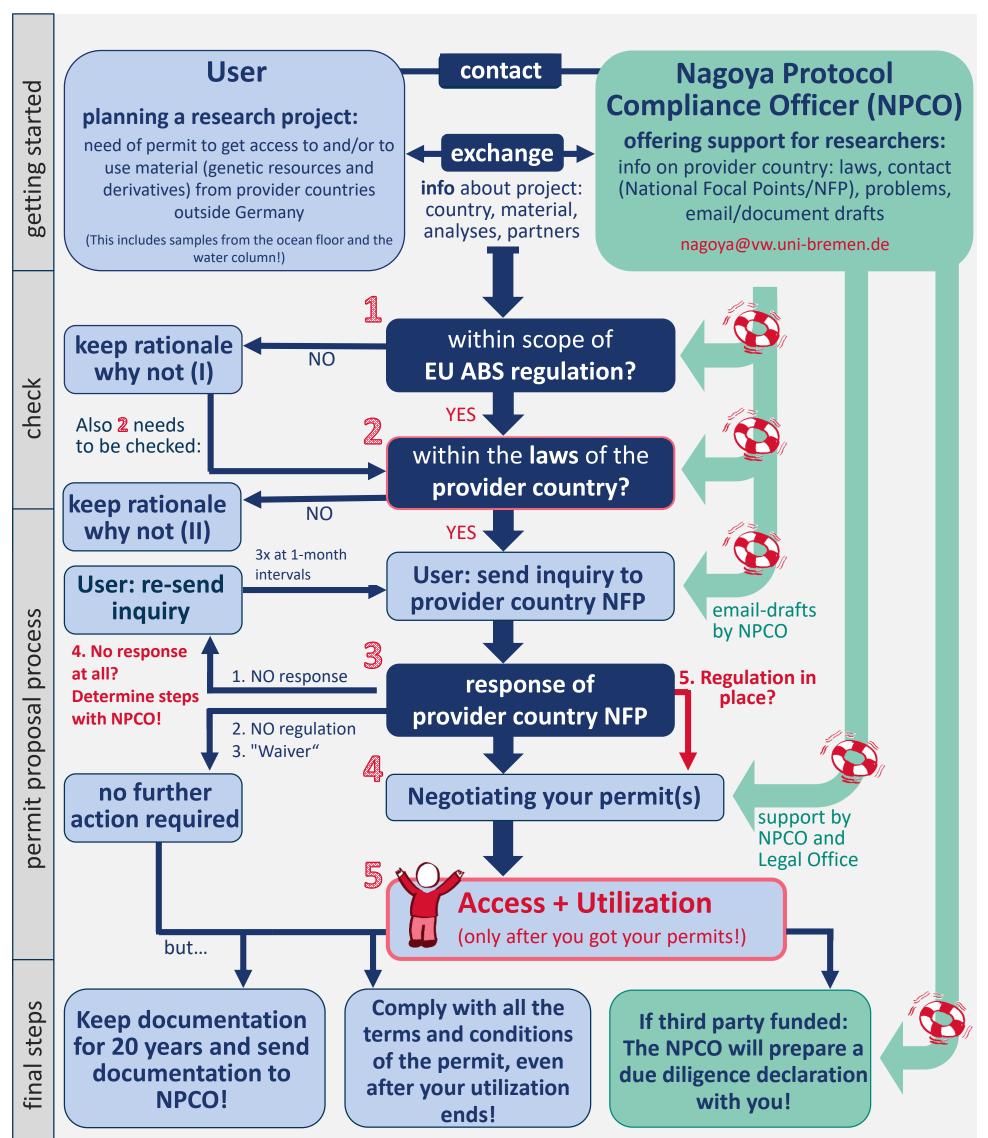


Nagoya Protocol Compliance Process





Nagoya Protocol Compliance Process

Do you need more information about the Nagoya Protocol Compliance Process at the University of Bremen? Read the description of the process steps to be followed below.

<u>The Compliance Process</u> for research projects of the University of Bremen falling within the scope of Access and Benefit-Sharing (ABS) in general, the Nagoya Protocol (NP) and/or the EU ABS Regulation **starts** as soon as you know that you want to access biological material and where exactly.

The researcher who conducts the research project is the *User* of the genetic resource. For cruises, the cruise leader usually applies for the permit.

To check weather a research project falls within scope of ABS, the NP and/or the EU ABS Reg, the User first contacts the *Nagoya Protocol Compliance Officer* (*NPCO*) to exchange information and discuss the case. There are two things to be checked:

- 1. Check if the research project falls within scope of the EU ABS Regulation. There are a guidance document and mutiple examples available to help you with this. If not, keep a rationale why not for 20 years.
- 2. Check if the research project falls within scope of the legislation in the provider country of the biological material. To obtain further information on the relevant laws and regulations in the provider country of the genetic resource you will contact the the country's National Focal Point. You can find the contact information on the ABS-CH website (link). The NPCO will assist you with drafts and information on the country, problems and alternative contacts. (If the research project is not covered by the EU ABS Reg. and/or the legislation in the provider country, please document why they are not and keep the rationale for 20 years.)
- There are several outcomes regarding a response from the NFP of the provider country:
 - 1. No response: Please follow up with the NFP on a monthly basis. If you have not received a response for three months, please inform the NPCO, who will try to explore other means of contacting the authorities of the provider country.
 - 2. Information that there are no regulations and no legislation: Please document that there are no obligations on your part and keep the rationale for 20 years. Please save the relevant email as a PDF document and send it to the NPCO if you have not already done so.
 - 3. A "waiver": The provider country's authorities answer that you can use the material without further permission. Also in this case, documentation for 20 years is required please save the relevant email as a PDF document and send it to the NPCO if you have not already done so.
 - 4. No response at all: Please determine your next steps with the NPCO. The NPCO will discuss your case with the Legal Office of the University or the Federal Agency for Nature Conservation.
- 5. Information that there are regulations in place: This is where the process of obtaining a permit and possibly the negotiation of a contract begins. The NPCO and the Legal Office will help you obtain the documents (and/or negotiate and establish your contract).
- Once all permits have been granted you may <u>access</u> the material in/of the provider country and start <u>utilization</u> (laboratory analysis).
 - → Remember that you are only allowed to perform the research permitted by the permit, and that only those (users/researchers/institutions) named in the permits are allowed to use the material!
 - → Take it seriously! Access and Utilization (analysis, publication and deposition) are only allowed after you obtained your permits!
 - → Don't forget to comply with all the terms and conditions of the permit, even after your utilization ends!
 - → <u>Documentation will be required for 20 years</u>, and you will need to keep all of your permits (no samples needed). Don't forget to share all ABS-relevant documentation with the NPCO!
 - → If your project is third-party funded, a Due Diligence Declaration (DDD) must be submitted according to the EU ABS Regulation. Please contact the NPCO (nagoya@vw.uni-bremen.de) who has access to the European DECLARE portal. She will send you a form to fill in your information! Please send the form back to her so that she can submit your DDD via the University of Bremen account!
 - → If you want to <u>pass on the material</u> at some point, you must also redistribute all associated documentation and establish an <u>MTA</u> first.



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Glossary

ABS Access and Benefit-Sharing

ABSCH Access and Benefit-Sharing Clearing House (https://absch.cbd.int/en/)

BfN German Federal Agency for Nature Conservation – Bundesamt für Naturschutz,

the entity which starts the inspection of the Nagoya Protocol Compliance

EU ABS Regulation The EU ABS Regulation ((EU) No. 511/2014) governs the implementation of the

Nagoya Protocol obligations in the EU

Within scope A project that is covered by... (the EU ABS Regulation and/or the Nagoya Protocol)

MTA Material Transfer Agreement

NFP Provider Country's National Focal Point

NPCO Nagoya Protocol Compliance Officer (of the University of Bremen)

NP Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable

Sharing of Benefits Arising from their Utilization

Unit 12 Researchers and Early Career Researchers Unit (of the University of Bremen)

VP Research +Transfer Vice President for Research and Transfer (of the University of Bremen)

For more information please refer to https://www.uni-bremen.de/en/research/support-for-researchers/nagoya-protocol