Advancing Natural Product R&D&I: Guide for Compliance with Responsible Research and Innovation, Ethics, Nagoya Protocol, and Intellectual Property Protection

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Table S1. European codes of conduct, guidelines, and legal instruments related to research ethics and integrity.

Title	Scope and Purpose	Key Principles / Focus Areas	Target Audience	Legal Status / Type	Link
European Code of Conduct for Research Integrity (2021)	Promotes responsible research practices and integrity across the EU	Reliability, honesty, respect, accountability; guidance on good research practices and handling misconduct	Researchers, institutions, research funders	Non-binding, but widely adopted guideline	European Code of Conduct
Global Code of Conduct for Research in Resource-Poor Settings (2018)	Ensures equitable and ethical research in low- and middle-income countries; prevents ethics dumping	Fairness, respect, care, honesty; emphasis on equitable partnerships and local relevance	Researchers working internationally, especially in LMICs	Non-binding, endorsed by EU Horizon 2020	Global Code of Conduct
EU Guidance on Potential Misuse of Research (ENERI, 2018)	Addresses dual-use concerns and risks of research being misapplied (e.g., in weapons or surveillance)	Dual-use, misuse potential, biosecurity, risk-benefit assessment, researcher responsibility	H2020 applicants, ethics reviewers, institutions.	Non-binding, advisory document	Guidance on Misuse
Directive 2010/63/EU on the Protection of Animals Used for Scientific Purposes	Regulates use of animals in scientific procedures, emphasizing ethical treatment and animal welfare	3Rs (Replacement, Reduction, Refinement), ethical reviews, licenses, inspections	Researchers using animals, lab facilities, ethics committees	Legally binding EU directive	Directive 2010/63/EU
Directive 98/44/EC on the Legal Protection of Biotechnological Inventions	Regulates ethical boundaries and patentability of biotechnological inventions	Patent protection, human genome, exclusions (e.g., cloning, human embryos)	Researchers, biotech companies, legal experts	Legally binding EU directive	Directive 98/44/EC
Horizon 2020 Guidance on Ethics Self-Assessment (2018)	Provides practical steps to identify and address ethics issues in H2020 proposals	Human subjects, privacy, data, environment, animals, dual-use, compliance obligations	H2020 applicants, coordinators, ethics advisors	Non-binding, guidance document	H2020 Ethics Guidance
EU Grants Guidance on Ethics Self-Assessment (2021)	Provides practical steps to identify and address ethics issues in European Grant proposals	Human subjects, personal data, animals, Non-EU countries, environment, health and safety, artificial intelligence, and misuse of results compliance obligations	EU Programmes: Horizon Europe (HE), Digital Europe (DEP) and European Defence Fund (EDF) and other programmes that may require an ethics review to authorise funding (AMIF, ISF, EMFAF, EU4H, etc.)	Non-binding, guidance document	EU Grants Ethics Guidance

Table S2. National codes of conduct and research ethics or integrity guidelines.

Country	Title	Focus / Scope	Type	Link
Austria	Guidelines for Good Scientific Practice	Principles for scientific integrity and responsible conduct in research	National guidelines	Link
Belgium	Codes of Ethics for Scientific Research	Ethical standards for Belgian research institutions	National codes	Link
Italy	Guidelines for Research Integrity (CNR)	Ethical rules and scientific misconduct prevention	National institutional guidelines	Link
Denmark	Danish Code of Conduct for Research Integrity	National framework for responsible research	National code	Link
Denmark	Historical Guidelines for Good Scientific Practice	Earlier Danish guidance on scientific integrity	Historical guideline	Link
Estonia	Code of Ethics for Estonian Scientists	Ethical norms for researchers	National ethics code	Link
Estonia	Estonian Code of Conduct for Research Integrity	Principles and values for responsible research	National integrity code	Link
Finland	Guidelines on the Responsible Conduct of Research	Detailed procedures and handling of misconduct	National guideline	Link
France	Guide to Integrity and Responsibility in Research Practices (CNRS)	Research integrity, transparency, and responsibility	Institutional guide	Link
Germany	Safeguarding Good Scientific Practice (DFG)	Good practices and procedures in research	National framework	Link
Netherlands	Netherlands Code of Conduct for Research Integrity	Research principles and ethical standards	National code	Link
Norway	Guidelines for Research Ethics in Science and Technology	Ethics in research across STEM disciplines	National ethics guidelines	Link
Poland	Recommendations for Good Scientific Research Practices	Research quality and integrity recommendations	National recommendation	Link
Spain	Code of Good Scientific Practices (CSIC)	Standards for scientific integrity	Institutional code	Link

Table S3. Roles and Responsibilities of Parties, Authorities, Providers, and Users in the ABS Process under the Nagoya Protocol.

Step	Party (State)	CNA	Provider (incl. IPLCs where applicable)	User
1. Identification & preliminary consultation	Maintain ABS framework and ABSCH information	—	—	Identify GR/TK, consult ABSCH requirements
2. Contact with national authorities	Designate NFP and NCA	Provide guidance, receive access request	—	Contact NFP, submit access request to NCA
3. Granting of PIC	Exercise sovereign rights over GR	Formalize and grant PIC on behalf of Party	Grant PIC and/or approval & involvement (where required by law)	Request PIC, comply with conditions
4. Redaction of MAT	Enable legal certainty for MAT	—	Negotiate and agree on MAT	Negotiate and sign MAT
5. Access authorization (MAA, where applicable)	Establish national access procedures, Decide whether to use ABSCH system	Issue permit / access authorization, Upload permit to ABSCH (optional)	Authorize access via State mechanism	Receive authorization, comply Check existence, retain IRCC/permit
6. Collection, documentation and transport	Allow national practice on MTAs	Issue or validate MTA (if used)	Ensure MAT conditions respected	Collect/receive GR, document samples for traceability Sign and comply with MTA
7. Utilization and ongoing compliance	Implement user-side compliance laws	Receive due diligence declarations (EU, etc.)	—	Use within MAT scope, submit due diligence declarations where required
8. Monitoring through checkpoints	Monitor utilization within jurisdiction	Operate checkpoints, verify compliance	—	Demonstrate legal access and benefit sharing
9. Benefit sharing & commercialization	Ensure benefit-sharing compliance Allocate benefits nationally	—	Receive benefits per MAT, Distribute benefits to IPLCs, conservation, sustainability (if applicable)	Share benefits, notify commercialization
10. Onward transfer to User C	Enforce transfer rules	Verify compliance if needed	Authorize onward transfer via MAT	Ensure MAT allows transfer, pass obligations. If prohibited, no transfer
11. Compliance, enforcement & cooperation	Cooperate internationally, enforce laws	Investigate non-compliance	Request assistance if misuse suspected	Provide documentation, cooperate

Table S4. Intellectual Property Rights protection tools for Genetic Resources and Traditional Knowledge.

IPR Tool	Suitable For	Limitations
***Sui Generis* Laws**	TK, GR	Varies by country, limited international harmonization
Geographical Indications	Region-specific goods (crafts, food)	Requires strong regional link
Trademarks/Certifications	Community-made products, quality assurance	Does not protect underlying knowledge
Defensive Publication	Prevents misappropriation via patent	Does not grant ownership rights
ABS Agreements	Sharing benefits from resource use	Needs effective enforcement
Copyright	Cultural expressions (songs, stories)	Limited by collective/anonymous authorship
Patent	Bioprospecting outcomes	Strict novelty, inventiveness and industrial applicability requirements

Table 5. Major patent offices.

Country/Region	Patent Office	Website
United States	United States Patent and Trademark Office (USPTO)	www.uspto.gov
China	China National Intellectual Property Administration (CNIPA)	www.cnipa.gov.cn
Japan	Japan Patent Office (JPO)	www.jpo.go.jp
European States	European Patent Office (EPO)	www.epo.org
India	Office of the Controller General of Patents, Designs and Trademarks (CGPDTM)	www.ipindia.gov.in
South Korea	Korean Intellectual Property Office (KIPO)	www.kipo.go.kr
Germany	German Patent and Trademark Office (DPMA)	www.dpma.de
United Kingdom	UK Intellectual Property Office (UKIPO)	www.gov.uk/ipo
Brazil	National Institute of Industrial Property (INPI)	www.gov.br/inpi
Canada	Canadian Intellectual Property Office (CIPO)	www.ic.gc.ca/cipo
Australia	IP Australia	www.ipaustralia.gov.au

Table S6. Patent systems overview.

Level	System/Office	Covers
International	WIPO/PCT	150+ countries
Regional	EPO, ARIPO, OAPI, EAPO	Europe, Africa, Eurasia
National	USPTO, CNIPA, NIPO, INPI, JPO, etc.	Individual countries