



DEPARTMENT OF HEALTH & HUMAN SERVICES

National Institutes of Health
National Cancer Institute
Freedom of Information / Privacy Act Office
Bldg. 31, Room 10A48
9000 Rockville Pike, MSC 2580
Bethesda, Maryland 20892-2580
Ph: (240) 781-3340 Fax: (240) 541-4519

October 1, 2019

Kathryn Ardizzone
Counsel
Knowledge Ecology International
1621 Connecticut Ave NW Suite 500
Washington, DC 20009

Re: NCI 19-133, FOIA Case Number: 52838

Dear Ms. Ardizzone:

This is our final response to your Freedom of Information Act (FOIA) request addressed to National Cancer Institute (NCI), National Institutes of Health (NIH), dated September 17, 2019 and received September 17, 2019. You requested:

Documents of any kind that mention or refer to the actual or expected cost of three clinical trials, two intramural and one extramural, all funded by the National Cancer Institute (NCI). In this regard, if a single document provides a budget for the trial, that includes the entire cost of the trial, as opposed to a component of the trial or the expense of a single year, that would satisfy our request.

The two intramural trials are:

● **NCT03448393**

Title : "CD19/CD22 Chimeric Antigen Receptor (CAR) T Cells in Children and Young Adults With Recurrent or Refractory CD19/CD22-expressing B Cell Malignancies"

Link : https://clinicalstudies.info.nih.gov/ProtocolDetails.aspx?A_2018-C-0059.html

Other Study ID No : 18-C-0059

Actual Study Start Date : March 26, 2018

Estimated Primary Completion Date : December 1, 2021

Estimated Study Completion Date : December 1, 2032

NIH Grant : None listed

Principal Investigator : Nirali N Shah, M.D., National Cancer Institute (NCI)

● **NCT01593696**

Title : "Anti-CD19 White Blood Cells for Children and Young Adults With B Cell Leukemia or Lymphoma"

Link : <https://clinicaltrials.gov/ct2/show/NCT01593696?id=NCT01593696&rank=1>

Other Study ID Nos : 120112; 12-C-0112

Principal Investigator : Nirali N Shah, M.D. National Cancer Institute (NCI)

Actual Study Start Date : June 29, 2012

Actual Primary Completion Date : November 11, 2016

NIH Grant : None listed

Principal Investigator : Nirali N Shah, M.D., National Cancer Institute (NCI)

The one extramural trial:

● **NCT03241940**

Title : "Phase I CD19/CD22 Chimeric Antigen Receptor T Cells in Peds
Recurrent/Refractory B Cell Malignancies"

Link : <https://clinicaltrials.gov/ct2/show/NCT03241940?id=NCT03241940&rank=1>

Other Study ID Numbers : NCI-2017-01415 (Registry Identifier: CTRP (Clinical Trial Reporting Program)); PEDSCCT5007 (Other Identifier: Stanford Cancer Institute); and
IRB-41383 (Other Identifier: Stanford IRB)

NIH Grant : P30CA124435 (U.S. NIH Grant/Contract)

Principal Investigator : Crystal Mackall, Stanford University (Contact: Anne Marcy
650-721-9994, acmarcy@stanford.edu).

The National Cancer Institute Center for Cancer Research (CCR) searched its files and no records responsive to your request were located in regard to the intramural trials (Items 1 and 2 of your request). Records do not exist that show the budget of intramural research protocols because there is no singular budget for an individual protocol. Instead, funding stems from multiple sources and would involve estimation and creation of a record that does not already exist. The projects and budgets of NCI's IRP Principal Investigators can be found within NIH RePORTER: <https://projectreporter.nih.gov/reporter.cfm> by searching principal investigator name.

In regard to Item 3 of your request, budgets are available on the same RePORTER site but using the Grant number you provided above, P30CA124435. If you wish to receive actual copies of the grants themselves, feel free to file a new FOIA request for those records.

While we believe that an adequate search of appropriate files was conducted for the records you requested, you have the right to appeal this determination that no records exist in which would be responsive to your request. Should you wish to do so, your appeal must be sent within ninety (90) days of the date of this letter, following the procedures outlined in Subpart F of the HHS FOIA Regulations (<https://www.federalregister.gov/documents/2016/10/28/2016-25684/freedom-of-information-regulations>) to:

Assistant Secretary for Public Affairs/Agency Chief FOIA Officer
U.S. Department of Health and Human Services
Office of the Assistant Secretary for Public Affairs
Room 729H
200 Independence Avenue, S.W.
Washington, DC 20201
FOIARequest@hhs.gov
FAX: 202-690-8320

If you are not satisfied with the processing and handling of this request, you may contact the NCI FOIA Public Liaison and/or the Office of Government Information Services (OGIS):

NCI FOIA Public Liaison

MK Holohan
9000 Rockville Pike
Bldg 31, Room 10A38

240-781-3410
240-541-4519
ncifoia@mail.nih.gov

OGIS

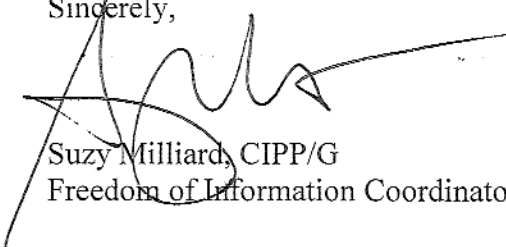
National Archives and Records Admin.
8601 Adelphi Rd – OGIS

College Park, MD 20740-6001
202-741-5770 (phone)
1-877-684-6448 (toll-free)
202-741-5769 (fax)
ogis@nara.gov (email)

In certain circumstances, provisions of the FOIA and HHS FOIA Regulations allow us to recover part of the cost of responding to your request. You requested a fee waiver, but there was no need to assess a fee waiver because fees were not incurred in response to your FOIA request.

Thank you for your interest in the National Cancer Institute.

Sincerely,



Suzy Milliard, CIPP/G
Freedom of Information Coordinator, NCI