	Biodiversity	Argentina	908,904	86,346	995,250
Total Grant Resources				908,904	86,346	995,250

E. PROJECT PREPARATION GRANT (PPG)¹

Please check in the appropriate box for PPG as needed for the project according to the GEF Project Grant:

\$50k for projects up to & including \$1 million

<u>Amount Requested (\$)</u>	<u>Agency Fee for PPG (\$)²</u>
50,000	4,750

PPG AMOUNT REQUESTED BY AGENCY(IES), FOCAL AREA(S) AND COUNTRY(IES) FOR MFA AND/OR MTF PROJECT ONLY

Trust Fund	GEF Agency	Focal Area	Country Name/Global	(in \$)		
				PPG (a)	Agency Fee (b)	Total c = a + b
NPIF	UNDP	Biodiversity	Argentina	50,000	4,750	54,750
Total PPG Amount				50,000	4,750	54,750

¹ On an exceptional basis, PPG amount may differ upon detailed discussion and justification with the GEFSEC.

² PPG fee percentage follows the percentage of the GEF Project Grant amount requested.

PART II: PROJECT JUSTIFICATION

A. Project Overview

A.1 Project Description

Overview: The proposed project seeks to strengthen the national and provincial ABS framework in accordance with the Nagoya Protocol, build the capacities needed for its implementation, and test ABS objectives by facilitating access to the genetic resources of guanacos under the principles of PIC, MAT, benefit-sharing and biodiversity conservation. The proposed strategy will facilitate the ratification of the Nagoya Protocol and its alignment with federal and provincial ABS regulations. INTA will access the genetic resources of guanacos in order to contribute to the development process of an anti-diarrheal product. The province of Chubut will provide the genetic resources of wild Guanacos used by INTA to develop this product. Chubut province will develop ABS laws or policies that reflect the minimum standards set by Federal Resolution 226/2010 in order to facilitate access to the genetic resources of guanacos and benefit-sharing arrangements.

1. **Global significance:** Argentina covers approximately 3.7 square kilometres (km²) of territory and is one of the most biodiverse countries in the world because of its latitudinal and altitudinal variation of climate, soil, and landscapes. The country has 18 ecoregions that include tropical forests, grasslands, and coastal/marine ecosystems. These ecoregions harbor more than 120,000 biological species. The country has 11,010 and 2,380 species of vascular plants and vertebrates, respectively. While the country lacks a complete inventory of invertebrates, preliminary records indicate that Argentina harbors approximately 111,000 species of arthropods, 550 species of mollusks, and 550 species of annelids. The largest number of endemic plant species is concentrated in the northwestern region of the country, particularly in Salta, Jujuy, Tucumán, Catamarca, and La Rioja provinces.

2. Argentina is one of the few countries of origin of the South American camelids (llamas, guanacos, and vicuñas). The Patagonia region of the country is home to the largest population of wild guanacos in the world (500,000 individuals). The guanaco (*Lama guanicoe*) is one of the largest herbivores in South America and is the largest of the wild camelids on the continent. The guanaco has evolved to occupy habitats with different vegetation structures, topography, climate, and the presence of human activities. Nevertheless, guanacos in Argentina have experienced a continuous decline in population due to European colonization.

3. The total human population of the Chubut province is approximately 506,668 (2010 census data). Chubut has a relatively low population density compared with the rest of the Argentinian provinces. Most of the population is located in the eastern coastal areas and in mountain valleys to the west. Small dispersed rural towns are found in the dry central plateau where the main economic activity is sheep farming. Guanacos are present in landscapes where the human population consists of rural communities, and to a lesser extent, indigenous peoples. In 2001, the rural population of the Chubut province was 43,427. In 2005, the total indigenous population of Chubut was 24,000, 53% of whom belong to the Mapuche group and the rest to the Tehuelche and Ona groups. Most of the indigenous population (72.2%) lives in urban centers, including the majority of the Mapuche (71.6%). In 2005, the Mapuche population living in a community comprised only 30% (3,955 people). Traditionally, guanacos have provided an alternative source of meat for rural people and their families.

4. **Threats to the guanacos:** Habitat transformation, competition for land because of the introduction of sheep, hunting, and climate change constitute the main threats faced by guanacos in the Chubut province. Habitat transformation is largely related to the overstocking of the natural feeding range of guanacos with domestic livestock, mainly sheep. The domestic sheep were introduced across the Guanaco's range, reaching 22 million heads within 50 years in the Argentine Patagonia region. Natural guanaco densities in the Chubut province are ≤ 2 individual/km², while sheep densities may reach more than 10 individuals/km². Both guanacos and sheep largely overlap in their foraging preferences, with more than 80% of their diets being identical. Sheep overstocking has resulted in the replacement of large native patches dominated by tall shrubs with high species richness with small dwarf shrub patches (dominated by *Larrea divaricata*) with low species richness, and the disappearance of natural grassy patches. Data on illegal hunting of guanacos for the 2006-2012 time period show that although there is a slight decrease in the number of illegal hunters intercepted, there is an increase in the number of confiscated animals; during this time 125 illegal hunters were detained and 376 animals were confiscated. Finally, according

to the International Union for Conservation of Nature (IUCN), land desertification due to overgrazing coupled with more severe and frequent droughts associated with climate change (models on climate change predict a sharp decrease in rain precipitation within the next 50 years in arid southern South America) may have major effects on the guanacos' abundance throughout their Patagonian range. Competition with sheep, hunting, and habitat modification have resulted in the guanacos occupying marginal, poor-quality lands in terms of vegetation cover and the availability of the most important plant species in their diet, since sheep ranching monopolizes the most productive areas.

5. *Biodiversity and ABS*: The Argentinean government recognizes the importance of the country's biological richness as a strategic resource for sustainable development as demonstrated by current biodiversity-related laws such as Law Nos. 24,375 and Resolution No 226. In this context, diversity found at the genetic level has a fundamental role in its enormous potential application in therapeutics, cosmetics, pharmaceuticals, biomedicines, and agroindustry among other industries. In turn, the way in which genetic resources are accessed and how the benefits of their use are shared, can create incentives for their research, conservation, and sustainable use, and can contribute to the creation of a fairer and more equitable economy in support of sustainable development.

6. *Baseline activities*: The baseline investment for this project builds on the following activities carried out since the late 1990s to strengthen the federal ABS and indigenous framework, conserve the guanaco population and unleash the potential of genetic resources of the guanaco in order to develop an anti-diarrheal treatment:

7. *Strengthening the federal and provincial ABS/indigenous peoples frameworks and capacity-building*: In 1994, Argentina ratified the CBD; three years later the Secretary of Environment and Sustainable Development (SAyDS) was designated as the institution in charge of facilitating implementation of the CBD. In 1997, the National Advisory Commission for the Conservation and Sustainable Use of Biodiversity (CONADIBIO) was also created in order to support SAyDS with the development of national policies to mainstream biodiversity principles into sustainable development. In 2011, the country signed the Nagoya Protocol; its ratification is currently under discussion in the National Congress. Argentina is a country with a federal and provincial system where federal laws set minimum standards that are adopted or strengthened at the provincial level through additional laws or policies. Today, ABS is regulated by Resolution No. 226, which establishes a federal regime including a registry for access applications. While provinces such as Jujuy and Misiones have approved ABS laws that are consistent with the federal resolution, other provinces such as Chubut still need to develop provincial-level ABS frameworks.

8. Implementing Resolution No. 226 on ABS and the Nagoya Protocol requires strengthening the capacities of key institutions and raising awareness about the importance of genetic resources and traditional knowledge, and the promotion of research and scientific knowledge on genetic resources and their utilization, to promote a fair and equitable benefit distribution of products derived from these resources. During the last few years, SAyDS has been undertaking capacity-building activities for several government organizations (e.g., customs, the National Institute of Fishing Research and Development [INIDEP], INTA, etc.) to facilitate the understanding of Resolution No. 226.

9. Argentina also has a comprehensive set of laws and policies to protect the rights of indigenous and local communities. These include Law No. 23,302, which promulgates indigenous policy and support to aboriginal communities, and Law 24,071, which ratifies the Indigenous and Tribal Peoples Convention No. 169 of the International Labor Organization. The National Institute of Indigenous Affairs (INAI) is the government organization in charge of developing channels and instruments to implement the rights of indigenous peoples protected by Article 75 of the National Constitution. To date, INAI has registered 925 indigenous communities in the National Registry of Indigenous Communities (RENACI) and is facilitating the participation of indigenous communities in the creation and implementation of development projects. INAI will also participate in requests involving PIC for use of genetic resources and the associated traditional knowledge,

10. *Conserving guanacos and their habitats*: In 2006, the National Guanaco Management Plan was approved; in 2007 the Chubut province adhered to this plan; and in 2007 the Ministry of Industry, Agriculture, and Cattle Ranching decided to formulate a provincial-level plan for the management of guanacos. In 2012, a 2013-2018 Guanaco Management Plan for the Chubut province was approved. The objective of the plan is to ensure the

conservation of the wild population of guanacos (*Lama guanicoe*) and estimate their biological, ecological, economic, cultural, and social value in Chubut. Key components of the plan include: a) maintaining the wild populations of guanacos and their habitat; b) using the populations of guanacos in a sustainable manner; and c) the ranking and re-valuation of the guanaco population by producers and the community.

11. *Using genetic resources from guanacos to develop an anti-diarrheal treatment:* Diarrhea is the second most common cause of childhood mortality worldwide, causing 1.3 million deaths among children under 5 years old. Group A rotavirus (RVA) is the leading cause of severe diarrhea in children and is responsible for approximately 29% of all diarrheal deaths, causing 453,000 deaths per year. Human rotaviruses have also been implicated as causative agents of diarrheal outbreaks occurring in nursing homes, among travelers, in daycare centers, and in patients suffering from a variety of immunodeficiency conditions. In Argentina, the RVA diarrhea mainly affects children from the northern region of the country.

12. Live-attenuated rotavirus vaccines are available to prevent rotavirus diarrhea in immunized children with demonstrated efficacy in developed countries. In Argentina, the vaccines are available but they are not included in the obligatory vaccine calendar, and their high cost precludes the low-income population from impoverished areas from accessing the vaccine. However, although they are excellent tools to control the disease, these kind of live-attenuated vaccines are not suitable for children suffering from immune deficiencies. Recent clinical trials showed that RVA vaccines have significantly lower efficacy in countries with limited infrastructure and resources, usually the countries with the highest RVA burden.

13. In 1989, a new type of antibody was identified, first in the sera of dromedaries and subsequently in all other species of the Camelidae family. Building on this research, INTA has been investigating llama-derived single-chain antibody fragments (VHH) recombinant nanoantibodies as complementary or alternative passive immunity strategies to prevent RVA-induced diarrhea and as a potential treatment option. INTA developed and filed applications for patent rights of two VHHs named 3B2 and 2KD1, which were able to neutralize heterotypic RVA strains independently of their serotype. Furthermore, with the support of a Fogarty Grant from the National Institutes of Health (NIH) in the United States, INTA demonstrated that supplementation of a milk diet with 3B2 VHH twice a day for nine days conferred full protection against rotavirus-associated diarrhea and significantly reduced virus shedding in a suckling mouse model as well as in gnotobiotic piglets experimentally inoculated with a human RVA. In addition, INTA developed VHHs against human norovirus, which is the main cause of food-borne diarrhea in humans of all ages. This infection represents a huge health problem in immuno-compromised patients, and to date there is no vaccine or specific treatment available to control norovirus-induced diarrhea.

14. All camelids possess heavy-chain antibodies and are potential sources of VHH libraries; however, wild guanacos have never been used for this purpose. INTA's goal with this GEF-funded project will be to explore wild guanacos as a source of VHH nano-antibodies and compare the structural and biochemical properties of their VHH with those obtained from domestic llamas.

15. During the timespan of the proposed GEF investment (2015-2018), the **baseline project** consists of foundational initiatives estimated at \$2,950,186. These initiatives will strengthen the federal and provincial capacity to enable ABS frameworks (\$1,332,936). Specifically, the support from GEF will facilitate the ratification of the Nagoya Protocol and will raise awareness about ABS access procedures, industry requirements, and monetary and non-monetary benefits that will be negotiated between the users and the providers of the genetic resources. Additionally, the baseline will enable the conservation of guanacos in Chubut province through the implementation of the Guanaco Management Plan (\$826,250), which has as its main objectives to conserve guanaco populations and their habitats in harmony with sheep production; to promote the sustainable use of guanacos with rural diversification; and to raise awareness among local communities and producers about the guanacos' biological and socioeconomic importance. Bioprospecting research with camelids aimed at developing an anti-diarrheal product or treatment will continue under the leadership of INTA (\$715,000). Specifically, INTA is aware that all camelids possess heavy-chain antibodies and are potential sources of VHH libraries. However, wild Guanacos have never been used for this purpose. INTA's baseline project activities will be to: a) provide support for the structural and functional comparisons of VHH from guanacos and VHH from llamas; b) provide support for an Argentinian student to travel to Belgium for the development of two VHH libraries from a guanaco and llama immunized with the antigens of interest; c) facilitate the training of technical staff for the development

of VHH libraries; and d) support a student for the evaluation of the efficacy of rotavirus VHH in a transgenic mouse model. The Vrije Universiteit Brussel will collaborate with INTA to provide technical and laboratory support for developing and testing the VHH-based alternative treatment for acute gastroenteritis (\$30,000). The company ALGENEX (Alternative Gene Expression) Spain (\$46,000) will provide support for the development of transgenic mice expressing the VHH anti-rotavirus in their milk and will cover the costs related to the patent for the protection of the VHH rotavirus in Spain.

16. **Baseline scenario:** Despite the importance of these initiatives, they are insufficient to demonstrate the effectiveness of the national ABS framework and scientific community in unleashing the potential of genetic resources or to ensure that monetary and non-monetary benefits derived from these resources are shared equitably and conserve the biodiversity associated with the biological and genetic resources. Also, the necessary institutional and individual capacities to implement ABS-related initiatives is limited, including the ability of provincial governments and local communities to negotiate, implement, and monitor ABS agreements. In addition, the survival of the guanacos in production landscapes will remain uncertain; national and provincial guanaco management plans will continue to lack guidelines for implementing biodiversity-friendly management practices that diminish the impact of land users on the guanacos and their habitat or to ensure that other threats are reduced, including illegal hunting. It has been hypothesized that wild guanacos are a source of VHH nano-antibodies that may serve as a complementary or alternative passive treatment to prevent RVA-induced diarrhea; however, advances in this direction will be modest since the government support and the technical and financial capacities to develop and test an anti-diarrheal product based on VHH nanoantibodies will remain limited. INTA's goal with this GEF-funded project will be to explore the use of wild guanacos as a source of VHH nano-antibodies, and assess the structural and biochemical properties of their VHH compared with those obtained from domestic llamas.

17. The **long-term solution** is to promote the sustainable use of the genetic and biochemical resources of guanacos through scientific research, biodiversity conservation, and a strengthened federal and provincial ABS framework. Argentina must increase its ability to add value to its genetic resources by developing scientific practices and procedures that facilitate the flow of these resources from their natural habitats to the market. In return, the economic benefits derived from the marketing of products must be shared between users and providers of the genetic resource and contribute to the conservation of guanacos in their natural habitat.

18. Three specific barriers prevent the fulfilment of the proposed solution:

Barrier 1. Weak national ABS framework, limited capacity, and lack of public support prevent the operationalization of the Nagoya Protocol obligations.
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<p>In 2011, Argentina signed the Nagoya Protocol and its ratification is currently under discussion by the National Congress. While key provisions of the Nagoya Protocol have already been taken into account by Federal Resolution No. 226 (2010,) the National Constitution establishes that provinces have jurisdiction over their natural resources. Consequently, provinces must enact laws and policies that comply with the minimum standards set by the Federal Resolution No. 226 and are consistent with provincial-level regulations. This means that the provinces must develop their own ABS frameworks in order to facilitate implementation of the Nagoya Protocol. For this reason, it is necessary to strengthen mechanisms that will provide national level policy with greater legal security and transparency for the stakeholders involved in the access and use of genetic resources, their derivatives, and traditional knowledge, as well as enabling the update of a legal framework that promotes the use of genetic resources, their derivatives, and traditional knowledge, and which strengthens the fair and equitable distribution of benefits. The institutional and individual capacities within the provincial governments or implementing ABS are limited—this is due to the lack of knowledge and information on the topic, weak institutional framework for implementing ABS, and limited resources for training activities to strengthen the regulatory framework related to ABS. Currently, there are no plans to strengthen capacities in order to increase knowledge about genetic resources or national technologies. Similarly, knowledge among the civil and academic sectors about ABS is limited; representatives of civil society (non-governmental organizations [NGOs], companies, etc.), indigenous peoples (INAI, DPO, communities of PO, etc.), technical and administrative security agencies, scientists, and specialists (INTA, CONICET, universities, etc.) lack the skills required to implement ABS (e.g., ABS rules and procedures, negotiation of ABS agreements, and monitoring and tracking to ensure compliance). Finally, there is limited awareness among the multiple stakeholders about ABS</p>

legislation, the CBD, the Nagoya Protocol, and the potential benefits derived from the use of genetic resources.

Barrier 2: Limited capacity to mainstream biodiversity principles into production landscapes inhabited by guanacos.

Although the Provincial Guanaco Management Plan and the National Guanaco Management Plan include biodiversity conservation principles, they are limited in scope. The plans do not consider protocols for the development of landscape management tools (e.g., live fences, agroforestry and/or silvopastoral systems, enrichment of existing forests, etc.) that will generate socioeconomic and environmental benefits for local communities living in landscapes where guanacos naturally occur; thus, it is necessary to strengthen both the provincial plan and the national plan for the effective mainstreaming of the conservation and sustainable use of guanaco into livestock production practices. Additionally, the local communities and indigenous peoples who reside in the production landscapes of the Chubut province must be trained in biodiversity conservation principles and the implementation of landscape management tools.

The Provincial Guanaco Management Plan was developed fairly recently (2012), and a survey protocol for studying the sanitary status of the guanaco population in Chubut province is still lacking, as well as a census of guanacos to determine the size and density of the population. The plan is implemented through annual work plans (AWPs); AWP 2013 is the first developed and is considered a pilot effort. The plan also requires the strengthening of its monitoring and surveillance component in order to address the threats guanacos currently face, including illegal hunting. Finally, aspects related the sustainable use of guanacos and their incorporation into the management plans of protected areas still need to be strengthened in both the Provincial Guanaco Management Plan and the National Guanaco Management Plan.

Barrier 3. Limited capacity to develop an anti-diarrheal tool based on genetic information from Guanaco

VHH nano-antibodies from guanacos may be used to develop an alternative treatment to gastrointestinal infections; however, in Argentina they have not been studied in depth largely due to the limited political support and the lack of scientific knowledge and technology required. Acute gastroenteritis is the second most common clinical condition after respiratory infections; globally, 3 to 5 billion cases of acute gastroenteritis and nearly 2 million deaths occur each year in children under 5 years old. In Argentina approximately 1 million cases of acute gastroenteritis are reported annually. The highest rates are reported in the northwestern region of the country, where acute gastroenteritis causes 100 deaths per year in children under 5 years old, or 1.2% of deaths in this age group; in the northern region of Argentina this rate doubles to 2.1%. Rotavirus is the main causative agent of acute gastroenteritis and is responsible for 150,000 cases, 15,000 hospitalizations, and 30 deaths per year in children under 5 years old in Argentina; this represents 30% all acute gastroenteritis in this age group.

Although a rotavirus vaccine is already available, vaccination is not part of the government's obligatory vaccine calendar and its high cost precludes it from being accessed by the most economically disadvantaged populations. On the other hand, there is no vaccine for norovirus, which is the main causative agent of food-borne diarrhea in humans of all ages. Despite the fact that a VHH anti-norovirus may represent an alternative treatment for gastrointestinal infections, especially in immunocompromised patients, and that guanacos may possess better molecular VHH structures than llamas, their development is currently not a priority in Argentina. Additionally, the provincial and federal authorities have limited knowledge of the alternative treatments for acute gastroenteritis, and the whole range of the monetary and non-monetary benefits derived from developing guanaco-based VHH treatments has not been fully assessed. Accordingly, there is limited support from the government for developing research by national institutions and universities, who despite their interest in the topic usually work in isolation and with limited resources. In addition, the scientific knowledge and technology required for developing and testing a VHH-based alternative treatment for acute gastroenteritis is still not in place in the country, and local institutions have to rely on external universities and research centers for new scientific developments. Although scientific cooperation among national and international universities and research centers already exists, this needs to be strengthened through joint research and technology transfer.

19. *The GEF Alternative Scenario*: The GEF's incremental funding and co-financing resources will be used to overcome the barriers mentioned previously. It will contribute to the long-term solution through three interconnected strategies: (a) supporting actions to strengthen the federal and provincial ABS laws/policies and institutions, including the development of capacity-building actions inspired by the bio-prospecting pilot project (Component 3); (b) carrying out efforts to conserve guanacos (as a biological resource that provides the genetic resource) in production landscapes of Chubut province, and (c) advancing multi-partnership research for the discovery of a treatment or product derived from antibodies found in the milk of guanacos. Collectively these will provide the integrated approach needed to conserve guanacos and to strengthen a national and provincial ABS framework that will facilitate future bio-prospecting efforts that bring economic, social, and environmental benefits to the country.

Component 1: Strengthening the national ABS regulatory framework and building capacity to facilitate implementation of the Nagoya Protocol.

20. This component will include: a) the ratification of the Nagoya Protocol; b) the development of a national framework for the protection of traditional knowledge; c) the systematization of information at the federal level to facilitate ABS implementation; and d) the development of a regulatory, institutional, and individual capacity framework for ABS implementation at the provincial level (i.e., Chubut province).

21. A main objective of this project component is to provide a precise and transparent legal framework for the fair and equitable sharing of benefits arising from the use of genetic resources in Argentina. This will entail securing political support and building knowledge among the National Congress regarding the importance of the ratification of the Nagoya Protocol, including their commitment to the protection of traditional knowledge associated with genetic resources and the potential scientific, technological, and socioeconomic benefits of their use. Accordingly the project will allow the ratification of the Nagoya Protocol by the National Congress and will develop traditional knowledge registries and community protocols as the basis for clarifying PIC and MAT requirements between users and providers of traditional knowledge and biological resources. As part of the process for establishing clear rules and procedures for PIC and MAT, the project will facilitate: a) drafting a proposal for ABS regulations and administrative procedures for accessing genetic resources and developing, implementing, and monitoring ABS agreements with PIC, MAT, and BS principles in the Chubut province; and b) defining guidelines for checkpoints that collect information related to PIC, the source of the genetic resource, and relevant information related to the use of genetic resources. These project outputs will be developed in close coordination with provincial authorities, who will be trained in ABS rules and procedures, including negotiation of ABS agreements and monitoring of bio-prospecting projects. (100 staff from provincial institutions in Chubut, including staff from the indigenous affairs, protected areas, forests, fishing, and agricultural divisions of the Environment Ministry of Chubut, will be trained by project end.) Similarly, the project will improve the capacities of the National or Federal Competent Authority (NCA) and local communities and indigenous peoples through training of 100 staff on processing access applications, negotiating ABS agreements, and monitoring and tracking to ensure compliance.

22. To create conditions to promote and encourage research contributing to biodiversity conservation and its sustainable use, the project will develop a training program and modules on bio-prospecting, value chains, marketing, business planning, codes of conduct, community participation protocols, and research procedures that will be made available to federal and provincial research institutions. This will be complemented by the integrated national information system on ABS projects on genetic resources and traditional knowledge linked to designated checkpoints, which will facilitate decision-making and compliance. Finally, to build public support for ABS, the project will carry out a campaign to raise awareness about the ABS law, the CBD, the Nagoya Protocol, and the scientific, technological, and socioeconomic benefits that targets researchers, local communities/indigenous peoples, industry, and relevant stakeholders. To assess enhanced awareness about the national ABS law, the CBD, and Nagoya Protocol KAP assessment surveys that target these specific groups who may use or benefit from ABS transactions will be carried out.

Component 2: Mainstreaming biodiversity principles into the production landscape inhabited by guanacos.

23. The GEF investment will promote the conservation of guanaco in Chubut province by mainstreaming principles for their conservation and sustainable use into production practices. This will be achieved by contributing

to the reduction of illegal hunting of guanacos in Chubut province (between 20% and 25%) and through the implementation of 200 ha of landscape management tools (e.g., live fences, agroforestry and/or silvopastoral systems, enrichment of existing vegetation, etc.), which will be strategically placed in the production landscape in order to improve the habitat of the guanacos (e.g., enhancing natural grasses and shrub vegetation) while improving the quality of life of the local communities.

24. The outcomes mentioned previously will be achieved by strengthening the Province Guanaco Management Plan and the National Guanaco Management Plan through: a) strengthening monitoring and surveillance mechanisms to reduce illegal hunting and other threats; b) the development of protocols for implementing landscape management tools (e.g., live fences, agroforestry and/or silvopastoral systems, enrichment of existing forests, etc.) that will generate socioeconomic and environmental benefits for local communities living in landscapes inhabited by guanacos; c) the development of a survey protocol for studying the sanitary status of the guanaco population in Chubut province; and d) estimating the size and density of guanaco populations. To facilitate the mainstreaming of biodiversity principles into the production landscape inhabited by guanacos, local communities and indigenous peoples who reside in the production landscapes of Chubut province will be trained in biodiversity conservation principles and in the implementation of landscape management tools. Capacity development will be measured using UNDP's capacity development scorecard; the baseline and target capacity development will be determined during the PPG and the scorecard will be completed at least once more during project implementation.

Component 3: Pilot project uses genetic resources from guanacos to develop an anti-diarrheal product and demonstrates PIC and MAT, including the fair and equitable sharing of benefits.

25. This component will facilitate the development and testing of an anti-diarrheal product based on guanaco VHH nano-antibodies, which take into account PIC, MAT, and fair and equitable sharing of benefits, while at the same time contributing the conservation of this species. Through this component, INTA (user) will apply for access to the genetic resources of wild guanacos and negotiate monetary and non-monetary benefits with government representatives of the Chubut province (provider).

26. The following studies will be completed through this component in order to develop an anti-diarrheal product: a) comparison of structural and biochemical properties of VHH derived from guanacos vs. those obtained from llamas using rotavirus and norovirus as model antigens; b) pre-clinical testing using VHH expressed in baculovirus or *E. coli* to supplement the milk diet as a preventive strategy for RVA and/or Norovirus diarrhea; and c) development of an optimal combination protocol of RVA and/or Norovirus VHHs tested to develop an anti-diarrheal product. By project end, the milk supplemented with the 3B2 and 2KD1 will constitute a treatment against the RVA-induced diarrhea and an anti-diarrheal product based on VHHs as a treatment to prevent diarrhea caused by rotavirus and/or norovirus will be available.

27. The GEF investment will add to the Fogarty Grant Project (NIH), which was recently concluded with promising results. The GEF investment will allow finishing the pre-clinical study initiated under the Fogarty Grant using the larvae crude extract containing VHHs to supplement the milk diet as a preventive strategy for RVA-induced diarrhea. In this second stage, the design of a functional food for RVA prevention as well as a pediatric medication for RVA and norovirus treatment will be explored and studies of the host immune response will be studied in more detail. Finally, the GEF investment will help to establish the knowledge and technology required in Argentina for the use of genetic resources from guanacos to develop an anti-diarrheal product. To this end, the hardware, software, and knowledge from the Vrije Universiteit Brussel will be transferred to the INTA.

28. **Global environmental benefits.** This project will contribute to the conservation and sustainable management of the Argentinean guanaco population, which according to the IUCN is estimated to be between 466,000 and 520,000 individuals (IUCN). The project will also contribute to the conservation of critical guanaco habitat consisting of arid and semi-arid shrublands and grasslands that include species of *Acantholippia*, *Benthamiella*, *Nassauvia*, and *Verbena* genera, two endemic species of the genus *Prosopis*, one species of *Larrea* and species of the genera *Lycium* and *Schinus*. Additionally, the guanaco's natural habitat is home to a variety of animals including the Darwin's iguana (*Diplolaemus darwini*), Patagonian gecko (*Homonata darwini*), lesser rhea (*Pterocnemia pennata*), Patagonian tinamou (*Tinamotis ingoufi*), grey eagle-buzzard (*Geranoaetus melanoleucus*),

peregrine falcon (*Falco peregrinus*), band-winged nightjar (*Caprimulgus longirostris*), lesser canastero (*Asthenes pyrrholeuca*), Patagonia mockingbird (*Mimus patagonicus*), Patagonian yellow-finch (*Sicalis lebruni*), mara (*Dolichotis patagonum*), chinchilla (*Lagidium viscacia*), Patagonian weasel (*Lyncodon patagonicus*), Patagonian opossum (*Lestodelphis halli*), Patagonian skunk (*Conepatus humboldti*), puma (*Felis concolor*), and the South American grey fox (*Dusicyon griseus*). These and other species of global significance will benefit from the project.

29. **Innovation, sustainability and scale-up potential:** *Innovation:* This project is not only innovative but novel as this is the first time that genetic resources of wild Guanacos will be accessed in order to develop an anti-diarrheal product. Furthermore, this project is also innovative in Argentina as it is the first time that this country has the opportunity to develop an ABS framework at a Provincial level. Further innovation comes from the project's role demonstrating the link between scientists and decision makers, which will serve as a model for other countries that seek to build a bio-knowledge society for sustainable human development.

30. *Sustainability:* The outcomes of Component 1 will be sustainable insofar as they will be mainstreamed into national and provincial laws and policies and financial resources will be assigned to ensure the implementation of the national and provincial (i.e., Chubut) ABS framework. The outcomes of Component 2 will also be sustainable as the Province of Chubut is committed to ensuring the conservation and sustainable use of the Guanaco population through its Guanaco management plan. Component 3 will be sustainable as long as an anti-diarrheal product is developed and contributes to a sustainable flow of monetary and non-monetary benefits for the Province of Chubut. The successful negotiation of benefits may also contribute to the sustainability of conservation outcomes of Component 3.

31. *Scale-up potential:* The lessons learned from the development of an ABS framework for the Province of Chubut will be instrumental in structuring and delivering similar ABS schemes for other provinces. The linkages between key national stakeholders such as INTA and the province of Chubut will surpass the duration of this project affording sustainability of efforts and providing lessons for scale-up potential between INTA and other provinces.

A.2. Stakeholders. The following key stakeholders were identified:

Stakeholders	Implementation role
Secretary of Environment and Sustainable Development (SAyDS)	The SAyDS is charged with implementing environmental policies and management in Argentina. It is the focal point for the CBD and the Nagoya Protocol and will implement Component 1 of the project.
National Institute of Agricultural Technology (INTA)	INTA is a federal agency charged with the development, adaptation, and diffusion of technologies, knowledge, and learning procedures for agricultural, forest, and agro-industrial activities within an ecologically pristine environment. INTA will implement Component 3 of the project and carry out the output of Component 2 on the sanitary status of the guanaco population of Chubut province. INTA will provide laboratory and technical support for the development of single-domain VHH antibodies and will serve as co-financier of the project.
Chubut province and local communities	Institutions in Chubut province will be in charge of implementing Component 2 of the project, including the management plan and landscape management tools for the conservation and sustainable use of guanacos. Local and indigenous populations will receive benefits from the development of an alternative treatment for acute gastroenteritis using guanaco VHH antibodies. Additionally, they will benefit from training related to the implementation of ABS (e.g., processing access applications, negotiating ABS agreements, and monitoring and tracking to ensure compliance) and conservation of biodiversity, and will use and benefit from the implementation of landscape management tools (e.g., live fences, agroforestry and/or silvopastoral systems, enrichment of existing vegetation, etc.).
Private sector: ALGENEX Spain	ALGENEX (Alternative Gene Expression) Spain is a biotechnology company whose main focus is the development of vaccines, diagnostic reagents, and therapeutic molecules to

	improve human and animal health. It will participate in the project by developing transgenic mice expressing the VHH anti-rotavirus in their milk. ALGENEX Spain will host an Argentinian student to evaluate the effectiveness of VHHs generated by transgenic females to prevent murine rotavirus diarrhea in infants. This company will cover the costs related to the patent for the protection of VHH rotavirus in Spain.
Vrije Universiteit Brussel	The Vrije Universiteit Brussel will provide technical and laboratory support for developing and testing the VHH-based alternative treatment for acute gastroenteritis. Additionally, it will be instrumental in the transfer of technology and the development of technical skills needed by Argentinian researchers for the development of an anti-diarrheal treatment using guanaco VHH nano-antibodies.

A.3 Risk

Risk	Rank	Mitigation strategy
ABS is not a priority in the political agenda of national and provincial authorities	Low	To mitigate this risk, the project will highlight the potential benefits of the Nagoya Protocol and implementing ABS (including monetary and non-monetary benefits derived from the use of genetic resources) as a strategy to foster the development of science and technology in Argentina. This will include the development of activities to raise awareness among decision-makers about ABS, the CBD, and the Nagoya Protocol. Additionally, the project will provide training related to ABS (e.g., processing access applications, negotiating ABS agreements, and monitoring and tracking to ensure compliance) and facilitate the development of tools (e.g., an integrated national information system on genetic resources and traditional knowledge, protocols for the conservation/management of guanacos) that will strengthen their roles while maintaining their commitment to ABS and the project. Additionally, national and provincial authorities will actively participate in the design and implementation of the project, will serve as members of the project's Steering Committee, and will be invited to participate in the project's Scientific Advisory Board. The project will maintain continuous and close communication with all national and provincial authorities associated with biodiversity conservation and genetic resources in order to maintain a fluid dialogue.
Local communities, indigenous people and stakeholders are not fully committed	Low	The project will coordinate efforts to ensure that the awareness-raising activities in ABS integrate key stakeholders. The strengthening and the adequacy of ABS-related norms (e.g., PIC, MAT, BS, and protection of traditional knowledge) will further contribute to the involvement of all stakeholders. Additionally, the project will develop a stakeholder participation plan to ensure that local communities, indigenous people, and other stakeholders participate in all stages of the project (design, planning, implementation, and evaluation) in order to promote their commitment to the project and ABS.
VHHs derived from guanacos do not have more beneficial characteristics than other alternatives	Low	In case that the VHH anti-nanobodies obtained from guanacos have similar properties to the ones obtained from domestic llamas, they will still constitute an alternative treatment for acute gastroenteritis that can replace conventional and monoclonal antibodies. The project will establish solid cooperation relations with the international research community (e.g., Dr. Serge Muyldermans, Department of Structural Biology, Vrije Universiteit Brussel; Dr. Linda Saif, Ohio State University; and Dr. Lijuan Yuan, VA-MD Regional College of Veterinary Medicine, Virginia Tech) to ensure the quality of project investigations related to VHH anti-nanobodies obtained from guanacos.
Climate change	Low	The project will implement landscape management tools (e.g., live fences, agroforestry and/or silvopastoral systems, enrichment of existing vegetation, etc.) that will contribute to restoring natural grasses and shrub vegetation with improved species richness, thereby increasing the resilience of the guanaco habitat to climate

	change. Additionally, as part of the strengthening of the National and Provincial Guanaco Management Plans, short- and long-term climate change mitigation strategies will be defined.
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A.4. Coordination with other relevant GEF financed and other initiatives:

32. The project will work closely with the GEF initiative to *Support to the updating (2014-2020) NBSAP*, in particular regarding the integration and coordination of activities to mainstream biodiversity principles into public policies and facilitating the conservation and sustainable use of species such as guanacos nationwide. Argentina’s National Biodiversity and Action Plan (NBSAP) activities will also contribute to strengthening the national framework for ABS at the national and provincial levels, including complementarity of actions between ABS laws and policies and other relevant regulations such as the Fauna Conservation Law No. 22421, the Forest Law No. 26331, and CITES. In addition, the NBSAP will promote the development of a national integrated system of genetic resources that includes coordination, communication, and monitoring mechanisms for genetic resources. Because the SAYDS will act as Executing Agency for the NBSAP initiative and the project proposed herein, coordination and complementarity between the two projects will be facilitated.

B. Description of the consistency of the project with:

B.1 Consistency with National strategies and plans and assessments under relevant conventions:

33. By strengthening the framework for ABS agreements, furthering multiple partnerships for bio-prospection, and transferring related technology to local institutions, this proposal contributes significantly to the implementation of the Nagoya Protocol in Argentina and facilitates access to the genetic resources of guanacos for the development of an anti-diarrheal treatment.

34. The project will support biodiversity conservation in Argentina in accordance with the principles of the National Constitution. Argentina ratified the CBD (November 22, 1994) and is a signatory country of the Nagoya Protocol (November 15, 2011). The project is consistent with Argentina’s NBSAP, which aims to guarantee the conservation and sustainable use of biological resources, reduce adverse effects of production activities on biodiversity, and ensure the equitable sharing of benefits derived from the appropriate use of genetic resources. More specifically, the project is consistent with the NBSAP’s objectives and actions regarding the sustainable use of biodiversity; bio-regional planning and use of land; communication and capacity-building; understanding of functions of genes, species and ecosystems; access to information related to biodiversity by different sectors of society; the fair and equitable sharing of the benefits derived from the use of genetic resources; and the conservation of the cultural heritage of Argentina, among others. The project will also support the implementation of the regulatory framework, namely the Fauna Conservation Law No. 22421, through the development of mechanisms and instruments to facilitate implementation. Moreover, the project will contribute to national programs such as the National Program for Management and Sustainable Use of Wild Species and the Program for Protection of Habitats of Wild Fauna, which are the key instruments of the SAYDS to promote conservation and sustainable use of biodiversity. Finally, the project will support the implementation of the three components of the National Guanaco Management Plan (2006): a) capacity development for the conservation, management, and sustainable use of guanacos; b) support and strengthen provincial management plans; and c) promote management through education, communication, and training. Similarly, the project will contribute to strengthening the Provincial Guanaco Management Plan for Chubut province (2012) and will contribute to its implementation, in particular to the conservation of the guanaco population and its habitat.

B.2. GEF focal area and/or fund(s) strategies, eligibility criteria, and priorities:

35. This project will undertake key actions needed to conserve biological and genetic resources of the population of guanacos in the province of Chubut and provide the basis for strengthening national and provincial-level ABS policies, including benefit-sharing arrangements between users and providers of genetic resources; it will foster local research capacity on camelids genetic resources and advance the discovery of anti-diarrheal treatments that could benefit children worldwide; and will strengthen the current federal and provincial ABS framework of the Chubut province. Ultimately the project will create conditions that facilitate turning bio-

prospecting of camelids into a driver for conservation of critically endangered species of global value and for advancing new development models in the country that optimize the fair and equitable sharing of benefits derived from its comparative advantage as a biodiversity-rich country. In doing so it is aligned directly with the objective 4 of the GEF5 Strategy, *Build capacity on Access to genetic resources and Benefit Sharing (ABS)*.

36. The project is also consistent with the Aichi Biodiversity Targets (4, 5, 18, 19), and will significantly contribute to Target 16: *By 2015 the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization is in force and operational, consistent with national legislation*. By setting the initial framework for the win-win strategy of bio-prospecting and ABS agreement as potential sources of revenues for conservation, it will also provide insights for advancing Target 20: *Mobilize financial resources for effectively implementing the Strategic Plan for Biodiversity 2011-2020*.

B.3 The GEF Agency’s comparative advantage for implementing this project:


The UNDP has experience working globally in biodiversity conservation projects and in Argentina has provided support to the government in numerous and diverse programmes involving multiple stakeholders to support strategies and mechanisms for biodiversity and sustainable development. Since 2012, the UNDP has consolidated implementation of the third objective of the CBD through GEF-funded projects that facilitate not only the ratification of the Nagoya Protocol but also access to genetic resources and benefit-sharing in about 20 countries. The UNDP is working with governments and stakeholders in developing countries that already have a policy framework in place for ABS in order to assist them in accessing financing and to facilitate ABS deals such as sustainable ethical biodiscovery programs or deals between corporations interested in accessing genetic resources and organizations representing the providers of these resources. In this context, UNDP is also supporting local and indigenous communities for the development of payment and benefit-sharing mechanisms and bio-cultural community protocols. The UNDP is also supporting countries with the development of national ABS frameworks. The project will have the specialized support of the Senior Technical Adviser (STA) for ABS who holds a Ph.D. on a related topic with direct experience in ABS projects and manages a growing portfolio of ABS projects globally. The UNDP’s mandate on ABS is underscored by the UNDP’s Biodiversity and Ecosystems Global Framework (2012-2020) and the 2014-2017 Strategic Plan. Both policy documents emphasize the UNDP’s role in ABS capacity-building initiatives, including the development of national ABS frameworks and support for ethical biodiscovery efforts that facilitate the sharing of monetary and non-monetary benefits between users and providers of genetic resources in line with the Nagoya Protocol provisions.

PART III: APPROVAL/ENDORSEMENT GEF OPERATIONAL FOCAL POINT AND GEF AGENCY

A. RECORD OF ENDORSEMENT OF GEF OPERATIONAL FOCAL POINT ON BEHALF OF THE GOVERNMENT.

NAME	POSITION	MINISTRY	DATE (MM/dd/yyyy)
Diana Celia Vega	Director Secretary of Environment and Sustainable Development	Secretary of Environment and Sustainable Development	APRIL 29, 2014

B. GEF AGENCY) CERTIFICATION

This request has been prepared in accordance with GEF/LDCF/SCCF/NPIF policies and procedures and meets the GEF/LDCF/SCCF/NPIF criteria for project identification and preparation.					
Agency Coordinator, Agency name	Signature	DATE (MM/dd/yyyy)	Project Contact Person	Telephon e	Email Address
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