MICROBE
the Microbiome Biobanking (RI) Enabler

Deliverable D5.2

Guiding principles for the use of microbiomes

Work package number and title	*WP5 Legal and ethical framework for microbiome biobanking*
Work package leader	*DSMZ*
Relevant Task	*T5.2 Evaluating liability risks for human and veterinary use of microbiomes*
Lead contributor to Milestone	*MUG*
Other contributors to Milestone	*DSMZ, EMBL*
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1. Aims of MICROBE's Task 5.2 & D5.2

Deliverable D5.2 is the result of Task T5.2 "*Evaluating liability risks for human and veterinary use of microbiomes*" which aimed to elaborate a set of guiding principles for the human and veterinary use of microbiomes, that is based on the collated inputs from

1. a desktop and literature research performed by MUG;
2. 10 semi-strutured, explorative interviews with experts conducted by MUG in person or virtually;
3. a workshop on "ELSI in Microbiome Biobanking/Research" conducted by MUG with support from DMSZ, AIT and rtds.
   Interview and workshop participants were from different European countries, covered different expertises such as in ethical, legal, societal issues (ELSI), biobanking, forensics, research, microbiome, human and veterinary fields, and included among others participants from BBMRI-ERIC headquarters and national nodes, and MICROBE.

Details on methodology of 2. and 3. are described in the MICROBE Milestone Ms7 Report Workshop "ELSI in Microbiome Biobanking" held.

2. Guiding Principles for the Use of Microbiomes: ELSI in Human and Veterinary Microbiome Biobanking and Research

2.1 Introduction

With the rapid advancement of microbiome research, an increasing number of biobanks are beginning to focus on—or integrate—collections of microbiota-related specimens for genomic or other research studies. These include microbiome-containing samples, isolated microbial species, or synthetic communities (SynComs).

While the ethical, legal, and societal implications (ELSI) in human and veterinary biobanking and large-scale data sharing for research are already complex, they become even more challenging when considering the use of biobanked human and veterinary microbiome materials.

Many ELSI issues raised by human microbiome biobanking and research are not fundamentally different from those encountered in 'conventional' biobanking of human or veterinary samples. However, aspects such as privacy, ownership, informed consent, and return of results may be further complicated by the collection and study of microbiomes intimately associated with individual humans or animals.

Based on a review of relevant literature, expert interviews, and a dedicated workshop conducted by MUG within the framework of the MICROBE project, major challenges were

identified and a set of guiding principles developed. These principles aim to address key ELSI concerns, and to mitigate potential risks related to microbiome biobanking in both human and veterinary contexts.

2.1. Human Microbiome Biobanking and Research

2.1.1 Overview

Human microbiome biobanking and research present transformative opportunities in medicine, public health, and environmental science. However, they also raise significant legal, ethical, and societal risks and challenges for which recommendations or guiding principles will be helpful. Here's a breakdown of the major topics.

Privacy & confidentiality

.. concerns about potential

- **re-identification** of individuals (e.g. by human DNA, by microbiome fingerprint)
- **profiling** (identifiability) of e.g., risk for developing disease, life-style, ethnic background, community/group affiliation
- **discrimination and/or stigmatisation** of individuals and communities (e.g. by insurance companies, employers, the community)
- privacy breaches (e.g. due to lack of data security)
- misuse of samples and data

Ownership & benefit sharing

.. concerns about challenges associated with

- **informed consent & autonomy**
- **benefit sharing**
- **return of results** (e.g. individual research results, incidental findings)
- different microbiome sample and data types
- Substances of Human Origin (SoHO)

Safety

.. concerns about potential

- risks from certain microbiome **sample collection** procedures leading e.g. to bodily harm or psychological problems (religion/culture dependent)

- **biosafety, pathogen release** and infections
- risks from **microbiome hype, commercialisation & too premature use** for public health applications based on research findings with uncertain validity and representativeness

Others issues

- Social justice considerations
- Intellectual Property (IP) rights – patenting

2.1.2 Privacy & Confidentiality

Privacy & Confidentiality

Privacy refers to an individual's right to control the collection, use, and disclosure of their personal information. **Confidentiality** is a professional or ethical duty to protect sensitive information from privacy breach, i.e. unauthorised access, use, or disclosure, often within a specific relationship or context. In essence, privacy is about the right to control information, while confidentiality is about the obligation to safeguard it.

Both privacy and confidentiality are major concerns for research participants, particularly in the area of genetic research but also in the microbiome field (McGuire et al. 2008).

In Europe the main law regulating privacy is the General Data Protection Regulation (GDPR), which regulates privacy concerns related to personal data. The GDPR establishes rules for how European natural or legal person, public authority, agency or another body should collect, store and manage personal data, ensuring individuals have control over their information, that they have certain privacy rights, and that data is processed fairly and transparently. (GDPR.EU, 2025; Your Europe/European Commission, 2025)

Re-identification – by Human DNA and "Microbial Fingerprints"

Human microbiome research samples generally contain both microbial communities and also **human cells and/or DNA.** Since these samples can be analysed in ways that allow re-identification of a person through DNA profiling, complete anonymisation is not truly possible.

An addidtional ethical issue is the potential **linking of microbial DNA data with human genomic information, clinical information** (Kling, 2019) and other personal data collected via biobank or research questionnaires.

Earlier efforts aimed at promoting international collaboration ledto broad data-sharing policies for genomic research. However the strategy of "de-identifying" genomic data before sharing them via publicly accessible databases became ineffective as advances in technology enabled re-identification based solely on genomic sequences (McGuire et al., 2008).

- *Recommendation: Human microbiome samples and associated data (e.g. from biobank or questionnaires) should be protected with the same privacy and confidentiality as any other human biological material. (Chuong et al., 2017)*

- *Recommendation: Establish multidisciplinary governance boards - comprising representatives from e.g. medicine, science, ethics, public or patient advocacy groups - to review future research proposals. (Lange et al.,2022)*

- *Recommendation: Implement improved methods to remove human DNA from microbiome samples and/or filtering techniques to eliminate host DNA contamination in metagenomic dtasets, (Chuong et al., 2017)*

Beyond re-identification through human DNA, the potential to **re-identify individuals using their** unique microbiome signatures is gaining relevance, particularly in forensic science. (Procopio et al., 2021; Ma et al., 2018)

The possibility that an individual could be identified simply by analysing microbiome (with or without human DNA) opens up a powerful new analytical dimension for forensic investigations or law enforcement. (Ma et al., 2018)

Each person hosts a personalized "microbial fingerprint" that may be used for identification, even in the absence of human DNA. (Ma et al., 2018) This opens new forensic avenues, such as identifying individuals when human DNA is degraded or absent. For example, microbiome traces from skin ("touch microbiome") or saliva can serve as unique identifiers, especially with advances in 16S rRNA and metagenomic sequencing. (Procopio et al., 2021; Kapoor & Chowdhry, 2018)

Forensic applications may include estimating the postmortem interval, determining cause of death (e.g. drowning), locating the place of death, or linking individuals to specific environments, contacts, or personal items. (García, 2020)

- *Recommendation:* There is a clear and urgent need for regulatory frameworks to address the specific risks of human microbiome research in different social and legal contexts. (Ma et al., 2018)

The potential to identify individuals through their microbial data, raises privacy concerns similar to those encountered in genetic and biobank-related research. These concerns may be further complicated by the evolving understanding of what microbiome data can reveal, as well as ongoing debates about the stability of microbial fingerprints over time (Ma et al., 2018)

It has been described that the microbiome composition is influenced by lifestyle and environment, which are tied to cultural practices. For instance, Westernized diets are linked to increased risks of obesity, cardiovascular disease, and colorectal cancer. (Chuong et al., 2017)

There is also evidence that microbiomes are shared among individuals in close contact, such as family members or housemates (Kling, 2019). One study even found reduced gut microbiota diversity in housemates of individuals taking antibiotics like amoxicillin or azithromycin. (Abeles et al., 2016)

Microbiomes are transmitted not only between humans but also between humans and other animals, as well as across abiotic environmentssuch as air, soil, and water.The transfer can also include pathogens or antibiotic resistance genes. (Sessitsch et al., 2023)

- *Recommendation:* In light of the identifiability (risk of profiling) and treacability of microbial samples, current protections for genetic information and privacy should be extended to microbiome research. (Ejtahed et al., 2023)

The human microbiome may also reveal sensitive information beyond identity. When combined with genomic and clinical data, it could provide insights into disease risks, diet, travel history, sexual practices, substance use (e.g. alcohol, drugs), and even ethnic background or communitty affiliations. (McGuire et al., 2008; Hawkins & O'Doherty, 2011; Ma et al., 2018)

- *Recommendation:* Given the potential of microbiome data to expose personal lifestyle information, it is essential to critically assess whether current privacy regulations are adequate for microbiome research. (Ejtahed et al., 2023)

Privacy Breaches, Data Misuse, Discrimination and Stigmatisation

As with other forms of data, **microbial data** have the potential to expose participant to **privacy breaches,** leading to the misuse of **personal information.** This carries significant social risks and may result in **discrimination and/or stigmatisation** of individuals, groups, or communities. (Ma et al., 2018; Chuong et al., 2017; Hawkins & O'Doherty, 2011)

Similar to concerns surrounding genetic data, fears exist that microbiome information could be used to discriminate against individuals—for example, in employment or access to insurance - based on perceived life expectancy or health risks. Microbiome-based discrimination may be particularly troubling, as it could reflect and reinforce biases tied to socioeconomic background, place of birth and upbringing, or international travel history. Moreover, linking diseases such as cancer to microbial causes - regardless of the accuracy of these association - could contribute to the stigmatisation of certain groups, similar to situation experienced with some infectious diseases (Hawkins & O'Doherty, 2011).

On the other hand, microbiome research also has the potential to counteract stigma in some cases. For example, identifying a microbial predisposition to obesity could foster greater acceptance and understanding of individuals affected by obesity. However, it remains unclear how public and institutional perceptions will evolve. (Hawkins & O'Doherty, 2011)

- *Recommendation:* **Prevent privacy breaches**: Biobanks and researchers must be mindful of the risk of privacy breaches and take proactive measures to guard against novel and unforeseen forms of discrimination that may arise from microbiome data (Hawkins & O'Doherty, 2011).

- *Recommendation:* **Cultural sensitivity**: As with other forms of biomedical research, microbiome biobanking and research must be sensitive to the socio-cultural and economic context of participants. This includes acknowledging differing levels of cultural and

personal acceptability regarding collection methods such as urogenital or fecal sampling and using culturally appropriate collection protocols (Hawkins & O'Doherty, 2011; Mangola, Lund, Schnorr et al., 2022).

- *Recommendation:* **Ensure data protection**: Adequate measures must be taken to protect personal data in order to avoid potential discrimination or other adverse outcomes. This includes the implementation of robust data storage and security mechanisms (Ma et al., 2018).

- *Recommendation:* **Guarantee confidentiality**: Maintaining participant confidentiality during and after the study is essential to prevent discrimination and stigmatisation. Researchers are encouraged to conduct human rights impact assessments (HRIA), which evaluate potential risks to rights such as non-discrimination and equality (Tzortzatou-Nanopoulou et al., 2023).

There is ongoing debate about the justification for maximizing the collection and documentation of patient/research participant-associated data for current or future research, or minimize data collection in light of risks such as misuse or privacy breaches. According to the principle of data minimization—a core requirement under the GDPR—only the minimum amount of personal data necessary for a specific research purpose should be collected, processed, and retained.

- *Recommendation:* **Legal compliance**: Biobanks and researcher must comply with legal requirements including the GDPR, by identifying and collecting the minimum personal data needed to fulfil the purpose of the research. They must also avoid retaining more data than necessary.

2.1.3 Safety Considerations

Risks from Microbiome Sample Collection

Microbiome samples are usually collected through **non-invasive procedures** involving minimal risk, such as fecal self-collection, oral, vaginal, and nasal swabs, saliva sampling, or skin brushes. However, **invasive procedures**, such as endoscopy to obtain gut microbiome samples, carry greater risk to patient safety and well-being and must be performed by a qualified physician. (Ejtahed et al., 2023; Ma et al., 2018; McGuire et al., 2008)

- *Recommendation*: Throughout the biobanking and research process, participant safety and well-being must be prioritized by both biobanks and researchers.

- *Recommendation*: Informed consent procedures must be – in addition to other important information - clearly communicate:
  - potential bodily safety risks associated with sample collection,
  - methods for privacy protection,
  - the right to withdraw consent at any time without justification,
  - policies on returning individual results and incidental findings

- Compliance with benefit-sharing requirements.
  (Ejtahed et al., 2023; BBMRI-ERIC, 2018; see also section 2.1.4 on informed consent)

Biosafety & Pathogen Release

There are also **biosafety risks** related to the **release of pathogenic microorganisms** from human microbiome samples. Such samples may unknowingly contain harmful species like *Clostridium difficile*, *Hepatitis A virus* (in stool), or SARS-CoV-2 (in saliva). Risks exist not only from whole samples but also from **isolated microbial strains**.

❖ *Recommendation:* Microbiome research and biobanking must include a risk assessment and have procedures that ensure compliance with relevant biosafety and biosecurity and requirements (ISO 20387:2018).

Because it is often unknown whether a sample contains pathogens:

❖ *Recommendation*: All primary microbiome samples should be treated as potentially pathogen- containing and/or infectious. The principle of universal precautions accounts.

Strict biosafety regulations and standards exist to prevent pathogen transmission and protect public health, especially when handling samples from infected humans or animals. (Müller et al., 2020).

Examples include

- **European biosafety/biosecurity legislation** (see www.ebsaweb.eu),
- **WHO Laboratory Biosafety Manual** (4th ed. 2020),
- **WHO Biorisk Management Laboratory Biosecurity Guidance,**
- **Laboratory Biosafety and Biosecurity Risk Assessment Technical Guidance** , and
- **ISO 35001:2019** on biorisk management for laboratories and related organisations.

❖ *Recommendation:* Biobanks handling potentially infectious materials must comply witih applicable biosafety and biosecurity regulations and standards, and operate to appropriate biosafety levels (BSL) based on the hazard classificsation of the organisms. These levels define the facility design, physical containment, equipment, and procedures required to minimise risks. (Müller et al., 2020)

Premature Use, Commercialization & Microbiome Hype

Concerns have been raised about the **premature application** of human microbiome research in healthcare, given that the field is still in its infancy. Current knowledge is not yet sufficient to draw firm conclusions about disease risk or therapeutic manipulation and treatment. (Chuong et al., 2017; Ma et al., 2018)

Despite these limitations, the human microbiome is gaining significant commercial interest, particularly through the development of microbiome-based interventions such as:

- probiotics and prebiotics,
- fecal microbiome transplantation,
- direct-to-consumer microbiome testings, and
- "wellness" products containing beneficial bacteria.
  (Kallergi & Zwijnenberg, 2025; Slashinski et al., 2012)

However, many of these products lack clinical validation and could potentially pose risks to both consumers and the environment. A recent study evaluating several microbiome testing kits found major shortcomings, including **non-transparent methodologies** and **unreliable results**. This leads to claims for a better regulation of direct-to-consumer microbiome testing. (Rodriguez et al., 2024; The Lancet, 2024)

It was further observed that **different microbiome analyses yielded divergent interpretations** of the same sample—highlighting the **lack of standardization and validated methods** in this field (Rodriguez et al., 2024; The Lancet, 2024).

❖ *Recommendation:* Biobanks, researchers and *in vitro* diagnostic manufacturers must comply to (the same) quality standards especially those addressing the **pre-analytical phase** of micriobiom samples – such as the standards **CEN/TS 17626:2021**) currently being developed into **ISO 18701.** [1]

❖ *Recommendation:* Both **pre-analytical** and **analytical workflows** must be fully validated to ensure **reliability** of results.

For clinical and therapeutic uses involving human-derived materials—including the intestinal microbiome—the new **EU Regulation on Substances of Human Origin (SoHO)**, adopted in May 2024, is applicable.This regulation defines SoHO as any substance collected from the human body, including blood, tissues, cells, embryos, and **other substances**, such as **the human intestinal microbiome** (Official Journal of the European Union, 2024).

It outlines (among others):

- safety requirements for donation, collection, processing, storage, and distribution,

[1] CEN/TS 17626:2020 or ISO 18701 - Molecular in vitro diagnostic examinations - Specifications for pre-examination processes for human specimen - Isolated microbiome DNA

- criteria for donor protection, and
- provisions for donor compensation when materials are used for therapeutic purposes.
  (Official Journal of the European Union, 2024)

The increasing commercialization of the microbiome raises **ethical and regulatory challenges**, as well as the need for better understanding of **public attitudes** and **decision-making processes** regarding microbiome use. (Rook & Zwart, 2025)

2.1.4 Ownership & Benefit Sharing

Ownership of Microbiome Samples and Data

Ownership of human samples and data is a complex legal issue involving intellectual property (IP) rights, privacy regulations, and contractual agreements. This complexity also applies to microbiome biobanking and research.

The human microbial genome is not a part of the human genome per se and could be viewed as "non human". However, it is increasingly referred to as the **"second genome"** and may be just as personal as human DNA. (Hawkins & O'Doherty 2011).

Human microbiome data (e.g., DNA sequences from microbial species in/on a person's body) may qualify as **personal data** if it can be **linked back to an individual** - as suggested by the concept of a **microbial fingerprint**. The EU Regulation on Substances of Human Origin (SoHO), effective as of May 2024, explicitly includes **human intestinal microbiome** within its scope of 'human-derived' samples.

The issue of ownership becomes especially prominent in the case of **stool samples**, traditionally regarded as biological waste, prompting to the provocative yet justified question '**Who owns your poop?'** (Hawkins & O'Doherty, 2011).

Complicating matters, the **microbiota composition is dynamic**—changing with diet, medications, and other lifestyle factors—raising questions about the enduring relevance and ownership of a specific sample. (Ejtahed et al., 2023; Chuong et al., 2017)

Benefit Sharing

Ownership issues naturally raise questions about **benefit sharing**, an area that remains **underdeveloped** in human biobanking. **Benefit sharing** refers to providing individuals or communities with **monetary and/or non-monetary benefits** derived from the use of their biological materials or data. Questions raised include which types and ranges of benefits, as well as who should be the beneficiary and by by whom. (Sudoi, 2021)

Key considerations include:

- **Types of benefits** may include:
  - financial returns
  - return of individual health results (e.g., blood test outcomes)
  - counseling or screening services
  - access to new treatments or public health benefits

  (Sudoi, 2021; Tzortzatou-Nanopoulou et al., 2023)
- In the **microbiome** context, benefits may extend to:
  - improved nutritional knowledge and dietary advice,
  - microbial transplantation techniques,
  - targeted microbiome manipulation strategies,
  - advances in pharmacomicrobiomics, public health, or forensic applications

  (Hawkins & O'Doherty, 2011; Schroeder, 2007)
- **Beneficiaries** may include:
  - participants,
  - communities,
  - broader society,
  - or marginalized groups, depending on context.
- **Responsible parties** for providing benefits could include:
  - researchers,
  - sponsors,
  - government bodies,
  - or industry actors.
- **Timing**: Benefit provision should occur both during and after research. (Sudoi, 2021)

Major benefit sharing challenges in human (research) biobanking identified are:

- Future use/re-use of samples is often uncertain.
- Research timelines are long—benefits may take years to materialize.
- Non-monetary benefit sharing still incurs costs.
- Definition and quantification of non-monetary benefits.
- Concerns exist that financial benefits could undermine altruism or commercialize participation.
- There's no guarantee that benefits reach those most in need or the correct beneficairies.

(Hawkins & O'Doherty, 2011)

Some authors (e.g., Ma et al., 2018) advocate for embracing the **principle of solidarity**, framing participation as a **social responsibility** rather than a transaction.

❖ *Recommendation:* Develop and implement policies and frameworks for **fair and equitable benefit sharing,** including clear rules on the involvement of commercial actors. (Tzortzatou-Nanopoulou et al., 2023) Ethical review boards should play a central role in this process.

It is important to consider indigenous people and local communities in discussions about ethics. There was consensus among the workshop participants that microbiome data should be considered as health data, and that public repositories and biobanks should be subject to strict regulations regarding access and usage of content.

❖ *Recommendation:* Raise awareness about the importance of ethics in microbiome research and the relevance of benefit sharing and ownership beyond legal compliance.

❖ *Recommendation:* In line with the **Nagoya Protocol**, ensure benefit sharing includes both **monetary and non-monetary** components (e.g., training, capacity building), and differentiate between **individual** and **community-level** benefit sharing. *(Workshop insight)*

Return of Results

In biobanking and research, return of results refers to the practice of informing participants about individual findings—particularly those with health relevance, such as genetic predispositions or microbiome-linked health risks.

Key ethical issues:

- Should results be returned at all?

- If yes, what type (individual vs incidental findings)?
- Who is responsible for disclosure and explanation?
- In what format and to whom (individual vs public)?

Some argue participants have a **right to know**, while others emphasize a **right not to know**. (Hawkins & O'Doherty, 2011)

Microbiome research presents special challenges:

- **Validity** and **clinical utility** of results are often unclear.
- Findings may not be actionable or evidence-based.
- Results could be misinterpreted without clinical guidance.
- The microbiome is **dynamic**; old samples may no longer reflect current health.

In addition:

- Biobanks using archived samples often lack contact with participants.
- Researchers may not inform biobanks of findings, making return impossible

❖ *Recommendation:* Before deciding whether to return results, conduct a **risk-benefit assessment**, especially for ambiguous or uncertain findings. Also consider **operational and financial feasibility**. (Ejtahed et al., 2023)

❖ *Recommendation:* Include return of results in the **informed consent process**. Provide participants with clear choices (e.g., checkboxes) to opt in or out of receiving individual or incidental findings.

❖ *Recommendation*: Biobanks and researchers should commit to **transparency with the public**, including sharing general research outcomes (e.g., inventions, biomarkers, treatments) derived from microbiome data, as a form of public benefit sharing.

❖ *Recommendation*: Develop clear **ethical guidelines** for returning microbiome-related findings. (Ejtahed et al., 2023)

Informed Consent and Autonomy

Informed consent in biobanking and research is the process of obtaining permission from individuals to collect, store, and use their biological samples and associated data for research purposes (BBRMI.at, 2025). It is a fundamental expression of participant **autonomy and agency**.

However, what makes the informed consent process in biobanking difficult is the question, how can one fully disclose the risks and benefits of the research to a potential research

participant when the type and purpose of future research, examination methods, health applications and implications are not yet known? (Kling, 2019; Hawkins & O'Doherty, 2011).?

Microbiome research poses several distinct challenges:

- Future uses and risks may be **unforeseeable**.
- Clinical relevance is still emerging.
- Specific (narrow) consents may hinder future research, leading to calls for **alternative consent models**.

As a response to such questions alternative consent forms have been developed

- **Broad consent**: agreement to future unspecified studies
- **Open consent**: one-time consent for unrestricted future use
- **Dynamic consent**: ongoing participant control via digital platforms
- **Tiered consent**: options to choose among levels of involvement
  (Wiertz, 2022; Hallinan, 2015; Muller, 2023)

Concerns also arise with data/sample sharing across institutions and borders, which complicates withdrawal or deletion of samples.

❖ *Recommendation*: Biobanks and researchers should express respect for autonomy of participants and provide consent forms and adequate information.

Consent forms should:

- be written in accessible, local language,
- account for different literacy levels,
- include the right to withdraw without explanation at any time.
  (Tzortzatou-Nanopoulou et al., 2023)

In the process of obtaining informed consent, research participants may also be informed about e.g.

- insurance
- compensation,
- IP and commercialization, and
- conflict of interest.

(Tzortzatou-Nanopoulou et al., 2023)

2.1.5 Others Considerations

Social Justice

Social justice in biobanking and research entails **fair access**, **representation**, and **benefit sharing**, especially for marginalized groups.

- *Recommendation*: Ensure **fair participant selection**, including ethnic, geographic, gender, and socioeconomic diversity. (NIH, 2025; Kling, 2019)

- *Recommendation*: Equitably distribute the **benefits** of microbiome research (e.g., diagnostics, therapies, public health applications).

Intellectual Property (IP)

Microbiomes, being natural substances, present challenges for traditional IP protection, yet commercial interests persist. **Ethical debates** have emerged over questions like: "Should it be permissible to patent microbes and restrict their use for public health or environmental benefit?" (Lange et al., 2022)

- *Recommendation:* The microbiome research community—academic and commercial—with transparency and togheter with the public opinion, should engage in open discussion about **patentability**, **IP sharing**, and **ethical use** of microbiome resources

2.2 Veterinary Microbiome Biobanking and Research

2.1.1 Scope and Understanding

In Task 5.2 of the MICROBE project, the original focus on ethical, legal, and social implications (ELSI) in the veterinary field was primarily focused on *veterinary clinical biobanks*. These biobanks serve as the counterparts to human clinical research biobanks, as they collect, process, and store biological samples and associated data from 'animal patients'—often including data from animal owners. The structure and governance of veterinary clinical biobanks closely mirror those of human biobanks, and many core biobanking principles apply to both domains (LaLonde-Paul et al., 2023).

In discussions with interview partners and workshop participants during Task 5.2 the term *"veterinary"* was used in its broader interpretation and encompassed not only clinical settings but also:

- Laboratory research animals (e.g., mice, flies),
- Wildlife species (free-ranging or protected),

- Animals in agriculture and food production (e.g., livestock).

The veterinary microbiome biobanking landscape also includes various types of biobanks, such as:

- Veterinary clinical research biobanks,
- Laboratory animal biobanks,
- Domesticated and livestock animal biobanks,
- Wildlife and conservation biobanks,
- Strategically oriented or species-specific research biobanks.

2.2.2 Ethical and Legal Foundations

Despite the expanding role of microbiome biobanking in veterinary and animal research, explicit literature addressing ELSI issues in this area remains scarce. However, several ethical, legal, and policy frameworks offer relevant guidance, particularly regarding safety, animal welfare, and responsible data and sample management.

Key ELSI considerations for veterinary microbiome biobanking and research are supported by established laws, guidelines, and principles, such as:

- **European and national legislation on animal welfare**, including:
    - *Directive 2010/63/EU* on the protection of animals used for scientific purposes (European Commission, 2025),
    - *Natianal Animal Welfare Acts such as those in Austria*[2]*, Germany, Switzerland, UK or USA.*
- **National ethical guidelines** for the use of animals from national bodies such as the *National Committee for Research Ethics in Science and Technology (NENT)* (National Research Ethics Committees, 2019).
- **Guiding principles for ethical animal research**, including:
    - The **3Rs Principle**—Replacement, Reduction, and Refinement (European Animal Research Association, 2025), which aims to minimize animal use and suffering while ensuring scientific validity.
    - The **ARRIVE Guidelines** (Animal Research: Reporting In Vivo Experiments) (ARRIVE, 2025), which support transparency in research reporting.

[2] Austrian Federal Act on the Protection of Animals (Rechtsinformationssystem des Bundes, 2025)

- The **PREPARE Guidelines** (Planning Research and Experimental Procedures on Animals: Recommendations for Excellence), which highlight ethical and legal, issues to consider in research (Smith et al., 2017).

- **The Nagoya Protocol on Access and Benefit Sharing** governs access to microbiome material from the envirorment and from non-human genetic resources. While microorganisms (including viruses) found on or in the human body are not explicitly excluded from the Protocol's scope, individual Parties retain discretion over how to regulate genetic resources derived from the human microbiome—some countries opt to exclude these materials from their implementing legislation.some include them..

❖ Recommendation*:* Veterinary biobanking and microbiome research should **follow best practices and internationally recognized standards**, **in parallel with the human biobanking field.** Compliance with legal and ethical requirements is essential when collecting, processing, and using animal-derived samples and data.

❖ *Recommendation:* Whenever feasible, **involve ethics committees** in the planning and oversight of microbiome biobanking, regardless of animal species or context.

❖ *Recommendation:* In accordance with the **3Rs principle,** the following **ethical guidelines** (adapted from National Research Ethics Committees, 2019) should be applied across all veterinary and animal microbiome biobanking activities, including those involving research, wildlife, farm, or companion animals:

- Respect the dignity and intrinsic value of animals.
- Actively consider alternatives (Replacement).
  - Apply proportionality: weigh the expected benefits against potential animal suffering.
  - Minimize harm and improve welfare (Refinement).
  - Limit the number of animals used (Reduction).
  - Demonstrate responsibility for protecting biodiversity.
  - Utilizes biodiversity in a sustainable manner
  - Take care when intervening in natural habitats.
  - Promote transparency and sharing of data and materials.
  - Ensure staff have appropriate animal-related expertise.
  - Exercise due care and comply with relevant national laws, international conventions, and institutional policies.

Although experimental use of laboratory animals is well regulated, certain animal-related activities are exempt from formal legal or ethical review. For instance, *Article 1 of Directive 2010/63/EU* explicitly excludes:

- non-experimental agricultural practices;
- non-experimental clinical veterinary practices;
- veterinary clinical trials
- practices undertaken for the primary purpose of identification of an animal
- Procedures unlikely to cause pain, suffering, distress, or lasting harm.

(European Commission, 2025)

As a result, some areas of veterinary microbiome biobanking seem to operate outside formal ethical oversight. This gap raises concerns, particularly as awareness of animal ethics and welfare expands. Increasingly, scientific journals require evidence of ethical compliance and approval by an independent ethics committee—even for studies not legally mandated to seek such review (Adami, 2023).

2.2.5 Liability and Consent Considerations

Veterinary microbiome biobanking and research may also raise liability risks, particularly in the following scenarios:

- **Consent issues**: Samples are collected without proper consent from animal owners or caretakers.
- **Ethical breaches**: Invasive or non-compliant procedures cause harm to animals, potentially constituting ethical or legal violations.
- **Technology-related risks**: Owners may face exposure to data risks e.g., when using animal-related apps (Harper et al., 2022).

❖ *Recommendation:* Consent forms from pet owners or animal caretakers—especially for farm or companion animals—should be systematically obtained and retained to mitigate ethical and legal risks.

2.2.6 Privacy Issues

While privacy is a cornerstone in human microbiome research, the concept of *animal privacy* is still emerging and debated. The notion of privacy interests for animals is controversial—ranging from cautious support to skepticism and criticism.

With the rise of digital technologies in animal monitoring—across households, farms, zoos, research settings, and even in wildlife—data protection becomes increasingly relevant. For example:

- Farmers using electronic monitoring tools for livestock must address cybersecurity risks to protect their own and their animals' data.
- In wildlife research, GPS data from collars or tracking devices may expose animals to risk of being captured and killed by poachers.

Although the motivation for data protection in these cases often stems from concerns about human interests (e.g. economic loss, privacy, legal responsibility), **animal safety and welfare can be directly affected** by data breaches (Paci et al., 2022; Coghlan et al., 2025; Rubel et al., 2025).

❖ *Recommendation:* Veterinary microbiome researchers and biobankers should consider the aspects of both privacy issues in general and animal privacy in particular.

3. Outlook

This report presents the preliminary outcome of the MICROBE Task 5.2 (T5.2), based on an in-depth literature review, expert interviews, and a workshop conducted by MUG within the framework of the MICROBE project. It provides an initial overview of ethical and legal issues that may arise in biobanking and research involving human and veterinary/animal microbiome samples. However, it does not claim to be exhaustive.

A joint opinion paper on ELSI (Ethical, Legal, and Social Issues) in microbiome biobanking and research is planned, in collaboration with MICROBE Work Package 5 (WP5) members and volunteer contributors from the interviews and workshop. The working title is: *"Liability Risks and Ethical Considerations in Microbiome Biobanking and Research."*

In addition, the results of this workshop and the broader findings of T5.2 are intended to feed into Task 3.2, *"Implementation of Recommended Standards and Metadata Harmonisation Tools."* Ethical and legal requirements related to human health-associated metadata, including data security aspects, will be considered as part of this process.

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