A European infrastructure
for farmed animal genotype to phenotype research

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Open samples policy

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Table of Contents

1. Executive Summary

Background	While the European Union has been widely promoting an open data policy, the sharing of biological samples is not organized to the same extent. This remains the responsability of biobanking infrastructures, such as BBMRI, MIRRI and EMBRC. Sharing of biological samples is crucial both for verification of results and reduction of number of animals in experiments. Thus, EuroFAANG RI aims at promoting open access to and reuse of research samples as well as data, following the "as open as possible, as closed as necessary" principle.
Objectives	To achieve equitable sharing of biological samples and models to produce new scientific knowledge and facilitate partnership with breeding industry. To integrate an open sample chapter in the TNA policy of EuroFAANG (D2.2). To propose a Biological Resources Management Plan (BRMP) template that aligns with the guidelines of other biobanking infrastructures.
Methods	- Expand the open data philosophy from the DMP of EuroFAANG (D3.1); - Combine contents of D4.2 and D4.4; - Interview managers of open data policy in research institutions; - Study the BRMP in preparation by the French Biobanking infrastructure for agriculture, biology and environment (https://agrobrc-rare.org).
Results & implications	As for open data, an open sample policy has to address the main questions related to the type of samples, storage conditions, safety issues, request procedure and regulatory issues. A template for a Biological Resources Management Plan (BRMP) is proposed to collect information on: what will be shared (type and origin of samples, unqiue ID)?, where and how are the samples stored? are there any biological risks or specific regulations applying to the samples, are there sensitive issues? who are the expected users of the samples? for which purpose? how will the sharing take place? Two main limitations are still encountered for samples sharing: - unsufficient documentation, that is the reason why completion of metadata is so critical and supported by EuroFAANG RI; - ownership feeling of researchers on their samples which underlines the need for acknowledgements of samples providers as a mandatory step for an open samples policy; EuroFAANG RI has to lead communication on the benefits from sample sharing in order to advocate for an open samples policy for G2P research.

2. Introduction

The EuroFAANG Research Infrastructure project is committed to the principles of open science and acknowledges the essential role of access to high-quality biological samples in advancing scientific discovery and fostering innovation.
The purpose of this deliverable is to describe an “open sample“policy framework in order to achieve the equitable sharing of biological resources and cellular models developed for G2P research.

This document outlines the principles and procedures governing access to, sharing of, and reuse of biological samples collected, generated by or in collaboration with the EuroFAANG RI. It addresses the expectations of EuroFAANG RI for the management and sharing of biological samples, by applying FAIR principles to samples in addition to data. It defines the principles for accessing samples in alignment with ethical standards, legal requirements, and best practices in biological resource management. This policy is intended to complement the EuroFAANG Guide for Transnational Access (TNA), which will also be made available from the EuroFAANG website (https://eurofaang.eu/).
By implementing this open sample policy, the EuroFAANG RI aims to foster a transparent, responsible, and collaborative research environment. This supports efficient use of biological resources, facilitates reproducibility and comparability of G2P research in farmed animals, ensured broad and fair access to valuable materials by the European research community and beyond.
To achieve this, we used the Data Management Plan (DMP) of EuroFAANG as a basis and integrated the input on biobanking rules from D4.2 and the input on biobanking protocols from D4.4. We also interviewed INRAE colleagues involved in open data management, and considered the current initiative of the French biobanking infrastructure for agriculture, biology and environment (agrobrc-rare.org), to develop a Biological Resources Management Plan (BRMP). This deliverable will define the requirements to share biological samples and associated data for all users of the future EuroFAANG infrastructure, and beyond, in compliance with FAIR principles and existing European policies.

3. Open Sample Policy

3.1 Definitions and Scope of an Open Sample Policy

The Open Sample Policy of EuroFAANG has to include all steps governing the collection, identification, preservation, use and sharing of biological samples and associated metadata generated by or made available through the TNA policy of the infrastructure.

As for open data, an open sample policy has to address the main questions related to the type of samples, storage conditions, safety issues, request procedure and regulatory issues. Typically, this will translate into the following questions:

- What will be shared? (type of samples, origin of samples: input from D4.4)

- Where and how are the samples stored, under which conditions, for how long?
- Are there any biological risks or specific regulations applying to the samples, are there sensitive issues (Sanitary regulations, Nagoya Protocol, GPDR.)?
- Who are the expected users of the samples? For which purpose?
- How will the sharing take place (how to place a request, property rights, access and benefit sharing, material transfer agreement, acknowledgement of the samples provider: input from D4.2)

Open access to well-characterized samples is essential not only for reproducibility and transparency but also to maximize their scientific value through broader community reuse. The EuroFAANG RI endorses the principle of "as open as possible, as closed as necessary" in managing access to biological samples and associated metadata. By default, biological samples made available through EuroFAANG RI, especially under Transnational Access (TNA) policy, will be shared openly as much as possible. However, access may be subject to justified restrictions, including ethical considerations, biosafety requirements, conservation concerns, or intellectual property rights.

Two main limitations to sample sharing are currentlyl encountered:

- Samples are not sufficiently documented, which strongly limits their reuse, that is the reason why completion of metadata is so critical and heavily supported by EuroFAANG RI;

- Researchers collecting samples may have a selfish attitude, considering '*it was a lot of effort to collect this sample, it is for my research only'*, which underlines the need for acknowledgements of samples providers as a mandatory step for a research infrastructure supporting an open samples policy.

The inclusion of samples originating from either academic or industrial contributors provides an opportunity to strengthen collaboration and innovation within the G2P research community. However, it also necessitates a clear policy framework for managing access, particularly where commercial sensitivity or proprietary interests exist. The EuroFAANG RI is therefore developing nuanced access rules that balance open sharing with the protection of contributor rights.

Access to samples will be governed by sample types and user categories, aligning with the options for EuroFAANG TNA policy previously described in D2.2.

- **Types of samples covered (EuroFAANG Resources)**.

EuroFAANG offers access and use of a wide range of tissues, cryobanked organoids, *in vitro* models and genome edited cell lines from different species, breeds and populations. It has expertise in a wide variety of techniques to use these resources to further knowledge regarding G2P. Presently, biobanking of animal biological materials is not coordinated at the European level. The BioSamples database (https://www.ebi.ac.uk/biosamples/) makes it possible to discover biological resources, but not to put in a request to use them. The existing national repositories of tissue samples are not sufficiently inter-connected and are often dispersed, and should be upgraded. This upgrade will include development of an open sample policy to allow equitable

sharing of created models for building new scientific knowledge and for facilitating bilateral competitive G2P research for the breeding industry stakeholders. This corresponds to use category II of D2.2:

- **Types of Use**

I. Retrieve data stored at the infrastructure and use locally
II. Obtain biological resources stored at the infrastructure and use locally
III. Online access to and use of the compute resources of the infrastructure
IV. On site access to and use of the compute resources of the infrastructure
V. On site access to and use of the experimental facilities of the infrastructure

The types of users are those described in D2.2 :

I. Academic user fully open access
II. Academic user partial open access (e.g. for use of the infrastructure within an ongoing collaboration between an academic and industrial partner)
III. Industrial user fully open access
IV. Industrial user partial open access
V. Industrial user, private use only

3.2 Building an Open Sample Policy for EuroFAANG

Building a Policy aims at ensuring that the broader research community will agree to give access to valuable biological resources in line with EU open science and public funding principles, while industrial partners can engage with and benefit from the infrastructure.

Development of an open sample policy for EuroFAANG will use elements and information that have been reported in the previous deliverables, D2.2, D4.2 and D4.4 (Figure 1). These elements include: TNA options that will create mechanism through which researchers can request and use samples under transparent and standardized conditions as described in D2.2. This supports openness by widening participation, and ensuring that access is not restricted to a limited user. The second element is the biobanking access rules for future TNA (D4.2). These rules will provide a basis for equitable sharing of biobanked resources through sample deposit and distribution request procedures. It also provides clarity on ethical and legal requirements, ensuring compliance with data protection laws, and material transfer agreements. Lastly, the development and standardization of biobanking protocols across species and biological materials is critical to ensuring reliability, reproducibility, traceability, and comparability of biological samples (D4.4). By implementing species-adapted standards, EuroFAANG will enable samples to be openly shared with confidence in their quality and integrity. It will also provide quality insurance and comparability across research projects.

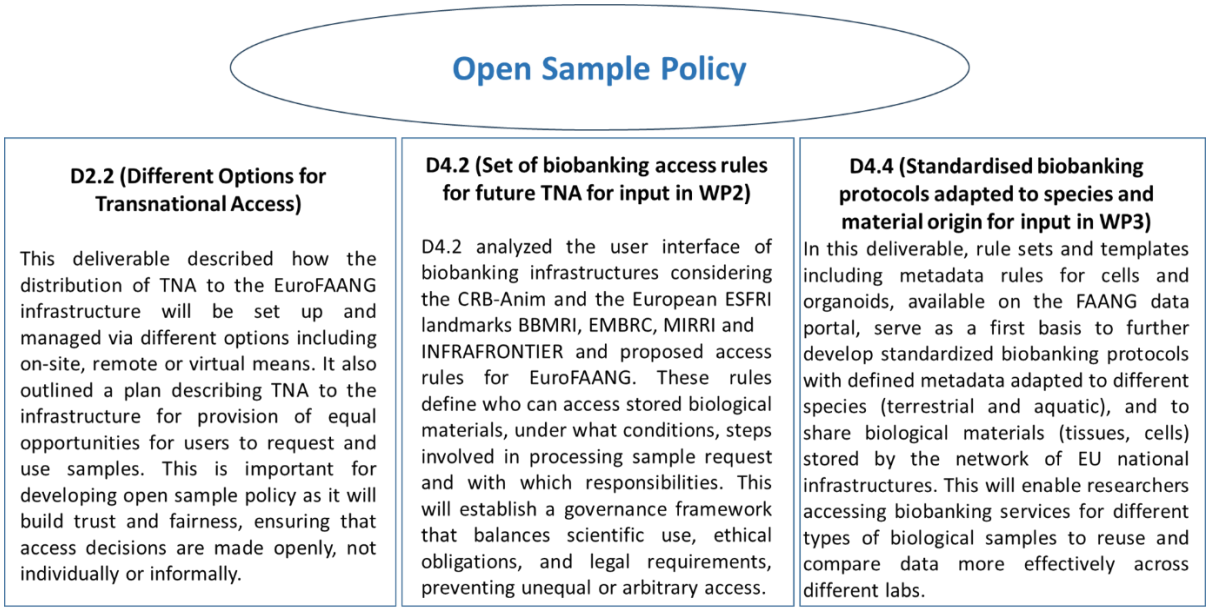

Figure 1: Combining information from D2.2, D4.2 and D4.4 to prepare the EuroFAANG Open Sample Policy

Experience from BBMRI showed that implementating the ISO 20387 biobanking standard was instrumental is promoting FAIRness of biobank collections.
Experience from INFRAFRONTIER showed that affecting a doi to a set of samples would be a solution to acknowledge the samples provider, on the model of a doi associated to a data set. One solution would be to link a set of samples to an open access publication, either a 'samples paper' inspired from the structure of a 'data paper', or the first scientific paper making use of the samples.

4. Developing a Biological Resources Management Plan (BRMP)

4.1 Definitions and Scope of a BRMP

A Biological Resources (BR) Management Plan is a formal document that describes how biological samples/materials will be collected, handled, stored, shared, used and preserved in a responsible, ethical and sustainable way.
It ensures that BR are managed efficiently while respecting IP rights and fair benefit sharing.
As proposed by the French Network of BRC for Agricultural, Environmental and Life Science (https://agrobrc-rare.org) the Biological Resources Management Plan (BRMP) is a concept designed to address the global challenge of managing and preserving biological resources (BR) obtained through scientific research. It focuses on inventorying, tracing, and optimizing the conservation of BR, enhancing their visibility, promoting sharing, and fostering global scientific collaboration. Unlike Data Management Plans, the BRMP specifically tackles the materiality of biological resources, offering a comprehensive approach for their sustainable management.

Similarly to a DMP, the BRMP will outline the Research Infrastructure's (RI) commitment to FAIR principles (Findable, Accessible, Interoperable and Reusable), safe conservation and ethical management of biological resources to support research. This BRMP has been developed in alignment with Horizon 2020 guidelines and best practices for biological material stewardship, and draws on established frameworks for open science and resource sharing under the EU Open Research Data Pilot. This plan ensures that biological samples, including tissues, cells, DNA, and other biomaterials – are collected, preserved, catalogued, accessed, and reused in a manner that maximizes scientific value, promotes collaboration, and adheres to legal and ethical standards.

4.2 Why is a BRMP needed?

Despite significant investment across research institutions, thousands of valuable biological resources remain disseminated and underutilized within research labs, often forming part of so called "dark collections" – biological materials that are insufficiently documented, in accessible, and disconnected from shared infrastructures. This lack of visibility hinders their attractiveness to external stakeholders and significantly limits opportunities for scientific collaboration. As a result, these resources often fall outside the scope of competitive funding mechanisms, which increasingly emphasize openness, interoperability, and long-term accessibility. This also sometimes occur with the requirement of Data Management Plan to get funds. Moreover, without a well coordinated effort of cataloging and preservation, there is a substantial risk of loss due to personnel turnover, institutional restructuring, or degradation of samples overtime. The absence of systematic sharing protocols not only impedes scientific progress but also leads to duplication of effort and inefficient use of public and private funds, as resources are re-collected or re-developed instead of re-used.
To address these challenges, biobanks represent a key solution by offering safety, long term preservation, and traceability for biological resources. Integrating the anticipation of potential deposit in biobanks into early project planning would significantly enhance resource sustainability, align with FAIR principles, and ensure that valuable collections remain accessible and useful for future research.

4.3 Key Sample Management Procedures for BRMP

The BRMP should include 6 chapters as described in annex 1, that will address the following questions.

- **Sample Collection, Processing and Preparation**

This will include metadata requirements, standardized protocols and guidelines for sample collection, processing and quality control. This is crucial to ensure consistency and reliability. Standardized procedures help minimize variations and errors during sample collection, which can affect the quality and integrity of the samples. In particular, documenting the possible uses of a biological sample will be important to address the 'Fitness for purpose' concept described in Iso 20387.

- **Sample Registration and Traceability**

A unique ID is needed to find and access to a biological resource in a biobank**.** EuroFAANG will encourage registration of samples in a centralized, FAIR compliant sample catalogue or database such as Biosamples or ELIXIR registeries, and assignment of unique, persistent identifiers (DOIs, accessions) to each sample.

- **Sample Storage and Preservation**

This will describe defined conditions for short and long-term storage, procedures for labelling, barcoding, and cataloguing samples in secure inventory systems, and contingency and risk management plans such as backup storage, equipment failure protocols, etc. The expected length of conservation should be documented and criteria to eliminate samples considered to be not useful any longer (obsolete) should be given, unless the samples are connected to a program for biodiversity preservation, where conservation will always remain justified, as for instance in the case of semen bank.

- **Access and Sharing of Samples**

EuroFAANG will include procedures for requesting access to samples via EuroFAANG portal, TNA framework or direct collaboration. Access conditions such as open access, restricted access with justifications and template of Material Transfer Agreement will also be listed.

- **Ethical and Legal Compliance**

EuroFAANG requires that all samples are collected, stored, and distributed in compliance with the regulations and guidelines for the use of animals for scientific purposes. This includes that the appropriate approval of the animal experiment that collected the samples has been granted by an appropriate ethics committee and/or regulatory body (ethical committee or legal permit). This is particularly critical for the reuse of animal samples, since any further scientific publication of results obtained with ’old‘ samples will have to provide the proof of this approval to comply with the legal and ethical requirements of the country in which the user of samples operates.

- **Sample Reuse and Reporting**

Sample reuse through open or controlled access repositories will be encouraged and facilitated. Mechanism for users to report back on sample usage, publications, and results will be put in place. Lastly, guidance on proper acknowledgment of EuroFAANG in publications will be defined.

4.4 Enhancing community ownership

Even if metadata are complete, findable and accessible, the reuse of biological samples (the R of FAIR) is still a rare practice. For instance, a tissue collection set up in France at the beginning of the FAANG initiative has not been used by colleagues others than those who created it, although

the collection was findable and accessible on the portal of the CRB-Anim biobanking infrastructure, and was described in an open-access paper included in a special issue or Frontiers in Genetics for FAANG (doi: 10.3389/fgene.2021.666265).
It seems that researchers do not think of searching for available samples in biobanks before setting a new project. This is a major challenge for EuroFAANG RI, which requires investing in communication to raise awareness of the advantage of sharing samples as much as data.

5. Conclusions

Open samples policy will rely on the development of a Biological Resources Management Plan (BRMP). It will ensure that biological samples within EuroFAANG are collected, stored, accessed, and reused in a transparent, ethical and efficient manner by aligning with open science and FAIR principles. Collaborative use of biological samples within Europe would also be beneficial to make open samples policy become reality.
Additionally, it enables the effective integration of biological samples with data access strategies under TNA policy, ensuring that publicly funded resources are shared responsibly while protecting legitimate interests.
The infrastructure should take the lead to encourage the implementation of a BRMP by research laboratories to meet the demand of researchers and to value biological resources. This will aid in planning research projects, visibility needs for new collections, enhance trust and transparency, and maximise the long-term value of biological resources for scientific research.
Ultimately, the open sample policy will be integrated in the biobanking component of GenoPHEnix, if accepted as an ESFRI project.

6. Annex 1- Content of a Biological Resources Management Plan (BRMP) for EuroFAANG

1. **Resource Description and Collection**
    - What types of biological resources are included (tissues, cell lines, organoids, DNA, mircrobiomes, etc.)?
    - What is the origin of the resources? This will include species, breeds, populations, research project, geographical sources, etc.
    - What is the expected size/volume of resources to be managed?
    - What are the standard operation procdedures (SOPs) for sample collection?
    - How are ethical, legal and biosafety aspects addressed (e.g., permits, animal welfare)?
    - Have harmonized protocols across biobanking infrastructures been used ?
2. **Sample Data Quality and Documentation**
    - What metadata standards will be used, for example FAANG rulesets?
    - How will metadata be captured, validated, and linked to samples?
    - How will persistent identifiers (e.g., DOIs) be assigned?
    - How will interoperability with FAANG and other portals such as ELIXIR, EMBL-EBI, CRB-Anim) be ensured?
3. **Quality Storage and Back up Policy**
    - What quality insurance and control measures will be applied?
    - How will reproducibility across labs be guaranteed?
    - What preservation methods will be used (cryopreservation, fixation, etc.)?
    - What services and facilities are available for long term storage?
4. **Legal, Ethical and Regulatory Requirements**
    - How does BRMP comply with the Nagoya protocol and ABS regulations?
    - How are intellectual property rights handled (MTAs)?
5. **Access, Data sharing and Long-term Storage**
    - How will resources be made accessible (open access, TNA, controlled access)?
    - What are the eligibility criteria for access requests?
    - How will requests be submitted, reviewed, and approved?
    - Will there be cost-recovery mechanisms or user fees?
    - What mechanism will ensure long-term conservation of biological resources?
    - How will financial sustainability be achieved (recurrent funding, collaborations, cost recovery mechanisms)?
    - How will BRMP adapt to technological advances and community needs ?
6. **Contact staff management and Responsibilities**
    - Who is responsible for managing the biological resources (biobanking RI, research consortia, public institutions, private bodies)?
    - What management structures are in place (e.g., steering committees, expert groups)?
    - How are roles and responsibilities divided among partners (users, providers, biobank)?