



Institutional Review Board #00000029  
FWA00004775

March 25, 2020

PI: Gabriela Maron, MD  
Department: SJ - Infectious Diseases

IRB Number: 20-0465  
Mnemonic: PIDTRAN-6\_COVID-19  
Reference Number: 007237

Project Title: A multi-center study to describe the epidemiology, clinical presentation, and outcomes of pediatric patients with Covid-19 across the United States.

Submission Type: Initial Review Submission Packet  
Regulation Review: 2018 Common Rule Requirements

IRB Member Determination: Exempt Category 4: Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens if at least one of the following criteria is met: Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects;

IRB Approval Date: 03/25/2020

This submission was reviewed by an IRB Member; whereby, the IRB member considered there were adequate protections for the privacy of subjects and the submission included adequate plans to maintain the confidentiality of the data.

- Modifications to the study must be reviewed and approved by the IRB before implementation.
- Unanticipated problems must be submitted and reviewed by the IRB.
- Study closure/completion application is to be submitted via iRIS to close out the study in the system.

NOTE: We have determined that the other sites providing clinical (NON-HIPAA identifiable) data to this project are NOT engaged in human subjects activities based on OHRP's October 16, 2008 *Guidance on Engagement of Institutions in Human Subjects Research*. Therefore, their role in the project does NOT need local IRB approval at their sites unless local policy dictates otherwise.

Other institutional/departmental approvals may be required. Please keep this letter for your files.

For further assistance, please contact the Office of Human Subjects' Protection at 901-595-4357 or email [hsp-1@stjude.org](mailto:hsp-1@stjude.org). All OHSP policies and procedures can be located

at <https://home.stjude.org/hrpp/Pages/policies.aspx>.

Submission Components		
Form Name	Version	Outcome
Review Response Form - IRB	Version 1.0	Approved
Initial Review Submission Packet	Version 1.0	Approved
Research Review Application	Version 1.1	Approved