



PHS Appeal No.: 11-0303
NIH Case No.: 38445

AUG 17 2011

H. Peter Aleff
2097 Cottonwood Drive
Vineland, NJ 08361

Dear Mr. Aleff:

This is in response to your letter of March 18, 2011, in which you appealed the response you received to part of your January 10, 2011, Freedom of Information Act (FOIA) request submitted to the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD), National Institutes of Health (NIH). You originally asked for a number of records related to a particular clinical study published in the New England Journal of Medicine. After consulting with the NICHD's FOIA Coordinator, you narrowed the scope of your request to agency records for one NICHD-funded grant that supported the study, including documents supporting the ethical approval of that study, consent forms for the project, a list of hospitals that participated in the study, the Institutional Review Board (IRB) approvals for the study sites, and funding information regarding any similar but more recent studies.

On February 16, 2011, NICHD responded and provided you with records responsive to your request. Additionally, NICHD advised you that it was unable to locate any consent forms. NICHD explained to you that it does not require grantees to provide consent forms and that such documents are instead maintained by the grantee's institution. Nevertheless, NICDH conducted a search and it did not find the consent forms.

You appealed NICHD's inability to locate the consent forms. In your appeal, you requested that the consent forms of NICHD be searched and copies be provided to you. You stated that because the law mandates those forms, you cannot accept that they cannot be found.

Upon receipt of the appeal, I contacted NICHD about its inability to locate the consent forms. NICHD explained that it does not require grantees to submit the forms and provided a description of its search for responsive records. That search produced a copy of the grant application and certain information regarding IRB approvals, but did not produce the consent forms.

When a study involves human subjects, the IRB for the location where the study is to be performed must review and approve the proposed study. That review includes reviewing the consent forms the subjects are asked to sign giving their consent to participate in the study. Those consent forms are not required to be provided to the NIH as part of the grant application or management process. Therefore, these consent forms do not constitute agency records subject to the FOIA. NIH did search for the consent forms, however, and I am satisfied that although NIH was unable to locate agency records responsive to this aspect of your request, an adequate search was conducted.

The Office of Government Information Services (OGIS), National Archives and Records Administration was created to offer mediation services to resolve disputes between FOIA requesters and Federal agencies as a non-exclusive alternative to litigation. Using OGIS services does not affect your right to pursue litigation. You can learn about OGIS at <http://www.archives.gov/ogis/>.¹

This letter constitutes the final decision of the Department in this matter. If you wish, you may seek judicial review in the district court of the United States in the district in which you reside, have your principal place of business, in which the agency records are located, or in the District of Columbia.

Sincerely,



Bill Hall
Director, News Division
Office of the Assistant Secretary
For the Public Affairs

¹ The contact information for OGIS is: Office of Government Information Services, Room 510, 8601 Adelphi Road, College Park, MD 20740-6001; E-mail: ogis@nara.gov; Telephone: 301-837-1996; Facsimile: 301-837-0348.