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Internet Archive
300 Funston Avenue
San Francisco, CA 94118

# DECLARATION OF DUNCAN HALL

1. I am a Records Request Processor at the Internet Archive, located in San Francisco, California. I make this declaration of my own personal knowledge.

2. The Internet Archive is a website that provides access to a digital library of Internet sites and other cultural artifacts in digital form. Like a paper library, we provide free access to researchers, historians, scholars, and the general public. The Internet Archive has partnered with and receives support from various institutions, including the Library of Congress.

3. The Internet Archive has created a service known as the Wayback Machine. The Wayback Machine makes it possible to browse more than 450 billion pages stored in the Internet Archive's web archive. Visitors to the Wayback Machine can search archives by URL (i.e., a website address). If archived records for a URL are available, the visitor will be presented with a display of available dates. The visitor may select one of those dates, and begin browsing an archived version of the Web. Links on archived files in the Wayback Machine point to other archived files (whether HTML pages or other file types), if any are found for the URL indicated by a given link. For instance, the Wayback Machine is designed such that when a visitor clicks on a hyperlink on an archived page that points to another URL, the visitor will be served the archived file found for the hyperlink's URL with the closest available date to the initial file containing the hyperlink.

4. The archived data made viewable and browseable by the Wayback Machine is obtained by use of web archiving software that automatically stores copies of files available via the Internet, each file preserved as it existed at a particular point in time.

5. The Internet Archive assigns a URL on its site to the archived files in the format http://web.archive.org/web/[Year in yyyy][Month in mm][Day in dd][Time code in hh:mm:ss]/[Archived URL] aka an "extended URL". Thus, the extended URL http://web.archive.org/web/19970126045828/http://www.archive.org/ would be the URL for the record of the Internet Archive home page HTML file (http://www.archive.org/) archived on January 26, 1997 at 4:58 a.m. and 28 seconds (1997/01/26 at 04:58:28). The date indicated by an extended URL applies to a preserved instance of a file for a given URL, but not necessarily to any other files linked therein. Thus, in the case of a page constituted by a primary HTML file and other separate files (e.g., files with images, audio, multimedia, design elements, or other embedded content) linked within that primary HTML file, the primary HTML file and the other files will each have their own respective extended URLs and may not have been archived on the same dates.

6. Attached hereto as Exhibit A are true and accurate copies of screenshots of the Internet Archive's records of the archived files for the URLs and the dates specified in the attached coversheet of each printout.

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7. I declare under penalty of perjury that the foregoing is true and correct.

DATE: Jan 4, 2022

Duncan Hall

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# EXHIBIT A

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https://web.archive.org/web/20090507184629/https:/clinicaltrials.gov/ct2/show/NCT00891215

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# Pilot Study for Patients With Chemotherapy Resistant or Refractory CD19 Leukemia and Lymphoma (CART-19)

**This study is not yet open for participant recruitment.**
Verified by University of Pennsylvania, April 2009

First Received: April 29, 2009 Last Updated: April 30, 2009 History of Changes

| | |
|---|---|
| **Sponsors and Collaborators:** | **University of Pennsylvania**<br>Lentigen Corporation |
| **Information provided by:** | University of Pennsylvania |
| **ClinicalTrials.gov Identifier:** | NCT00891215 |

## Purpose

This is a study for people who have been previously treated for Leukemia/Lymphoma. In particular, it is a study for people who have a type of Leukemia/Lymphoma that involves B cells (a type of white cell), which contain the cancer. This is a new approach for treatment of Leukemia/Lymphoma that involves B cells (tumor cells). This study will take the subject's white blood cells (T cells) and modify them in order to target the cancer.

The subject's T cells will be modified in one or two different ways that will allow the cells to identify and kill the tumor cells (B cells). Both ways of modifying the cells tells the T cells to go to the B cells (tumor cells) and turn "on" and potentially kill the B cells (tumor cells). The modification is a genetic change to the T cells, or gene transfer, in order to allow the modified T cells to recognize your tumor cells but not other normal cells in the subject's body. These modified cells are called CART-19 T cells.

The two types of CART-19 T cells will be given back to subject's through an infusion. In addition to determining the safety of this approach, the purpose of the study is to determine which way of modifying the T cells works better in turning them "on" to fight cancer. This is done by monitoring levels of both types of modified cells in the subject's blood stream, and if possible, in the bone marrow and tumor tissue for four weeks after the infusion. It is expected that one type of modified cell will grow better than the other in the subject's blood. However, it is possible that there will be no difference between the two types of cells.

| Condition | Intervention | Phase |
|---|---|---|
| Acute Lymphocytic Leukemia<br>Follicular Lymphoma<br>Chronic Lymphocytic Leukemia (CLL)<br>Mantle Cell Lymphoma<br>Prolymphocytic Leukemia<br>Large Cell Lymphoma | Biological: CART-19 | Phase I |

MedlinePlus related topics: Cancer Leukemia, Adult Acute Leukemia, Adult Chronic Lymphoma

U.S. FDA Resources

Study Type: Interventional
Study Design: Treatment, Open Label, Single Group Assignment, Safety/Efficacy Study

Official Title: Pilot Study of Redirected Autologous t Cells Engineered to Contain Anti-cd19 Attached to tcrζ and 4-1bb Signaling Domains in Patients With Chemotherapy Resistant or Refractory cd19+ Leukemia and Lymphoma

**Further study details as provided by University of Pennsylvania:**

Primary Outcome Measures:

- The change in the ratio of the vector transduced cells to each other between baseline and week four will be evaluated. Observation and monitoring of patients will continue on a monthly basis until week 24 post dosing. [ Time Frame: 24 Weeks ] [ Designated as safety issue: Yes ]

Secondary Outcome Measures:

- Subjects 6 to 10 will be dosed with mixtures of TCR:4-1BB and TCR only cells, using a competitive repopulation strategy to determine the optimal signal transduction module in the chimeric receptor. [ Time Frame: 24 Weeks ] [ Designated as safety issue: No ]

Estimated Enrollment: 10
Study Start Date: June 2009
Estimated Study Completion Date: June 2010
Estimated Primary Completion Date: June 2010 (Final data collection date for primary outcome measure)

Intervention Details:

Biological: CART-19
Total dose of CART-19 T Cells = ~2xE9 - 5xE10. CART-19 Cell infusion given over 3 days (Day 1, Day 2, Day 11) Each infusion is approximately 20 minutes.

**Detailed Description:**

This is an open label, single center, pilot study to evaluate the safety and tolerability, and differential persistence and engraftment of autologous T cells engineered to express a chimeric antigen receptor targeting CD19 which is linked either to the CD3 or CD3:4-1BB signaling chains in a competitive repopulation setting in patients with chemotherapy-resistant or - refractory CD19+ leukemia or lymphoma. Upon enrollment, patients will undergo leukapheresis (10L) and an optional bone marrow +/- lymph node biopsy approximately four weeks prior to dosing. T cells will be isolated from the leukapheresis by elutriation, split and genetically modified in paralliel by a lentiviral vector expressing one of the two chimeric antigen receptors, and then the cells will be expanded in parallel. Between dosing and treatment, patients may undergo an additional chemotherapy treatment depending upon their disease. At dosing, patients will receive a mixture of the redirected autologous T cells against CD19 (CART-19 cells), which were produced in parallel. Twenty minutes after dosing, blood samples will be taken to serve as a baseline control for the ratio between the cells with either vector. Patients will be monitored weekly for four weeks. At the end of four weeks, patients will undergo a second leukapheresis (2L) and second optional bone marrow +/- lymph node biopsy. At

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