



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health  
Freedom of Information Office  
Building 31, Room 5B-35  
31 Center Drive, MSC 2107  
Bethesda, Maryland 20892-2107  
phone: (301) 496-5633  
fax: (301) 402-4541

Via email: [james.love@keionline.org](mailto:james.love@keionline.org)

July 9, 2018

James Love  
Knowledge Ecology International  
1621 Connecticut Avenue, Suite 500  
Washington, DC 20009

Re: FOI Case No. 48080

Dear Mr. Love:

This acknowledges your June 29, 2018, Freedom of Information Act (FOIA) request submitted to the FOIA Office, National Institutes of Health (NIH), and received in this office on that same day. You requested a copy of the enrollments and costs of specific clinical trials related to CAR T and mesothelin cancers; (2) documents related to the NIH analysis to determine whether a term of exclusivity less than the life of a patent would be appropriate and sufficient; and (3) and the NIH request for antitrust advice from the Attorney General, under 40 U.S.C. § 559. You also requested expedited processing of your request and a fee waiver.

The FOIA, 5 U.S.C. §552(a)(6)(E), requires agencies to consider requests for expedited processing and grant them whenever a “compelling need” is shown and in other cases as determined by the agency. The term “compelling need” is defined as (1) involving “an imminent threat to the life or physical safety of an individual,” or (2) in the case of a request made by “a person primarily engaged in disseminating information, urgency to inform the public concerning actual or alleged Federal Government activity.” The compelling need standard is “intended to be narrowly applied.” *Al-Fayed v. CIA*, 254 F.3d 300, 310 (D.C. Cir. 2001).

In support of your request, you state that, “There is... an urgent need to inform the public...”. I have determined that your request for expedited processing does not meet the criteria under the FOIA. You have not demonstrated a compelling need that involves an imminent threat to the life or physical safety of an individual. Neither have you demonstrated that there exists an urgency to inform the public concerning actual or alleged Federal Government activity. Therefore, I am denying your request for expedited processing. This office will process your request in the order in which it was received.

Your request will be processed by the NIH FOIA Office for records responsive to your request. If any responsive documents are located, they will be reviewed for releasability, and all releasable information will be sent to you. We will do everything possible to comply with your request in a timely manner. Please feel free to contact that office at 301-496-5633 or via email at [nihfoia@od.nih.gov](mailto:.nihfoia@od.nih.gov) for additional information or to inquire about the status of your request’s case.

Provisions of the FOIA allow us to recover part of the cost of complying with your request. We shall charge you for records in accordance with the Department of Health and Human Services FOIA Regulations as they apply to educational institution requesters; i.e., you will be charged for duplication at 10-cents per page although the first 100 pages are free; there is no charge for search or review time. Because we are uncertain that applicable fees will exceed our minimum charge (\$25.00), we are not addressing your request for a fee waiver at this time. However, if we determine that there will be fees associated with processing your request, we will contact you at that time.

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

NIH FOIA Public Liaison

Stephanie Clipper  
Public Affairs Specialist  
Office of Communications and Public Liaison  
Building 31, Room 5B35  
31 Center Drive  
Bethesda, MD 20814  
301-496-1828 (phone)  
301-496-0818 (fax)  
[nihfoia@mail.nih.gov](mailto:.nihfoia@mail.nih.gov) (email)

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](mailto:ogis@nara.gov) (email)

In addition, you have the right to appeal this determination to deny you expedited processing of 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 C of the HHS FOIA Regulations <http://www.nih.gov/icd/od/foia/cfr45.htm> 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

Clearly mark both the envelope and your letter “Freedom of Information Act Appeal.”

Sincerely,



Gorka Garcia-Malene  
Freedom of Information Officer, NIH