

September 30, 2021

Muna Qayed, MD, MsCR
Children's Healthcare of Atlanta, Inc.

Dear Dr. Qayed,

SUBJECT: INSTITUTIONAL BIOSAFETY COMMITTEE DETERMINATION

Sponsor: Novartis Pharmaceuticals
Protocol: **CCTL019G2201J**, Version 1.0, dated 02-11-2020
Protocol Title: A phase II trial of tisagenlecleucel in first-line high-risk (HR) pediatric and young adult patients with B-cell acute lymphoblastic leukemia (B-ALL) who are minimal residual disease (MRD) positive at the end of consolidation

The Institutional Biosafety Committee (IBC) for Children's Healthcare of Atlanta, Inc. has reviewed this research and made the following determination:

MEETING DATE: September 30, 2021

MEETING TYPE: Continuing Review of Protocol and Site

IBC DETERMINATION: **Approved** **Disapproved**
 Conditionally Approved **Tabled**
Applicable Section of the NIH Guidelines: III-C-1

EXPIRATION DATE: September 30, 2022

Biosafety Level approved for this site: **BSL-2**

IBC Oversight Period approved for this site: **3 months after the last subject's final dose**

This IBC is administered by WCG IBC Services. If we can be of assistance, please contact us at IBCServices@wcgirb.com or by phone at (360) 252-2850.

If you have changes to your research to submit, please complete the "IBCS Change in Research Submission Form" on our website (<https://www.wcgirb.com/how-to-submit/ibc-forms/>), and submit the completed form with any other applicable documents to IBCServices@wcgirb.com.

cc: Sarah Marie Huban, Children's Healthcare of Atlanta, Inc.
Janet Fernandez, BS, RRT-NPS, CPFT, CCRC, Children's Healthcare of Atlanta, Inc.
Ashlea Moore, CCRP, Children's Healthcare of Atlanta, Inc.
Megan Hanby, Children's Healthcare of Atlanta, Inc.
Judson Russell, MPH, Children's Healthcare of Atlanta, Inc.
Morgan Coleman, Children's Healthcare of Atlanta, Inc.
Mark DiMatteo, MS, Novartis Pharmaceuticals Corporation
Study File

ALL IBC-APPROVED INVESTIGATORS MUST COMPLY WITH THE FOLLOWING:

1. Report the following site-specific information to the IBC within 5 days:
 - a. Violations of the *Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* (NIH Guidelines).
 - b. New information bearing on the NIH Guidelines.
 - c. Significant research-related accidents and/or illnesses.
 - d. Research-related spills, exposures, and/or laboratory-acquired infections.
 - e. Loss of containment.
 - f. Suspension or termination of the study by the sponsor, investigator, or institution.
 - g. Unresolved complaints related to biosafety.
2. Training:
 - a. Be adequately trained in good microbiological techniques and IBC-approved standard operating procedures.
 - b. Instruct and train the research staff in:
 - i. The practices and techniques required to ensure safety;
 - ii. The procedures for dealing with accidents, spills, and/or exposures.
 - c. Inform the research staff of the reasons and provisions for any precautionary medical practices advised or requested.
3. Safety:
 - a. Supervise the safety performance of the research staff to ensure that the required safety practices and techniques are employed.
 - b. Make available to all research staff descriptions of the potential biohazards and the precautions to be taken.
 - c. Adhere to IBC-approved emergency plans for handling accidental spills and personnel contamination.
 - d. Remain in communication with the IBC throughout the conduct of the project.
4. Accountability:
 - a. Correct work errors and conditions that may result in the loss of containment of recombinant or synthetic nucleic acid molecules.
 - b. Ensure the integrity of the physical and biological containment of recombinant or synthetic nucleic acid molecules.
 - c. Comply with shipping requirements for recombinant or synthetic nucleic acid molecules.
 - d. Notify WCG IBC Services and obtain IBC approval before making any changes to the protocol, facilities, practices, and key study staff associated with the research.

The NIH Guidelines require that the IBC conduct periodic reviews of approved research. You will receive Continuing Review Report Forms from WCG IBC Services. These reports must be returned in a timely manner, even if research at your site has not yet begun.