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Collaborative Transplant Study | INF 305 | 69120 Heidelberg, Germany

Patient Label

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

**"Antibody formation against the graft after SARS-CoV-2 infection"**

***Information Handout***

***for transplanted patients as a control group for patients with***

***SARS-CoV-2 infection after transplantation***

Dear Patient

By this letter we invite you to participate in the above mentioned multicenter study. Please read the following information carefully. On this basis, you can decide whether you would like to participate or not. Allow yourself sufficient time and ask the study staff any questions that are important to you. The study is funded by the Institute of Immunology in Heidelberg. In addition, project funding from third parties is sought. There are no conflicts of interest (both financial and personal) for any department or individual involved in the study.

**What is the objective of the study?**

In this study, we would like to investigate whether

(a) patients with a history of Corona Virus (SARS-CoV-2) infection before or after organ transplantation are more likely to develop antibodies against their transplant than control patients without infection depending on the severity of the disease

b) the formation of such graft-damaging antibodies affects the function of your transplant.

Furthermore, we would like to analyze how the subgroups of antibodies formed by patients with SARS-CoV-2 infection against the Corona virus change during the course of the disease and whether these changes have an impact on the course of the disease.

For the greater validity of a study, it needs a control group to better assess differences between transplanted patients with SARS-CoV-2 infection versus transplanted patients without SARS-CoV-2 infection. **You, as a transplanted patient without having experienced SARS-CoV-2 infection, would be suitable as a control patient to make clearer statements regarding the effects of SARS-CoV-2 infection in transplanted patients later on.**

After transplantation, new formation of graft-damaging antibodies may occur, which has been shown to increase the risk of rejection. We would like to investigate whether transplanted patients with SARS-CoV-2 infection form such graft-damaging antibodies more frequently.

Other aspects we would like to analyze include the influence of blood group and tissue characteristics on the incidence and severity of Covid-19 as well as the impact of the decrease in SARS-CoV-2 antibody strength on the severity of Covid-19 in transplanted patients. The question is whether there are genetically determined factors (such as blood type or various tissue characteristics) that influence the occurrence and severity of Covid-19. Therefore, in order to answer this question, specific testing of genetic material (blood) will be needed. At this time, it is not possible to predict which genetic variants might influence the occurrence and progression of Covid-19; thus, it is difficult to narrow down the scope of genetic testing. We would also like to investigate whether certain subsets of SARS-CoV-2 antibodies correlate with better control (neutralization) of the virus.

Until now, studies on these questions in transplanted patients have either not been performed at all or did not meet the necessary numerical requirements. The international Collaborative Transplant Study coordinated by us, in which more than 150 liver and kidney transplant centers from all over the world are actively participating, offers the unique opportunity to gather reliable information on the effects of Corona infection on organ transplantation outcomes in a relatively short time. We would like to subsequently make these results available to transplant centers for the benefit of transplanted patients.

**How does the study work?**

For you as a transplanted patient without SARS-CoV-2 infection, two additional tubes of blood (approximately 15 – 20 ml) will be taken during routine follow-up for testing of the immune activation marker sCD30, transplant-damaging and SARS-CoV-2 antibodies as well as the accurate typing of tissue characteristics (HLA antigens).

Another study-related blood sampling will take place one year after the first study-related blood collection, at which time an additional blood sample will again be taken (approximately 10 ml) to examine the development of the immune parameters mentioned above (sCD30, graft-damaging antibodies, and SARS-CoV-2 antibodies).

From experience we know that the collection of the additional blood samples requires less than 1 minute in addition. Experience has shown that the time required for explaining the study and discussing participation and consent can be expected to be 15 minutes depending on the amount of information required. The study-related additional collection of 10 to a maximum of 20 ml of blood will usually have only a minor effect on the total blood volume and your general condition.

**Do I have a personal benefit?**

Since the findings are only elaborated within the framework of the study and the examination will be pseudonymized[[1]](#footnote-1), there will be no direct individual benefit for you. It is planned to publish the results in medical or biological journals and to present the study at national and international congresses for further discussion of the results.

**What are the risks associated with participation?**

A small amount of blood will be taken from you three times at the most. Adverse effects or risks are not expected from the blood collection and the amount of blood collected. All blood collections will be obtained as part of routine care. No additional study-related punctures will occur. Blood sampling may cause local irritation, infection, bleeding as well as bruising in addition to mild pain from the puncture in rare cases. There is also a risk of nerve injury with superficial numbness. All these risks have nothing to do with this study, but represent general risks of blood collection.

According to the current state of science, the occurrence of incidental findings is unlikely. Nevertheless, incidental findings may occur in the course of the examinations of the material obtained. In principle, this may result in indications of already existing or future diseases that are not related to the objectives of the study (incidental findings). We will inform you about such findings upon request. However, the notification of incidental findings may have far reaching, even negative consequences for you and your blood relatives' further life. For example, you may be required to provide this information when taking out insurance policies or during a health examination with the aim of obtaining a civil service position. Not least because of these potentially negative consequences, but also because of the constitutionally guaranteed right not to know, the decision on how to deal with such findings is left to you. Therefore, if you do not wish to be informed about incidental findings or only those that are likely to have the potential to prevent or treat disease at an early stage, please tick the appropriate option as part of the consent form. All data will be treated strictly confidentially and will only be evaluated in pseudonymized form.

**Privacy information**

General:

Medical confidentiality and data protection regulations are observed. During the study, medical findings and personal information will be collected from you and written down in your personal file or stored electronically at the trial site. The data important for the study will additionally be stored in pseudonymized (encrypted) form, evaluated and, if necessary, passed on to university clinics and cooperation partners, possibly also in countries where data protection requirements are lower than in the European Union.

The study management will take all reasonable steps to ensure the protection of your data in accordance with European Union data protection standards. The data is secured against unauthorized access. Decryption will only occur in the event of withdrawal from the study for the purpose of data destruction. As soon as possible according to the research or statistical purpose, personal data will be anonymized [[2]](#footnote-2). Data collected during the study will be kept indefinitely in the Collaborative Transplant Study database in Heidelberg for use in future scientific studies. Any biological material from you that is not needed will also be asserved indefinitely under a pseudonym at the study center after the study is completed in order to evaluate further biomarkers in Covid-19 research in the future. These include, for example, studies of tissue characteristics, blood group and genetic information important for organ transplantation. As soon as possible according to the research purpose, the samples will be pseudonymized. If you do not agree to the use of data for future research purposes, you can restrict your declaration of consent. The retention period of the biomaterials and data cannot be stated precisely, as it is currently not foreseeable which studies on the study blood regarding organ transplanted patients with SARS-CoV-2 infection might be relevant in the future. As a consequence, the biomaterials will be kept until further notice and made available for further medical research regarding transplanted patients with SARS-CoV-2 infection. 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 possible according to the research purpose.

Your data and samples may also be passed on to recipients in countries outside the EU (clinics, cooperation partners) if one of the following conditions is met:

a. The European Commission has determined that the country has an adequate level of data protection under the law.

b. On the part of the study director, contractual data protection clauses have been agreed with the research partners which have been adopted or approved by the European Commission or the competent supervisory authority. You may obtain a copy of these data protection clauses from the study managers mentioned below.

In addition, however, data and samples may also be transferred to research partners in third countries for which neither of these two requirements is met. These countries **may** have **a lower level of data protection than the EU**. The study managers mentioned below assure that, also in these cases, the research partners will be contractually obliged, as far as legally possible, to comply with the EU data protection level. Nevertheless, there is a risk that government or private agencies may access your data even though this would not be permitted under European data protection law. In addition, you may be subject to fewer or less enforceable data subject rights in these countries and there may be no independent supervisory authority to assist you in exercising your rights. **In this case, your samples and data can only be passed on if you have given your explicit consent. If you do not agree, you may delete the respective marked paragraph in the declaration of consent.**

We would like to point out that there is currently a high and also legitimate interest in Covid-19 research. Through good cooperation with other transplant centers, we hope to obtain as much data as possible regarding Covid-19 infections in transplanted patients as soon as possible. This requires an exchange of data between different transplant centers. We would like to point out again that the data important for the study will be stored in pseudonymized (encrypted) form, evaluated and, if necessary, passed on to university clinics and cooperation partners, possibly also in countries where data protection requirements are lower than in the European Union.

You have the right to request information from the persons responsible (see below) about the personal data stored about you. Likewise, you can request the correction of inaccurate data and the deletion of data or restrictions on their processing.

The persons responsible for the study-related collection of personal data are:

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If you have any concerns about data processing and compliance with data protection requirements, you may contact the following data protection officer at the facility:

Dr. jur. Regina Mathes

Im Neuenheimer Feld 672

69120 Heidelberg

Tel.: 06221/56-7036

datenschutz@med.uni-heidelberg.de

In the event of unlawful data processing, you have the right to lodge a complaint with the following supervisory authority:

The State Commissioner for Data Protection and Freedom of Information of Baden-Württemberg

P.O. Box 10 29 32, 70025 Stuttgart

Königstraße 10a, 70173 Stuttgart

Tel.: 0711/61 55 41 - 0

Fax: 0711/61 55 41 - 15

E-mail: poststelle@lfdi.bwl.de

Internet: http://www.baden-wuerttemberg.datenschutz.de

For the purposes of the study, it is useful to include data from your medical records with your physicians in charge. We would like to ask you to agree to an excerpt of the transplantation-relevant data being passed on to the study management and to release your physicians in charge from the medical confidentiality in this respect.

Any collection, storage and transmission of data from your biomaterials in the context of research projects involves confidentiality risks (e.g. the possibility of identifying you), especially with regard to information on your genetic make-up. These risks cannot be completely excluded and increase according to the amount of data that can be linked, especially if you yourself publish genetic data on the Internet (e.g. for genetic research). The study management assures you that it will do everything possible according to the state of the art to protect your privacy and that samples and data will only be passed on to projects that can demonstrate a suitable data protection concept.

**Voluntariness / Resignation**

Participation in the study is voluntary. If you wish to participate, we ask you to sign the enclosed consent form. You may revoke this consent at any time in writing or verbally without giving reasons and without incurring any disadvantages. If you wish to withdraw your consent, please contact the study director or the staff in charge of your treatment. If you revoke your consent, you may decide whether the data collected from you for study purposes should be deleted and the samples obtained should be destroyed or whether they may continue to be used for the purposes of the study. Even if you initially agree to further use, you may still change your mind later and request deletion of the data or destruction of the samples; please also contact the study management or the staff in charge of your treatment.

Please note that data that have already been included in scientific evaluations or data or samples that have already been anonymized can no longer be deleted or destroyed at your request.

**Do I incur any costs as a result of my participation? / Do I receive payment or reimbursement of expenses?**

Participation in the study is free of charge for you. However, you will not receive any payment either as the study participation is part of the general transplant follow-up care.

**More information**

For further information as well as for information on general results and the outcome of the study, please contact the following persons:

Responsible Study Physician:

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**We would be grateful for your participation in this research project!**

1. "Pseudonymization" means the processing of personal data in such a way that the personal data can no longer be attributed to a specific data subject without the use of additional information ("key"). This additional information is kept separately and is subject to technical and organizational measures that ensure that the personal data cannot be assigned to an identified or identifiable natural person. [↑](#footnote-ref-1)
2. "Anonymization" is the alteration of personal data in such a way that the data subject can no longer be identified or can only be identified at a disproportionate cost or time. [↑](#footnote-ref-2)