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National guidelines for evaluation of biobank collections

The guidelines were compiled on behalf of:
Health-RI theme Biobanks & Collections

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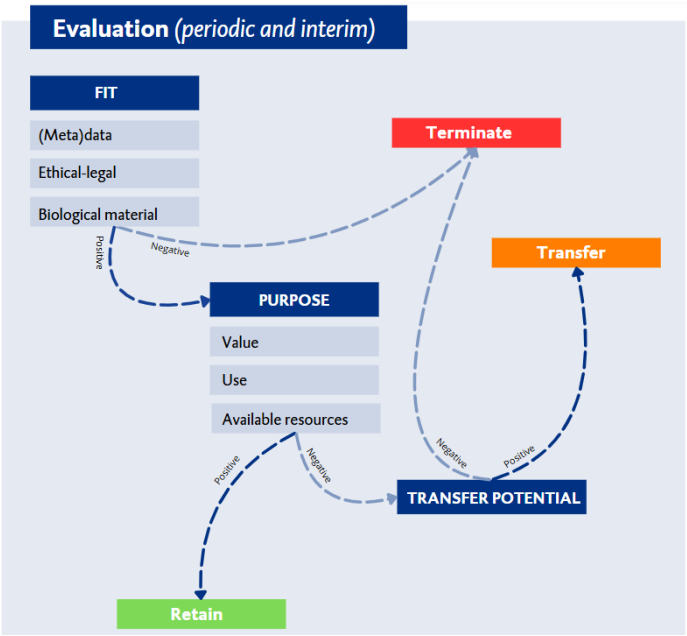
1. SUMMARY

Biobank collections are a fundamental pillar for translational biomedical research and significantly contribute to the improvement of healthcare. To ensure the long-term continuity of these collections, it is essential to strike a balance between the financial, societal, and operational aspects of the collections. This guideline outlines how to achieve this balance through:

The Suitability of the biobank collection	**The Purpose of the biobank collection**
(Meta)data	Value
Ethical-legal considerations	Use
Biological material	Available resources

A well-balanced approach to these elements ensures the continuous availability of sufficient, high-quality research materials and careful handling of materials. This balance is crucial for advancing scientific progress, ultimately resulting in new opportunities for prevention, diagnosis, and treatment.



Regular evaluation of biobank collections is necessary to ensure their future viability and maintain their value for scientific research. In this context, the present guidelines offer comprehensive directions and considerations to assist in making informed decisions regarding the retention, transfer, or termination of a biobank collection.

2. INTRODUCTION

2.1 Background

Human biological material and data from patients and/or healthy volunteers are collected for use in scientific research and stored on a large scale in University Medical Centers (UMCs) and other biomedical research institutions in the Netherlands. These collections are referred to as biobank collections.

Biobank collections are often seen as an essential component of translational biomedical research and the improvement of healthcare. However, it is critical to monitor the sustainability of these collections. Sustainability, in this context, refers to the capacity to remain operational, effective, and competitive over the expected lifetime of the biobank collection. How to best ensure sustainability is an important topic of discussion and concern for many research institutions. The overarching goal of a biobank collection is to provide sufficient high-quality biological material and data for scientific research, thus contributing to new possibilities for prevention, diagnosis, and treatment.

To assess whether a biobank collection remains sustainable and whether longer storage is desirable, periodic evaluations should be conducted. This prevents research institutions from expending unnecessary resources and ensures that the quality of the collection can be guaranteed. Periodic evaluations require a national approach due to the complexity and the context-dependent considerations of the interests involved.

Furthermore, the indefinite storage of a collection, when there is no longer a reason to retain it, is undesirable from a continuity perspective (e.g., storage space, costs, energy consumption, etc.). Similarly, regarding participant autonomy and privacy, it is undesirable to retain materials and personal data for longer than necessary for research purposes, as participants grant consent for their biological material to be stored and used only for the purposes specified in the information letter provided to them. When a collection no longer contributes to achieving these goals, there is no longer any justification for retaining the collection. Therefore, as outlined above, periodic evaluations are crucial to assess whether continued retention is still appropriate.

2.2 Objective and Scope

This national guideline provides tools for biomedical research institutions to develop and implement local policies for evaluating their biobank collections. The evaluation is based on the essential elements of suitability for scientific research ("Fit") and the scientific potential of the research institution ("Purpose"). It provides a framework for structured discussions between the collection manager and other stakeholders regarding the collection. The guideline outlines how sound decision-making can be achieved and which considerations play a role in retaining, terminating, or transferring

a biobank collection. It offers guidance for individual institutions to develop their own policies concerning the evaluation of biobank collections.

This guideline was developed with input from the relevant experts and their networks within the Health-RI Biobanks & Collections Theme, including UMCs, the Netherlands Cancer Institute, the Princess Máxima Center for Pediatric Oncology, the Health-RI ELSI Theme, and BBMRI nodes in Belgium and Germany.

3. EVALUATION OF THE BIOBANK COLLECTION

To assess whether a biobank collection is future-proof and whether longer retention is desirable, periodic evaluations (preferably at least every 5 years) should be conducted. This evaluation is commissioned by the research institution and effectuated typically by the central biobank facility or the managing department. There are also reasons for conducting an interim evaluation, such as:

- The person responsible for the biobank collection leaves the institution.
- The institution or department changes its research strategy, ICT strategy, and/or financial strategy.
- The person responsible wishes to terminate the biobank collection.

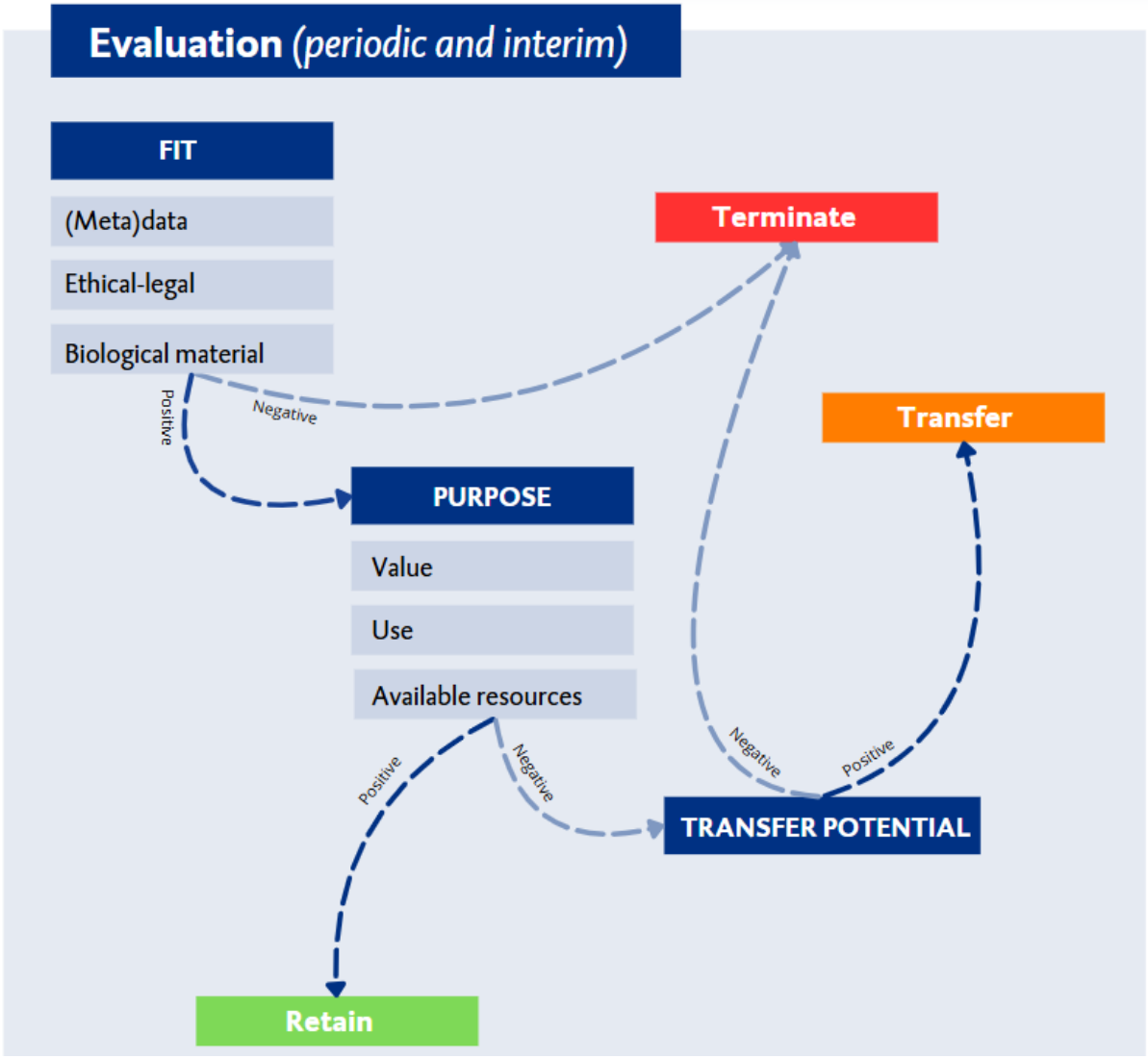
During a periodic or interim evaluation, the collection is assessed against evaluation criteria to determine whether it is suitable for scientific research ("Fit") and whether it has scientific potential for the institution ("Purpose"). To meet the "Fit" and "Purpose" evaluation criteria, sub-criteria in the following areas should be met:

- **Fit:** (Meta)data, ethical-legal aspects, biological material
- **Purpose:** Value, use, available resources

If the evaluation outcome is positive for both "Fit" and "Purpose," the biobank collection can be retained. If the collection is found unsuitable based on the "Fit" assessment, it should be terminated. If the "Fit" outcome is positive but the "Purpose" outcome is negative, consideration should be given to transferring the collection to another party. For the termination of a collection, the local research institution policy should be followed.

Figure 1 illustrates how the decision-making process can be systematically carried out. This chapter provides a detailed explanation of the evaluation criteria for "Fit" (3.1) and "Purpose" (3.2).

Figure 1: Flowchart Evaluatie Biobank Collection



3.1 Fit

When assessing whether a biobank collection is "Fit," the research institution evaluates the (meta)data, ethical-legal aspects, and biological material.

(Meta)data

(Meta)data
a. Is there a biobank/collection protocol available?
Explanation: The biobank collection must have at the least a biobank or collection protocol/regulations that outline the collection's purpose, involved parties, study population (inclusion/exclusion criteria), collected data and materials, and the consent procedure.    If no protocol is available, one should be created and, if necessary, reviewed by the local ethics committee.

(Meta)data
b. Are the associated (meta)data of the biobank collection available in the biobank's information system?
Explanation: (Meta)data refers to: • Data about the participant (e.g., gender, age, diagnosis, medical history). • Pre-analytical data related to the biological materials (e.g., tube type, collection date, storage temperature, centrifugation time, freeze-thaw cycles) – see Appendix I for the minimum pre-analytical data required for serum and plasma. **Note:** For each biobank collection, whether the associated (meta)data is in a format accessible to the institution should be assessed as well as whether it can be converted to an accessible format.    It should be established per collection which meta(data) is required. If this (meta)data cannot be made available, the collection should be terminated.

(Meta)data
c. Can the associated (meta)data be linked with the collection's biological material?
Explanation: The (meta)data and biological material must share the same pseudonyms/codes and be legible to allow linkage. If (meta)data can no longer be linked to biological material, the collection should be terminated.

Ethical-Legal Considerations

Ethical-Legal
a. Is the autonomy of all participants protected in a manner other than (explicit) informed consent?
Explanation: The assumption is that all participants have provided informed consent. There may be exceptions to consent requirements, for example, for historical collections, but these must be clearly justified by an ethics committee. If participants' autonomy is not sufficiently protected and there are no approved exceptions, the collection should be terminated. Note: Existing biobank collections are not always set up under the current legal principles. A solution to this issue is being worked on by means of new integrated legislation and regulations in the Obstacle Removal Trajectory (OVT) and in the Bill on the Control of Human Biomaterial (Wzl), by the Ministry of Health, Welfare and Sport (VWS) in collaboration with all stakeholders.

Ethical-Legal
b. Have all participants given informed consent, and are the information and consent forms (digitally) available?
Explanation: If participants have given informed consent, the information and consent forms must be available for consultation.    If informed consent is not recorded and accessible for part of the collection, the collection should generally be terminated unless exceptions apply or all participants can provide renewed consent, as assessed by an ethics committee (*see Fit – Ethical-Legal – c*). Note: Existing biobank collections are not always set up under the current legal principles. A solution to this issue is being worked on by means of new integrated legislation and regulations in the Obstacle Removal Trajectory (OVT) and in the Bill on the Control of Human Biomaterial (Wzl), by the Dutch Ministry of Health, Welfare and Sport (VWS) in collaboration with all stakeholders.

Ethical-Legal
c. Does the given consent cover the research purposes of the collection?
Explanation: All participants must have consented to the specified research purposes of the collection, which should be described in the information and consent documents. The research objective may be broad but must in any case be limited to one or more areas of medical-scientific research, and must be described in the participant information letter and the consent form. In case of doubt regarding the coverage of the consent, documents may be resubmitted to the institution's ethical review committee for interpretation.    If the review committee does not give or has not given approval for the research, the collection should be terminated. If an (old) participant information letter with a consent form does not meet current demands, this must be submitted for assessment to the relevant ethical review committee. For example, if the information and consent documents do not specifically state that data may be reused in line with the primary research objective. Here too, the principle is to obtain additional permission for missing components and any exceptions to permission must be submitted for assessment to an ethics committee (see Fit – Ethical-Legal – f).

Ethical-Legal
d. Does the provided consent cover sensitive applications? (If applicable)
Explanation: Explicit consent is required from participants for sensitive applications (as per the Code of Conduct for Health Research 2022). Applications deemed sensitive include: • Development of immortal cell lines/organoids. • Human-animal combinations involving substantial mixing of genetic material from human and animal origins (e.g., cybrids and chimeras). • Applications with a significant risk of re-identification (e.g., whole genome sequencing). • Applications with a considerable risk of incidental findings (e.g., broad research designs). • Amplifying biological material to gametes and embryo-like structures. • Using material/data for profit outside the EU. If the given consent does not cover sensitive applications, whether the collection remains usable/valuable without these applications should be assessed (see Fit – Ethical-Legal – e). Note: Deviation from the consent requirement for sensitive applications is allowed only in exceptional cases, such as historical collections where many participants are deceased, but an application like whole genome sequencing would provide significant value. Essentially, the ethical review committee of the institution assesses whether this is the case. If established, institution-specific agreements must be followed.

If the collection is not intended to facilitate research involving sensitive applications, proceed to *Fit – Ethical-Legal – f*.

Ethical-Legal
e. Is the collection usable/valuable without the sensitive application(s)?
Explanation: It should be determined whether the collection is usable/valuable without the sensitive application(s). If the collection becomes unusable or worthless without the application, it can no longer be used unless future changes to the sensitive applications occur, participants can provide renewed consent for sensitive applications, or the ethical committee has granted approval for continued use (see *Fit – Ethical-Legal – f*).

Ethisch-juridisch
f. Can consent be re-obtained from all participants?
Explanation: The lack of informed consent may prevent the use of the collection for research, including sensitive applications. One should evaluate whether renewed consent can be sought. In some cases, this may be impossible or require disproportionate effort from the researcher. Factors to consider include: • Are the contact details still current (to prevent data breaches)? • Are participants still alive (to avoid re-traumatizing family members with the participant's death)? • To what extent does seeking renewed consent burden the participants? • Is it feasible to approach all participants (~number of participants)? The decision on whether renewed consent should be sought must always be referred to the institution's ethical review committee.    If it is not possible to re-contact participants for renewed consent, the collection should be terminated unless permission for an exception is granted by the ethical committee.

Ethical-Legal
g. Has the (to be) established retention period expired?
Explanation: A retention period should be specified in the participant information and the biobank/collection protocol, for instance, a maximum period of 25 years or indefinite retention. For materials where the manufacturer has set a retention period, this must be followed. Additionally, one should assess whether material should continue to be retained in accordance with archiving obligations. If **no** retention period is specified, the default is 'indefinite retention'. However, indefinite retention should be avoided to ensure continued quality and sustainability of the collection. For research outside the scope of the *Medical Research involving Human Subjects Act (niet-WMO-plichtig)*, such as biobank research, there are currently no legal retention periods. The considerations of the Code of Conduct for Health Research* offer guidelines for the establishment of retention periods. If a maximum retention period is specified in the participant information and biobank protocol, the Code of Conduct for Health Research states that at the expiration of this period, the following should occur: "*Assess, possibly periodically, whether extended retention is still necessary. If so, a request for extension can be submitted to the institution's ethical review committee. It is important that, upon approval, participants are informed in advance via the participant information letter and have given consent for the extension via the consent form*."

"Your biomaterial and data will be retained for [15 / XX] years. If after this period the material and data are still valuable, the responsible party for the biobank may request multiple extensions. Only if approved by the [institution name] reviewing committee will the retention period be extended by [5 / XX] years." The ethical review committee decides whether the retention period may be extended and how it should be done.    If the ethical review committee denies extension, the collection must be terminated. Note: Biobank collections do not necessarily need to be available for distribution but must sometimes be retained to comply with retention obligations for administrative purposes and/or possible replication of the research utilizing data and/or biological material from the collection (see 4.2 Terminating the Collection).

* Code-of-Conduct-for-Health-Research-2022.pdf

Biological Material

Biological Material
a. Are Standard Operating Procedures (SOPs) available for processing biological material?
Explanation: Various SOPs exist for different types of biological material. There may also be multiple SOPs for one type of biological material due to the lack of (inter)national standards or specific intended uses of the material (fit-for-purpose). Furthermore, SOPs may change over time (e.g., adjustments to centrifuge speeds).    If no SOPs are present but the required metadata (see *FIT – (meta)data – b*) are available, the collection may still be maintained.

Biological Material
b. Are SOP deviations registered?
Explanation: A SOP deviation could involve storing material at the wrong temperature (e.g., storing material at -20°C instead of the required -80°C).    If SOP deviations are not registered, an assessment by a subject matter expert is required.

Biological Material
c. Does the biological material appear to be in good/usable condition?
Explanation: This involves a preliminary visual inspection of the stored material. Look for issues such as ice formation or mold, faded or missing labels, or discrepancies between stored material and the registered material in the database. The quality of biological material depends on storage conditions and intended use. Considerations from *Fit – Ethical-Legal – g* (retention periods) should also be considered. If there are doubts, an expert may be consulted. Depending on the intended use, specific quality control analyses may be performed which provide indications as to the degree of suitability of the material for the intended research purpose.    If the material appears unusable and an expert confirms this, possibly through additional analysis, the collection (or parts thereof) should be terminated.

3.2 Purpose

During the periodic evaluation to assess whether a biobank collection has scientific potential for the institution ("Purpose") and whether extended retention remains appropriate, the value, use, and available resources/facilities of the institution are central.

Purpose and value

Purpose and value
a. The collection has a clear purpose and sufficient scientific value for the institution.
Explanation: It is crucial for researchers to explain the value of the collection. This does not undermine academic freedom or expertise but aims to ensure that the scientific purpose and value are safeguarded, and the storage can be publicly justified. Additionally, it facilitates the disposal of outdated materials and data that no longer meet these criteria. Several interests must be considered, including: • The importance of proper use of public investment versus the efficient use of existing public resources. • The convenience of using available material for researchers and participants versus the potentially higher quality of a newly formed collection. • Whether the collection still aligns with the institution's research programs/focus areas. Note: Scientific value may also include cultural or historical value (e.g., the Dutch Hunger Winter Birth Cohort or the Vlagtwedde Vlaardingen Study). These collections may contain valuable data, such as questionnaires, that are significant from a cultural-historical perspective.    If the collection no longer holds scientific value for the institution (but is still *Fit*), one should consider whether it could be transferred to another institution (see *4.3 Transferring the Collection*).

Usage

Usage
b. The collection is used sufficiently by researchers.
Explanation: Biobank facilities and collections aim to make collected biological material and data available for scientific research through the process of distribution. In practice, the proportion of distributions often falls short of expectations (i.e., 50-70% of biobank facilities report distribution rates of only 0-10% of the total collection [#]). To determine whether a biobank collection is sufficiently used by an institution, both quantitative and qualitative criteria are relevant: • Quantification for sufficient use: The yield of a collection can be calculated in various ways, such as by dividing the number of aliquots distributed for scientific research by the total number of aliquots stored in the collection, or by calculating the number of distributions per unique patient. What constitutes sufficient use depends on factors like the collection's value and available (financial) resources. • Qualification for sufficient use: This includes rare disease collections or collections with unique characteristics that may not have an immediate impact but could be highly valuable in the long term. It is of significant societal importance for researchers to also substantiate quantitatively that a collection is useful and relevant for research. Therefore, it is advisable to track how often a collection is used, as this facilitates comparisons and discussions about "sufficient use." It also helps institutions align the use of public resources at national, regional, and institutional levels.    If it is determined that the collection is underused within the institution (but still *Fit*), one should explore the possibilities of transferring the collection to another institution (see *4.3 Transferring the Collection*).

[#] Simeon-Dubach, Goldring et al. 2018

Available Facilities/Resources

Available Facilities/Resources
c. The collection fits with the available services and resources of the institution.
Explanation: It is important for institutions to weigh the value of their unique assets against the potential benefits of collaborating with other institutions. Researchers should also carefully consider the support services and financial resources needed to maintain the collection. Are supporting services (e.g., subject matter experts or suppliers) or technological resources (e.g., hardware or software) still available? Is the researcher/institution willing to invest in the collection for the next five years? Are there any crucial (one-time) investments needed to maintain the collection (e.g., new freezers, storage costs, personnel costs, material costs)? However, using the collection may also generate revenue without leading to a profit objective. Developing a multi-year budget with expected costs and revenues related to a collection can help clarify the financial resources needed. Researchers must find a balance between generating new knowledge and using available resources effectively.    If it is determined that the collection no longer fits with the available services and resources of the institution (but is still *Fit*), it should be considered whether the collection can be transferred to another institution (see *4.3 Transferring the Collection*).

4. OUTCOME OF EVALUATION AND NEXT STEPS: RETAIN, TRANSFER, OR TERMINATE

4.1 Retaining the collection

If the collection meets the *Fit* and *Purpose* requirements for the responsible party and the research institution, the collection can remain under the current management. However, if the current responsible party within the institution is no longer able to manage the collection (e.g., due to retirement), a new responsible party should be identified within a specific timeframe, following the institution's guidelines. If no internal replacement can be found, the collection may be transferred to an external institution (see *4.3 Transferring the Collection*).

4.2 Terminating the collection

If the collection does not meet the *Fit* requirements, it should be terminated, and the institution's policy regarding the destruction of data and biological material must be followed. However, the termination may only involve a portion of the collection, such as removing sensitive data or destroying biological material whose quality cannot be guaranteed. The institution must also verify whether the collection can continue as a data collection/database, provided the data itself remains valuable.

Before the actual destruction of any part of the collection, the institution must carefully assess retention obligations for administrative purposes and/or potential replication of research utilizing data and biological material from the collection. Substantive discussion of the termination, archiving, and destruction process extends beyond the content of this guideline.

4.3 Transfering the collection

If the collection meets the Fit requirements but not the Purpose criteria, it is advisable to explore the possibility of external transfer. The collection may still hold value for another research institution, particularly if it aligns with their research programs, priorities, or available facilities. Terminating a collection without exploring the option of transferring it to other institutions would be undesirable for the participants who donated their data and biological material for a specific scientific purpose. Moreover, from a continuity perspective, it is undesirable to terminate a collection with potential value to other parties without exploring the option of transferring and thus preserving the collection.

However, not all collections can be transferred to external parties. The first question is whether the collection can legally be transferred to third parties, which depends on the consent provided by the participants and any applicable exceptions. Different conditions apply when transferring to an external institution within the Netherlands or the EU compared to institutions outside these regions. Legal departments within research institutions must advise on the possibilities.

Our recommendation is to use the current person's own network and/or the network of the Biobanks & Collections theme of Health-RI (www.health-ri.nl/biobankenteam) when searching for a new researcher to take responsibility for the collection. In addition, a national catalogue is available to give

insight into existing collections (www.health-ri.nl/services/catalogue). There are also several regional catalogues available. Furthermore, it is advisable to consider publication in the European catalogue, BBMRI sample locator (www.bbmri-eric.eu/services/sample-locator/) for human biomaterial.

If a collection is eligible for external transfer, the institution's policy on the duration and terms of transfer must be followed. Guidelines for this process are provided in ISO 20387 'Biotechnology - Biobanking - General Requirements for Biobanking' and ISBER Best Practices.

If another institution is interested in the collection, the new responsible party must assess its Purpose (and suitability) for their institution. If the collection can be transferred, a formal agreement must be drafted and signed by authorized representatives of both the transferring and receiving institutions. This agreement must specify the types of research for which the transferred data and materials can be used, in line with participant consent. Additionally, the transfer costs and how they will be divided between the institutions must be agreed upon.

APPENDIX I – MINIMAL PRE-ANALYTICAL DATA FOR SERUM AND PLASMA

What to minimally report on the pre-analysis of serum and plasma biobank samples in publications that comprise the results of measurements in biobank samples. Proposal based on the work of Jannes Jansen, Femmie de Vegt, Mariel van de Brand and Dorine Swinkels. Radboudumc, Nijmegen, The Netherlands – 2023-2024.

Variable (*)	**Description**
Biobank name	Name(s) of the biobank(s) used
Protocol	Use of multiple protocols during the study (yes or no)
External transport	Presence of external transport of the samples to different locations (yes or no)
Analysis purpose	Biomarker type that was measured in the samples
Biospecimen type	Presence of description of the biospecimen type (yes or no), and if so, if it was plasma or serum or both
Pre-analytical elements	**Description of elements**
Internal transport	Mention of temperature, or means of transport
Biological variables	Mention of fasting or non-fasting
Demographic characteristics	Mention of sex and age of the participants
Additive	Mention of the anticoagulant, for instance EDTA, heparin or citrate, or no anticoagulant (serum)
Separation gel	Mention of separation gel or no gel in the primary tube. If information about the type of tube is given but not the gel, and it is public knowledge that this type of tube always contains a gel, or never contains a gel this is acceptable.
Pre centrifugal delay	Mention of the delay between the collection and the moment of centrifugation
Post centrifugal delay	Mention the delay between the centrifuge step and the long-term storage and the total delay between collection and storage counts
Centrifuge time	Mention of duration of centrifugation
Centrifuge speed	Mention of speed of centrifugation
Centrifuge temperature	Mention temperature during centrifugation
Long-term storage temperature	Mention of temperature of long-term storage
Inclusion period	Mention of time range in which the samples were collected, processed, and stored
Analysing period	Mention of time period during which the samples are taken out of storage and analysed
Freeze-thaw cycle	Mention of the number of freeze thaw cycles that the samples went through

(*) Scoring criteria that chiefly followed the Sample PRE analytical Code (SPREC) and extended this by including elements of Biospecimen Reporting for Improved Study Quality (BRISQ).

Background

Several guidelines have been developed to assist researchers in reporting pre-analytical factors. Notably, the Sample PREanalytical Code (SPREC) and the Biospecimen Reporting for Improved Study Quality (BRISQ). SPREC focuses on metadata related to pre-analytical procedures, including information on sample type, primary containers, centrifugation conditions, and long-term storage protocols. Developed by the International Society for Biological and Environmental Repositories (ISBER), its primary goal is to ensure that each biobank sample is accompanied by a standardized set of metadata. In contrast, BRISQ offers broader guidance for reporting, including pre-acquisition procedures, transport parameters, and quality assurance steps relevant to downstream analysis. An analysis of BRISQ's implementation in high-impact journals revealed that pre-analytical factors were often poorly reported, with little improvement observed following the publication of the guidelines in 2011. These findings suggest that the BRISQ guidelines have not yet been widely adopted and may be overly ambitious as an initial step towards improving pre-analytical reporting in the scientific literature.

We developed a scoring system based on SPREC, supplemented by BRISQ elements, to evaluate the comprehensiveness of reporting. We included all SPREC elements that encompassed plasma and serum, as these are focused on pre-analytical processes for biomaterials in biobanks. This was extended to create a more complete image of reporting of pre-analysis by the following BRISQ elements: clinical characteristics, storage duration, transport parameters, fasting status, separation gel, and freeze-thaw cycles.

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