



# Standard Operating Procedure for Bioprospecting Collaborations

**NATIONAL BIODIVERSITY CENTRE  
MINISTRY OF AGRICULTURE AND FORESTS**



**STANDARD OPERATING PROCEDURE (SOP)  
FOR  
BIOPROSPECTING COLLABORATIONS**

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*Standard Operating Procedure (SOP) for Bioprospecting Collaborations August 2021*

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## **Abbreviations**

ABS	:	Access and Benefit Sharing
CNA	:	Competent National Authority
EoI	:	Expression of Interest
MoAF	:	Ministry of Agriculture and Forests
NBC	:	National Biodiversity Centre
NDA	:	Non-disclosure Agreement
NFA	:	National Focal Agency
NGOs	:	Non-Governmental Organizations
SOEs	:	State Owned Enterprise
SOP	:	Standard Operation Procedure



## **1. Introduction**

Bhutan being part of the Eastern Himalayan region, is rich in biological resources and have an age old tradition of living in harmony with nature that lead to accumulated rich Traditional Knowledge on the use of biological resources. Conservation has always played a pivotal role in Bhutan's development history but it is becoming an increasing challenge with the rapid socio-economic development of the country. There is a palpable need to incentivize and ensure the continuity of biodiversity conservation through bioprospecting and securing of fair and equitable sharing of benefits.

Bioprospecting or biodiversity prospecting is the exploration, extraction and screening of biological resources and its associated traditional knowledge for commercial utilization, such as the development of new drugs, seeds, health foods, cosmetics, agriproducts etc.

Bhutan has already institutionalized an Access and Benefit Sharing (ABS) Regime and have started engaging into bioprospecting with national as well as international collaborators. The Ministry of Agriculture and Forests (MoAF) is the Competent National Authority (CNA) for ABS. Discharging the functions conferred on it through the Secretary of the Ministry, the National Biodiversity Centre (NBC) is the National Focal Agency (NFA) facilitating the process. In line with this, the NBC has already ventured into developing collaborations as guided by the ABS Policy of Bhutan 2015 and Biodiversity Act of Bhutan 2003. Currently, there are eight ongoing bioprospecting collaborations with the Centre with few more still under negotiations. The existing bioprospecting collaborations, mainly the local ones are initiated by NBC while those with the International partner have been mostly established on requests from them.

Over the years, it has been realized that as the Partners enter into actualization phase or the commercial stage, it is important especially for the international companies to have a National Partner other than NBC to carry forward the commercial aspects of the collaboration. As a government organization, NBC cannot function as a collaborator especially in the commercial phase of the establishment. Furthermore, national investment agencies have also reached out to NBC showing their interest to venture into bioprospecting collaborations.

Towards this new developments, as there is no clear procedure in place for dealing with such cases of bioprospecting collaborations, this Standard Operation Procedure (SOP) is developed to provide





clear guidance for establishment and management any of the present or future bioprospecting collaborations. This is also in line with the directives of the Competent National Authority to streamline bioprospecting collaborations.

## **2. Title**

This procedure shall be called as the “Standard Operating Procedure (SOP) for bioprospecting collaborations”.

## **3. Rationale**

The rationale for developing this SOP is to ensure that a proper procedure and system is instituted to deal with bioprospecting collaborations.

## **4. Scope**

This SOP applies to all the bioprospecting collaborations established under the guidance of NBC and by NBC within the purview of ABS Policy of Bhutan 2015 and the Biodiversity Act of Bhutan 2003 or any subsequent legislations.

## **5. Objective**

The objective of this SOP is to guide the Competent National Authority and the National Focal Agency in dealing with bioprospecting collaborations. It will provide clarity to the collaborating partners and also serve as administrative measures for developing such collaborations.

## **6. Responsibilities**

It is the responsibility of the National Biodiversity Centre as the National Focal Agency and the Ministry of Agriculture and Forests as the Competent National Authority for the Access and Benefit Sharing to ensure that this procedure is adhered to while dealing with matters of bioprospecting collaborations.

## **7. Effective date**

This SOP shall come into effect from 1<sup>st</sup> August 2021 with the endorsement by the 123<sup>rd</sup> RNR GNHC of the Ministry of Agriculture and Forests.

## **8. Role of NBC in bioprospecting**

The NBC being the National Focal Agency facilitates the processing of bioprospecting proposals received from National or International Applicants as per the ABS Policy of Bhutan 2015 and Biodiversity Act of Bhutan 2003 or subsequent legislation. The Centre also facilitates networking with National Partners for International Collaborator upon their request. In addition, to add value to potential biological resources and promote community based natural resources management, the Centre initiates collaboration with National Partners and International Collaborators for natural product development as well as collaborates with International Applicants upon their request.

Before the categorization of the types of collaboration, it is imperative to understand the facilitating role of NBC in processing the bioprospecting proposals received from National or International Applicants, and management of bioprospecting research initiated by NBC without any partners or utilization of surrendered bioprospecting research results.

### **a. Processing of any type of Bioprospecting proposal**

NBC as the National Focal Agency would receive bioprospecting proposals and facilitate in its processing guided by the ABS Policy of Bhutan 2015, and as per the procedures outlined in Biodiversity Act of Bhutan 2003 or its subsequent legislations.

### **b. Bioprospecting Research without any partners**

As part of the bioprospecting research program, NBC on its own would explore and initiate research on potential biological resources or associated traditional knowledge without any partners. Further, there would be cases where bioprospecting research result is surrendered to NBC when the applicant/collaborator is not in a position to continue the research or when termination clause is triggered in the Scoping agreement etc. When the outcome of the bioprospecting research or surrendered results merits commercialization, the Centre would explore potential National or International Users including community groups or cooperatives as per the procedures outlined in the clause 11.2.





## **9. Types of potential bioprospecting collaborations**

In the field of bioprospecting, like in any other fields, there could be many intermediaries (such as private firms, governmental agencies, Non-Governmental Organizations (NGOs), State Owned Enterprise (SOEs,) individual entities etc.) along the process till the resources is utilized by the final end user. However, to comprehend the utilization aspect of the accessed genetic resources or associated traditional knowledge, the focus is on the end user. Currently, the known type of industries which are the main end users can be broadly categorized as below:

- pharmaceutical
- agribusiness (biotechnology, seed, crop protection and horticulture)
- cosmetics and personal care
- fragrance
- botanicals
- food and beverage

These industries being the end users are the main collaborators in the bioprospecting collaboration and would normally reach out or will be approached for any potential bioprospecting collaboration. The bioprospecting collaborations established under the guidance of NBC and by NBC can be broadly categorized into two groups namely collaboration facilitated by NBC and collaboration with NBC;

- a. Bioprospecting collaboration facilitated by NBC:** The collaboration facilitated by NBC is when an International Applicant request NBC to find a National Partners for them at the initial point of contact.
- b. Bioprospecting collaboration with NBC:** The collaboration with NBC is when NBC is a party to a collaboration.

## **10. Principle for Negotiations**

Any negotiations with bioprospecting collaborators shall be guided by the ABS policy of Bhutan 2015 and the Biodiversity Act of Bhutan 2003 or any subsequent legislations. The following core principles shall be taken into consideration during the negotiations.



- **National interest to benefit all:** The collaboration shall be of national interest benefiting all the people and the nation at large.
- **National Capacity building:** The collaboration shall result or focus in building or strengthening national capacities to develop a better understanding of our biological resources for effective conservation and sustainable utilization.
- **In-country Research and technology transfer:** As much as possible, in country research and technology transfer shall be encouraged for the collaboration.
- **Long term mutually supportive relationships:** The collaboration should be of mutually beneficial and respectful, long-term relationship by identifying common interests and possible areas of conflict with Bhutanese values.
- **Benefit sharing:** The collaboration shall generate tangible benefits for the conservation and sustainable use of biodiversity and securing ecosystem services.

## 11. Procedure

The procedure for the aforementioned bioprospecting collaborations shall be dealt as below:

### 11.1 Collaboration facilitated by NBC

- When an International Applicant requests NBC to find a National Partner for them at the initial point of contact, based on the merit of the proposal, NBC with the guidance of the Competent National Authority shall explore potential community groups/cooperatives to act as partners as well as stakeholders in the supply chain for the biological resources.
- Upon identification of the potential community groups/cooperatives, NBC shall seek their consensus as well as assess their capacity to act as the National Partner.
- Based on the above results, NBC shall connect the identified potential community groups/cooperatives with the International Applicant for them to formalize their collaboration and submit a bioprospecting proposal.
- The turnaround time for NBC to process and connect the identified community groups/cooperatives would be within a maximum of one month.





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- However, if the collaboration with community groups/cooperatives is not materialized, then NBC shall call for Expression of Interest (EoI) from interested eligible national parties through MoAF website and/or NBC website or any other suitable media platform upon the approval of the Ministry.
- The terms and conditions of the EoI shall set the criteria for the selection.
- After screening of all the applicants, NBC shall select the potential partners.
- NBC shall connect all the identified potential partners with the International Applicant for them to select their National Partner.
- The turnaround time for NBC to process and connect the parties would be within a maximum of two months.
- In the event that the parties are not able to form a collaboration even when the bioprospecting proposal benefits the community or conservation at large, in such cases, NBC may enter into a collaboration with the International Applicant upon approval from the Ministry.
- NBC shall not facilitate exploration of collaborators for National Applicants as it will be the responsibility of the National Applicants to already have an identified Collaborator.

### **11.2 Collaboration with NBC**

- NBC will be a collaborator when NBC is a party to any bioprospecting collaboration such as but not limited to:
  - When a request to collaborate from a national or international applicant is accepted by NBC based on the merits of the bioprospecting proposal,
  - When a collaboration with national partners is not formalized under clause 11.1. When NBC maintains status quo with all existing Collaborators under clause 11.2.
- When NBC is party to a collaboration and at the actualization phase or the commercialization stage, NBC shall consider the community groups/cooperatives established for the supply chain to act as business collaborator.
- In the event that the community groups/cooperatives are not in a position to act as a business collaborator, then NBC shall call for EoI from interested eligible parties





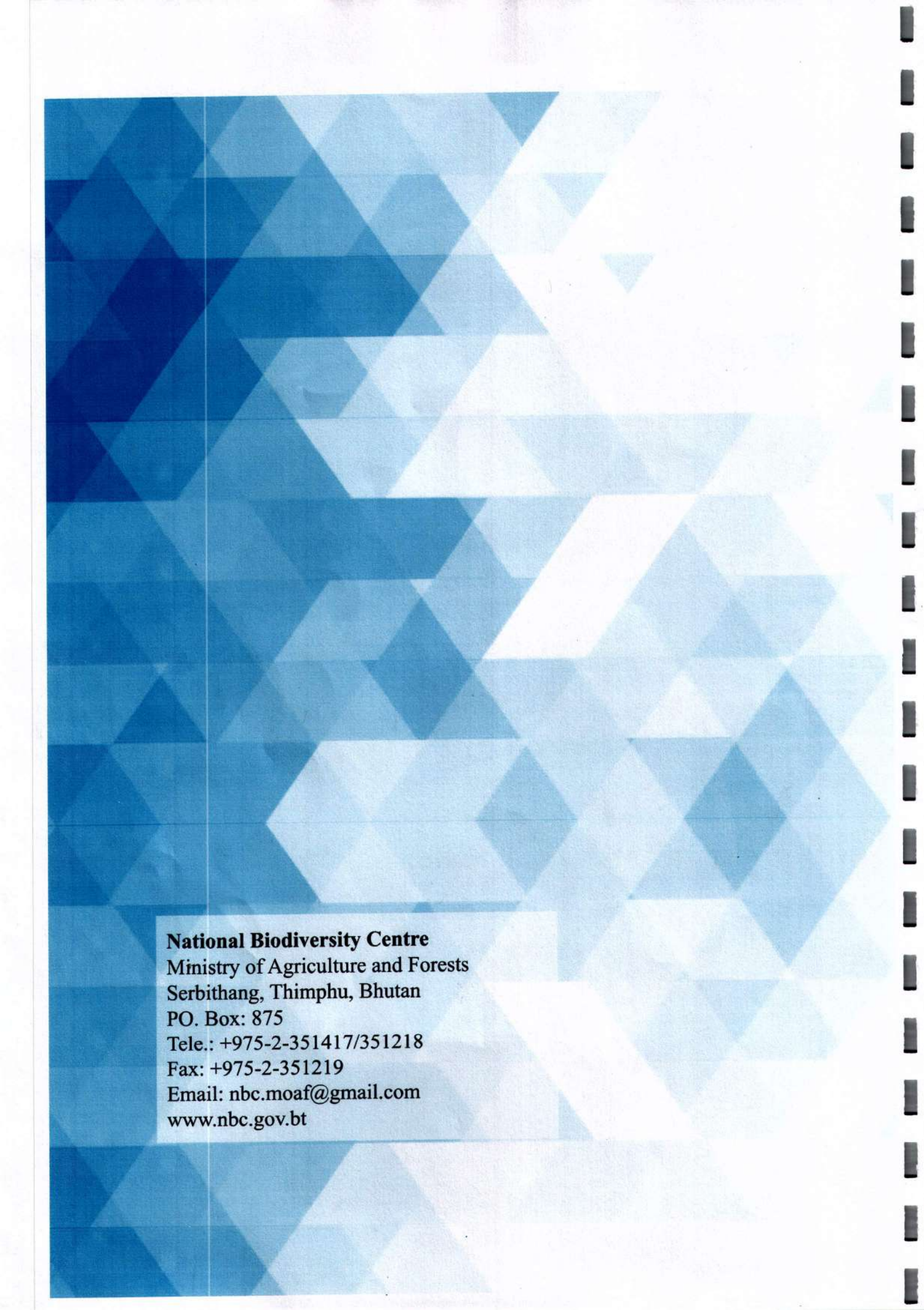
through MoAF website and/or NBC website or any other suitable media platform upon the approval of the Ministry to act as a business collaborator.

- The terms and conditions within the EoI shall set the criteria for the selection.
- Based on the nature of the project, NBC may charge certain payments for the investment incurred which shall be stipulated clearly in the EoI.
- After screening of all the applicants, NBC shall select the best applicant as the potential business collaborator and rank the others as standby.
- A non-disclosure agreement (NDA) shall be executed between NBC and the selected business collaborator to formalize the selection.
- After the formalization of the selection, NBC shall connect the parties for taking forward the collaboration.
- Upon reaching an agreement between the parties, NBC shall formalize the collaboration and accordingly apprise the Ministry.
- However, in case where the parties are not able to form a collaboration, NBC upon the endorsement of the Ministry may maintain status quo with all the existing Collaborators when the collaboration benefits the community or conservation at large.
- The turnaround time for NBC to process and the parties would be within a maximum of two months.

## **12. Amendment**

This SOP shall be subjected to periodic amendment by the RNR-GNHC, MoAF based on the developments within the ABS and practicality of its implementation or any other related complications.





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