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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 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. I agree to voluntarily participate in the study. I had sufficient time to make my decision. I have received a copy of the information leaflet and the declaration of consent.

I agree to the reporting of incidental medical findings:

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 during this study. The processing of the data is carried out in accordance with legal provisions and requires the following declaration of consent in accordance with Art. 6 Para. 1 lit. a of the General Data Protection Regulation (GDPR):**

**I have been informed and voluntarily consent that my data collected in the study, in particular information about my health**[[1]](#footnote-1) **, may be recorded in pseudonymized form for the purposes described in the information notice, evaluated and, if necessary, also passed on in pseudonymized form to university clinics or cooperation partners, possibly also in countries with lower data protection requirements than in the European Union. Third parties will not be given access to personal documents. My name will not be mentioned when results of the study are published. 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 at any time in writing or verbally without giving reasons and without any disadvantages for me. The lawfulness of the data processing carried out until the revocation is not affected by this. In this case, I may decide whether the data collected from me should be deleted or may continue to be used for the purposes of the study.**

**We are asking for very broad permission to use your biomaterials and data. These are being provided for medical research that will lead to new insights in understanding the effects of SARS-CoV-2 infection in organ transplant patients. They will be used in the spirit of maximizing public benefit in organ transplant research. If you do not fully agree with the described type and duration of 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 my data for other/future research purposes as follows:

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

**I have been informed and voluntarily consent that my data collected in the study, in particular information about my health and genetics, may be used and also disclosed for the purposes described in the information document (if not desired, please delete!).**

I would like to limit the use of my 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 Signature of the participant

**Informing person**

The patient was informed by me in a discussion about the aim and procedure of the study and about the risks. I gave the patient a copy of the information leaflet and the declaration of consent.

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

Place, date Last, first name of the informing person

(in print)

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

Signature of the 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)