Genetic material in Swiss research: the legal framework and the role of Swiss Biobanking

Scope

- Question
  - Here you talk about **Whole genome sequencing (WGS)**. What about **scRNAseq / scATACseq**? Or **spatial transcriptomics data** such as Xenium? Are these considered genomic data as well?
- Answer:
  - ✓ The legal test is not the name of the method but whether it yields genetic data, i.e. information on hereditary properties or properties acquired during the embryonic phase, obtained by genetic testing (Art. 3(g) HRA). Raw reads contain the donor's inherited sequence variants, so they should be treated as genetic and identifiable data. Processed outputs carry less risk, but linkage cannot be ruled out. Methods that measure expression without reading inherited sequence can give non-genetic health data as an output. In practice, classify each data layer separately and, when in doubt, treat it as genetic.

Data sharing

- Question
  - Can WGS datasets be **FAIR-shared** at the end of a project?
- Answer:
  - ✓ Yes, but FAIR does not necessarily mean open. Sharing requires that donors were told their data may be passed on to third parties (Art. 29 HRO), and deposition abroad requires consent to export genetic data (Art. 42(1) HRA) as well as compliance with data-protection rules on cross-border disclosure (Arts. 16–17 FADP or cantonal equivalent). In practice, raw genomes belong in a controlled-access repository, where a data access committee reviews requests and users sign a data use agreement; and the metadata remains openly findable. Switzerland joined the Federated European Genome-phenome Archive (FEGA) in 2025; its Swiss node, coordinated by the SIB Swiss Institute of Bioinformatics, is designed to keep data in Switzerland and went live as a service in October 2026.

Anonymization/ anonymized samples or genetic data

- Question
  - **Anonymized human samples** can often be purchased from commercial suppliers. What are the ethical and regulatory requirements for working with such samples particularly when experiments generate or provide access to genetic information? Are there specific requirements regarding informed consent, ethics approval, data handling or the continued use of these samples in different projects? Are there any differences depending on sample type?
- Answer:
  - ✓ If the material is truly anonymized, the HRA does not apply (Art. 2(2) HRA), meaning that no ethics approval or HRA consent is needed. However, a supplier simply labeling material as anonymized does not settle the question. Therefore, the following checks should be made. First, how was anonymity achieved? According to Art. 3(i)

HRA and Art. 25 HRO, the link to the donor must be impossible to re-establish without disproportionate effort. Note that in a case where the supplier keeps a key, the material is coded, not anonymized. Second, it is worth asking for and looking into evidence of ethical sourcing: the donor's consent should cover research use, distribution to third parties and genetic analysis. Third, genetic / genome data can make a donor identifiable again, so the data may not be anonymous even if the sample was.

Moreover, read the supplier's terms. They can restrict sequencing, data deposition or reuse, and they govern use in later projects. Research with human embryonic stem cells requires ethics committee approval (Art. 11 StRA); importing, exporting or deriving them additionally requires a license from the Federal Office of Public Health (FOPH) (Arts. 7, 15 StRA).

Finally, commercial availability and a supplier's anonymization claim do not automatically exempt research from ethical review, data protection requirements, or restrictions on future use. Where the status is unclear, submit a Clarification of Responsibilities form through BASEC; the ethics committee will confirm in writing whether the HRA applies.

- Question
  - I'm still confused - if a company sells "fibroblasts" - can I sequence them? Typically, they don't even say **coded or anonymized**.

- Answer:
  - ✓ Not automatically. Ask the supplier three things: what the donor consented to (including genetic analysis and data sharing), whether the cells are anonymized or coded, and whether the terms of use allow sequencing and data deposition. Established cell repositories often document this. If the answers support anonymity and the terms allow it, sequencing falls outside the HRA (see the first answer above), but treat the resulting genome as identifiable. If the status cannot be established, do not assume anonymity: submit a Clarification of Responsibilities form through BASEC.

Retrospective human generic studies

- Question
  - What are the current legal and ethical framework and recommendations to perform **retrospective human genetic studies** on archived material in tissue collections predating the modern biobank era.

- Answer:
  - ✓ The HRA has no general exemption for collections that predate it, so any research use today can be a further use under Arts. 32–34 HRA. First, establish what donors were told and agreed to, and whether any refusals are documented. If adequate consent is missing, there are two routes: obtain consent where donors can still be reached, or apply for the exceptional authorization of Art. 34 HRA. The ethics committee can grant it if the following conditions are met: obtaining consent is impossible, disproportionately difficult or unreasonable for the donor, no documented refusal exists, and the research interest outweighs the donor's interest in deciding. For genetic data, an exception may be difficult to obtain. Anonymization is not a shortcut: any planned anonymization of material or genetic data requires prior information and no objection (Art. 32(3) HRA) from the donor, and genetic/genome-

wide data are hard to anonymize in practice.

Informed consent and genetic data/ samples

- Question
  - Is **general consent (GC)** sufficient to collect and store residual material from routine diagnostics in a biobank for future research purposes?
- Answer:
  - ✓ Yes, this is the core purpose of the general consent (GC): it allows coded material and genetic data from routine care to be further used for research (Art. 32(2) HRA; information requirements in Art. 29 HRO), provided the material is stored under appropriate safeguards (Art. 43 HRA). Three limits remain. Each research project using the material still needs ethics approval (Art. 45 HRA). A GC does not cover uncoded use of material or genetic data, which needs project-specific consent (Art. 32(1) HRA). And drawing additional samples solely for the biobank is a research project in its own right, requiring separate approval and consent (Art. 6 HRO).

- Question
  - Ist eine generelle **Überarbeitung** (u.a. im Zusammenhang mit Gensequenzierungen) der aktuell im Einsatz stehenden **GKs** in näherer Zukunft in Planung?
- Answer:
  - ✓ Two processes are relevant. First, the Federal Council has mandated a revision of the HRA, which covers the further use of data and biological material; the FOPH expects the consultation to open in the second quarter of 2027. Second, in November 2025 swissethics published an optional template for information and consent for genomic research (whole-genome sequencing), for use alongside the general consent or a project consent; it is now listed as “under review”, and the general consent template itself dates from 2019.

- Question
  - Did I understand correctly: A person does not have the right to **object in genetic coded data for further research**?
- Answer:
  - ✓ It is the other way round. For coded genetic data and biological material, a mere right to object is not enough: the person must give consent, although a general consent suffices (Art. 32(2) HRA). The right-to-object model applies to coded non-genetic health data (Art. 33(2) HRA) and to the planned anonymization of material or genetic data (Art. 32(3) HRA). In every case, the person can refuse or revoke consent at any time without giving reasons (Art. 7(2) HRA), and a documented refusal excludes the exceptional route of Art. 34 HRA.

- Question
  - I think the **scope of the informed consent form (ICF)** should be broader than “genomic testing”. The scenario proposes whole genome sequencing (WGS), so the ICF should explicitly cover WGS, not only the analysis of a single gene, for example. Is that reasoning correct?
  - Discussion:
    - Participant A: Good point. If I want to sequence only your BRCA1 and BRCA2 genes, why should that be treated differently from WGS? I also

don't see a fundamental difference between WGS and using your medical records for research.
- ➢ Participant B: WGS data can identify a patient, whereas a single gene can't be traced back to an individual.
- ➢ Participant A: That's true, but once you look at more than about 20 variants, the combination of a person's alleles at those positions works as a unique identifier.
- ➢ Participant C: Exactly, so consent to "genomic testing" alone doesn't allow you to perform WGS.

- Answer:
  - ✓ Both sides of this exchange are right, because two separate questions are involved. The first is the legal category. Swiss law does not distinguish between one gene and the whole genome: any information on hereditary properties obtained by genetic testing is genetic data (Art. 3(g) HRA), so BRCA1/2 results and WGS fall under the same rules. Identifiability is a separate question of degree, so neither "a single gene" nor "about 20 variants" is a reliable cut-off.

    The second is the scope of consent. Consent covers what the person was informed about. A project consent for testing one gene does not cover WGS, and "genomic testing" should be explained, not merely named. Conversely, an ICF that clearly describes broad genomic research, including whole-genome sequencing, may be sufficient without listing every individual gene or future analysis.

    We strongly advise including genome-specific information. Where a consent covers coded genetic data but lacks such information, recontact donors with an opportunity to opt out before sequencing; a one-gene project consent instead needs new consent or an Art. 34 HRA authorization.

    Finally, Swiss law treats genetic data more strictly than other health data, such as medical records.

- Question
  - ➢ **How the informed consent should be prepared for persons undergoing psychiatric treatment**. In addition, in case of reuse for future genomic studies?
- Answer:
  - ✓ A psychiatric diagnosis does not mean a lack of capacity – capacity is assessed for each decision. For patients with capacity, the usual consent rules apply, with extra care: allow enough time for reflection (Art. 16(3) HRA), avoid periods of acute crisis, check understanding (Art. 8(4) HRO), and where possible have consent taken by someone outside the treating team. Information can be given in stages (Art. 8(3) HRO). For patients who lack capacity, research is possible only if capable patients cannot yield equivalent findings (Art. 11(2) HRA) and under the conditions of Art. 24 HRA: documented prior consent or the consent of the legal representative, a designated trusted person or next of kin, no visible opposition and, where there is no direct benefit, only minimal risks and burdens and the prospect of substantial findings for others in the same situation. The person must be involved as far as possible (Art. 21 HRA). The same consent rules apply to future genomic reuse (Art. 32 HRA). For the general consent, swissethics specifies that patients must give their own consent once they regain capacity. Genomic findings in psychiatry can be stigmatizing, so the information should explain how results and data sharing will be handled.

Research on the genome of microorganisms

- Question
  - Are there recommendations or guidelines for **research on the genome of microorganisms** (as incidental bystander sequencing of human genetic material)?
- Answer:
  - ✓ Shotgun or metagenomic sequencing of human specimens (stool, swabs, tissue) also captures human DNA, and those reads should be treated as genetic data about the donor. Good practice is to remove human reads as early as possible, before analysis and certainly before deposition, and not to analyze them unless the protocol and consent provide for it. NCBI encourages submitters to screen out human reads and offers a tool for this. If the study concerns human disease or the structure and function of the human body and uses non-anonymized patient specimens or clinical data, the HRA applies in any case.

    Incidental capture works in both directions. The primary objective may be to study human genetics, but sequencing can also reveal bacterial, viral, fungal, or parasitic DNA or RNA. Conversely, microbial sequencing may incidentally capture human genetic information.

    Where the research concerns human disease or the structure and function of the human body, coded specimens remain within HRA until they are anonymized (Art. 2(2) HRA). Whether Swiss Nagoya law (Nagoya Ordinance, NagO) applies is a separate question. Human genetic resources are excluded from NagO, but microorganisms are not. The research question is thus decisive: work on the human microbiome as a whole, focused on human health, is governed by health law, whereas research and development on individual isolates, or work focused on human pathogens, falls under NagO. The two regimes are also not mutually exclusive: a project on coded specimens that also works on microbial isolates falls under both.

Biobanking solutions and sample management

- Question
  - Do any **biobanking solutions for sample management** system, life cycle of the samples exist?
- Answer:
  - ✓ Biobank/laboratory information management systems (BIMS/LIMS) track each sample across its life cycle (collection, processing, storage location, consent status, distribution and destruction) and should link to consent and transfer records. Traceability is a core requirement of ISO 20387:2018, the international biobanking standard.

    Swiss Biobanking offers a BIMS solution (DiData x SMPL) developed with our partner DiData, which supports the interoperability pillar of the Swiss Biobanking infrastructure. It is designed to ensure that samples and associated data are documented in a standardized, comparable, and FAIR (Findable, Accessible, Interoperable, Reusable) manner across participating biobanks.
- Question
  - I am particularly interested on **Swiss biobanking governance**, legal/ethical handling of human genetic material, and practical coordination challenges at the discovery translational clinical interface.
- Answer:

- ✓ At the interface between discovery, translational and clinical research, most problems trace back to three decisions made early: what the consent at collection allows, who holds the coding key, and which contract governs the transfer (an MTA when material moves; a data transfer and use agreement when only data move). How findings may be returned to patients also needs to be settled before analysis starts. Swiss Biobanking supports these steps through its VITA governance label, template biobank regulations and MTAs, the Reference Guide on the biobanking process developed with SCTO, and ELSI advice. We are happy to discuss a specific project.

- Question
  - ➢ **Safety aspects** needed and apprehension for personnel and user/animals/plants?

- Answer:
  - ✓ Worker protection is governed by a dedicated ordinance on microorganisms (SAMV, SR 832.321). It requires a risk assessment before work begins, renewed regularly and whenever conditions change. Staff must be informed and trained before starting, with attention to the particular risks for vulnerable workers such as pregnant women or immunocompromised persons. Activities with genetically modified, pathogenic or alien organisms in contained systems fall under the Containment Ordinance (ContainO, SR 814.912), which protects humans, animals and the environment. It requires Class 2 activities (and Class 1 activities with genetically modified organisms) to be notified to the Federal Coordination Centre for Biotechnology (via ECOGEN) no later than their start, and higher-risk Class 3 and 4 activities to be authorized beforehand. It also requires a designated biosafety officer and a written biosafety concept. In practice, this means controlled and labeled access, protective equipment and containment matched to the risk, documented decontamination and waste disposal, and secure storage with alarms and backup. Shipments of infectious material follow international dangerous-goods rules (typically UN 3373, Category B). Handling such organisms in the environment, including field trials, falls under the Release Ordinance (RO, SR 814.911).

- Question
  - ➢ How to proceed with **archived samples**:
    - A: for which a general consent was not available
    - B: for which there was a consent but no specific mentioning of genetic analysis

- Answer:
  - ✓ (A) Without a general consent, try to obtain consent where donors can be reached; otherwise, apply to the ethics committee for authorization under Art. 34 HRA (see the answer on retrospective studies above).
  - ✓ (B) Where consent exists but does not mention genetic analysis, the wording decides. A valid consent to the coded research use of biological material can legally cover genetic analysis, but ethics committees will ask whether donors were adequately informed for genome-wide work, and where consent covers genetic data but lacks genome-specific information, the guidance of the Swiss Personalized Health Network (SPHN) recommends recontact and an opt-out before sequencing. A consent given for a different, specific project does not cover a new one. If genetic analysis was expressly excluded, that is a refusal and must be respected.