INTERNATIONAL STANDARDS, BEST PRACTICES, GUIDELINES AND RECOMMENDATIONS RELEVANT FOR ISIDORe WORK PACKAGES PROVIDING BIOSPECIMENS AND REFERENCE MATERIALS

Although international standards, guidelines and scientific recommendations are an essential basis for the provision of reference materials, biospecimens (human, animal and pathogen origin) and their derivatives, not every service provider within the ISIDORe consortium must follow the same standards. Table 4 represents an overview list of the most common international standards, best practices, guidelines and recommendations for service providers offering reference materials and biospecimens. The selection of the appropriate standards depends on the type of use of the material (fitness for purpose).

Table 4: Overview list of international and European standards, best practices and scientific recommendations for ISIDORe work packages that provide reference material or biospecimens (although the intention was to be comprehensive, we make no claim to completeness)

Work package		International and European standards / best practices / scientific recommendations
WP7	General	**Quality management:** - ISO 9001:2015 - Quality management systems - Requirements **Laboratories:** - DIN EN ISO 15189:2022 - Medical laboratories - Requirements for quality and competence - DIN EN ISO 17025:2017 - General requirements for the competence of testing and calibration laboratories - DIN EN ISO 17020:2012 - Conformity assessment - Requirements for the operation of various types of bodies performing inspection

		- DIN 58959-6:2019-06 - Medical microbiology - Quality management in medical microbiology - Part 6: Requirements relating to test organisms and their use in performance testing **Occupational Health and safety** - DIN ISO 45001:2018 - Occupational health and safety management systems - Requirements with guidance for use **Biorisk** - CWA 15793 "Laboratory Biorisk Management Standard" - CEN Workshop Agreement 16393: Laboratory Biorisk Management Standard- Guidelines for Implementation of CWA 15793 - ISO 35001:2019 – Biorisk management for laboratories and other related organizations **Environmental management systems** - DIN ISO 14001:2015 - Environmental management systems - Requirements with guidance for use **Information security:** - DIN ISO/IEC 27001:2022 - Information security, cybersecurity and privacy protection - Information security management systems - Requirements
	Provision of reference material	**Reference material producers:** - DIN EN ISO 17034:2016 - General requirements for the competence of reference material producers **EVAg guidelines:** - provision of biological resources with high pathogenicity is done through a review process by an appointed expert panel to ensure that the recipients of these reagents are genuine researchers who have appropriate **expertise and containment/safety facilities** - Virus batches that guarantee accurate and reproducible experiments - Quality of virus reference material (defined by identification and purity of the isolates, end-user stability, homogeneity and quantity) - Quality controls will be adapted to the need/service (purity, folding, post-translational modifications stability, activity, antigenicity, etc.).

WP8	Biobanking	**Biobanking-relevant standards:** (overview list available at https://www.bbmri-eric.eu/services/standardisation/) - DIN EN ISO 20387:2018 – Biotechnology – Biobanking – General requirements for biobanking - ISO/TR 22758:2020 – Biotechnology – Biobanking – Implementation Guide for ISO 20387 - ISO 24651:2022 – Biotechnology – Biobanking – Requirements for human mesenchymal stromal cells derived from bone marrow - ISO 24603:2022 – Biotechnology – Biobanking – Requirements for human and mouse pluripotent stem cells - ISO 21709:2020 – Biotechnology – Biobanking – Process and quality requirements for establishment, maintenance and characterization of mammalian cell lines - ISO 21899:2020 – Biotechnology – Biobanking – General requirements for the validation and verification of processing methods for biological material in biobanks - ISO/TS 22859:2022 – Biotechnology – Biobanking – Requirements for human mesenchymal stromal cells derived from umbilical cord tissue **Guidelines:** - Guideline No.164/2017 "Handbook for risk assessment from exposure to hazardous chemical agents and carcinogens and mutagens" (Italy) - Guidelines for Biobank certification - Presidency of the Council of Ministers National Committee for Biosafety and Biotechnology April 19th, 2006 (Italy) **Best practices:** - ISBER – Best Practices – Recommendations for Repositories 4th edition, 2018 - IARC – Common minimum technical standards and protocols for biobanks dedicated to cancer research – IARC Technical Publication No. 44, 2017 - NCI – Best Practices for Biospecimen Resources, 2016 - OECD – Best Practice Guidelines for Biological Resource Centres, 2007 - ABN – Australasian Biospecimen Network – Biorepository Protocols, 2007 **Scientific recommendations:**

		- SPREC - **S**tandard **PRE**analytical **C**ode Version 3.0, Biopreservation and Biobanking, Volume 16, Number 1, 2018, https://doi.org/10.1089/bio.2017.0109 - a seven-letter code developed by the International Society for Biological and Environmental Repositories (ISBER) - BRISQ - Biospecimen reporting for improved study quality (BRISQ). Journal of proteome research. 2011 Aug 5;10 (8):3429-38. - the three-tiered **B**iospecimen **R**eporting for **I**mproved **S**tudy **Q**uality (BRISQ) - MIABIS - Toward global biobank integration by implementation of the minimum information about biobank data sharing (MIABIS 2.0 Core). Biopreservation and biobanking. 2016 Aug 1;14(4):298-306 - **M**inimum **I**nformation **A**bout **Bi**obank data **S**haring (MIABIS)
	Materials	**International and European standards for the pre-examination and preparation of selected biospecimens** (overview list available at https://www.bbmri-eric.eu/services/standardisation/): **Frozen tissue:** - **ISO 20184-1:2018** - Specifications for pre-examination processes for frozen tissue Part 1: Isolated RNA - **ISO 20184-2:2018** - Part 2: Isolated proteins - **ISO 20184-3:2021** - Part 3: Isolated DNA **FFPE tissue:** - **ISO 20166-1:2018** - Specifications for pre-examination processes for formalin-fixed and paraffin-embedded (FFPE) tissue Part 1: Isolated RNA - **ISO 20166-2:2018** - Part 2: Isolated protein - **ISO 20166-3:2018** - Part 3: Isolated DNA - **ISO 20166-4:2021** - Part 4: In situ detection techniques **Venous whole blood:** - **ISO 20186-1:2019** - Specifications for pre-examination processes for venous whole blood - Part 1: Isolated cellular RNA - **CEN/TS 17742:2022** - Specifications for pre-examination processes for venous whole blood – Isolated circulating cell free RNA from plasma

- **ISO 20186-2:2019** - Part 2: Isolated genomic DNA
- **ISO 20186-3:2019** - Part 3: Isolated circulating cell free DNA from plasma
- **ISO 23118:2021** - Specifications for pre-examination processes in metabolomics in urine, venous blood serum and plasma - Metabolomics in urine, venous blood serum and plasma

Exosomes and other extracellular vesicles in venous whole blood:

- **CEN/TS 17747:2022** - Specifications for pre-examinations processes for exosomes and other extracellular vesicles in venous whole blood – DNA, RNA and proteins

Saliva:

- **ISO 4307:2021** - Specifications for pre-examination processes for saliva - Isolated human DNA

Circulating tumor cells (CTC):

- **CEN/TS 17390-1:2020** - Specifications for pre-examination processes for circulating tumor cells (CTCs) in venous whole blood Part 1: Isolated RNA
- **CEN/TS 17390-2:2020** - Part 2: Isolated DNA
- **CEN/TS 17390-3:2020** - Part 3: Preparations for analytical CTC staining

Fine Needle Aspirates:

- **CEN/TS 17688-1:2021** - Specifications for pre-examination processes for Fine Needle Aspirates (FNAs) Part 1: Isolated cellular RNA
- **CEN/TS 17688-2:2021** - Part 2: Isolated proteins
- **CEN/TS 17688-3:2021** - Part 3: Isolated genomic DNA

Urine, Serum, Plasma:

- **ISO 23118:2021** - Specifications for pre-examination processes in metabolomics in urine, venous blood serum and plasma - Metabolomics in urine, venous blood serum and plasma

Urine and other body fluids:

	- **CEN/TS 17811:2022** - Specifications for pre-examinations processes for urine and other body fluids – Isolated cell free DNA **Stool, saliva, skin and urogenital specimens:** - **CEN/TS 17626:2021** - Specifications for pre-examination processes for human specimen Isolated microbiome DNA

WP14	**Best practices/Guidelines:**
	- **VetBioNet** best practice guidelines: https://www.vetbionet.eu/best-practice-guidelines/
	- International veterinary biosafety workgroup (**IVBW**) - best practice in biocontainment of high consequence pathogens; https://ivbw.wildapricot.org/
	- **RSPCA** and **LASA –** Guiding principles on good practice for animal welfare and ethical review bodies (3rd edition 2015)
	- National Research Council – Guide for the Care and Use of Laboratory Animals (2011, 8th edition)
	- IACUC (The Institutional Animal Care and Use Committee) of the National Institute of Health – Office and Laboratory Animal Welfare
	- ARRIVE Guidelines – Guidelines for reporting animal research (2010, 2020)
	- PREPARE Guidelines – Guidelines for planning animal research testing (2018)
	- **FELASA** (Federations of European Laboratory Animal Sciences Associations) guidelines.
	  ○ Glossary and reporting of clinical signs (2015)
	  ○ Guidelines for the care and welfare of Cephalopods in research (2015)
	  ○ A harmonized health reporting format for international transfer of rodents (2014)
	  ○ FELASA guidelines for the refinement of methods for genotyping genetically-modified rodents (2013)
	  ○ FELASA guidelines and recommendations (2012)
	  ○ Guidelines for continuing education for persons involved in animal experiments (2010)
	  ○ Guidelines for the veterinary care of laboratory animals (2008)
	  ○ Guidelines for the production and nomenclature of transgenic rodents (2007)
	  ○ Guidance paper for accreditation of laboratory animal diagnostic laboratories (1999)
	
	Scientific recommendations:

- Infravec2 guidelines for the design and operation of containment level 2 and 3 insectaries in Europe (Pathog Glob Health 2023 May; 117 (3):293-307. doi: 10.1080/20477724.2022.2108639. Epub 2022 Aug 22.)

Scientific recommendations Sandflies:

- Leishmania in Sand Flies: Comparison of Quantitative Polymerase Chain Reaction with Other Techniques to Determine the Intensity of Infection, J Med Entomol. 2008 Jan;45(1):133-8. doi: 10.1603/0022-2585(2008)45[133:lisfco]2.0.co;2.
- Establishment and maintenance of sand fly colonies, J Vector Ecol. 2011 Mar;36 Suppl 1:S1-9. doi: 10.1111/j.1948-7134.2011.00106.x.
- Laboratory colonization and mass rearing of phlebotomine sand flies (Diptera, Psychodidae), Parasite. 2017; 24:42. doi: 10.1051/parasite/2017041. Epub 2017 Nov 15.
- Comparative Study of Promastigote- and Amastigote- Initiated Infection of Leishmania infantum (Kinetoplastida: Trypanosomatidae) in Phlebotomus perniciosus (Diptera: Psychodidae) Conducted in Different Biosafety Level Laboratories, J Med Entomol. 2020 Feb 27;57(2):601-607. doi:10.1093/jme/tjz199.