Good Practice Guide & Agreement Toolkit for Access to Genetic Resources & Benefit-Sharing

for

Non-Commercial Research

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Background

2003 Swiss Academy of Sciences received mandate of the Swiss Federal Office for the Enviroment (BAFU / FOEN) to develop

- Tools, program on awareness-raising and capacity-building
- implement the Bonn Guidelines within academic research in Switzerland

2004 First survey among academia about its knowledge and experiences related to ABS

First Conclusions

Low and insufficient knowledge / awareness among scientists Plenty of research with transnational GR

Feedback by scientists: Need fast, simple procedures for noncommercial intent

Academia largest user



All biological material <u>containing functional units of heredity</u> subject to ABS regulations (CBD/Nagoya Protocol)

- → Collecting any GR → <u>all research</u> automatically falls under ABS regulations <u>regardless</u> of the type of utilization
- $\rightarrow~$ Academic research the largest user in <u>numbers of requests</u> for access to GR
- → Not reflected in the CBD/ABS negotiations nor in its regulations
- → ABS system geared towards <u>industrial product development</u>, with the aim of generating (monetary) benefits



•	Utilization = doing research	
•	With biological material (from another country)	\rightarrow Non-commercial utilization
•	Protect results with a patent	
-	Develop a new product	\rightarrow Commercial utilization
	Put product on the market	
	Make a commercial profit	

resources.

 \rightarrow All these activities have to be done according to the rules /laws of the country where you want to access the biological material.

Dual role of of non-commercial, basic research ("academia")



1) User of GR

- 2) Producer (provider) of urgently needed knowledge for the CBD goals 1 and 2:
 - Conservation AND
 - Sustainable use of <u>biodiversity</u>

→ Special role of science, important stakeholder

Analysis of academic activities regarding GR



- First access to GR
- Intermediary role (transfer of knowledge and / or material GR)
- $\rightarrow~$ Clear need of Provider to control flow of GR
- Academia generates (non-monetary) benefits
- \rightarrow Need for increased acknowledgement and awareness by Provider

Academic (scholarly) requirements

- Fullfil a set of goals in a given time period (with public funding)
- <u>Publication</u> and dissemination of results and conclusions
- Disclosure of information to peers for evaluation and <u>reproduction</u> of results
- Storage of material and data required → repositories
- Collaboration with specialists e.g. for <u>taxonomic identification</u> of GR (need to transfer the GR)

Ai	ms & requirements o	fP	roviders & Academia
Pro	vider	Ac	ademia
1)	Carefully assess proposal	1)	Fullfil a set of goals in a
2)	Keep information locked,		given time period
	precontrol of findings	2)	Publication of results
	(potential interest in IP by	3)	Disclosure for
	Provider)		reproduction of results
3)	Control the flow of GR and	4)	Storage of material and
	data		data
4)	Control of utilization of GR	5)	Collaboration with
5)	Control the transfer of GR	<i>.</i>	specialists e.g. for
·	to Third Party		taxonomic identification

Background analysis

Each research situation is unique, regarding

- Span of research
 - Basic (non-commercial) research → research & development R&D in an applied (and potentially commercial) context
 - Disciplines: Botany, zoology, ecology, agriculture, medicine, pharmacology, ethnobotany...
- Access situation
 - In-situ, collecting in the natural environment (,in the field')
 - Ex-situ, outside their natural habitat (repositories = storage facilities, such as germplasm collections, seed banks, botanic gardens...

Types of research	A	5	c	D		
with genetic resources ABS relevant research steps	Inventories (characterization & evaluation)		Functionality, Propagation ¹⁴ & Modification		[Research & Development, Commercialization]	
Type of accessed resources	Preserved genetic resources (dead material)	Living genetic resources	Preserved or living genetic resources Preserved or living genetic resources			
Overall goal of research activity			Identification, isolation, and characterization of active compounds Genomics and proteomics	nds horticulture and aquaculture; ¹⁵ development of		
Use made of resources	Collection, identification, classification; phenotype and functional characterization; measuring: basic molecular analyses (e.g. DNA sequencing, microsatellites) ¹⁶		Isolation of active compounds; characterization, purification; synthesis; multiplication of oegan- isms or parts thereof (unableced); staditional biotechnological processes Based on collection, identification; classification; basic molecular analysis	Isolation and insertion of target genes; molecu- lar cloning and transformation of genes, (struc- tures and characteristics); multiplication of cells and/or organisms Based on collection, identification; classification; basic molecular analysis		
Storage of samples	Researchers store samples in own lab Storage for scientific and/or educational use in public collections (museums, herbaria)	Researchers store samples in own lab Storage for scientific and/or educational use in public collections (2006, botanic gardens, seed banks, culture collections)	Besearchers store samples in own lab or in stock centre Culture collections ¹⁷			
Transfer of genetic resources to third parties (including	For identification purposes; loans for scientific work		Scientific cooperation with peers Stock centers, culture collections			
exchange with peers)	Sharing of duplicate specimens with other collection					
Products of research ¹¹	Publications, determination kays, presentations and reports Distribution maps Collections for scientific or educational purposes (museums, herbaria) Organismic and molecular data in private or public data bases	Publications, determination keys, presentations and reports Distribution maps Collections for scientific or educational purposes (e.g. botanical, zoological garden, cubure collections) Organismic and molecular data in private or public data bases	Publications, presentations and reports Purified camples; chemical formulas, isolated and identified genes Elaboration of new methods and technologies Organismis and molecular data in private or public data bases	Publications, presentations and reports located and identified genes, genetically modi- fied cells or organisms Elaboration of new methods and technologies Organismic and molecular data in private or public data bases		
Potential for further use of research results towards commercial product development ¹⁹	Published results can be further developed into commercial products		Published results (e.g. chemical formulae) can be further developed into commercial products Unauthorized use after access to stock centre or stored samples			
Benefits of research (P = for providing country; S = for scientists)	Bacic trowtedge of the living ventre (PBS) Biodiversity assessment, monitoring; information for biodiversity conservation & management (PBS) Scientific cooperation with peers (S) Education and outreach material (PBS) Capacity building (P) University ranking (S) Academic career benefits (S)	Basic knowledge of the living world (P&S) Biodiversity assessment; monitoring: information the biodiversity conservation & management (P&S) Its-situ and ex-situ biodiversity conservation (P) Scientific cooperation with pares (S) Education and outwach material (P&S) Capacity building (P) University ankings (S) Academic career benefits (S)	Back knowledge of the king world (P&S) Scientific and technological advancements (P&S) Patents (P and/or S) Scientific cooperation with peers (S) Capacity building (P) University rankings (S) Academic career benefits (S)			

Support for noncommercial academic research

- Good Practice Guide on ABS
- Toolbox with Model Clauses for Contracts (Mutually Agreed Terms)
- Website: <u>abs.scnat.ch</u>



Goal

- <u>Good Practice Guide and Agreement Toolbox</u> integrate different settings in their concept, structure and explanations.
- Consideration of different interests and concerns of <u>Users</u> and <u>Providers</u> (work included peer-reviewing)
- As <u>complex</u> as necessary but as <u>simple</u> as possible → Easy to understand for non-lawyers (e.g. affected scientists)
- No ready-made recipes
- Suggestions and hints on how best to proceed



The Good Practice Guide

Utilization of genetic resources and associated traditional knowledge in academic research

A good practice guide for access and benefit sharing

First version published in 2006

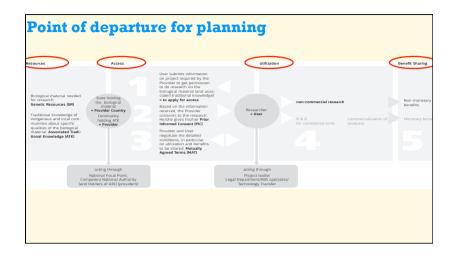


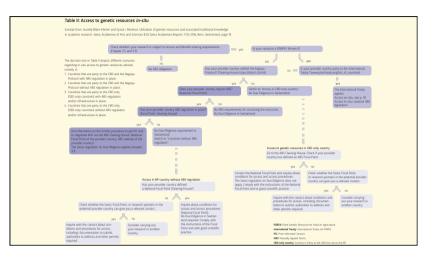
Intent

- General overview of ABS system and implications for academic research. Focuses on basic research supported by <u>public funding</u>
- Comprehensive information to assist scientists <u>and research</u> <u>institutions</u> in
 - planning and carrying out research projects that include GR an TK
- Presents legal obligations of scientists working in Switzerland according to the <u>Swiss legislation</u> and to ethical principles of <u>good scientific</u> <u>practice</u>.
- <u>Does not replace</u> legally binding obligations for researchers according to domestic ABS legislations or regulatory requirements in countries providing genetic resources.

Content

Purpose of the Manual Essentials of Access and Benefit-sharing for academic research 2.1 What is Access and Benefit-sharing? 2.2 Steps involved in ABS: where to find the pertinent information 2.3 The meaning of fundamental terms 2.4 Which legal framework applies to your research? 2.5 Recommendations on how to proceed 3 Implementation of the Nagova Protocol and the International Treaty in Switzerland 4 Case Studies 5 In-depth information on ABS 5.1 The rationale of ABS 5.2 The responsibility of academic researchers 5.3 Key terms: Genetic Resources, Access and Utilization and Benefit-sharing 5.4 International legal framework 5.5 Associated Traditional Knowledge 5.6 Elements of the ABS procedure: Authorities and instruments Additional permits for research on Genetic Resources II Glossary III Benefit-sharing in the context of academic, non-commercial research IV Links and Sources V National Focal Point





Case-study Medicine: Evolution and epidemiology of tuberculosis Tuberculosis (TB) causes many deaths....

This project aims to identify population-based surveys for the <u>cultivation of Mycobacterium</u> clinical and molecular determinants of tuberculosis epidemiology, to ascertain new evidence of the evolutionary pathway of TB in humans and livestock.

The project will establish a molecular characterization and clustering of TB strains in relation to prevalence, animal-human transmission and resistance to antibiotics. Repeated observational field studies will be conducted in close collaboration with the national tuberculosis programme in an African West and East Africa. country...

Livestock carcasses will be collected in abattoir tuberculosis complex.

Region-deletion polymerase chain reaction (PCR) and <u>sequencing</u> of single-nucleotide polymorphism of genes responsible for antibiotic resistance of all isolated TB strains will provide specific information on the evolutionary pathways of TB at the interface between humans and live-stock and between

Genetic resource	Mycobacterium tuberculosis complex: M. tuberculosis, M. bovis
Access	In-situ: Livestock carcasses containing Mycobacterium sp. Collecting of bacteria in carcasses and in humans.
Utilization	Isolation and cultivation of Mycobacterium tuberculosis, identification of strains with region-deletion polymerase chain reaction, and sequencing of single-nucleotide polymorphism.
Stakeholders involved in ABS-procedures	Research institute and Competent National Authority.
Steps	Apply for PIC and negotiate MAT for access to the micro-organisms.
Notes	Only microbial genetic resources are accessed. Human genetic resources are not included in the CBD.

Selection of benefits to be shared. from an academic perspective Training of students (graduate & postgraduate), capacity building

- Training of technical staff, technology transfer
- Involve local stakeholders as field assistants •
- Inform all stakeholders about research results .
- Provide information in an adequate language •
- Share specimens
- Involve partners as co-authors in publications, cooperation
- Facilitate access to scientific information
- Provide access to research findings •
- Maintain institutional and professional relationships
- Provide research infrastructure .

Evaluate the benefits your research generates \rightarrow "Marketing"

Toolbox: Agreement on Access and Benefit-Sharing for Academic Research

In support of the negotiation and compilation of Mutually Agreed Terms Offers

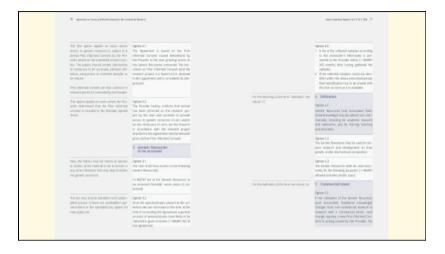
- A basic agreement that can be used as such in simple research situations
- Optional clauses that allow to adapt and complement the agreement to the specific needs of the user and the provider Adresses
- Users and providers
- Competent units of research institutions
- Project managers
- Serves as
- Template in a country that does not have a ready-made form
- Checklist for items to take into account
- Work is available as https://creativecommons.org/licenses/by-nc-sa/4.0/legalcode



Basic assumptions

- GR is accessed by researcher/team under the lead of a research institution
- Primary research purpose is <u>non-commercial</u>
 - Results will be publicly available
 - Results have to be published according to good scientific practice
- Unexpected findings might spark reflections on utilization in a commercial context (both User and/or Provider)
- Benefits are non-monetary as a rule

Preamble		9	
Parties to	the Agreement	10	18 Clauses
Clause 1	Lise of Terms in the Agreement	11	10 Clauses
Clause 2	Prior Informed Consent		
Clause 3	Genetic Resources to be accessed		
Clause 4	Utilization		
Clause 5	Commercial Intent		
Clause 6	Commercialization		
Clause 7	Intellectual Property Rights		
Clause 8	Transfer of Genetic Resources [and Associated Traditional Knowledge]		
	to Third Parties		
Clause 9	Storage of Genetic Resources	20	
Clause 10	Benefit-sharing		
Clause 11	Rights and Obligations of the Provider		
Clause 12	Rights and Obligations of the User		
Clause 13	Reporting		
Clause 14	Publication		
Clause 15	Duration and Termination of the Agreement		
Clause 16	Handling of the Genetic Resources after Termination of the Agreement		
Clause 17	Settlement of Disputes		
	Other provisions		🔬 e 📷



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