COVID-19 IN IMMUNOSUPPRESSED CHILDREN

July 1st 2020

INFORMED CONSENT

INITIAL INFORMATION

In this hospital, research on infection caused by Coronavirus in transplanted children is being carried out and we would like to invite your child to be part of this study. It is important that you read carefully and understand the following information about the study. Please ask any questions you want. You must read and sign this consent form before you can participate.

CONTEXT AND OBJECTIVES OF THE STUDY

This research is designed to assess whether your child has an asymptomatic infection with the new Coronavirus and, in case of symptoms, what symptoms were these, how did this infection alter laboratory tests and imaging tests (X-ray, tomography or magnetic resonance) and how it evolved. This study is very important and has already been approved by the Research Ethics Committee responsible for this hospital.

HOW MY CHILD'S PARTICIPATION WILL BE

For the study we will collect data from the medical record, which are usually recorded during the outpatient consultation or hospitalization. If your child does not have any signs or symptoms of infection with the new Coronavirus, we will collect only a drop of blood through a pinprick with a needle on the tip of one of the fingers or maybe this is not even necessary, as we can take the opportunity to remove a drop of blood if he/she takes tests for another purpose. Our intention is to check if he/she had an infection with the new Coronavirus without symptoms. This exam usually hurts a little at the time of the puncture at the fingertip, but it is a mild pain, which children usually endure well. If your child has symptoms of infection with the new Coronavirus, no specific tests will be taken because of this study. The collected exams would be collected anyway, whether or not he/she was in the study. It is important that you know that the inclusion of your child in the study will not change the treatment that he / she will receive in any way.

VOLUNTARY PARTICIPATION AND EARLY WITHDRAWAL

Participation in this study is entirely voluntary. You can refuse this proposal or accept it and then abandon it at any time, without prejudice to your child's treatment. Failure to participate in this research will not cause any harm to your child, as he / she will receive all the treatment he / she needs, regardless of whether he / she is participating in this study.

RISKS

This study does not pose important risks for your child, since the only test that will be done specifically for the study will be the collection of a drop of blood obtained by a needle stick on the tip of one of the fingers to know if he /she have had infection with the new Coronavirus without symptoms. During this blood collection, there will be pain due to the prick of one of the fingers with a needle, but it will be done by an experienced

person and children usually tolerate this test well. This may not even be necessary, as we will be able to take a drop of blood if he/she collects tests for another purpose. On the other hand, as we are going to collect data from the medical record, there is a risk that these data will be seen by people who are not part of the study team or the treatment team. However, researchers will make every effort to ensure that your child's data is kept confidential and only known by the research team.

BENEFITS

The research may bring indirect benefits to your child and other children in the future, as it may contribute to better understand the role of infections by the new Coronavirus in immunosuppressed children.

CONFIDENTIALITY

Your child's data will remain confidential. At no point in the survey will he / she will be identified. That is, when the results of this study become public, doctors will not use your name or that of your child and will not let anyone know about your personal data. The doctors who lead the study, the doctors who participate in the study and the Research Ethics Committee, can review your files. Government agencies (federal, state and municipal) can inspect any medical research record, upon legal request, but every effort to ensure secrecy or confidentiality will be maintained.

COSTS AND PAYMENT

You will not need to pay anything to participate in this study, nor will you receive payment for your child's participation.

DOUBTS - WHO TO CONTACT

You can ask questions at any time. For answers to questions related to this survey, for any research-related issues or for information on survey procedures, you can contact:

• Dr. Thaís Lira Cleto Yamane, Researcher in charge
E-mail: thaiscleto@yahoo.com.br Tel: (21) 3883-6000.
Hours: Monday to Friday, from 2 pm to 6 pm.

Questions about your and your child's rights as volunteers can be asked to the Research Ethics Committee at Instituto D'Or de Pesquisa e Ensino, which evaluated the ethical aspects of this study:
• IDOR Research Ethics Committee
Diniz Cordeiro nº 30 - Botafogo, Rio de Janeiro, RJ, CEP: 22.281-100
E-mail: cep.idor@idor.org Tel: (21) 3883-6013
Opening hours: Monday to Friday, from 8 am to 6 pm.

INFORMED CONSENT

I declare that I am receiving a copy of this document, signed by me and / or the child's legal representative and the researcher, who also represents the research institution.

All pages of this document have been initialed by us. The researcher will keep the other original copy in his file.

_____ _____

Full Name of Participating Child Register number

_____ _____

Full Name of Mother / Father / Legal Representative Phone number

PARTICIPANT / LEGAL REPRESENTATIVE

I confirm that the information contained in this Informed Consent Form was precisely explained to me and understood by me and that the consent was provided voluntarily by me.

_____ _____

Signature of Mother / Father / Legal Representative Date (dd / mmm / yyyy)

_____

In case of signature by the Legal Representative, specify the relationship with the Participant.)

RESEARCHER

I confirm that I explained the nature and objectives of this research and the potential risks and benefits to the participant and / or the child's legal representative. I declare that I will comply with the requirements contained in resolution 466/12.

_____

Researcher's Full Name

_____ _____

Researcher's Signature Date (dd / mmm / yyyy)

IMPARTIAL WITNESS (The presence of at least one impartial witness is mandatory when the participant or legal guardian cannot read or write. An impartial witness must be present throughout the discussion of free and informed consent.)

I confirm that the information contained in this Informed Consent Form was precisely explained and apparently understood by the Participant and / or his Legal Representative and that consent was provided voluntarily by the Participant and / or his Legal Representative.

_____

Full Name of the Impartial Witness

_____	_____
Signature of the Impartial Witness	Date (dd / mmm / yyyy)