ACCREDIA
ENTE ITALIANO DI ACCREDITAMENTO

Calibration Laboratories Department

Requirements for the accreditation of Research and Development Biobanks

RT-38

REVISION
01

DATE
30-09-2020

TITLE **Requirements for the accreditation of Research and Development Biobanks**

REFERENCE **RT-38**

REVISION **01**

DATE **30-09-2020**

NOTE

PREPARATION
The Department Director

APPROVAL
The Directive Council

AUTHORIZATION
The General Director

APPLICATION DATE
20-04-2026

Contents

0. Introduction

0.1.

This Technical Regulation specifies the general criteria for accreditation of Biobanks performed by the Department of Calibration Laboratories (DT) of ACCREDIA, the Italian Accreditation Body.

It was elaborated by a specific working team coordinated by ACCREDIA, composed by representatives of ISS and many other Parties involved in the subject, in order to reach the widest level of sharing of provisions contained in the Regulation itself.

0.2.

The application of these criteria has the target to help build and keep confidence in the activities of Biobanks, and in the impartiality and integrity of technical and commercial operations related to them. ACCREDIA accreditation is granted to Biobanks compliant with the requirements of UNI EN ISO 20387 international standard: "*Biotechnology – Biobanking -General requirements for Biobanking*" (below simply "the standard"), or of standards in future recognized for this scope at international level compliant with EA (European Cooperation for Accreditation) and ILAC (International Laboratory Accreditation Operation) requirements and requirements of this Technical Regulation and other ACCREDIA prescriptive documents applicable to Biobanks.

0.3.

This Technical Regulation refers to the provisions of standard UNI EN ISO 20387. The paragraph numbers from 4 to 8 coincide with those of the standard. These chapters show the clarifications introduced by ACCREDIA to the requirements of the standard, sometimes coincident with the NOTES of the standard itself.

0.4.

UNI EN ISO 20387 specifies the general requirements for *biobanking* activities of biological material from multicellular organisms and microorganisms for research and development.

0.5.

This document does not apply to organizations that carry out biobanking activities of biological material intended for the production of food/feed, to laboratories that perform analyses for the production of food/feed and/or therapeutic use.

1. Scope and application field

1.1.

This Regulation specifies the general, managing and technical competence requirements for Biobanks. Standard UNI EN ISO 20387 and the current Technical Regulation refer to biobanking activities of all biological materials. ACCREDIA introduces provisions for the accreditation of Biobanks based on:

- the different categories of biological material and their suitability for purpose of use
- the working locations;
- the updating of the provisions of the standard, of EA and ILAC;
- biobanks activities.

1.2.

This Technical Regulation applies to Biobanks.

The Biobank (hereinafter BBK) obtains accreditation for the activities described in the accreditation table using specific procedures. Consequently, the accreditation covers all the activities and the categories of biological material that belong to the scope of accreditation managed after the granting of the accreditation. However, it may include existing materials if BBK demonstrates their compliance to the set requirements and ACCREDIA considers them as such.

1.3.

In order to get and keep the accreditation, the BBK shall show their compliance to all requirements of applicable standards, for all the expected biobanking activities.

1.4.

Where the standard prescribes documented procedures, the BBK shall prepare this documentation, which will be evaluated by ACCREDIA DT, including any subsequent variations.

1.5.

The BBK is compelled to respect what provided for in the ACCREDIA Regulation RG-09 concerning the use of the accreditation mark.

1.6.

Where the organization uses an internal laboratory for the characterization of the material, the UNI CEI EN ISO/IEC 17025, the UNI CEI EN ISO 17034 and the UNI EN ISO 15189 standard can be used as regulatory references.

2. Terms and definitions

For the purposes of this document, the definitions given in reference standards UNI EN ISO 9000, UNI CEI EN ISO/IEC 17000, UNI CEI 70099, UNI EN ISO 20387.

Below are some definitions.

Requirement, provision: A disposition that defines the needs to meet and is expressed by the modal "shall". The requirements of a regulatory document must be respected in order to comply with the document itself.

Guide, guideline: Document that contains indications on how to meet the requirements of a regulatory document. It does not contain binding provisions, but a BBK that decides not to follow the indications of a guideline indicated by ACCREDIA takes on the responsibility to show that he meets the requirements equivalently.

Biological material: any substance derived, or part obtained from an organic entity such as a human, animal, plant, microorganism(s) or multicellular organism(s) that is(are) neither animal nor plant (e.g., brown seaweed, fungi) (UNI EN ISO 20387 §3.7).

3. Reference standards and documentation

The list of applicable documents (LS-16) can be consulted on the ACCREDIA website at www.accredia.it. It is the responsibility of the organization to verify the validity of the documents reported.

All national and international mandatory legislation is considered applicable.

Where health and safety requirements are present in the standard, BBK is required to comply with current laws updated in the versions at the time of application of the standard. Therefore, in this document there are no specific references to this effect.

Where the standard contains requirements relating to the protection and management of personal data, the BBK is required to comply with current laws updated in the versions at the time of application of the standard.

Where in the Standard there are requirements relating to the management of the date and time, it is recommended that BBK use formatting according to the UNI ISO 8601: 2010 standard.

4. General requirements

4.1. General

4.1.1.

The BBK, for the biological materials listed in the annex to the Accreditation Certificate, must have procedures that describe the applicable processes and fall within the scope of accreditation. In establishing the extent and level of detail of the procedures, the BBK must assess the risk of satisfactory coverage of the activities and the resulting opportunities for improvement, considering the biosecurity and bio protection requirements (see for example the Safety Manual in laboratories - WHO).

4.1.2.

The standard requirement applies. The 'should' is applied as a 'must' considering the state of available knowledge.

BBK of plant germplasm: to fulfil its purposes, BBK must guarantee itself a quantity of material that allows it to regenerate it when needed and to carry out the minimum tests to evaluate its vitality.

Note: for plant germplasm BBKs see: for agricultural species, FAO IPGRI Gene bank standards (https://www.bioversityinternational.org/fileadmin/user_upload/online_library/publications/pdfs/424.pdf); ISTA Chapter 5 Regulations; Official methods of seed analysis DM 22 December 1992; for spontaneous species, APAT Manual for the collection, study, conservation and ex situ management of germplasm (http://www.isprambiente.gov.it/contentfiles/00003400/3470-manuali-2006-37.pdf) and ENSCONET Seed Collection manual for wild species (http://ensconet.maich.gr/PDF/Collecting_protocol_Italian.pdf)

4.1.3.

If the BBK has an autonomous legal entity, the BBK mission is mandatory. If the BBK is part of a legal entity, it is accepted that the mission is consistent with the functions of the legal entity to which it belongs.

Regardless of the definition of the scope of accreditation published by ACCREDIA on its website, the BBK must define and make available (for example on its website) the object and details of the accredited biobanking activity. The BBK must inform interested parties about the meaning of accreditation and the accreditation of biobanking activities (extent and limits of the scope of accreditation, as published).

As regards the use of references to accreditation and, in particular, the use of the ACCREDIA accreditation mark and/or the reference to accreditation, the BBK is required to comply with the provisions of these Regulations and the Regulations for the use of the ACCREDIA RG-09 mark.

4.1.4.

The standard requirement applies, where "information" means the relevant information (for example information for accessing the material and associated data). By 'understandable format' we mean, for example, both suitable electronic formats and information available in English, if you operate in an international context.

4.1.5.

The standard requirement applies.

4.1.6.

The standard requirement applies.

4.1.7.

It is required to document at least the identity of all internal staff and personnel in charge of the conservation of the material in order to ensure the availability of the records to establish an audit path for each Report of biological material.

4.1.8.

The standard requirement applies. As for the data associated with the material, it is required that the information be kept for at least 10 years, unless otherwise provided by law in which case the latter prevail.

4.2. Impartiality

4.2.1.

The standard requirement applies.

4.2.2.

The standard requirement applies.

4.2.3.

The standard requirement applies.

Accredia does not guarantee the evaluation of impartiality.

4.2.4.

The standard requirement applies considering that the risks of impartiality must be assessed on the basis of objective, possibly measurable parameters.

E.g., in a research project, the principal researcher must have biological material belonging to a Biobank in which the employees participate in the research project. The risk could be mitigated, for example, by defining the criteria for access to the material verified by one or more committees in charge that code the selected materials and ensure their circulation anonymously within the project.

Note: For risk management, please refer to ISO Guide 31000 "Risk management - Principles and guidelines".

4.2.5.

The standard requirement applies.

4.3. Confidentiality

4.3.1.

The standard requirement applies.

The evidence of transposition of the requirement is the presence and compliance with ethical and legal obligations that BBK manages in terms of consent/contract with suppliers/users.

Note 1: It is recommended that documented procedures to protect confidential information and property rights be prepared, and that adequate IT security measures are in place.

Note 2: see Annex 1 of these Regulations.

4.3.2.

The standard requirement applies. The implementation of any element that may influence the accredited activity must also take into account the confidentiality requirement.

Note 1: see Annex 1 of these Regulations.

Note 2: It is recommended to identify i) the personnel authorized to access the BBK premises, ii) the personnel authorized to access the data of the client/donor/user (whether in paper or electronic format), and iii) the envisaged methods for controlling such accesses.

4.3.3.

The standard requirement applies.

Note: see Annex 1 of these Regulations.

4.3.4.

The standard requirement applies.

Note 1: it is recommended to provide for the signing by all staff operating in the BBK of the formal commitment to confidentiality with respect to the information they become aware of in normal work and the acknowledgment of the disciplinary sanctions resulting from any violations of these obligations.

Note 2: it is recommended to consider that any contracts with non-employees of BBK who act on its behalf must report the confidentiality aspects of the information and the termination clauses expressed for any violation of these obligations.

Note 3: see Annex 1 of these Regulations.

5. Structural requirements

5.1.

The standard requirement applies.

Note: ACCREDIA requires the BBK to attach the Chamber of Commerce company registration to the DA-00 application, in order to verify that the BBK is a legal entity or part of it that has full responsibility for the activities covered by the accreditation. If the subject is a public legal person, the Chamber of Commerce Registration is replaced by the Statute or, in its absence, by the Constitutive Act.

5.2.

The standard requirement applies.

Note: It is recommended to identify the figure that conducts the management review as evidence of liability and the authority required by the standard.

5.3.

The standard requirement applies.

It is permissible for a governance body to consist of only one person.

5.4.

The standard requirement applies.

5.5.

The standard requirement applies.

The evidence of the provision of adequate action plans may be:

a. creation of a declaration/agreement on the limits of liability;
b. assistance from legal professionals;
c. contractual clauses that address legal responsibilities.

It may also be appropriate to provide for legal liability insurance.

5.6.

The standard requirement applies.

5.7.

The standard requirement applies considering that there must be a **document** officially issued by the management in which the extension and coverage of the activities that BBK performs in accordance with the standard is declared. If BBK outsources activities, these cannot be considered as accredited.

Note: ACCREDIA requires the BBK to attach to the DA-12 application the document from which the accreditation table is extracted, or the one that describes the technical detail of the accreditation purpose, including the activities outsourced.

5.8.

The standard requirement applies.

Note 1: ACCREDIA evaluates among other evidence:

- the overall organization chart of the organization to which the BBK belongs, which highlights the position of the BBK:
- the functional organization chart of the BBK, in cases where this does not coincide with that of the entity, containing the relationships between the functions, including those of support and the activities of the BBK provided externally;
- the organization chart of the BBK staff, with the identification of any figures who, while operating both in the body and within the BBK, cover different roles in the two areas;
- internal system of proxies, where this cannot be inferred from the Statute.

Note 2: if the management system also extends to activities other than those concerning the BBK accreditation field, it is recommended that these are clearly defined and identified.

5.9.

The standard requirement applies. If the staff in this role is external to BBK (for example, external consultants), the exact definition of the tasks that the roles entail, the time limits of the same and the declaration of absence of conflicts of interest must be formalized in the related contracts.

a. The standard requirement applies.

Note: It is recommended to identify the person who performs the management review as evidence of the responsibility and authority required by the standard.

b. The standard requirement applies.
c. The standard requirement applies.
d. The standard requirement applies.

5.10.

The standard requirement applies.

a. Changes to the management system are required to have a tracked indication of the modification dates.
b. The standard requirement applies.
c. Identification of the interested parties is required, for example the citizen, the scientific community, the supplier/depositor (§3.41), the governmental authorities responsible for control. Examples of insurance of communications to interested parties are flyers, website, conferences, radio communications.
d. The standard requirement applies.

Note: it is recommended to identify ways of evaluating the effectiveness of communications, appropriate to the size and type of the BBK.

6. Resource requirements

6.1. General

6.1.1.

The standard requirement applies.

6.1.2.

The standard requirement applies.

The availability of a documented strategy that allows for ongoing financial sustainability can be demonstrated, for example, through:

- Strategic Plan;

- business plan;
- agreements between BBK and funders/sponsors;
- sustainability plan;
- relations between BBK and the body to which it belongs.

The financial strategy should also consider point §6.3.6 (future expansion). In case of modifications of the aforesaid documents, due to structural changes and criticality of the activities, the same must be traced.

6.2. Personnel

6.2.1. General

6.2.1.1.

The standard requirement applies.

6.2.1.2.

The standard requirement applies.

Note: see Annex 1 to this Regulation.

6.2.1.3.

The standard requirement applies.

6.2.1.4.

The standard requirement applies.

Note: it is recommended that evidence be given that all staff are aware of the relevance and importance of their operations relating to accredited activities.

6.2.1.5.

The standard requirement applies. If the BBK has its own integrated health and safety management system, ACCREDIA will evaluate the extension of this system to the activities of the BBK in relation to the standard requirements.

Note: Consider for example the Laboratory Safety Manual - WHO

6.2.2. Competence and competence assessment

6.2.2.1.

The standard requirement applies.

Note: ACCREDIA evaluates, among other evidence, that the BBK has established the competence requirements (school curriculum, work experience, executive skills) necessary to assume the functions provided in the organization chart.

6.2.2.2.

The standard requirement applies.

E.g., For plant germplasm BBKs, skills related to disciplines such as seed physiology, genetics, taxonomy and plant pathology are required.

6.2.2.3.

The standard requirement applies.

6.2.2.4.

The standard requirement applies.

6.2.2.5.

The standard requirement applies.

6.2.3. Training

6.2.3.1.

The standard requirement applies.

Note: ACCREDIA also evaluates, among other evidence, those for evaluating the effectiveness of training and education activities (for example questionnaires, interviews, quizzes, open questions, certificates of achievement).

6.2.3.2.

The standard requirement applies.

6.2.3.3.

The standard requirement applies.

6.3. Facilities/dedicated areas and environmental conditions

6.3.1.

The standard requirement applies.

Note 1: Examples of requirements are the characteristics of the storage rooms in terms of temperature, relative humidity and capacity.

Note 2: for plant germplasm BBKs see, for example, for agricultural species, FAO IPGRI Gene bankstandards (*https://www.bioversityinternational.org/fileadmin/user_upload/online_library/publications/pdfs/424.pdf*) and for spontaneous species, APAT Manual for the collection, study, conservation and ex situ management of germplasm (*http://www.isprambiente.gov.it/contentfiles/00003400/3470-manuali-2006-37.pdf*) and ENSCONET Curation Protocols & Recommendations (*http://ensconet.maich.gr/PDF/Curation_protocol_Italian.pdf*).

6.3.2.

The standard requirement applies.

6.3.3.

The standard requirement applies.

The BBK shall:

- identify incompatible activities;
- define procedures that allow effective separation of incompatible activities;
- implement a workflow that prevents cross-contamination.

The separation of incompatible activities can be achieved by:

- carrying out activities in separate premises or dedicated areas;
- carrying out activities at different times and with adequate separation;
- defining paths that prevent the contamination of biological material.

The standard requirement applies.

If the BBK shares its infrastructures with other organizations, procedures must be defined for the management of spaces and responsibilities between the various organizations.

6.3.4.

The standard requirement applies. The BBK must identify systems for measuring and monitoring environmental conditions (e.g., data loggers for temperature and hygrometers). The instrumentation used must be calibrated to guarantee the metrological traceability of the measurements of the environmental conditions. Any records of environmental conditions and systems involved in the accredited activities must be kept for at least the 'conservation' time of the material in the BBK and for the following 5 years. The BBK must document the actions implemented in the event of failure to meet the established limits.

6.3.5.

The standard requirement applies.

By expansion we mean an opportunity for improvement and changes to the system that ensure its integrity following the expansion of activities.

6.3.6.

The standard requirement applies.

The contingency plan must be documented.

6.4. Processes, products and services provided from outside

Note: see Annex 1 of these Regulations.

6.4.1.1.

The standard requirement applies.

Examples of services provided externally are: maintenance service of cryopreservation plants, instrumentation calibration service, tests on biological material (purity test, molecular integrity, cell count, composition, growth capacity, gene expression).

An example of a product is liquid nitrogen.

6.4.1.2.

The standard requirement applies.

6.4.1.3.

The standard requirement applies.

6.4.1.4.

The standard requirement applies.

6.4.1.5.

The standard requirement applies.

6.4.1.6.

The standard requirement applies.

6.5. Equipment

6.5.1.

The standard requirement applies.

The equipment may include analogue or digital measurement devices, (personal) protective devices, reference material, physical and digital backup systems, incubators, ultra-deep freezers, freeze dryers and useful tools for long-term storage.

BBK's access to the use of equipment outside of its property, for example on loan for use or shared with other groups, must be documented and regulated in terms of responsibility for control and maintenance.

6.5.2.

The standard requirement applies.

Calibration procedures are required where there are internal calibrations.

6.5.3.

The standard requirement applies. The choice of using the manufacturer's manual as operating instructions is acceptable if BBK demonstrates that its staff have effectively understood its content and that it ensures correct use of the equipment.

6.5.4.

The standard requirement applies.

6.5.5.

The standard requirement applies.

6.5.6.

The standard requirement applies.

6.5.7.

The standard requirement applies.

6.5.8.

The standard requirement applies.

6.5.9.

The standard requirement applies.

6.5.10.

The standard requirement and the provisions of ILAC document P10: 07/2020 *ILAC Policy on Metrological Traceability of Measurement Results.* Apply.

6.5.11.

The standard requirement applies.

6.5.12.

The standard requirement applies.

7. Process requirement

7.1. General

7.1.1.

The standard requirement applies.

Note: it is recommended to refer to Appendix A of the Standard.

7.1.2.

The standard requirement applies.

7.1.3.

The standard requirement applies.

7.2. Collection of biological material and associated data

7.2.1. Documented Information Requirements

7.2.1.1.

The standard requirement applies.

Note: BBKs of plant germplasm are recommended to view the following documents: for agricultural species, FAO/IPGRI Multicrop Passport Descriptors; decree of registration to the R.N. of the varieties and/or varieties for conservation and/or to the regional repertoires; UPOV/CPVO descriptive cards GIBA characters; for spontaneous species, APAT Manual for the collection, study, conservation and ex situ management of germplasm (http://www.isprambiente.gov.it/contentfiles/00003400/3470-manuali-2006-37.pdf) and ENSCONET Seed Collection manual for wild species (*http://ensconet.maich.gr/PDF/Collecting_protocol_Italian.pdf*).

7.2.1.2.

The standard requirement applies. The minimum information to always be associated with the sample collection is given in appendix A.2. Examples are given in Appendix B.2.

For plant, animal and microorganism BBKs see the Nagoya protocol.

7.2.2. Pre-acquisition information

7.2.2.1.

The standard requirement applies. The minimum information to always be associated with the sample collection is given in appendix A.2. Examples are given in Appendix B.2.

BBK of plant germplasm. In the case of seeds, check the data of origin, certainty of identity/homogeneity (species, variety and/or ecotype), botanical classification (current botanical name), quantity, quality of the seed (germination capacity, health status).

7.2.3. Collection Procedure

7.2.3.1.

The standard requirement applies. In cases where the collection procedure is specified by the recipient/user, the registration of this request is required.

Note 1: it is recommended to include in the procedure the appropriate collection methods to avoid sample exchanges, to ensure correct and univocal identification and to record the relevant information.

Note 2: BBKs of plant germplasm of spontaneous species are recommended to view the APAT manuals Manual for the collection, study, conservation and ex situ management of germplasm and ENSCONET Seed Collecting Manual for Wild Species.

7.2.3.2.

The standard requirement applies.

7.2.3.3.

The standard requirement applies. The requirements of §6.2 apply to personnel qualified and authorized for collection, even if recipient/user of the activity.

7.2.3.4.

The standard requirement applies.

The ethical requirements are linked to the nature and type of BBK, the type of biological material and the regulations and policies applied at international, national and local level.

Before collecting biological material, BBK is recommended to define any relevant ethical requirements.

Note: see Annex 1 of these Regulations.

7.3. Reception and distribution of biological material and associated data

7.3.1. Access principles

7.3.1.1.

The standard requirement applies.

Examples of interested parties are:

- management of the BBK and/or responsible for a specific collection of biological material;
- the guarantor or a person designated with the decision-making authority on behalf of BBK;
- reference public bodies;
- those involved in the governance of the BBK;
- researchers;
- depositors;
- donors/patients.

7.3.2. Reception

7.3.2.1.

The standard requirement applies.

7.3.2.2.

The standard requirement applies.

Note: for plant germplasm BBKs it is recommended to consult the UPOV database, CPVO for agricultural species and the Portal of the flora of Italy (http://dryades.units.it/floritaly) for spontaneous species.

7.3.2.3.

The standard requirement applies.

7.3.2.4.

The standard requirement applies.

7.3.2.5.

The standard requirement applies.

In the absence of relevant documented information, the BBK must review the suitability of the material and data associated with the originally intended purpose.

7.3.2.6.

The standard requirement applies (riferimento DA 10).

7.3.3. Distribution

7.3.3.1.

The standard requirement applies.

Note: it is recommended to set up control and monitoring systems for the distribution and quantities of biological material also through an adequate IT management system.

7.3.3.2.

The standard requirement applies.

Note: see Annex 1 of these Regulations.

7.3.3.3.

The standard requirement applies.

7.3.3.4.

The standard requirement applies.

7.4. Transport of biological material and associated data

7.4.1.

The standard requirement applies.

7.4.2.

The standard requirement applies.

If no critical chain of custody record is identified to be maintained and/or if it is not deemed necessary to track/monitor the shipment, these reasons must be documented.

7.4.3.

The standard requirement applies.

Note: for plant germplasm BBKs see, for example, for agricultural species, §43 FAO IPGRI Gene bank standards (*https://www.bioversityinternational.org/fileadmin/user_upload/online_library/publications/pdfs/424.pdf*) and for spontaneous species, APAT Manual for the collection, study, conservation and ex situ management of germplasm (*http://www.isprambiente.gov.it/contentfiles/00003400/3470-manuali-2006-37.pdf)* and ENSCONET Curation Protocols & Recommendations (*http://ensconet.maich.gr/PDF/Curation_protocol_Italian.pdf*)

7.4.4.

The standard requirement applies.

7.4.5.

The standard requirement applies. The relevant requirements of 6.2.2 apply.

7.4.6.

The standard requirement applies.

7.4.7.

The standard requirement applies.

Note: see Annex 1 of these Regulations.

7.5. Traceability of biologic material and associated data

7.5.1.

The standard requirement applies.

7.5.1 c)

Note:'labelling' means the visual and identifiable way of signalling any deviation. It also applies to electronic records.

The standard requirement applies.

Personnel means authorized personnel.

7.5.2.

The standard requirement applies.

7.6. Preparation and preservation of biological material

7.6.1.

The standard requirement applies.

Note: for plant germplasm BBKs see, for example, for agricultural species, §15-24 FAO IPGRI Gene bank standards (*https://www.bioversityinternational.org/fileadmin/user_upload/online_library/publications/pdfs/424.pdf*) and for spontaneous species, APAT Manual for the collection, study, conservation and ex situ management of germplasm (*http://www.isprambiente.gov.it/contentfiles/00003400/3470-manuali-2006-37.pdf*) and ENSCONET Curation Protocols & Recommendations (*http://ensconet.maich.gr/PDF/Curation_protocol_Italian.pdf*).

7.6.2.

The standard requirement applies.

A risk-based approach can help define critical activities, as well as appropriate monitoring parameters and measures of the preparation and/or storage procedure in place. The documentation of these procedures can be developed as described in Appendix A (a.4)

7.6.3.

The standard requirement applies.

7.7. Storage of biological material

7.7.1.

The standard requirement applies. In the event of a disaster, a documented protection plan is always required, which also specifies actions and responsibilities (reference §8.5.2 b and §8.5.2.c). This plan could include, for example, alternative information systems, infrastructures and/or equipment.

7.7.2.

The standard requirement applies.

7.7.3.

The standard requirement applies.

Note: for plant germplasm BBKs see, for example, §45-46 of the IPGRI Gene bank standards (*https://www.bioversityinternational.org/fileadmin/user_upload/online_library/publications/pdfs/424.pdf*.)

If changes are made to the storage methods, these must be validated and verified by the BBK (see also §7.9.2.1).

7.7.4.

The standard requirement applies.

7.7.5.

The standard requirement applies.

7.7.6.

The standard requirement applies.

7.7.7.

The standard requirement applies.

The 'should' is applied as a 'must' considering the inventory to be important.

Both the inventory check and the choice of method and timing must be based on risk analysis.

7.7.8.

The standard requirement applies.

Note: see Annex 1 of these Regulations.

7.8. Quality control of biological material and associated data

7.8.1. General

The standard requirement applies.

7.8.1.1.

The standard requirement applies.

If the critical activities that impact on quality are chosen by the recipient or user, BBK is responsible for carrying out the re-examination (for example, verifying, if known, that the choice of anticoagulant preserves the qualities of the plasma for the purposes for which it is intended.).

7.8.1.2.

The standard requirement applies.

BBK of plant germplasm - The BBK must implement a monitoring system to verify the state of vitality of the materials at appropriate intervals depending on the longevity of the typical seed of each species. Seed longevity can be increased if proper attention is paid to post-harvest handling, drying and storage.

7.8.1.3.

The standard requirement applies.

7.8.2 Quality control of processes

7.8.1.4.

The standard requirement applies.

7.8.1.5.

The standard requirement applies.

7.8.1.6.

The standard requirement applies.

7.8.1.7.

The standard requirement applies.

7.8.1.8.

The standard requirement applies.

7.8.1.9.

The standard requirement applies.

7.8.1.10.

The standard requirement applies.

7.8.1.11.

The standard requirement applies.

7.8.1.12.

The standard requirement applies.

Note: BBK of plant germplasm - The BBK, for agricultural species, should identify reference varieties for the expression of morphological characters to be used for the verification of the preserved materials. For the evaluation of molecular profiles, if associated with the material, an allelic catalogue must be identified that represents the variability within the species relating to the method used. The BBK must monitor any changes in the taxonomic identification of the materials stored by checking the taxa on official databases. For spontaneous species, the collection of a reference herbarium sample is required.

7.8.1.13.

The standard requirement applies.

7.8.2. Quality control of data

7.8.2.1.

The standard requirement applies.

7.8.2.2.

The standard requirement applies.

7.9. Validation and verification methods

7.9.1. General

7.9.1.1.

The standard requirement applies.

7.9.2. Validation

7.9.2.1.

The standard requirement applies.

7.9.2.2.

The standard requirement applies.

7.9.2.3.

The standard requirement applies.

7.9.3. Verification

7.9.3.1.

The standard requirement applies.

7.9.3.2.

The standard requirement applies.

7.9.3.3.

The standard requirement applies.

7.10. 7.10 Management of information and data

7.10.1. 7.10.1

The standard requirement applies.

Note: plant germplasm BBKs, for agricultural species, can, for example, refer to the FAO/IPGRI Multicrop Passport Descriptors, 2015 for information on the conserved material and for spontaneous species to the Passport Data Forms in ENSCONET Seed Collecting Manual for Wild Species (*http://ensconet.maich.gr/PDF/Collecting_protocol_Italian.pdf*).

7.10.2.

The standard requirement applies.

7.10.3.

The standard requirement applies.

Note: see Annex 1 of these Regulations.

7.10.4.

The standard requirement applies.

7.10.5.

The standard requirement applies.

7.10.6.

The standard requirement applies.

7.11. Non-conforming output

7.11.1. General

7.11.1.1.

The standard requirement applies.

7.11.1.2.

The standard requirement applies.

The BBK must consider among the non-compliant outputs the malfunctions of the equipment that can negatively affect the storage conditions of the material and implement actions to prevent its use and possibly prepare alternative plans.

7.11.1.3.

The standard requirement applies.

7.11.1.4.

The standard requirement applies.

7.11.1.5.

The standard requirement applies.

7.11.1.6.

The standard requirement applies.

7.11.2. Control of non-conforming output

7.11.2.1.

The standard requirement applies.

7.11.2.2.

The standard requirement applies.

7.11.2.3.

The standard requirement applies.

7.12. Report requirements

7.12.1. General

7.12.1.1.

The standard requirement applies.

7.12.1.2.

The standard requirement applies.

7.12.1.3.

The standard requirement applies.

7.12.2. Content of the report

7.12.2.1.

The standard requirement applies.

7.12.2.2.

The standard requirement applies.

7.13. Complaints

7.13.1.

The standard requirement applies.

7.13.2.

The standard requirement applies.

7.13.3.

The standard requirement applies.

7.13.4.

The standard requirement applies.

7.13.5.

The standard requirement applies.

7.13.6.

The standard requirement applies.

7.13.7.

The standard requirement applies.

8. Quality management system requirements

8.1. Options

8.1.1. General

The standard requirement applies.

Note 1: If the management system documentation should also deal with activities other than those concerning the BBK accreditation field, it is recommended that the latter are clearly identified and meet the requirements of the standard and this regulation.

Note 2: The documentation that BBK may consider convenient or necessary to update, for various reasons, such as the quality manual and/or technical procedures, must be sent to ACCREDIA DT within the first programmed on-site assessment.

Note 3: In the case of updates of documents of external origin (e.g., Rules, methods, laws, regulations), unless otherwise indicated, BBK is required to apply the new versions within three months of entry into force.

8.1.2. Option A

The standard requirement applies.

Note: ACCREDIA assesses the compliance of the management system as documented (e.g., in a Management system manual, in management and technical procedures) by the BBK.

8.1.3. Option B

ACCREDIA in evaluating the management system of a BBK recognizes that the same operates with a management system compliant with the ISO 9001 standard and is able to obtain the same results that it would have had by directly implementing the requirements reported in paragraphs 8.2 to 8.9 of UNI EN ISO 20387. ACCREDIA's evaluation extends to this correspondence.

ACCREDIA does not evaluate the certified system in compliance with the requirements of the ISO 9001 standard but evaluates its coverage with respect to all the requirements of the UNI EN ISO 20387 standard, i.e., it evaluates that the management system contains the necessary references to fully describe how the *biobanking* activities are compliant with all the paragraphs of UNI EN ISO 20387. As

evidence of coverage of the field of activity ACCREDIA evaluates the presence of references to *biobanking* in all the records provided by the management system.

8.2. Documented information for the quality management system (option A)

8.2.1.

8.2.1 b)

By appropriate we mean the fulfilment of §8.3.2

8.2.1 c)

By appropriate we mean the fulfilment of §8.3.2

8.2.2.

The standard requirement applies.

8.2.3.

The standard requirement applies.

8.2.4.

The standard requirement applies.

8.2.5.

The standard requirement applies.

8.2.6.

The standard requirement applies.

8.3. Control of quality management system documents (option A)

8.3.1.

The standard requirement applies.

8.3.2.

The standard requirement applies.

8.4. Control of records (option A)

8.4.1.

The standard requirement applies.

8.4.2.

The standard requirement applies. The BBK in defining the retention period of the records must also consider the needs of 'users'.

8.4.3.

The standard requirement applies.

In the case of a human biological sample with confidentiality aspects, it also means the pseudonymisation of this sample and the data associated with it.

8.5. Actions to address risks and opportunities (option A)

The responsibility for deciding which risks and opportunities need to be established lies with BBK, it being understood that the standard requires a risk analysis for the following points:

§4.1.1 biosecurity and bio protection

§4.2.4 impartiality

§6.2.1.5 biosecurity

§6.3.7 contingency plan

§6.4.1.4 processes, products, services provided externally

§6.4.1.6 planning of internal audits of the external supplier

§ 6.5.4 equipment

§7.7.5 storage of biological material

§7.11.2.1 control of non-compliant output

ACCREDIA assesses whether the BBK has established appropriate actions to address risks and opportunities.

A risk analysis is also recommended for at least the following points:

§7.6.2. choice/definition/identification of critical activities

§7.7.3 choice/definition/identification of critical activities and relevant processing parameters

§7.7.7 intervals and methodologies for carrying out the inventory of biological material.

It is recommended to consider among the risks also those related to the use of information systems.

8.5.1.

The standard requirement applies.

8.5.2.

The standard requirement applies.

8.5.3.

The standard requirement applies.

8.6. Improvement (option A)

8.6.1.

The standard requirement applies.

8.6.2.

The standard requirement applies.

8.7. Corrective action for non-conforming output (option A)

8.7.1.

The standard requirement applies.

If non-compliant activities are identified such as to compromise the service offered under BBK accreditation, BBK - in addition to the provisions of its quality management system in application of the standard requirements - must promptly inform ACCREDIA and, if necessary, proceed with the request for self-suspension according to the provisions of the RG-22 Regulation.

8.7.2.

The standard requirement applies.

8.7.3.

The standard requirement applies.

8.8. Internal audits (option A)

8.8.1.

The standard requirement applies.

Note: It is recommended that the evaluation of the effectiveness of corrective actions relating to findings of previous audits, both first-party and third-party, is included in the planning of internal audits.

8.8.2.

The standard requirement applies.

8.9. Quality management review (option A)

8.9.1.

The standard requirement applies.

8.9.2.

The standard requirement applies.

8.9.3.

The standard requirement appl

9. Annex 1

This annex is intended to provide clarifications related to the aspects of Privacy, Confidentiality and Processing of personal data present within the Standard referring to the European Data Protection Regulation (GDPR 2016/679) and to the specific Provisions issued by the Guarantor for the Protection of Personal Data. It is recalled that the specific measures relating to the processing of genetic data and data for scientific research prevail over the general provisions of the GDPR.

Req. Standard	EU REGULATION 2016/679	Provision identifying the provisions contained in the General Authorizations nos. 1/2016, 3/2016, 6/2016, 8/2016 and 9/2016 which are compatible with the Regulation and with the legislative decree n. 101/2018 to adapt the Code - 13 December 2018 (9068972)
4.3.1	**Art. 32 - Security of Treatment**	**4.2 Specific requirements** In any case, the following precautions are adopted for the custody and safety of genetic data and biological samples: a) access to the premises must take place according to a documented procedure established by the data controller, which provides for the identification of persons, previously authorized, who access for any reason after closing time. These checks can also be carried out with electronic tools. The use of biometric data is permitted with regard to the aforementioned physical access procedures, in compliance with the principles on the protection of personal data and the specific processing requirements referred to in art. 9 of the Regulation; b) the storage, use and transport of biological samples are implemented in ways also aimed at ensuring their quality, integrity, availability and traceability;

Req. Standard	EU REGULATION 2016/679	Provision identifying the provisions contained in the General Authorizations nos. 1/2016, 3/2016, 6/2016, 8/2016 and 9/2016 which are compatible with the Regulation and with the legislative decree n. 101/2018 to adapt the Code - 13 December 2018 (9068972)
		c) the transfer of genetic data, with electronic messaging systems including mail, is carried out with the following precautions: transmission of the data in the form of an attachment and not as a text included in the body of the message; data encryption, taking care to make the cryptographic key known to the recipient through communication channels other than those used for data transmission; use of protected communication channels, taking into account the state of the art of the technology used; protection of the attachment in ways suitable to prevent the illicit or fortuitous acquisition of the transmitted data, such as a password for opening the file made known to the recipient through communication channels other than those used for data transmission. The use of "web application" communication channels is allowed, which envisage the use of protected transmission channels, taking into account the state of the art of technology, and guarantee, after verification, the digital identity of the server that delivers the service and the client station from which the data is accessed, using digital certificates issued in compliance with the law by a certification authority; d) the consultation of genetic data processed with electronic tools is permitted subject to the adoption of authentication systems based on the combined use of information known to the designated persons and devices, including biometric, in their possession; e) the genetic data and biological samples contained in lists, registers or databases are treated with encryption or pseudonymisation techniques or other solutions which, considering the volume of data and samples processed, make them temporarily unintelligible even to those authorized to access it and allow the data subjects to be identified only in case of need, so as to minimize the risks of accidental knowledge and unauthorized or abusive access. Where the lists, registers or databases are kept with electronic tools and also contain data concerning the genealogy or the state of health of the interested parties, the

Req. Standard	EU REGULATION 2016/679	Provision identifying the provisions contained in the General Authorizations nos. 1/2016, 3/2016, 6/2016, 8/2016 and 9/2016 which are compatible with the Regulation and with the legislative decree n. 101/2018 to adapt the Code - 13 December 2018 (9068972)
		aforementioned techniques must also allow the separate treatment of genetic and health data from other data personal data that allow the persons concerned to be directly identified.
4.3.2	**Art. 13 - Information to be provided if personal data are collected from the data subject** **Art. 14 - Information to be provided if personal data have not been obtained from the data subject**	**4.3 Information to interested parties** The information to be made to the interested parties pursuant to art. 13 and 14 of Regulation (EU) 2016/679 and pursuant to art. 77 and 78 of the Code for general practitioners and free choice paediatricians also highlight: a) the achievable results also in relation to unexpected news that may be known as a result of the treatment of genetic data; b) the right or not, for the interested party, to limit the scope of communication of genetic data and the transfer of biological samples, as well as the possible use of such data for further purposes. After reaching the age of majority, information on the processing of personal data is also provided to the interested party for the purpose of acquiring a new manifestation of consent (with 38, 58, and articles 5 and 8 of Regulation (EU) 2016 / 679 and article 82, paragraph 4, of the Code). **4.11.1 Information to interested parties** In relation to the treatments carried out for scientific and statistical research purposes, the information provided to the interested parties is also highlighted:

Req. Standard	EU REGULATION 2016/679	Provision identifying the provisions contained in the General Authorizations nos. 1/2016, 3/2016, 6/2016, 8/2016 and 9/2016 which are compatible with the Regulation and with the legislative decree n. 101/2018 to adapt the Code - 13 December 2018 (9068972)
		a) the measures adopted to allow the identification of data subjects only for the time necessary for the purposes of the collection or subsequent processing (Article 25 of EU Regulation 2016/679); b) the ways in which interested parties, who request it, can access the information contained in the research project. The treatments carried out through genetic tests, including screening, for research purposes require the consent of the interested parties; in these cases, the interested parties are asked to declare whether or not they want to know the results of the research, including any unexpected news concerning them, if the latter represent a concrete and direct benefit for the interested parties in terms of therapy or prevention or awareness of the reproductive choices.
4.3.3	**Art. 13 - Information to be provided if personal data are collected from the data subject** **Art. 14 - Information to be provided if personal data have not been obtained from the data subject**	**4.3 Information to interested parties** The information to be given to the interested parties pursuant to art. 13 and 14 of Regulation (EU) 2016/679 and pursuant to articles 77 and 78 of the Code for general practitioners and free choice paediatricians also highlight: a) the achievable results also in relation to unexpected news that may be known as a result of the processing of genetic data;

Req. Standard	EU REGULATION 2016/679	Provision identifying the provisions contained in the General Authorizations nos. 1/2016, 3/2016, 6/2016, 8/2016 and 9/2016 which are compatible with the Regulation and with the legislative decree n. 101/2018 to adapt the Code - 13 December 2018 (9068972)
		b) the right or not, for the interested party, to limit the scope of communication of genetic data and the transfer of biological samples, as well as the possible use of such data for further purposes. After reaching the age of majority, information on the processing of personal data is provided to the interested party also for the purpose of acquiring a new manifestation of consent (with 38, 58, and articles 5 and 8 of Regulation (EU) 2016/679 and art. 82, paragraph 4, of the Code). **4.11.1 Information to interested parties** In relation to the treatments carried out for scientific and statistical research purposes, the information provided to the interested parties is also highlighted: a) the measures adopted to allow the identification of data subjects only for the time necessary for the purposes of the collection or subsequent processing (Article 25 of EU Regulation 2016/679); b) the ways in which interested parties, who request it, can access the information contained in the research project. The treatments carried out through genetic tests, including screening, for research purposes require the consent of the interested parties; in these cases, the interested parties are asked to declare whether or not they want to know the results of the research, including any unexpected news

Req. Standard	EU REGULATION 2016/679	Provision identifying the provisions contained in the General Authorizations nos. 1/2016, 3/2016, 6/2016, 8/2016 and 9/2016 which are compatible with the Regulation and with the legislative decree n. 101/2018 to adapt the Code - 13 December 2018 (9068972)
		concerning them, if the latter represent a concrete and direct benefit for the interested parties in terms of therapy or prevention or awareness of the reproductive choices.
4.3.4	**Art. 29 - Processing under the authority of the data controller or processor**	**4.6 Data Communication and dissemination** Without prejudice to the general rules governing the communication and dissemination of specific categories of data, including genetic data, these processing operations can be carried out in compliance with the following requirements (Article 9, EU Regulation 2016/679 and Article 2e of the Code). Except for the personal data previously provided by the same interested party, the genetic data must be made known to the interested party or to the subjects referred to in Article 82, paragraph 2, letter a), of the Code by health professionals and health organizations only through a doctor designated by the person concerned or by the owner. The data controller or data processor may authorize in writing the health professions other than doctors, who in the exercise of their duties have direct relationships with patients and are designated to process genetic data or biological samples, to disclose the same data to the interested party or to the subjects referred to in art. 82, paragraph 2, letter a) of the Code. In the instructions to persons authorized to process the data, appropriate methods and precautions are identified in relation to the context in which the data are processed. Genetic data must, as a rule, be disclosed directly to the interested party or to persons other than the person concerned only on the basis of a written authorization from the latter, adopting all suitable

Req. Standard	EU REGULATION 2016/679	Provision identifying the provisions contained in the General Authorizations nos. 1/2016, 3/2016, 6/2016, 8/2016 and 9/2016 which are compatible with the Regulation and with the legislative decree n. 101/2018 to adapt the Code - 13 December 2018 (9068972)
		means to prevent unauthorized knowledge by even co-present subjects. The communication in the hands of a delegate of the interested party is carried out in a closed envelope. The results of genetic tests and screening, as well as the results of research if they entail a concrete and direct benefit for the interested party in terms of therapy, prevention or awareness of reproductive choices, must be communicated to the same interested party also in compliance with his declaration of willingness to know or not such events and, where necessary, together with appropriate genetic counselling. The results of genetic tests and screening, as well as the results of research, if they entail a concrete and direct benefit in terms of therapy, prevention or awareness of reproductive choices, even for those belonging to the same genetic line as the interested party, can be communicated to the latter, at their request, if the interested party has expressly consented to it or if these results are essential to avoid damage to their health, including reproductive risk, and the consent of the interested party is not given or cannot be given for actual unavailability. In the case of research conducted on population groups or isolated populations, any research results that are of therapeutic or preventive importance for the protection of the health of people belonging to these communities must be disclosed to the communities concerned and to local authorities.
6.2.1.2	**Art. 29 - Processing under the authority of the data controller or processor**	**4.6 Data Communication and dissemination** Without prejudice to the general rules governing the communication and dissemination of specific categories of data, including genetic data, these processing operations can be carried out in

Req. Standard	EU REGULATION 2016/679	Provision identifying the provisions contained in the General Authorizations nos. 1/2016, 3/2016, 6/2016, 8/2016 and 9/2016 which are compatible with the Regulation and with the legislative decree n. 101/2018 to adapt the Code - 13 December 2018 (9068972)
		compliance with the following requirements (Article 9, EU Regulation 2016/679 and Article 2e of the Code). Except for the personal data previously provided by the same interested party, the genetic data must be made known to the interested party or to the subjects referred to in Article 82, paragraph 2, letter a), of the Code by health professionals and health organizations only through a doctor designated by the person concerned or by the owner. The data controller or data processor may authorize in writing the health professions other than doctors, who in the exercise of their duties have direct relationships with patients and are designated to process genetic data or biological samples, to disclose the same data to the interested party or to the subjects referred to in art. 82, paragraph 2, letter a) of the Code. In the instructions to persons authorized to process the data, appropriate methods and precautions are identified in relation to the context in which the data are processed. Genetic data must, as a rule, be disclosed directly to the interested party or to persons other than the person concerned only on the basis of a written authorization from the latter, adopting all suitable means to prevent unauthorized knowledge by even co-present subjects. The communication in the hands of a delegate of the interested party is carried out in a closed envelope. The results of genetic tests and screening, as well as the results of research if they entail a concrete and direct benefit for the interested party in terms of therapy, prevention or awareness of reproductive choices, must be communicated to the same interested party also in compliance with his declaration

Req. Standard	EU REGULATION 2016/679	Provision identifying the provisions contained in the General Authorizations nos. 1/2016, 3/2016, 6/2016, 8/2016 and 9/2016 which are compatible with the Regulation and with the legislative decree n. 101/2018 to adapt the Code - 13 December 2018 (9068972)
		of willingness to know or not such events and, where necessary, together with appropriate genetic counselling. The results of genetic tests and screening, as well as the results of research, if they entail a concrete and direct benefit in terms of therapy, prevention or awareness of reproductive choices, even for those belonging to the same genetic line as the interested party, can be communicated to the latter, at their request, if the interested party has expressly consented to it or if these results are essential to avoid damage to their health, including reproductive risk, and the consent of the interested party is not given or cannot be given for actual unavailability. In the case of research conducted on population groups or isolated populations, any research results that are of therapeutic or preventive importance for the protection of the health of people belonging to these communities must be disclosed to the communities concerned and to local authorities. **4.11 Processing of genetic data for scientific and statistical research purposes** The processing of genetic data and biological samples for scientific and statistical research purposes is allowed only if aimed at protecting the health of the data subject, third parties or the community in the medical, biomedical and epidemiological fields, also in the context of clinical trials or scientific research aimed at developing genetic analysis techniques.

Req. Standard	EU REGULATION 2016/679	Provision identifying the provisions contained in the General Authorizations nos. 1/2016, 3/2016, 6/2016, 8/2016 and 9/2016 which are compatible with the Regulation and with the legislative decree n. 101/2018 to adapt the Code - 13 December 2018 (9068972)
		The processing must be carried out on the basis of a project drawn up in accordance with the standards of the relevant disciplinary sector, also in order to document that the processing of data and the use of biological samples is carried out for suitable and effective scientific purposes. The project specifies the measures to be adopted in the processing of personal data to ensure compliance with this provision, as well as with the legislation on the protection of personal data, also for the profiles concerning the custody and security of data and biological samples, and identifies any data processors (Article 28 of EU Regulation 2016/679). In particular, where the research involves the collection and/or use of biological samples, the project indicates the origin, nature and methods of taking and storing the samples, as well as the measures adopted to ensure the voluntary nature of the provision of the biological material by the interested party. The project is kept confidential (being the consultation of the project possible for the sole purpose of applying the legislation on the protection of personal data) for five years from the scheduled conclusion of the research. When the purposes of the research can be achieved only through the identification, even temporary, of the interested parties, the data controller adopts specific measures to keep the identification data separate from biological samples and genetic information already at the time of collection, unless this is impossible in due to the characteristics of the processing or requires a manifestly disproportionate use of means.
6.4	**Art. 28 – Processor**	

Req. Standard	EU REGULATION 2016/679	Provision identifying the provisions contained in the General Authorizations nos. 1/2016, 3/2016, 6/2016, 8/2016 and 9/2016 which are compatible with the Regulation and with the legislative decree n. 101/2018 to adapt the Code - 13 December 2018 (9068972)
7.2.3.4	Art. 7- Conditions for consent	**4.5 Consent** Consent to the processing of genetic data is required for: 1. purposes of protecting the health of a third party according to the provisions of point 4.7 below; 2. the carrying out of genetic tests in the context of defensive investigations or for the exercise of a right in court, unless an express provision of the law, or a provision of the judicial authority in accordance with the law, provides otherwise (see below point 4.9); 3. treatments carried out by genetic testing, including screening, for research or family reunification purposes. In these cases, the interested party is required to declare whether or not he wants to know the results of the examination or research, including any unexpected news concerning him, if the latter represent a concrete and direct benefit for the interested party in terms of therapy. o prevention or awareness of reproductive choices (see below point 4.10); 4. scientific and statistical research purposes not provided for by law or other specific requirements referred to in art. 9 of the Regulation (see point 4.11 below). **4.11.2 Consent** Without prejudice to the provisions of point 4.5, the genetic data and biological samples of people who cannot provide their consent due to incapacity, can be processed for scientific research purposes

Req. Standard	EU REGULATION 2016/679	Provision identifying the provisions contained in the General Authorizations nos. 1/2016, 3/2016, 6/2016, 8/2016 and 9/2016 which are compatible with the Regulation and with the legislative decree n. 101/2018 to adapt the Code - 13 December 2018 (9068972)
		that do not entail a direct benefit for the same interested parties if the following conditions apply simultaneously: a) the research is aimed at improving the health of other people belonging to the same age group or suffering from the same pathology or who are in the same conditions and the research programme is subject to a reasoned favourable opinion from the competent ethics committee at the local level; b) a search for a similar purpose cannot be carried out through the processing of data referring to people who can give their consent; c) the consent to the processing is acquired by those who legally exercise parental authority, or by a close relative, a family member, a cohabitant or, in their absence, by the manager of the facility where the person is staying; d) the research does not involve significant risks to the dignity, rights and fundamental freedoms of the data subjects.
7.3.3.2	**Art. 26 – Joint Data Controllers**	**4.11 Processing of genetic data for scientific and statistical research purposes** The processing of genetic data and biological samples for scientific and statistical research purposes is allowed only if aimed at protecting the health of the data subject, third parties or the community in the medical, biomedical and epidemiological fields, also in the context of clinical trials or scientific research aimed at developing genetic analysis techniques.

Req. Standard	EU REGULATION 2016/679	Provision identifying the provisions contained in the General Authorizations nos. 1/2016, 3/2016, 6/2016, 8/2016 and 9/2016 which are compatible with the Regulation and with the legislative decree n. 101/2018 to adapt the Code - 13 December 2018 (9068972)
		The processing must be carried out on the basis of a project drawn up in accordance with the standards of the relevant disciplinary sector, also in order to document that the processing of data and the use of biological samples is carried out for suitable and effective scientific purposes. The project specifies the measures to be adopted in the processing of personal data to ensure compliance with this provision, as well as with the legislation on the protection of personal data, also for the profiles concerning the custody and security of data and biological samples, and identifies any data processors (Article 28 EU Regulation 2016/679). In particular, where the research involves the collection and/or use of biological samples, the project indicates the origin, nature and methods of taking and storing the samples, as well as the measures adopted to ensure the voluntary nature of the provision of the biological material by the interested party. The project is kept confidential (since consultation of the project is possible for the sole purpose of applying the legislation on the protection of personal data) for five years from the scheduled conclusion of the research. When the purposes of the research can be achieved only through the identification, even temporary, of the data subjects, the data controller adopts specific measures to keep the identification data separate from biological samples and genetic information already at the time of collection, unless this is impossible due to the characteristics of the processing or requires a manifestly disproportionate use of means.
7.4.7	**Art. 32 – Security of Processing**	**4.2 Specific requirements**

Req. Standard	EU REGULATION 2016/679	Provision identifying the provisions contained in the General Authorizations nos. 1/2016, 3/2016, 6/2016, 8/2016 and 9/2016 which are compatible with the Regulation and with the legislative decree n. 101/2018 to adapt the Code - 13 December 2018 (9068972)
		In any case, the following precautions are adopted for the custody and safety of genetic data and biological samples: (…) c) the transfer of genetic data, with electronic messaging systems including mail, is carried out with the following precautions: transmission of data in the form of an attachment and not as a text included in the body of the message; data encryption, taking care to make the cryptographic key known to the recipient through communication channels other than those used for data transmission; use of protected communication channels, taking into account the state of the art of the technology used; protection of the attachment in ways suitable to prevent the unlawful or fortuitous acquisition of the transmitted data, such as a password for opening the file made known to the recipient via communication channels other than those used for data transmission. The use of "web application" communication channels is allowed, which envisage the use of protected transmission channels, taking into account the state of the art of technology, and guarantee, after verification, the digital identity of the server that delivers the service and the client station from which the data is accessed, using digital certificates issued in compliance with the law by a certification authority;
7.7.8	**Art. 17 – Right to erasure («right to be forgotten »)** **Art. 21 c. 6 – Right to object**	**4.5.1 How to collect and withdraw consent** For information relating to the unborn child, consent is validly given by the pregnant woman. In the event that the treatment carried out through prenatal tests may also reveal genetic data relating to the future onset of a pathology of the father, the consent of the latter is also previously acquired.

Req. Standard	EU REGULATION 2016/679	Provision identifying the provisions contained in the General Authorizations nos. 1/2016, 3/2016, 6/2016, 8/2016 and 9/2016 which are compatible with the Regulation and with the legislative decree n. 101/2018 to adapt the Code - 13 December 2018 (9068972)
		The opinion of the minor, to the extent that his age and degree of maturity permits, is, where possible, taken into consideration, the interests of the minor remaining paramount in any case. In other cases of incapacity, the processing is permitted if the purposes pursued involve a direct benefit for the person concerned and his opinion is, where possible, taken into consideration, the interest of the incapable being preeminent in any case. In case of revocation of consent by the interested party, the treatments must cease and the data must be deleted or made anonymous also through the destruction of the biological sample taken. **4.11.2 Consent** Without prejudice to the provisions of point 4.5, the genetic data and biological samples of people who cannot provide their consent due to inability, may be processed for scientific research purposes that do not entail a direct benefit for the same interested parties if the following conditions apply simultaneously: a) the research is aimed at improving the health of other people belonging to the same age group or suffering from the same pathology or who are in the same conditions and the research programme is subject to a reasoned favourable opinion from the competent ethics committee at the local level;

Req. Standard	EU REGULATION 2016/679	Provision identifying the provisions contained in the General Authorizations nos. 1/2016, 3/2016, 6/2016, 8/2016 and 9/2016 which are compatible with the Regulation and with the legislative decree n. 101/2018 to adapt the Code - 13 December 2018 (9068972)
		b) a search of similar purpose cannot be carried out through the processing of data referring to persons who can give their consent; c) consent to the processing is acquired by those who legally exercise parental authority, or by a close relative, a family member, a cohabitant or, in their absence, by the person in charge of the facility where the person is staying; d) the research does not involve significant risks to the dignity, rights and fundamental freedoms of the data subjects. In such cases, the foregoing remains valid with regard to the need to take into account, where possible, the opinion of the minor or the incapable. In the event that the interested party withdraws consent to the processing of data for research purposes, the biological sample is also destroyed as long as it has been taken for such purposes, unless, originally or following processing, the sample can no longer be referring to an identified or identifiable person.
7.10.3	**Art. 32 – Security of Processing**	**4.2 Specific requirements** In any case, the following precautions are adopted for the custody and safety of genetic data and biological samples:

Req. Standard	EU REGULATION 2016/679	Provision identifying the provisions contained in the General Authorizations nos. 1/2016, 3/2016, 6/2016, 8/2016 and 9/2016 which are compatible with the Regulation and with the legislative decree n. 101/2018 to adapt the Code - 13 December 2018 (9068972)
		a) access to the premises must take place according to a documented procedure established by the data controller, which provides for the identification of persons, previously authorized, who access for any reason after closing time. These checks can also be carried out with electronic tools. The use of biometric data is permitted with regard to the aforementioned physical access procedures, in compliance with the principles on the protection of personal data and the specific processing requirements referred to in art. 9 of the Regulations; b) the conservation, use and transport of biological samples are put in place in ways also aimed at ensuring their quality, integrity, availability and traceability; c) the transfer of genetic data, with electronic messaging systems including mail, is carried out with the following precautions: transmission of data in the form of an attachment and not as a text included in the body of the message; data encryption, taking care to make the cryptographic key known to the recipient through communication channels other than those used for data transmission; use of protected communication channels, taking into account the state of the art of the technology used; protection of the attachment in ways suitable to prevent the unlawful or fortuitous acquisition of the transmitted data, such as a password for opening the file made known to the recipient via communication channels other than those used for data transmission. The use of "web application" communication channels is allowed, which envisage the use of protected transmission channels, taking into account the state of the art of technology, and guarantee, after verification, the digital identity of the server that delivers the service and the client station from which the data is accessed, using digital certificates issued in compliance with the law by a certification authority;

Req. Standard	EU REGULATION 2016/679	Provision identifying the provisions contained in the General Authorizations nos. 1/2016, 3/2016, 6/2016, 8/2016 and 9/2016 which are compatible with the Regulation and with the legislative decree n. 101/2018 to adapt the Code - 13 December 2018 (9068972)
		d) the consultation of genetic data processed with electronic tools is permitted subject to the adoption of authentication systems based on the combined use of information known to the persons designated for the purpose and devices, including biometric ones, in their possession; e) the genetic data and biological samples contained in lists, registers or databases are treated with encryption or pseudonymisation techniques or other solutions which, considering the volume of data and samples processed, make them temporarily unintelligible even to those authorized to access it and allow the data subjects to be identified only in case of need, so as to minimize the risks of accidental knowledge and unauthorized or abusive access. Where the lists, registers or databases are kept with electronic tools and also contain data concerning the genealogy or the state of health of the interested parties, the aforementioned techniques must also allow the separate processing of genetic and health data from other personal data that allow to directly identify the persons concerned.

ACCREDIA
Via Guglielmo Saliceto, 7/9 – 00161 Roma
T +39 06 8440991 / F +39 06 8841199
info@accredia.it

Dipartimento Certificazione e Ispezione
Via Tonale, 26 -– 20125 Milano
T +39 02 2100961 / F +39 02 21009637
milano@accredia.it

Dipartimento Laboratori di prova
Via Guglielmo Saliceto, 7/9 – 00161 Roma
T +39 06 8440991 / F +39 06 8841199
info@accredia.it

Dipartimento Laboratori di taratura
Strada delle Cacce, 91 – 10135 Torino
T +39 011 328461 / F +39 011 3284630
segreteriadt@accredia.it