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Istituto Superiore di Sanità

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Recommendations for collection, transport and storage of COVID-19 biological samples

ISS Working group on Translational Research COVID-19

Version April 15, 2020

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As a result of the exceptional health emergency caused by the COVID-19 epidemic, an unprecedented action is underway to collect biological samples and personal and health data from the population, which are crucial for effective research on COVID-19. In this context, it is essential that the collection and storage of samples are carried out according to consolidated international standard operating procedures as well as guaranteeing the protection of people's rights and the proper use of samples and associated data. The report is the result of the collaboration between the ISS Translational Research Working Group and BBMRI.it. It gathers recommendations, guidance documents and international guidelines approved and consolidated to date.

The original Italian version of ISS COVID-19 Reports are available at: **https://www.iss.it/rapporti-covid-19**

The reports translated in English are available from: **https://www.iss.it/rapporti-iss-covid-19-in-english**

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Introduction

Most of the current knowledge on diseases and the consequent diagnostic and therapeutic possibilities are based on the study of biological samples and the data associated with them. Following the exceptional health emergency caused by the outbreak of the COVID-19 epidemic, which dramatically involves Italy, an unprecedented action is underway to collect biological samples and personal and health data from the population. These samples and data, collected for diagnostic procedures and the consequent care of the affected people are also pivotal for effective research to defeat COVID-19, a disease on which the world scientific community is focusing its own resources in an extraordinary effort, in order to give concrete and quick responses to the health expectations of the entire citizenship. In this context, structuring a coordinated and extensive collection and biobanking of samples (nasopharyngeal swabs, *sputum*, blood and its derivatives, broncho-alveolar lavage, post-mortem tissues etc.) from all the infected and recovered population, take priority. It is indeed crucial to collect and store the biological materials of the population concerned according to the established international criteria and in compliance both with ELSI (ethical-legal-social) requirements and the rights of the patients involved, in order to make them available over time for collaborative research projects.

In this perspective, it is recommended to keep the collections of COVID-19 samples in biobanks which, as an entity recognized by the competent authorities, must ensure and manage, according to proven quality standards and in a stable and continuous manner, the collection, preparation, storage and distribution of samples and related information for future research and/or diagnosis.

BBMRI Italia – national node of the European Research Infrastructure of Biobanking and BioMolecular Resources BBMRI-ERIC – supports the scientific community in the research on COVID-19.

This report stems from the collaboration of the ISS Translational Research working group and BBMRI.it.

This report is not exhaustive and further information and resources are available in the COVID-19 section of the website https://www.bbmri.it/, constantly updated.

Informed biobanking for a quality research

The cornerstone of the entire biobank-based research process, from collection to conservation, is the recognition and the inclusion of the citizen as an aware participant: access to the sample and related information as well as the possibility over time to enrich the initially collected sample with further data (follow-up data), are determined by the expressed informed consent. The biobank fully exercises its third, custody function by ensuring that the biobanked samples are accessible, utilized and distributed to develop future research, in accordance with the expressed will.

For biobank-based research it is essential that all the useful information to understand and consciously choose is shared with the person to whom it is proposed to biobank, before the collection of biological materials (and over time). Through biobanking, a pact of responsibility is established among participant, biobank and researcher. The informed consent, which is to be understood as a dynamic process, modulated from the information needs of the person to whom the samples belong, proves to be a living instrument and a tool for responsible research as well as maximum protection of the participant.

The COVID-19 emergency strongly highlights the importance and the sensitivity of this process. It commits us to act with increased responsibility so that an informed process of collection of the precious samples it is possible and shared. A process respectful of rights and circumstances, and at the same times with the ethical-legal requirements for the collection of samples to be stored over time and for all the actions for a collaborative research necessary to give health responses to the citizens.

The prediction and compliance with these requirements will allow to biobank the samples collected even in an emergency, to connect them to the personal data (e.g., clinical, genetic, lifestyle) of the person to whom they belong, and to avoid their anonymization at the end of the emergency for the impossibility of recovering informed consent.

In addition, for COVID-19 research it is necessary from now to involve non-contagious and non-hospitalized citizens in biobanking, with a public information campaign and a dedicated informed consent model, designed to facilitate understanding of the importance of COVID-19 biobanking (available at the following link https://www.bbmri.it/nodo-nazionale/elsi-covid-19/). (Appendix A).

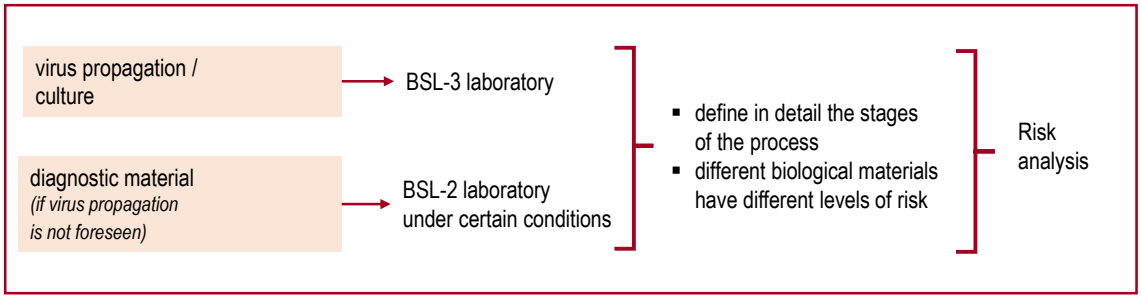
Highlights:

- Biobank-based research as a collaborative and responsible process over time;
- the informed consent of the person to whom the samples/data belong determining access and use of the samples/data;
- ethical-legal requirements of COVID-19 emergency sample collection for future research purposes.

Risk analysis

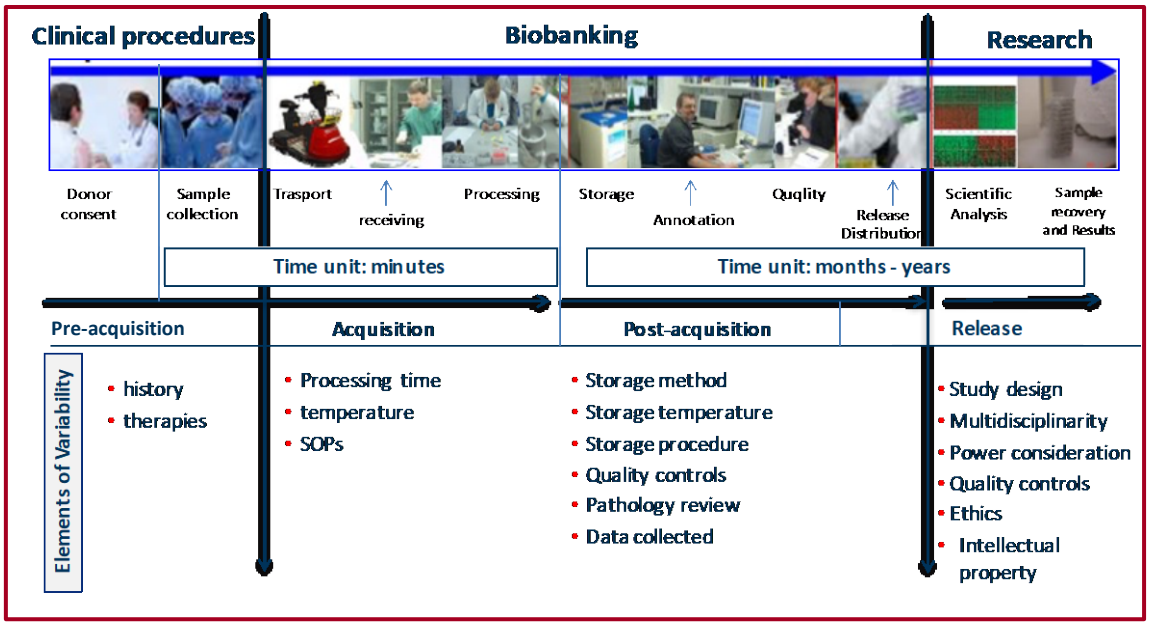
SARS-CoV-2 is considered a risk group 3 pathogen.

Biological samples shall be processed and analyzed according to the WHO and CDC guidelines according to the following scheme.



In order to start a collection of COVID-19 related biological samples, a thorough knowledge of the entire process is needed, starting from the involvement of the patient / participant, to continue with collection, transport, acceptance, handling of the different types of samples, preparation, labelling and storage, data management, distribution and use for research.

Stages of the biobanking process



For each of these phases and for each type of sample an accurate risk analysis is mandatory, taking into account the type of risk, the possible causes, the probability of the event and the severity of the effects. On the basis of this information and of a classification of risk in order of seriousness, it is possible to define strategies for dealing, through preventive actions, with potential problems. The institution where the biobank

operates, or in which the collection and storage of samples takes place, should set up a working group, including at least the biobank manager, an infectious disease specialist, a hygienist, an epidemiologist and a representative of the protection and prevention department. Based on the results of the risk analysis conducted by the group, the most suitable ways to minimize risks should be defined. It is necessary to keep in mind that knowledge about the virus and the disease caused by the virus is constantly updated, and consequently, risk analysis is a dynamic process, for which continuous updating and frequent analysis of the reference guidelines are essential. For the analysis, it is advisable to use available tools and risk matrices.

Example of risk analysis of some phases of the process

Risk event	Category	Possible reasons	Probability	Effect severity
Hazard at sample reception	preanalytics	inadequate handling of contaminated material	< 5%	
Endagement by contaminated material	preanalytics	Tube surface contaminated; tubes damaged	< 10%	
Aerosol generation during sample opening	preanalytics	Unavoidable	100%	

The first aspect to be considered is the competence of the staff, who shall be qualified, operate in a quality system that guarantees correct management of the entire process and have access to agreed and constantly updated written procedures and to the guidelines and reference standards. The work environment shall be adequate to the risk, the parameters to be monitored shall be defined to ensure safety and the monitoring shall be documented.

Based on the type of risk, adequate measures shall be provided: personal protection for all operators participating in the process, correct management of sensitive information, protection of laboratories and the environment, prevention of accidental use of dangerous substances, correct waste disposal, protection of the researchers who will use the samples.

The samples distributed for research use shall be accompanied by a technical sheet that defines the risk associated with the sample.

If it is true that all biological samples shall be considered potentially infectious, the risk should be taken into account that COVID-19 positive samples, collected before the spread of the epidemic, could have already been unknowingly preserved.

References

WHO Guideline

https://www.who.int/publications-detail/laboratory-testing-for-2019-novel-coronavirus-in-suspected-human-cases-20200117;

https://www.who.int/emergencies/diseases/novel-coronavirus-2019/technical-guidance/laboratory-guidance)

ISO 31000:2018 Risk management — Guidelines (freely available)

https://www.cdc.gov/coronavirus/2019-ncov/lab/guidelines-clinical-specimens.html

https://www.bbmri-eric.eu/wp-content/uploads/HH-BBMRI_COVID-19.pdf

Recommendations for biosafety, biosecurity and quality for collection and management of the biological sample

Appropriate and internationally recognized processing and management of the biological samples are essential and necessary conditions for obtaining comparable and reproducible results in biomedical research.

Risk analysis has to be performed before definition and implementation of each individual procedure.

The final destination of use (fitness to purpose) of the collected samples is at the basis for choosing the sampling conditions (e.g., type of anticoagulant), pre-analytical treatment, analysis and conservation of biological material.

Currently, the main types of samples relevant for COVID-19 research are: nasopharyngeal swab; oropharyngeal swab; BAL (BronchoAlveolar Lavage); tracheal aspirate; sputum; blood and derivatives; urine; feces.

The standard "ISO 20387:20387 Biotechnology-Biobanking-General requirements for biobank" details the necessary conditions for quality management of biological material for research use.

Personnel

Personnel should be properly trained for collection, shipping and storage of infectious samples and shall work according to good microbiological practices and procedures [Annex 1 Core requirements 1. Good microbiological practice and procedure (GMPP) of the *WHO Laboratory biosafety guidance related to coronavirus disease 2019 (COVID-19): interim guidance, 12 February 2020*: https://apps.who.int/iris/handle/10665/331138].

All personnel should be trained in safety and personal protection and be aware of the dangers present in the laboratory and the associated risks. The training requirements correspond to their function-specific responsibilities.

Laboratory personnel must wear appropriate Personal Protective Equipment (PPE), as determined by a detailed risk assessment.

Sample management: environment and procedures

- All specimens collected should be regarded as potentially infectious, therefore workplaces, facilities and equipment necessary for their manipulation must be identified and organized on the base of risk assessment. The environment conditions must be defined, verified, monitored and recorded. The use of automated equipment and sealed centrifuge rotors, for example, should be preferred to minimize risks for the environment and the operator.
- For the biobank, acquisition sources of the biological material infected, or potentially infected, by SARS-CoV2 vary and may include triage ambulatory, pathology departments, targeted screening programs in high-risk situations or more likely hospital laboratories of microbiology, virology and

pathology. In any case, the acquisition process must be recorded, documented and associated with the date, time and method of collection, and with all procedural information that the sample underwent before arrival in the biobank.

Each collection procedure must be considered of high potential risk and must be carried out by competent personnel and after the implementation of all the necessary measures to minimize the risk for the operator. Some indications for the collection of the biological samples are:

- ✓ Bronchoalveolar lavage, tracheal aspirate. Collect 2-3 mL into a sterile, leak-proof, screw-cap sputum collection cup or sterile dry container.
- ✓ *Sputum*. The patient has to rinse the mouth with water and then expectorate deep cough sputum directly into a sterile, leak-proof, screw-cap collection cup or sterile dry container.
- ✓ Nasopharyngeal swab, oropharyngeal swab. A single polyester swab with a plastic shaft should be used. Swabs should be placed immediately into sterile tubes containing 2-3 mL of viral transport media (*see* https://www.cdc.gov/coronavirus/2019-nCoV/lab/guidelines-clinical-specimens.html).
- ✓ Blood, urine and feces has to be collected in sterile containers according to procedures used for clinical analysis.

- Each sample has to be labelled with the ID number of the patient (e.g., number of the clinical record) and / or unique ID of the sample (e.g., number of the laboratory request). Acquisition data have to include: date and time sample collection and type of sample (e.g., serum).
- The pre-analytical and analytical procedures must be conducted according to the standard operating procedures (Standard Operating Procedures, SOP) of the biobank in compliance with the procedures of good practice of the microbiology laboratory (*WHO Laboratory testing for coronavirus disease (COVID-19) in suspected human cases: interim guidance, 19 March 2020*: https://apps.who.int/iris/handle/10665/331500).
- Each single manipulation of potentially infectious materials, and in particular those that may cause aerosols of infectious materials (e.g., opening of containers of infectious materials whose internal pressure may be different from the ambient pressure; vigorous shaking or mixing; aliquoting), has to be performed in appropriately maintained and validated BSCs, and with use of other primary containments such as personal protective equipment, face shields/visors, medical mask, and / or other physical barriers (https://www.cdc.gov/coronavirus/2019-nCoV/lab/lab-biosafety-guidelines.html).
- Molecular (sequencing, gene amplification, etc.) and serological tests should be conducted in facilities with levels of biological risk containment comparable to BSL-2, while virus culture, isolation or neutralization assays should be conducted in the BSL-3 laboratory (https://apps.who.int/iris/handle/10665/331138).
- The decontamination of the environment is an integral part of the correct maintenance procedures of the dedicated areas and equipment and it must be performed with appropriate disinfectants with proven activity against enveloped viruses, considering dilution, contact time, and expiring date of daily working solution. Current knowledge suggests that SARS-CoV-2 is susceptible to sodium hypochlorite (bleach) (0.1%) for general surface disinfection and 1% for disinfection of biological material spills, 62-71% ethanol, 0.5% hydrogen peroxide, quaternary ammonium compounds and phenolic compounds, if used according to manufacturer's recommendations. Other biocidal agents such as 0.05-0.2% benzalkonium chloride or 0.02% chlorhexidine digluconate can be less efficacious.

Storage

The methods of storage should be defined, monitored and recorded. Fresh samples can be stored for a maximum of 72 hours at 2-8°C from the collection. Long term storage must take place at temperatures below -70°C.

In choosing the final storage temperature, the type and, above all, the purposes of use of the sample must be considered. It is highly recommended that cryogenic storage takes place in nitrogen vapors.

Biological biosafety and biosecurity requirements for shipping and transport of SARS-CoV-2 samples

The fresh samples can be transported at 2-8°C within a maximum of 72 h from the collection and their transport within these times must take place on ice pack.

All materials transported within and between laboratories should be placed in a secondary container to minimize the potential for breakage or a spill.

Already stored samples must be transported on dry ice and must have appropriate packaging, labelling, documentation (http://un3373.it/ENG/Information_about_infectious_substance_UN2814_UN2900.html).

The packaging products for a safe and secure shipment of biological material must be designed to avoid any accidental loss (e.g., due to vibrations or changes in temperature, or pressure) and in compliance with the packaging instructions P.I. 650 IATA: (http://un3373.it/Istruzione_di_imballaggio_P.I.650_IATA.html).

Packaging and shipping of biological samples must also comply with the current edition of the International Air Transport Association (IATA) (Dangerous Goods Regulations external), considering that:

- specimens from suspected or confirmed cases should be transported as "Biological Substance, Category B UN-No. 3373" (http://un3373.it/definizioni_sulle_materie_biologiche_UN3373.html);
- viral cultures or isolates should be transported as "Biological Substance Category A A, UN2814" (http://un3373.it/istruzione_di_imballaggio_P620_ADR_per_UN2814_e_UN2900.html).

Data to be associated to the samples

Information on patients and their samples is an integral part of biobanking. The minimum dataset for COVID biobanking is still being defined internationally. Here we propose a non-exhaustive set of information, useful to shape a harmonized dataset.

The dataset should contain at least: information on SARS-CoV-2 infection (positive test, negative test, inconclusive result, test not carried out), on the motivation of the collection (suspected infection, screening, confirmation of recovery), on the clinical symptoms (absent, mild or severe), on the duration of symptoms, on the clinical course and comorbidities, on the treatment protocol, on the follow-up and on the disease status (unaffected, affected, healed, deceased). Other relevant information are the assays used for diagnosis and follow-up (several tests are in the validation phase), the IgG and IgM antibody titer, the link to the medical records, the results of laboratory tests at hospitalization, access to CT and / or lung radiography images.

References

Interim guidelines for collecting, handling, and testing clinical specimens from persons for coronavirus disease 2019 (COVID-19)
https://www.cdc.gov/coronavirus/2019-ncov/lab/guidelines-clinical-specimens.html

Interim laboratory biosafety guidelines for handling and processing specimens associated with coronavirus disease 2019 (COVID-19)
https://www.cdc.gov/coronavirus/2019-nCoV/lab/lab-biosafety-guidelines.html

Laboratory biosafety guidance related to the novel coronavirus (2019-nCoV). Interim guidance 12 February 2020
https://www.who.int/docs/default-source/coronaviruse/laboratory-biosafety-novel-coronavirus-version-1-1.pdf?sfvrsn=912a9847_2

Laboratory testing for 2019 novel coronavirus (2019-nCoV) in suspected human cases. Interim guidance 19 March 2020
https://www.who.int/publications-detail/laboratory-testing-for-2019-novel-coronavirus-in-suspected-human-cases-20200117

BBMRI.QM Web Conference
https://www.bbmri-eric.eu/services/bbmriqm-covid

From the emergency to the territory: the informed biobanking for research

In emergency

If it is impossible to inform and collect informed consent of the hospitalized person due to the emergency clinical situation:

- The collection of samples and data for research purposes, as well as the procedures for the collection of informed consent to the research biobank, to the recovery of the patient, is tracked and documented in the medical records;
- The proposal to biobank for research and the verbally expressed consent, where the patient is able to talk, is documented in the medical records;
- The collected samples and data are pseudonymized by replacing the patient's personal data with codes that do not allow the patient's identity to be traced, only the data controller can connect the patient's identity with the collected samples/data;
- Keep the samples and data collected safely.

Context	Healthcare structure
When	In emergency
Recipient	Infected patient, unable to express consent or in critical conditions (intensive care)
Healthcare personnel	Healthcare personnel unable to gather consent given the emergency situation in which they operate
Information tools	Oral communication to the patient of the short-term collection of samples, consent is deferred at the time of stabilization and / or discharge. The collection of biological materials with deferred consent is reported in the patient record, creating an alert (e.g., The patient is informed orally of the emergency collection of his samples of .... for scientific research in the COVID-19 pandemic. The collection of consent is postponed until stabilisation and / or discharge") Always available: simplified informed consent; glossary; in-depth information sheets.
Regulatory-ethical framework	Decreto Legge n. 14 del 9 marzo 2020, Disposizioni per il potenziamento del Servizio sanitario nazionale in relazione all'emergenza COVID-19 https://www.gazzettaufficiale.it/eli/id/2020/03/09/20G00030/sg EDPB - Statement on the processing of personal data in the context of the COVID-19 outbreak. Adopted on 19 March 2020 https://edpb.europa.eu/sites/edpb/files/files/file1/edpb_statement_2020_processingpersonaldataandcovid-19_en.pdf

As the patient recovers

- Share with the patient the reasons and modalities of the emergency biobanking process
- Acquire informed patient consent to the COVID-19 biobanking

In the case of a refusal, the collected samples / data must be anonymized and destroyed once the purpose, for which they were collected in an emergency, has been finalized.

Context	Healthcare structure		
When	In ward	To hospital discharge	To the communication of swab results
Recipient	Infected, stabilized patient	Cured patient, able to express his own will	Patients with mild symptoms, sent back to the territory
Healthcare personnel	Nurses and ward doctors	Nurses and hospital doctors	Hospital healthcare personal or professionals identified by the regional health organization
Information tools	Simplified informed consent; glossary; in-depth information sheets		
Regulatory-ethical framework	General Data Protection Regulation (GDPR), in particular ART. 5-7,13 https://eur-lex.europa.eu/legal-content/IT/TXT/?uri=celex%3A32016R0679 Provvedimento recante le prescrizioni relative al trattamento di categorie particolari di dati, ai sensi dell'art. 21, comma 1 del d.lgs. 10 agosto 2018, n. 101 https://www.gazzettaufficiale.it/eli/id/2019/07/29/19A04879/sg REGULATION (EU) No 536/2014 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 April 2014 on clinical trials on medicinal products for human use, in particular CHAPT. V https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-1/reg_2014_536/reg_2014_536_en.pdf Recommendation CM/Rec(2016)6 of the Committee of Ministers to member States on research on biological materials of human origin https://search.coe.int/cm/Pages/result_details.aspx?ObjectId=090000168064e900 WMA Declaration of Taipei on ethical considerations regarding health databases and biobanks 2016 https://www.wma.net/policies-post/wma-declaration-of-taipei-on-ethical-considerations-regarding-health-databases-and-biobanks/		

With patients at home or with cured/asymptomatic citizens

Context	In the territory, at home		
When	At the territory take-over	Follow-up	On the basis of the provisions in place
Recipient	Patient with mild symptoms	Cured citizen	Asymptomatic citizen
Healthcare personnel	professionals identified by the regional health organization.		
Information tools	Simplified informed consent; glossary; in-depth information sheets.		
Regulatory-ethical framework	GDPR, in particular ART. 5 -7,1 https://eur-lex.europa.eu/legal-content/IT/TXT/PDF/?uri=CELEX:32016R0679&from=IT Provvedimento recante le prescrizioni relative al trattamento di categorie particolari di dati, ai sensi dell'art. 21, comma 1 del d.lgs. 10 agosto 2018, n. 101 https://www.gazzettaufficiale.it/eli/id/2019/07/29/19A04879/sg REGULATION (EU) No 536/2014 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 April 2014 on clinical trials on medicinal products for human use, in particular CHAPT. V https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-1/reg_2014_536/reg_2014_536_en.pdf Recommendation CM/Rec(2016)6 of the Committee of Ministers to member States on research on biological materials of human origin https://search.coe.int/cm/Pages/result_details.aspx?ObjectId=090000168064e900 WMA Declaration of Taipei on ethical considerations regarding health databases and biobanks 2016 https://www.wma.net/policies-post/wma-declaration-of-taipei-on-ethical-considerations-regarding-health-databases-and-biobanks/		

Conclusions

These recommendations are intended to provide the tools for the proper collection, storage and use of COVID-19 samples. The report collects the recommendations, guidance documents and guidelines that have been consolidated to date.

Biological samples and associated data, collected in compliance with ethical and regulatory requirements, and on the basis of proven quality and safety standards, are essential for achieving comparable and reproducible scientific results. This process assumes a decisive value in an emergency situation, such as the current COVID-19 pandemic, to guarantee the possibility of adequate and rapid responses to health needs and the future scientific knowledge

The report will be updated according to the ongoing national and international debate and the results of research in progress.

Appendix A

A1. Informed Consent

Editable form available at the following link: https://www.bbmri.it/nodo-nazionale/elsi-covid-19/

INFORMED CONSENT TO
the collection, storage and use of biological materials (biobanking)
for COVID-19 research
at the biobank …….. of (name of the institution)

Dear Madam/Sir,

For COVID-19 research, it is essential to have access to human biological material and to the associated personal data. Thus, we would like to propose that you consent to the collection and storage of your biological material and associated data for COVID-19 research.

Even in an emergency, this document is intended to support healthcare professionals in providing you with correct information so that you can make a free and informed choice.

Hereby the most important information to know:

Scope of the biobanking for COVID-19 research

We would like to biobank your biological material (samples), and store and process your personal data (health, genetic, lifestyle, etc.) to:

a. study the immune response to the SARS-CoV-2 virus, which caused the COVID-19 epidemic;
b. develop the scientific knowledge needed to produce new systems of accurate and rapid diagnosis, vaccines and effective antiviral drugs, so that in the coming months the health response for all will be timely;
c. carry out future research related to COVID-19 and related diseases, also in the epidemiological and preventive medicine fields.

Rights and responsibilities

The Biobank, as a service structure, takes into custody samples and process personal data in quality and in respect of participant's rights, as defined by current legislation. At any time, you may withdraw or modify your consent, access your personal data, request the rectification of your personal data, request the transfer of your data to another data controller, request the deletion of your personal data, lodge a complaint with the supervisory authority.

Type of samples to biobank for COVID-19 research

We may need to collect, at different times:

❑ the leftover material from the swab
❑ one or more aliquots of blood
❑ broncho-alveolar lavage,
❑ …… (specify if other)

Benefits and risks

The biobanking of your samples helps to make COVID-19 research possible and to provide health responses for the current community and for future generations. Operating on the basis of quality and safety standards, as the guardian of your samples, the Biobank is committed to avoid potential damage resulting from the misuse of sensitive information obtained from the study of your samples / data.

Handling and protection of your samples/data

To protect your privacy, your samples / data will be given a code (pseudonymization). In this way, they will be shared and used for research purposes so that you cannot be directly identified. The Biobank is responsible for their use: The Data Processor is at your disposal for any clarification, **provide contact details**. While the Data Controller is responsible for their use, **provide contact details**. Finally, the Data Protection Officer (DPO) is available **provide contact details.** Your samples / data will be stored as long as they remain scientifically useful in order to achieve the above objectives. After this period, your personal data will be used only to the extent that they are anonymized (it will be impossible to trace your identity, even to the Biobank).

Access and transfer of your samples/data

In order to develop the necessary research, your samples / data may be shared and transferred to public and / or private research groups in Europe, and non-European countries, only on the basis of specific formalized agreements, in compliance with the General Data Protection Regulation (GDPR). This transfer is subject to the positive evaluation of the competent Ethics Committee and on the basis of the access policies of the biobank (**indicate where available**). You can request and have access to your data by contacting **provide contact details**.

Returning research results

You are entitled to be informed about the results of the research carried out thanks to your samples / data in the following ways **specify ways (report/newsletter/site).** In the course of the studies that will be developed, it is possible that information concerning your health that was not initially foreseen in the research objectives - unexpected findings / secondary results - may emerge: it is your right to decide whether to be informed or not.

Commercial use of research products

It is possible that patents and / or commercial products (e.g. diagnostic kits) may be developed from the research carried out also thanks to your samples / data. Any economic income from these activities will not result in direct compensation for you.

Contacts

Further information (https://www.bbmri.it/nodo-nazionale/elsi-covid-19/, please **indicate where**) is available to you in order to understand more deeply what a biobank is and how it is essential to be able to effectively counteract COVID-19.

PARTICIPANT CONSENT

The undersigned ..... born in ..... on .....

Resident in .....

Phone/Mobile. ..... E-mail (if available) .....

After understanding the proposal to biobank her/his own biological material for COVID-19 research and having had the opportunity to ask and receive information

DECLARES to:

❑ CONSENT ❑ NOT TO CONSENT
To the collection, storage and use of her/his samples, and to the processing of associated personal data

❑ CONSENT ❑ NOT TO CONSENT
To a pseudonymized sharing of samples and associated personal data for research purposes.

❑ CONSENT ❑ NOT TO CONSENT
To the use of her/his samples/data for the development of products such as diagnostic kits, vaccines, etc. (possible commercial use of research products).

❑ WISH ❑ NOT TO WISH
To be informed of any unexpected findings/results concerning her/his health.

Place, date .....

..... Participant signature

..... Signature of the health care professional

A2. Regulatory-Ethical Framework

Below we share the ethical-regulatory references for informed biobanking, with special attention to the limits established by the health circumstances and the vulnerable conditions in which the person, to whom biobanking is related, could be at the time of the first collection. The documents are both legislative acts with binding legal value (Regulation, European Directive, Legislative Decree, Measure, Authorization, etc.) and documents (Recommendation, Convention, Declaration, etc.) that address, recommend good practices but are not binding.

Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 (General Data Protection Regulation)

In exceptional circumstances such as an epidemic and for reasons of public interest, the Regulation temporarily allows data to be processed with the public interest as the legitimate legal basis for processing, even in the absence of consent. This does not relieve data controllers and data processors from the protection of the personal data of those involved.

https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016R0679&from=EN

NATIONAL LEVEL - FOR ITALY
Decreto legge n. 14 del 9 marzo 2020, Disposizioni per il potenziamento del Servizio sanitario nazionale in relazione all'emergenza COVID-19. In particular, art. 14.

Data collected must be processed in compliance with principles set out in Article 5 of the GDPR by adopting measures proportional to the need, taking into account the emergency situation. Article 14 of Decree-Law [No 14 of 9 March 2020] provides, until the end of the emergency [established on 31 January 2020], the possibility of simplifying certain aspects of processing of personal data [in the name of public interest in the public health sector and, in particular, to ensure protection against health emergencies by means of appropriate prophylactic measures, as well as to ensure the diagnosis and health care of those infected or the emergency management of the National Health Service]. In particular, paragraph 5 of the Article introduces the possibility to omit the information referred to in Article 13 of the GDPR or to provide simplified information, subject to oral notification of the restriction to the persons concerned. Paragraph 4 allows data controller or data processor to assign, under their own responsibility and within their organizational structure, specific tasks and functions related to the processing of personal data to expressly designated natural persons operating under their authority, in a simplified manner, including orally. "At the end of the emergency referred to in the resolution of the Council of Ministers of 31 January 2020, the persons referred to in paragraph 1 (i.e. the health care personnel) shall adopt appropriate measures to bring the processing of personal data carried out in the context of the emergency back to the ordinary powers and rules governing the processing of personal data."

https://www.gazzettaufficiale.it/eli/id/2020/03/09/20G00030/sg

EDPB - Statement on the processing of personal data in the context of the COVID-19 outbreak. Adopted on 19 March 2020

The European Data Protection Board, while recognizing that emergency is a legal condition that may legitimize restrictions on personal freedoms, clarifies that such restrictions must be proportionate and confined to the emergency period, and that in any case, data controllers and data processors must ensure the protection of the personal data of data subjects. In particular, the Board states that:

- personal data necessary to achieve the objectives pursued should be processed for specified and explicit purposes,
- data subjects should receive transparent information on the processing activities carried out and their main characteristics, including the retention period of the data collected and the purposes of the processing,

- information should be easily accessible and formulated in simple and plain language.

Not least, the measures put in place to manage the current emergency and the underlying decision-making process must be appropriately documented.

https://edpb.europa.eu/sites/edpb/files/files/file1/edpb_statement_2020_processingpersonaldataandcovid-19_en.pdf

EMA. Guidance on the Management of Clinical Trials during COVID-19 (Coronavirus) pandemic. Version 2 (27/03/2020)

By analogy, from the EMA recommendation for the management of clinical trials during COVID-19 pandemic: Changes to informed consent (8) “In case of acute life-threatening situations, where it is not possible within the therapeutic window to obtain prior informed consent from the patient (or her/his legal representatives(s)), informed consent will need to be acquired later, when this is allowed in national legislation. In these cases, the investigator is expected to report the reason why it was not possible to obtain consent from the participant prior to enrollment”.

https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-10/guidanceclinicaltrials_covid19_en.pdf

World Medical Association, Helsinki Declaration, 2013

By analogy, in the paragraph explicitly dedicated to research involving subjects physically or mentally unable of giving consent (e.g. unconscious patients) as well as establishing that research with these people can be developed only if:

- the physical or mental condition that prevents giving informed consent is a necessary characteristic of the research group and that the physician should obtain informed consent from the legally authorized representative (If the legal representative is not available and the research cannot be deferred, the study may proceed without informed consent provided that the specific reasons for involving subjects with a condition that renders them unable to give informed consent have been stated in the research protocol),
- the study has been approved by an ethics committee,

it is hereby declared that the consent of the participant for his/her stay in the research must be obtained as soon as possible from the subject or his/her legally authorized representative.

https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/

UNESCO, Universal declaration on bioethics and human rights, 2005

Article 8. Respect for human vulnerability and personal integrity

In applying and advancing scientific knowledge, clinical practice and associated technologies, human vulnerability should be taken into account. Individuals and groups of special vulnerability should be protected, and the personal integrity of such individuals respected.

https://unesdoc.unesco.org/ark:/48223/pf0000146180

Post-mortem sample collection and biobanking

National level - for Italy: LEGGE 10 febbraio 2020, n. 10. Norme in materia di disposizione del proprio corpo e dei tessuti post mortem a fini di studio, di formazione e di ricerca scientifica. The law, in force since 19 March 2020, is related to "the disposition of one's own body and post-mortem tissues for the purposes of study, training and scientific research by persons who have expressed their consent during their lifetime (art.1)". The modalities and requirements of the consent to the post-mortem donation of one's own body are established by Article 3: the declaration of consent must be drawn up, by analogy with Law n.219/2017 on informed consent and DAT, in the forms provided for the anticipated declarations of treatment (DAT), i.e. by public deed, by

authenticated private deed or by private deed delivered personally by the disponer at the Civil Status Office of the municipality of residence. In addition, the declaration of consent must be delivered to the local health authority to which it belongs, which is responsible for storing it and transmitting it electronically to the DAT database. Consent may be withdrawn at any time and in the manner described above. Unlike the law n. 219/2017, the declaration of consent to post-mortem donation provides that a trustee must be indicated, who is responsible for communicating the existence of the consent to the doctor who ascertains the death.

https://www.gazzettaufficiale.it/eli/id/2020/03/04/20G00024/sg

Recommendation CM/Rec(2016)6 of the Committee of Ministers to member States on research on biological materials of human origin. The European Recommendation, updated in 2016, states that biological materials may be removed from the body of a deceased person for storage for future research only with the consent or authorization required by law, preceded by appropriate information, including on the right to refuse. Furthermore, biological materials should not be removed for storage for future research if it is known that the deceased person objected to their post-mortem storage

https://search.coe.int/cm/Pages/result_details.aspx?ObjectId=090000168064e900

Rapporti ISS COVID-19 in Italian

Available from **https://www.iss.it/rapporti-covid-19**

1. Gruppo di lavoro ISS Prevenzione e controllo delle Infezioni.
   Indicazioni ad interim per l'effettuazione dell'isolamento e della assistenza sanitaria domiciliare nell'attuale contesto COVID-19. Versione del 7 marzo 2020.
   Roma: Istituto Superiore di Sanità; 2020 (Rapporto ISS COVID-19, n. 1/2020)

2. Gruppo di lavoro ISS Prevenzione e controllo delle Infezioni.
   Indicazioni ad interim *per un utilizzo razionale delle protezioni per infezione da SARS-CoV-2 nelle attività sanitarie e sociosanitarie (assistenza a soggetti affetti da COVID-19) nell'attuale scenario emergenziale SARS-CoV-2.* Versione del 28 marzo 2020.
   Roma: Istituto Superiore di Sanità; 2020 (Rapporto ISS COVID-19, n. 2/2020 Rev.)

3. Gruppo di lavoro ISS Ambiente e Gestione dei Rifiuti.
   Indicazioni ad interim *per la gestione dei rifiuti urbani in relazione alla trasmissione dell'infezione da virus SARS-CoV-2.* Versione del 31 marzo 2020.
   Roma: Istituto Superiore di Sanità; 2020 (Rapporto ISS COVID-19, n. 3/2020 Rev.)

4. Gruppo di lavoro ISS Prevenzione e controllo delle Infezioni.
   Indicazioni ad interim per la prevenzione e il controllo dell'infezione da SARS-CoV-2 in strutture residenziali sociosanitarie. Versione del 17 aprile 2020.
   Roma: Istituto Superiore di Sanità; 2020 (Rapporto ISS COVID-19, n. 4/2020 Rev.)

5. Gruppo di lavoro ISS Ambiente e Qualità dell'aria *indoor*.
   Indicazioni ad per la prevenzione e gestione degli ambienti indoor in relazione alla trasmissione dell'infezione da virus SARS-CoV-2. Versione del 21 aprile 2020.
   Roma: Istituto Superiore di Sanità; 2020. (Rapporto ISS COVID-19, n. 5/2020 Rev.).

6. Gruppo di lavoro ISS Cause di morte COVID-19.
   Procedura per l'esecuzione di riscontri diagnostici in pazienti deceduti con infezione da SARS-CoV-2. Versione del 23 marzo 2020.
   Roma: Istituto Superiore di Sanità; 2020. (Rapporto ISS COVID-19, n. 6/2020).

7. Gruppo di lavoro ISS Biocidi COVID-19 e Gruppo di lavoro ISS Ambiente e Rifiuti COVID-19.
   Raccomandazioni per la disinfezione di ambienti esterni e superfici stradali per la prevenzione della trasmissione dell'infezione da SARS-CoV-2. Versione del 29 marzo 2020.
   Roma: Istituto Superiore di Sanità; 2020. (Rapporto ISS COVID-19, n. 7/2020).

8. Osservatorio Nazionale Autismo ISS.
   Indicazioni ad interim per un appropriato sostegno delle persone nello spettro autistico nell'attuale scenario emergenziale SARS-CoV-2. Versione del 30 marzo 2020.
   Roma: Istituto Superiore di Sanità; 2020. (Rapporto ISS COVID-19, n. 8/2020).

9. Gruppo di Lavoro ISS Ambiente – Rifiuti COVID-19.
   Indicazioni ad interim sulla gestione dei fanghi di depurazione per la prevenzione della diffusione del virus SARS-CoV-2. Versione del 3 aprile 2020.
   Roma: Istituto Superiore di Sanità; 2020. (Rapporto ISS COVID-19, n. 9/2020).

10. Gruppo di Lavoro ISS Ambiente-Rifiuti COVID-19.
    Indicazioni ad interim su acqua e servizi igienici in relazione alla diffusione del virus SARS-CoV-2 Versione del 7 aprile 2020.
    Roma: Istituto Superiore di Sanità; 2020. (Rapporto ISS COVID-19, n. 10/2020).

11. Gruppo di Lavoro ISS Diagnostica e sorveglianza microbiologica COVID-19: aspetti di analisi molecolare e sierologica
Raccomandazioni per il corretto prelievo, conservazione e analisi sul tampone oro/nasofaringeo per la diagnosi di COVID-19. Versione del 7 aprile 2020.
Roma: Istituto Superiore di Sanità; 2020. (Rapporto ISS COVID-19, n. 11/2020).

12. Gabbrielli F, Bertinato L, De Filippis G, Bonomini M, Cipolla M.
Indicazioni ad interim per servizi assistenziali di telemedicina durante l'emergenza sanitaria COVID-19. Versione del 13 aprile 2020.
Roma: Istituto Superiore di Sanità; 2020. (Rapporto ISS COVID-19, n. 12/2020).

13. Gruppo di lavoro ISS Ricerca traslazionale COVID-19.
Raccomandazioni per raccolta, trasporto e conservazione di campioni biologici COVID-19. Versione del 15 aprile 2020.
Roma: Istituto Superiore di Sanità; 2020. (Rapporto ISS COVID-19, n. 13/2020).

14. Gruppo di lavoro ISS Malattie Rare COVID-19.
Indicazioni ad interim per un appropriato sostegno delle persone con enzimopenia G6PD (favismo) nell'attuale scenario emergenziale SARS-CoV-2. Versione del 14 aprile 2020.
Roma: Istituto Superiore di Sanità; 2020. (Rapporto ISS COVID-19, n. 14/2020).

15. Gruppo di lavoro ISS Farmaci COVID-19.
Indicazioni relative ai rischi di acquisto online di farmaci per la prevenzione e terapia dell'infezione COVID-19 e alla diffusione sui social network di informazioni false sulle terapie. Versione del 16 aprile 2020.
Roma: Istituto Superiore di Sanità; 2020. (Rapporto ISS COVID-19, n. 15/2020).

16. Gruppo di lavoro ISS Sanità Pubblica Veterinaria e Sicurezza Alimentare COVID-19.
Animali da compagnia e SARS-CoV-2: cosa occorre sapere, come occorre comportarsi. Versione del 19 aprile 2020.
Roma: Istituto Superiore di Sanità; 2020. (Rapporto ISS COVID-19, n. 16/2020).

17. Gruppo di lavoro ISS Sanità Pubblica Veterinaria e Sicurezza Alimentare COVID-19.
Indicazioni ad interim sull'igiene degli alimenti durante l'epidemia da virus SARS-CoV-2. Versione del 19 aprile 2020.
Roma: Istituto Superiore di Sanità; 2020. (Rapporto ISS COVID-19, n. 17/2020).

18. Gruppo di lavoro ISS Ricerca traslazionale COVID-19.
Raccomandazioni per la raccolta e analisi dei dati disaggregati per sesso relativi a incidenza, manifestazioni, risposta alle terapie e outcome dei pazienti COVID-19. Versione del 26 aprile 2020.
Roma: Istituto Superiore di Sanità; 2020. (Rapporto ISS COVID-19, n. 18/2020).

19. Gruppo di lavoro ISS Biocidi COVID-19.
Raccomandazioni ad interim sui disinfettanti nell'attuale emergenza COVID-19: presidi medico-chirurgici e biocidi. Versione del 25 aprile 2020.
Roma: Istituto Superiore di Sanità; 2020. (Rapporto ISS COVID-19, n. 19/2020).

20. Gruppo di Lavoro ISS Prevenzione e Controllo delle Infezioni.
Indicazioni per la sanificazione degli ambienti interni per prevenire la trasmissione di SARS-COV 2. Versione dell'8 maggio 2020.
Roma: Istituto Superiore di Sanità; 2020. (Rapporto ISS COVID-19, n. 20/2020).

21. Ricci ML, Rota MC, Scaturro M, Veschetti E, Lucentini L, Bonadonna L, La Mura S.
Guida per la prevenzione della contaminazione da Legionella negli impianti idrici di strutture turistico recettive e altri edifici ad uso civile e industriale, non utilizzati durante la pandemia COVID-19. Versione del 3 maggio 2020.
Roma: Istituto Superiore di Sanità; 2020. (Rapporto ISS COVID-19, n. 21/2020).

22. Gruppo di lavoro ISS Salute mentale ed emergenza COVID-19
Indicazioni ad interim per la gestione dello stress lavoro-correlato negli operatori sanitari e socio-sanitari durante lo scenario emergenziale SARS-COV-2. Versione del 7 maggio.
Roma: Istituto Superiore di Sanità; 2020. (Rapporto ISS COVID-19, n. 22/2020)

23. Gruppo di lavoro ISS Salute mentale ed emergenza COVID-19
Indicazioni di un programma di intervento dei Dipartimenti di Salute Mentale per la gestione dell'impatto dell'epidemia COVID-19 sulla salute mentale. Versione del 6 maggio 2020.
Roma: Istituto Superiore di Sanità; 2020. (Rapporto ISS COVID-19, n. 23/2020).