INTERNATIONAL LAWS

As many ISIDORe partners provide services across European borders and since infectious disease research often involves international collaboration, as infectious diseases occur worldwide and their control requires global efforts, this overview of international laws and regulations is intended to facilitate collaboration with partners from different countries. It complements other initiatives in this area, such as the Vertic BWC legislation database (https://www.vertic.org/programmes/nim/biological-weapons-and-materials/bwc-legislation-database/) and the resources provided by the International Experts Group of Biosafety and Biosecurity Regulators (https://iegbbr.org/). It can be used to determine what legal requirements apply and what approvals or agreements are needed to facilitate the exchange of research materials, data, and expertise. This includes aspects such as laboratory practices, validation of test procedures, compliance with Good Clinical Practice (GCP) or Good Laboratory Practice (GLP) and documentation of research data. By knowing and complying with these international laws, ISIDORe services can ensure high quality and ethically responsible research.

Table 1: Overview of international laws applicable for biospecimen handling

The following laws/requirements are essential for the handling, collection, processing, storage, provision and transport of biospecimens (human, animal and pathogen origin), with GMOs occupying a special position. In addition to the handling of biospecimens, regulations governing the conduct of clinical trials and medical products also play a major role in infectious disease research (although the intention was to be comprehensive, we make no claim to completeness).

International Laws		
Transport	 	- **ADR -** Agreement concerning the International Carriage of Dangerous Goods by Road - UN2814 / UN2900 – regulation on packaging P620 **(applicable for infectious samples Category A - Risk Group (RG) 3 and RG 4)** - UN3373 - on packaging P650 **(applicable for infectious samples Category B – RG 2 and RG 3)** - WHO Guidelines for the Safe Transport of Infectious Substances and Diagnostic Specimens - International Air Transport Association Dangerous Goods Regulations (**IATA DGR**)
Dual-use items		**Council Regulation (EC) No 428/2009** of 5th May 2009 setting up a Community regime for the control of exports, transfer, brokering and transit of dual-use items (import/export restrictions

		regarding highly pathogenic agents such as human pathogens, zoonoses and “toxins”, animal pathogens and plant pathogens)
Occupational safety and health		- **Council Directive 90/679/EEC** on the protection of workers from risks related to exposure to biological agents at work (seventh individual Directive within the meaning of Article 16 (1) of Directive 89/391/EEC) - **Directive 2000/54/EC** on the protection of workers from risks related to exposure to biological agents at work - **EU Directive 2019/1833 amending** Annexes I, III, V and VI to Directive 2000/54/EC
GMOs		- **United Nations - The Nagoya Protocol** on Access to genetic resources and the fair and equitable sharing of benefits arising from their utilization to the convention on biological diversity - **Regulation (EU) No 511/2014** of the European Parliament and of the Council of 16th April 2014 on compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union - **Directive 2009/41/EC** of the European Parliament and of the Council of 6th May 2009 on the contained use of genetically modified micro-organisms (recast **Council Directive 90/219/EEC**) - **Directive 2001/18/EC** of the European Parliament and of the Council of 12th March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC - **Commission Directive (EU) 2018/350** of 8th March 2018 amending Directive 2001/18/EC of the European Parliament and of the Council as regards the environmental risk assessment of genetically modified organisms
Animals		- **Regulation (EC) No 1069/2009** of the European Parliament and of the Council of 21st October 2009 laying down health rules as regards animal by-products and derived products not intended for human consumption and repealing Regulation (EC) No 1774/2002 (Animal by-products Regulation) - **Commission Regulation (EU) No 142/2011** of 25th February 2011 implementing Regulation (EC) No 1069/2009 of the European Parliament and of the Council laying down health rules as regards

animal by-products and derived products not intended for human consumption and implementing Council Directive 97/78/EC as regards certain samples and items exempt from veterinary checks at the border under that Directive

- **Commission Regulation (EU) 2021/1891** of 26th October 2021 amending Annexes XIV and XV to Regulation (EU) No 142/2011 as regards imports into and transit through the Union of animal by-products and derived products
- **Commission Regulation (EU) 2022/384** of 4th March 2022 amending Annex XIV to Regulation (EU) No 142/2011 as regards adaptation of the lists of third countries, territories or zones thereof from which the entry into the Union of animal by-products and derived products is permitted
- **Commission Implementing Regulation (EU) No 1097/2012** of 23rd November 2012 amending Regulation (EU) No 142/2011 implementing Regulation (EC) No 1069/2009 of the European Parliament and of the Council laying down health rules as regards animal by-products and derived products not intended for human consumption and implementing Council Directive 97/78/EC as regards certain samples and items exempt from veterinary checks at the border under that Directive as regards dispatch of animal by-products and derived products between Member States
- **Commission Regulation (EU) No 1063/2012** of 13th November 2012 amending Regulation (EU) No 142/2011 implementing Regulation (EC) No 1069/2009 of the European Parliament and of the Council laying down health rules as regards animal by-products and derived products not intended for human consumption and implementing Council Directive 97/78/EC as regards certain samples and items exempt from veterinary checks at the border under that Directive
- **Directive 2010/63/EU** of the European Parliament and of the Council of 22nd September 2010 on the protection of animals used for scientific purposes
- The **EU Recommendation 2007/526** of 18th June 2007 on guidelines for the accommodation and care of animals used for experimental and other scientific purposes.
- The **EC Regulation No 1/2005** of 22nd December 2004 on the protection of animals during transport and related operations and amending Directives 64/432/EEC and 93/119/EC and regulation (EC) No 1255/97

Data protection		- **Regulation (EU) 2016/679** of the European Parliament and of the Council of 27th April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) - The **Charter of Fundamental Rights of the European Union** (signed in Nice, 7th December 2000, 2000/C 364/01) in particular Article 3 "Right to the integrity of a person" and Article 8 "Protection of Personal Data"
Biobanking		- **Recommendation CM/Rec(2016)6** of the Committee of Ministers to member States on research on biological materials of human origin
Medical products		- **Directive 2001/20/EC** of the European Parliament and of the Council of 4th April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use - **Directive 2001/83/EC** on medicinal products for human use (amended with Commission Directive 2003/63/EC) - **Directive 2001/83/EC** of the European Parliament and of the Council of 6th November 2001 on the Community code relating to medicinal products for human use, as amended - **Directive 2003/94/EC** of the European Commission of 8th October 2003 laying down the principles and guidelines of good manufacturing practice in respect of medicinal products for human use and investigational medicinal products for human use - **Regulation (EC) No 726/2004** of the European Parliament and of the Council laying down Community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency - **Directive 2005/28/EC** of the European Commission of 8th April 2005 laying down principles and detailed guidelines for good clinical practice as regards investigational medicinal products for human use

Clinical Trials		- Clinical Trial Regulation, **Regulation (EU) No 536/2014** on clinical trials on medical products for human use, and repealing Directive 2001/20/EC - For additional international recommendations that apply to the conduct of clinical trials, see Research and Ethics
Research		- The principles of good practice expressed in the European Charter for Researcher and in the Code of Conduct for the Recruitment of Researchers which were adopted by the European Commission with a Recommendation on 11th March 2005 - **EU Directive 2005/28/EC** of 8th April 2005 on good clinical practice - The guidelines for **Good Clinical Practice** (GCP) - International Conference on Harmonization E6(R2)
Ethics		- WMA Declaration of Helsinki - Ethical Principle for medical research involving human subjects (2013) - WMA Declaration of Taipei on ethical considerations regarding health databases and biobanks (2016) - Convention for the protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine (Oviedo Bioethics Convention) - The Additional Protocol to the Convention on Human Rights and Biomedicine, concerning Biomedical Research, Strasbourg, 25.01.2005
Others		- WHO International Health Regulations (2005) - importance of ensuring access to human pathogens for public health preparedness and response purposes.