

# IVIG for Infection Prevention After CAR-T-Cell Therapy

NCT05952804

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Status	RECRUITING
Phase	Phase 2
Sponsor	Fred Hutchinson Cancer Center
Enrollment	150 participants

## Key Eligibility Criteria

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### Inclusion (6)

- Capable of understanding the investigational nature, potential risks and benefits of the study, and able to provide valid informed consent
  - For patients with medical incapacity or impaired consciousness such that they are not able to give fully informed voluntary consent, the subjects' legal representative must sign an institutional review board (IRB) approved informed consent document prior to the initiation of any screening or study-specific procedures
  - Participants must be 18 years of age or older
  - Participants will receive an Food and Drug Administration (FDA)-approved CD19-CAR T-cell product for the treatment of hematologic malignancies. Patients receiving an FDA-approved product are eligible even if the product is being administered as part of a clinical trial or expanded access program (e.g., product is 'out of specification'; concomitant anti-tumor treatment such as acalabrutinib)
  - Serum total IgG  $\lt$  600mg/dL within the prior three months
- ... and 1 more (see full listing online)

### Exclusion (10)

- Primary congenital selective IgA deficiency
  - Prior serious adverse event/s related to intravenous immune globulin (IVIG) administration
  - Known serious allergy to any component of IVIG
  - Has a history or current evidence of any condition, therapy, lab abnormality, or other circumstance that might confound the results of the study or interfere with the patient's ability to participate for the full duration of the study or would put the patient at undue risk as judged by the investigator, such that it is not in the best interest of the patient to participate in this study
  - SUBSEQUENT INFUSIONS: Ongoing symptoms of cytokine release syndrome (CRS) and/or immune effector cell-associated neurotoxicity syndrome (ICANS) meeting criteria for grade 3 or higher
- ... and 5 more (see full listing online)

## Locations (7 total)

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City of Hope Cancer Center, Duarte, California, United States  
University of Miami Miller School of Medicine-Sylvester Cancer Center, Miami, Florida, United States  
Moffitt Cancer Center, Tampa, Florida, United States  
... and 4 more locations

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<https://clinicaltrials.gov/study/NCT05952804>

DISCLAIMER: This document is for informational purposes only and does not constitute medical advice. Always consult your healthcare provider before enrolling in any clinical trial. Information may not be up to date — verify details at [ClinicalTrials.gov](https://clinicaltrials.gov). Generated by [ClinicalTrialsFinder.org](https://clinicaltrialsfinder.org).