



19 May 2022

Dear [REDACTED],

Freedom of Information request: FOI2022/00155

Thank you for your Freedom of Information request received on the 20 April in which you requested the following:

Your request:

I am looking for confirmation that the appropriate approvals process for clinical trials of Factor 8 and DDAVP/Desmopressin had been in place from 1979 - 1992.

This request is with my personal interest being in the following products of: Factor 8 1979-81 and DDAVP/desmopressin 1982 - 1992.

Also could you also provide evidence to prove that such appropriate approvals had been in place?

Our response:

I can confirm UK Research and Innovation (UKRI) may hold information relevant to your request. Although information is not held directly in relation to research with DDAVP/desmopressin covering the period outlined in your request, we have investigated if any information is held that may assist in responding to your request.

We have estimated that the cost of complying with your request would exceed the appropriate statutory limit as specified within Section 12 of the FOIA which for UKRI is set at £450. This represents the estimated cost of 18 hours of staff resource on locating, retrieving and extracting the information.

In order to determine if the information is held, we consulted with the appropriate teams within MRC in order to identify and locate any relevant files, and then retrieve these from our archive facility. Nine grant files were identified and retrieved for review, with each file containing an average of 150-200 pages. To date, this process alone has utilised 11 hours of staff time.

We estimate it will take 2 minutes to review each page to identify and extract any relevant information, so consequently it would require 5 to 6.5 hours of staff time to review each file. This would therefore greatly exceed the 18-hour limit.

Although UKRI is not obliged under Section 12 of the FOIA to respond to your request, we would like to provide advice and assistance as to how you could narrow your request further. This may be achieved by specifying one of the 9 following grant titles for review:

1. Biochemical & Immunological studies of Factor VIII in Health & Disease (awarded 1977)
2. To determine the site of synthesis of procoagulant factor VIII (awarded 1978)
3. The Interaction of activated factor IX, Factor VIII, Factor X, Calcium and platelets in normal haemostasis & disease (awarded 1979)
4. Biochemical, Immunologic and functional characterisation of the Von Willebrand factor in human factor VIII (awarded 1980)
5. Biosynthesis of Factor VIII in Vivo (awarded 1982)

6. Studies to elucidate the mechanism of humoral control of plasminogen activator and factor VII release (awarded 1982)
7. In Vivo and In Vitro studies of factor VIII/Phospholipid mixtures (awarded 1983)
8. The production of monoclonal antibodies to factor VII (awarded 1983)
9. Molecular genetics of classical haemophilia: Cloning of the Factor VIII gene (awarded 1983)

Furthermore, we have also identified additional files that are not held by UKRI, but have been transferred to [The National Archives](#)¹ and may be of interest in case they also hold relevant information:

1. The MRC Blood Transfusion Research Committee, which operated between WWII and 1981. Over the course of its lifetime, the Committee also has several working parties that reported to it, but only two working during the period covered by the request might have relevant info: the Working Party on Post-Transfusion Hepatitis and the Working Party on Use of Factor IX Concentrate for Conditions other than Christmas Disease. Both of these disbanded when the Committee did in 1981.
2. The MRC Clinical Trials Committee, whose remit was: “to undertake the detailed technical scrutiny of proposed protocols and oversee the progress of [trials]” already agreed in principle by MRC’s Board. This committee operated between roughly 1981 and 1994.

You can search and request files from The National Archives [catalogue](#)².

If you have any queries regarding our response or you are unhappy with the outcome of your request and wish to seek an internal review of the decision, please contact:

Head of Information Governance


Email: foi@ukri.org or infogovernance@ukri.org

Please quote the reference number above in any future communications.

If you are still not content with the outcome of the internal review, you may apply to refer the matter to the Information Commissioner for a decision. Generally, the ICO cannot make a decision unless you have exhausted the review procedure provided by UKRI. The Information Commissioner can be contacted at: www.ico.org.uk.

If you wish to raise a complaint regarding the service you have received or the conduct of any UKRI staff in relation to your request, please see UKRI’s complaints policy: <https://www.ukri.org/about-us/policies-and-standards/complaints-policy/>

Yours sincerely,


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Information Rights Team
UK Research and Innovation
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¹ <https://www.nationalarchives.gov.uk/>

² <https://discovery.nationalarchives.gov.uk/>