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Information
Compliance

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[REDACTED]

By email only to: [REDACTED]

24th April 2024

Dear [REDACTED]

Request for information under the Freedom of Information Act 2000 ("the Act")

Further to your recent request for information held by King's College London, I am writing to confirm that the requested information is held by the university.

Your request

We received your information request on 26th March 2024 and have treated it as a request for information made under section 1(1) of the Act.

You requested the following information:

I am emailing to seek the disclosure of information under the Freedom of Information Act 2000 (FOIA).

The information in question relates to the Mirocals clinical trial, which investigated the use of low dose Interleukin-2 for the treatment of ALS (amyotrophic lateral sclerosis). It is now almost two years since the conclusion of the trial and over one year since the high level results were announced. I ask for the results of the trial to be provided alongside the analysis that has been undertaken of the results, which may be in the form of a draft academic paper intended for publication. I request the release in full of all documents which may contain the information requested above.

The FOIA requires a public interest to be applied and I contend there is a strong public interest in this case. First, the trial has been entirely funded by taxpayers through a grant made under the EU Horizon programme and grants from charitable bodies (most significantly, the MND Association). Second, the high level results suggest the treatment trialled could have a significant effect on slowing progression of ALS. ALS (also known as motor neuron disease) is a terminal illness, with sufferers only surviving between 2-5 years. The treatment - Interleukin-2 - is already available in NHS pharmacies for the treatment of Kidney cancer but cannot be prescribed without clinical trial data confirming safety and efficacy. It is in the strong public interest of those living with the disease, their families and doctors to have access to this data so that the treatment can be prescribed as a matter of urgency.

Our response

The University holds the information that you have asked for. However, the information which you have requested was obtained in the course of, or derived from, a programme of research, therefore your request is refused under Section 22a of the Act.

Section 22a applies if:

- (a) the research programme is continuing with a view to the publication of a report of the research by a public authority or any other person, and;
- (b) disclosure of the information would, or would be likely to, prejudice: (i) the programme of research; (ii) the interests of any individual participating in the programme; (iii) the interests of the authority which holds the information; or (iv) the interest of the authority who will be publishing the report of the programme.

The release of the information you have requested would be likely to prejudice the programme of research, the interests of the University and/or the interests of other authorities which hold relevant information for the following reasons:

Analysis, checking and auditing of the trial data is not yet complete. Once this has been undertaken, and after submission of the main paper and Clinical Study Report (CSR) (both of which are currently in draft form only) there remain a number of actions to complete before the research outputs will be fit for publication. MIROCALS is an extremely complex study with a vast amount of data, all of which has to be analysed and presented in the final CSR.

Premature disclosure of the requested information could lead to incomplete, unchecked trial data being in the public domain. This would not be in the best interests of the research participants, the University or any other members of the research consortium. Were the University to release this incomplete data, outside of the terms of the consortium agreement, this would be likely to prejudice our ability to secure research partners and funding in the future.

Without expert analysis and interpretation, release of raw or draft data would at best be meaningless and at worst prejudicial to the aims of the study.

Please note that under the terms of s22a, any published report of the research may or may not include the specific information which has been requested, without affecting the application of the exemption.

In line with the terms of this exemption, the University has considered whether it would be in the public interest for us to provide you with the information ahead of the research programme's publication. The University acknowledges that there are strong public interest considerations in respect of the release of information which may be of particular interest to those seeking treatments for related conditions. However, the University's view is that the public interest in making disclosure is outweighed by the prejudice that would be caused and that, on balance, the public interest is better served by withholding the information until the research report is published.

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It is expected that the research paper will be ready for publication within the next 6 months. In addition, we understand that there have been and will continue to be opportunities for interested parties (including representatives from the Doddie Weir Foundation) to meet with the researchers leading the study, to ask questions and to be provided with updates on the study.

This completes the university's response to your information request.

Your right to complain

If you are unhappy with the service you have received in relation to your information request or feel that it has not been properly handled you have the right to complain or request a review of our decision by contacting the Director of Information Governance & Data Protection Officer within 60 days of the date of this letter.

Further information about our internal complaints procedure is available at the link below:
<https://www.kcl.ac.uk/policyhub/freedom-of-information-policy>

In the event that you are not content with the outcome of your complaint you may apply to the Information Commissioner for a decision. Generally, the Information Commissioner cannot make a decision unless you have exhausted the internal complaints procedure provided by King's College London.

The Information Commissioner can be contacted at the following address:
The Information Commissioner's Office
Wycliffe House
Water Lane
Wilmslow
Cheshire
SK9 5AF

Yours sincerely,


Information Compliance