

BBMRI-ERIC ELSI SERVICES & RESEARCH

Q&A COVID-19 & ELSI V1

The world is facing an unprecedented public health challenge with the COVID-19 pandemic; this has necessitated numerous efforts being deployed by governments, health agencies and individual institutions – including in the biobanking community – to develop effective tests, toolkits, treatments and vaccines to stem its spread and help fight it. To achieve this goal, the collection, analysis and timely sharing of samples and related data becomes instrumental in collective global research efforts. Aligned to these efforts is the prevalence for automated data processing and digital technologies such as location data and contact tracing applications as part of the toolkits. In this respect, biobanks are important infrastructures for access to these samples and data. Besides availability, quality and technical infrastructures, also ethical, legal and societal issues (ELSI) are particularly crucial in this regard. Public health ethics, personal data protection, ethics of data sharing, protection of consent and vulnerability as well as compliance issues within international data sharing have gained urgency in COVID-19 research. Against this backdrop, BBMRI-ERIC ELSI Services & Research held a webinar that took a closer look at these issues. The webinar took place on April 24th, 2020; the recording is available [here](#).

This document not only answers the questions posed during the webinar but ventures into much detail on the topics raised as a result. It also showcases two examples from Germany (presented by Prof. Roland Jahns) and Italy (presented by Prof. Marialuisa Lavitrano), as well as a detailed commentary on contact-tracing-apps from a legal perspective (presented by Gauthier Chassang). The document thus lays the foundation for further discussion on ELSI and COVID-19 in the context of biobanking.

This is a living document. If you have additional questions or if you want to share further insights or cases from your national node, please contact us: elsi@helpdesk.bbmri-eric.eu

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Q1: IS BROAD CONSENT APPLICABLE FOR PATIENTS IN INTENSIVE CARE UNITS? (I.E. INTUBATED/UNCONSCIOUS PATIENTS, PATIENTS IN SEVERE DISTRESS AND/OR SHORTNESS OF BREATH)?

Consent is one of the legal bases for processing data as provided for in **Art. 6 GDPR**. It must be freely given, specific, informed and unambiguous and can be withdrawn at any time by the data subject. See further **Article 29 Working Party, Guidelines on consent under Regulation 2016/679, Adopted on 28 November 2017, as last Revised and Adopted on 10 April 2018 [or “Guidelines on Consent”]**.

During the COVID-19 outbreak, when consent is sought directly at the time of data collection in the healthcare context, patients may be seen as vulnerable people and the consent may not be valid under the GDPR because of the imbalance between the data controller and data subject. This is expressly explained within the European Data Protection Board (EDPB) **“Guidelines on Consent” document** at **Page 9** where it is stated, *“As highlighted by Working Party 29 in several Opinions, consent can only be valid if the data subject is able to exercise a real choice, and there is no risk of deception, intimidation, coercion or significant negative consequences (e.g. substantial extra costs) if he/she does not consent. Consent will not be free in cases where there is any element of compulsion, pressure or inability to exercise free will”*.

Though cautiously, the EDPB (which replaced Working Party 29) suggests that consent to non-interventional research obtained by researchers would be legitimate as long as there was no pressure or threat of disadvantage. Yet, the EDPB does not specify if this may be affected by the severity of illness or by the consent being obtained by the treating physician. In such circumstances, in which patients are critically ill, it may be impracticable to obtain their consent. A broad consent may, however, be the way to circumvent the strict requirement that consent be “specific”, especially when it is improbable to identify the purpose of personal data processing for scientific research at the time of data collection (**Recital 33 GDPR**). However, caution must be employed as not all data protection regulators would acknowledge these broad purposes as satisfying consent requirements without a subsequent consenting of individual projects. It is advised that where the specific research purpose cannot be readily established, other ways should be found to ensure that consent is provided.

With this in mind, it is germane to state that the EDPB in its most recent guidelines on COVID-19 makes no mention of “additional consents” for broad consent that may be suitable for research

related to a pandemic. See further: [European Data Protection Board, Guidelines 03/2020 on the processing of data concerning health for the purpose of scientific research in the context of the COVID-19 outbreak \(Adopted 21 April 2020\) \[or “EDPB COVID-19 Research Guidelines”\]](#)

In this vein, the logic behind the views of some data protection regulators insisting on “additional consents” for broad consent links into the intersection of the purpose limitation principle and processing for research. Provided processing for research purposes is not incompatible with the initial purpose, data may be further processed for such research with appropriate safeguards (**Art. 5.1.b GDPR**). Where consent is the legal basis relied upon, this broadening of the purpose limitation principle for research purposes is key. Thus, a failure to do this means any secondary use of data for research purposes would always require obtaining consent from the data subject.

In conclusion, a very important piece of advice for researchers who are tasked with the collection and processing of data for research on COVID-19 is the existence of other legal bases apart from consent, such as that which supports processing to fulfill a legal obligation to which the controller is subject (**Art. 6.1.c GDPR**), supports processing in the vital interest of a data subject or another natural person (**Art. 6.1.d GDPR**), or supports a task performed in the public interest (**Art. 6.1.e GDPR**). Of these, the latter is the preferred option: this view is supported by the EDPB as more appropriate than consent for research in clinical trials. See further: [European Data Protection Board, Opinion 3/2019 concerning the Questions and Answers on the interplay between the Clinical Trials Regulation \(CTR\) and General Data Protection Regulation \(GDPR\)](#)

CASE FROM GERMANY:

There is much societal support for efforts to develop a drug or vaccine against COVID-19. Considering this, even if the patient is in distress, if they agree that samples will be taken for the advance of research and therapies, then this could be ethically acceptable, since drawing blood samples for research is only done within the frame of routine venipuncture. The relevant parameters that are obtained from the analysis of the blood would be additional to necessary parameters, such as blood count. In the case that the patient revokes this afterwards permission, the additional samples would be destroyed, and data anonymized or deleted.

CASE FROM ITALY:

(Please note: There is no broad consent for biobanking in Italy.)

While healthcare professionals are trying their best to respond to the challenge by treating the patients as their highest priority, efficient and quality storage of samples for research is essential to end the crisis in the long run. Beyond informative resources for the general public, BBMRI.it, the Italian National Node of BBMRI-ERIC, was involved in ensuring which resources (data and samples) would be available for research at national and international levels, by providing recommendations for collection, transport and storage of biological samples, as well as IT and ELSI support. A national ELSI group developed a simplified informed consent prototype for COVID-19 biobanking.

COVID-19 biobanking was key from the very beginning of the outbreak, although critical to be finalized both for the difficulty of collecting consent in such an emergency situation and for the ethical requirements required by the committees. The aim was to develop an informed consent for the collection, storage and use of biological materials specifically for COVID-19 research as well as to share a simplified procedure to support the healthcare personnel. The prototype contains all the information needed to allow the patient to understand and to provide consent for COVID-19 biobanking. The collection can be done in an emergency like triage or when a patient is hospitalized in an intensive care unit. It is possible to inform the patient orally of the short-term collection of samples and to defer written consent at the time of stabilization or when the patient is in a better condition. 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/her samples for scientific research in the COVID-19 pandemic. The collection of consent is postponed until stabilization and/or discharge").

The Regulatory-Ethical Framework in Italy supporting this is [Decreto Legge n. 14 del 9 marzo 2020, Disposizioni per il potenziamento del Servizio sanitario nazionale in relazione all'emergenza COVID-19](#). 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. [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](#)

Q2: HOW IS BROAD CONSENT APPLICABLE TO ELDERLY PEOPLE THAT CAN HAVE THEIR COGNITIVE CAPACITIES IMPAIRED (E.G. DEMENTIA)?

A: This relates to the answer given in **Q1** above.

CASE FROM GERMANY

The situation is relieved if the patient already has a patient's provision or a person determined who can make decisions for the patient. Even in the Intensive Care units and even from our Italian patients (because we have currently five or six or intubated patients from Italy here in our hospital) by this manner we were able to get biosamples according to a schedule (scheme) we decided together with our immunologists, virologists and the implicated medical staff. In addition, for bio-sampling we have different entry points for COVID-19 patients in the hospital: Urgencies, Isolation Ward, and the IC-units.

Q3: WHAT TO DO WHEN A PATIENT DIES BEFORE HAVING BEEN ABLE TO GIVE CONSENT AND AFTER MATERIAL HAS ALREADY BEEN COLLECTED?

It may be useful to remember that the **Recommendation [CM/Rec\(2016\)6](#) of the Committee of Ministers to member States on research on biological materials of human origin**, updated in 2016, specifies in **Article 12 and Article 14 that biological materials from persons who are not able to consent** may be removed from the body of a deceased person for storage for future research only with the consent or authorization provided for by (national) 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.

CASE FROM ITALY:

In Italy, when a patient dies without giving their consent, the material should be anonymized, or, thanks to specific prescriptions concerning the processing of personal data for purposes of medical, biomedical and epidemiological research, when the processing is necessary for the conduct of studies carried out with data/samples previously collected for health care purposes, the research must be carried out on the basis of a project, which has been positively evaluated by the competent ethics committee at territorial level. Where it is not possible to obtain the consent of the persons concerned, because they are deceased, the data controller must document this as an exceptional reason in the research project.

Q4: ARE SAMPLES FROM CHILDREN (ESPECIALLY UNDER 15 YEARS OLD) BEING COLLECTED?

CASE FROM ITALY:

Although there are very few cases of young children affected by COVID-19, there is an initiative at the Bambino Gesù Hospital in Rome, where samples from children under the age of 12 are collected. For these cases there is a specific informed consent form for parents and for mature children (14-18 years old). The pediatrician decides whether and how to inform the children about the collection of samples.

CASE FROM GERMANY:

The results of research utilizing samples from young children will be very important to understand why this virus is less infectious for children than for adults. In Germany, there are several initiatives from the Pediatric Society that involve data collection from children.

Q5: REGARDING DATA SHARING ONCE THE CRISIS IS OVER, ARE ANY PARTICULAR PRECAUTIONS BEING TAKEN DURING THE COLLECTION PROCEDURE WHICH SHOULD BE INCLUDED IN THE CONSENT FORM TO INFORM THE PATIENTS?

Any consent form should include a specific paragraph including information about the fact that data will be shared in agreement with the GDPR.

Q6: WHAT ARE THE SPECIFIC RECOMMENDATIONS BY THE GDPR CONCERNING HOW TO DEAL WITH PROJECT PARTNERS IN THE US?

Transfer of personal data outside of the EU is dealt with in **Chapter V of the GDPR**. Data controllers planning to transfer personal data to a non-EU/EEA country or international organization (including for onward transfers of personal data from the third country or an international organization to another third country or to another international organization) must be aware of the limitations imposed by the GDPR. Notwithstanding, instruments exist which can be employed for lawful international data transfer. In the context of a pandemic, an adequacy decision granted by the European Commission allows international data exchange under the same conditions as that which applies within the EEA. See further **Art. 45 GDPR**. Furthermore, in the absence of an adequacy decision, data can still be transferred internationally if the data controller or processor have appropriate safeguards in place (**Art. 46 GDPR**). In this respect, a legally binding and enforceable instrument between public authorities and bodies may suffice as a satisfactory safeguard for data transfer between health agencies (**Art. 46.2.a GDPR**). Some institutions may also rely on the standard contractual clauses provided by the European Commission (**Art. 46.2.c GDPR**). This option may be less suitable especially when it comes to negotiating indemnification and jurisdiction clauses with some US government departments, public universities or other healthcare institutions.

Similarly, contractual clauses between the data controller and recipient that are authorized by a data protection regulator and subsequent approval by the European Commission (**Art. 46.2.d GDPR**). A lingering weakness of this method may be the difficulty to negotiate or receive authorization on time.

Another instrument available is derogations for specific situations as provided for in **Art. 49 GDPR**. Cross-border transfers can be legitimated by explicit consent (**Art. 49.1.a GDPR**). Following the guidelines given by the EDPB, explicit consent may only be suitable for private entities conducting COVID-19 research but provides no further guidance. See further **EDPB COVID-19 Research Guidelines**. Even if this was feasible, it does still create a practical barrier that has to be overcome such as that which specifies that consent is only valid upon the data controller informing the data subject of the possible risks of such transfers due to the absence of an adequacy decision and appropriate safeguards. **See further European Data Protection Board. Guidelines 2/2018 on derogations of Article 49 under Regulation 2016/679 (Adopted 25 May 2018) [or “Article 49 Guidelines”].**

A further solution could be centered around transfers necessary for important reasons of public interest (**Art. 49.1.d**); wherein this public interest is recognized in Union law or national law to which the data controller is subject (**Art. 49.4**). Although this might yet become the way to solve cross-border collaborative efforts pertaining to the COVID-19 outbreak, the EDPB also cautions that transfers according to this derogation shall ‘not become the rule in practice’, be restricted to ‘specific situations’, and be ‘strictly necessary’ for the purposes for processing. See further **Article 49 Guidelines**.

Therefore, in the compelling circumstances of the COVID-19 outbreak, the EDPB has conceded “that the fight against COVID-19 has been recognised by the EU and most of its Member States as an important public interest”, with supporting premises on the provisions of EU law interpreted from the viewpoint of the responses by its Member States to this crisis. It is worth noting that this stance taken by the EDPB may be opened to the test based on the fragmented interpretations of the national law of its Member States. See further **EDPB COVID-19 Research Guidelines**.

Q7: REGARDING TRACKING APPS, WHICH KIND OF PRACTICAL INFORMATION WOULD BE USEFUL TO SHARE WITH THE GENERAL PUBLIC IN ORDER TO SHOW HOW THESE APPS COMPLY WITH THE GDPR?

The EDPB has actively engaged on this topic. The EDPB has previously provided guidance to organizations and to individuals regarding aspects of personal data processing and COVID-19. Since the COVID-19 outbreak, apart from the adoption of its [**EDPB COVID-19 Research Guidelines**](#), it has also published [**Guidelines 04/2020 on use of location data and contact tracing tools in the context of the COVID-19 outbreak \[or “EDPB Tracing Guidelines”\]**](#).

Following the EU's **EDPB Tracing Guidelines**, data protection regulators have also issued guidance in this area. For example:

- The French CNIL issued an opinion regarding contact-tracing mobile applications based on Bluetooth technology, confirming that such apps would entail personal data processing (pseudonymized data) and that GDPR rules apply. In brief, personal data processing should be voluntary and could be either legally based on data subjects' informed consent according to Article 9(2)(a) GDPR or on Article 9(2)(i) GDPR regarding processing necessary for reasons of public interest in the area of public health. The CNIL position favours the second legal basis as an appropriate legal basis for such processing pursuing a public health interest but does not exclude the possibility to base the processing on explicit consent. In any case, users must receive prior information by data controller in the respect of Article 12 to 14 GDPR and data subjects shall be able to exercise their rights in the respect of provisions from Article 12 to 22 GDPR. Discussions are still ongoing on this specific topic. See further [Délibération n° 2020-046 du 24 avril 2020 portant avis sur un projet d'application mobile dénommée « StopCovid »](#). See also [Opinion from the CNPEN Enjeux d'éthique concernant des outils numériques pour le déconfinement du 14 mai 2020](#), which supports the practice of explicit consent for such digital tools.
- The UK's Information Commissioner issued an opinion in response to the joint effort announced by Apple and Google to enable the use of Bluetooth technology to help governments and health agencies reduce the spread of COVID-19 by building contact tracing technology into iOS and Android smartphones. See further <https://ico.org.uk/media/about-the-ico/documents/2617653/apple-google-api-opinion-final-april-2020.pdf>

We thank the experts for their valuable contributions!

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