# Overview of the different types of Data-registries/Biobanks[1]

| Registry/biobank Research project | Consent | Protocol of the research project | Does the data-registry/biobank fall within the scope of HRA | Submit the data-registry/biobank to the Ethics Committee? | Cave | Example |
|---|---|---|---|---|---|---|
| Routine data/samples[2] feed into a registry/biobank.<br><br>There is **no** research question. | General Consent | None.<br><br>There is no research question. | No | Optional.<br><br>The ethics committee can give an advice as per Article 51 lit 2 HRA. | The data/samples may not **yet** be used for research[3]. | Swiss Stroke Registry. |
| Routine data feed into a registry at the hospital/clinic for quality assurance and quality control studies[4].<br><br>Data are **not** used for research, and **won't** be used for research in the future. | No consent required | None.<br><br>There is no research question. | No | No | The data may not be used for research. | Evaluating triage of patients in an emergency department. |

[1] For simplicity, it is here assumed that data or samples flow into a registry or biobank in coded form. The storage of data/samples in an uncoded form would be an exception that would have to be clearly justified in the registry/biobank regulation.
In principle, a consent from the participants/donors is always required: If there is any doubt about the need to obtain the consent from the participants/donors for a particular registry or biobank, it is strongly recommended that the ethics committee be contacted before establishing the registry or the biobank. An exception to this is if the registry is requested by the FOPH and the data won't be used for research purposes.
Additional information is available on swissethics.ch / Topics / Biobanks and data registries (link). Please see in particular the guidance document "Guiding principles for registries in human research" available in German and French.
[2] Samples = biological material.
[3] If research question is planned in the future, the Data registry/Biobank must fulfil the requirements set by HRO for further use research projects.
[4] Refer to the swissethics guidance document « Quality assurance, or research subject to approval? When is approval by the cantonal ethics committee required, and when not? » to distinguish between quality assurance/quality control studies, and research projects requiring ethics committee approval. The guidance is available in German, French, Italian and English.

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| Routine data feed into a company registry ordered by the FOPH under the market authorization.<br><br>Data are **not** used for research, and **won't** be used for research in the future. | No consent required | None.<br><br>There is no research question. | No | No | The data may not be used for research. | |
| Routine data feed into a company registry ordered by the FOPH under the market authorization.<br><br>There is a possibility that the data will be used for research in the future, but there is **no** research question **yet**. | General Consent | None.<br><br>There is no research question. | No | Optional.<br><br>The ethics committee can give an advice as per Article 51 lit 2 HRA. | The data may not **yet** be used for research[3].<br><br>No samples are collected. | |
| Routine data feed into a company registry ordered by the FOPH under the market authorization.<br><br>Additionally, the data is also used for a research question. | General Consent | HRO<br>Chapter 3 Further use of biological material and health-related personal data for research.<br><br>It must be guaranteed that only routine data/samples are used. | Yes<br>HRO Art. 33 | Yes | No samples are collected. | |

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| Routine data/samples feed into a registry/biobank for a research project[5]. | General Consent | HRO<br>Chapter 3 Further use of biological material and health-related personal data for research.<br><br>It must be guaranteed that only routine data/samples are used. | Yes<br>HRO Art. 33 | Yes | No additional, study-related data/samples may be collected. Time windows for visits must not be defined in the protocol. | Research project with data from the Swiss Stroke Registry. |
| Routine data/samples feed into a registry/biobank. Additional data/samples are collected for research purposes.<br><br>There is **no** research question[6]. | Research project specific informed consent form. | HRO<br>Chapter 2 Research involving measures for sampling of biological material or collection of health-related personal data from persons. | Yes<br>HRO Art. 6b | Yes | The consent must clearly state the procedure and risks. It is described that the additional data/samples will be collected for future research projects. | Constitution of the Rheumatology registry/biobank with a blood sample collection. |

[5] In addition, it is possible that historical data or samples from other patients are included in the research project. This would be a further use of data/samples with or without consent, which must be described in the study protocol (coding, time span, which patient collective, which consent was obtained – see protocol template for the submission of a project "further use with or without consent" published on swissethics.ch).

[6] If routine clinical data or samples from the patient are also included in the data registry/biobank, this will be stated in the study-specific consent and in the study protocol.

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|---|---|---|---|---|---|---|
| Routine data/samples feed into a registry/biobank.<br><br>Additional data/samples are collected for research purposes; there **is a** research question[7]. | Research project specific informed consent form. | HRO<br>Chapter 2 Research involving measures for sampling of biological material or collection of health-related personal data from persons. | Yes<br>HRO Art. 6a | Yes | The consent must clearly state the procedure and risks. The aim of the research project is explained, optionally with an additional consent (or general consent) for future research projects. | Swiss Transplant Cohort Study: Registry with a blood sample collection. |

[7] In addition, it is possible that historical data or samples from other patients are included in the research project. This would be a further use of data/samples with or without consent, which must be described in the study protocol (coding, time span, which patient collective, which consent was obtained – see protocol template for the submission of a project “further use with or without consent” published on swissethics.ch).