Heidelberg University Hospital | Institute of Immunology,

Institute of Immunology

Prof. Dr. med. S. Meuer  
Medical Director

**Principal Investigators:**

**Prof. Dr. med. C. Süsal**

Institute of Immunology

Tel: +49 6221-564013

[caner.suesal@med.uni-heidelberg.de](mailto:caner.suesal@med.uni-heidelberg.de)

**Prof. Dr. med. Christian Morath**

Department of Nephrology

Tel: +49 6221 9112 0

christian.morath@med.uni-heidelberg.de

Collaborative Transplant Study | INF 305 | 69120 Heidelberg

Patient-ID

**Collaborative Transplant Study Covid-19 Serum Study**

**“Antibody formation against the transplant after SARS-CoV-2 infection”**

***Declaration of consent***

***by legal representatives of transplanted patients with SARS-CoV-2 infection***

I read the information leaflet and was also informed verbally by Mr/Mrs \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ about the aim and procedure of the study as well as about the risks in a detailed and comprehensible way. During the information session I had the opportunity to ask questions. All my questions were answered to my satisfaction. As the legal representative of the above-mentioned patient, I agree on his/her behalf to participate in the study. I had sufficient time to make my decision. I received a copy of the information leaflet and the consent form.

I agree to be informed about incidental medical findings regarding the patient in my care:

1. Yes □
2. Yes, in case of possible prevention or early

treatment of diseases □

1. No □

**Data Protection**

**I am aware that personal data will be processed in this study. The data will be processed in accordance with legal regulations and requires the following declaration of consent in accordance with Art. 6 Para. 1 lit. a of the General Data Protection Regulation (GDPR):**

**I was informed and voluntarily consent that the data collected in the study regarding the patient in my care, in particular information about his/her health**[[1]](#footnote-1)**, may be recorded in pseudonymized form, evaluated and, if necessary, also passed on in pseudonymized form to university clinics or cooperation partners for the purposes described in the information notice, possibly also in countries with lower data protection requirements than in the European Union. Third parties will not be given access to personal documents. When results of the study are published, the name of the patient in my care will not be mentioned. Personal data will be anonymized as soon as this is possible according to the research purpose. The data collected during the study will be stored in the database of the Collaborative Transplant Study in Heidelberg according to "Good Clinical Practice (GCP)" guidelines. I am aware that this consent can be revoked in writing or verbally at any time without giving reasons and without any disadvantages for the patientinmy care. The lawfulness of the data processing carried out until the revocation is not affected by this. In this case, I can decide whether the collected data should be deleted or may continue to be used for the purposes of the study. Should the patient in my care regain the capacity to consent, he or she will be informed again about the idea and purpose of the study and may then also withdraw his or her consent.**

**We are asking for a very broad permission to use the biomaterials and data of the patient in your care. These will be provided for medical research that will lead to new insights in understanding the effects of SARS-CoV-2 infection in organ transplant patients. The data will be used in organ transplant research. If you do not fully agree with the described type and duration of data and biomaterial use, you should not give your consent. Because the results obtained in this study may play an important role in the treatment of organ transplanted patients with SARS-CoV-2 infection and further studies may be necessary, the exact retention period of the biomaterials and data cannot be specified. Therefore, the biomaterials and data will be kept indefinitely and made available for further medical research. We will review every five years whether further retention of the biomaterials and data is still necessary. The personal data will be anonymized as soon as this is possible according to the research purpose. You have the right to make individual restrictions (e.g., exclusion of certain research, exclusion of disclosure of the materials to third parties) in your consent form.**

I would like to limit the use of the patient's data in my care for other/future research purposes as follows:

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**I was informed and voluntarily consent that the data collected in the study concerning the patient in my care, in particular information about his/her health and genetics, may be used and also passed on for the purposes described in the information document (if not desired, please delete!).**

I would like to limit the use of the data for other/future research purposes as follows:

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

I consent to the collection of personal and medical data by the following physicians for the purposes of the study. In this respect, I release the respective physicians from their medical confidentiality (please delete if not desired).

Please enter below the contact data of the physicians you want to release from medical confidentiality for the disclosure of health-related data:

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Place, date Last, first name of the study participant in print

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Participant number Last, first name of the legal representative of the study

participant in print

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of the legal representative

**Informing person**

The patient's legal representative was informed by me in an interview about the aim and procedure of the study as well as the risks. I provided the legal representative with a copy of the information leaflet and the declaration of consent.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Place, date Last, first name of the informing person in print

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of informing person

1. In accordance with Art. 9 Para. 1 GDPR, health-related data are personal data of a special category the processing of which requires the explicit consent of the study participant. The same applies to data revealing racial and ethnic origin, political, religious or ideological opinions or trade union membership as well as processing of genetic data, biometrical data for unambiguous identification of a natural person, data on sex life and sexual orientation. [↑](#footnote-ref-1)