Dear

Freedom of Information Response (Our Ref: K/20/235)

Thank you for your Freedom of Information (FOI) request dated 20 June 2020, reference K/20/235.

Your request read:

“Q1: Since the 30th of April 2018 has the university changed or created policy/policies regarding registration of clinical trials on clinical trial registries, by the university itself and/or by university staff? If yes, please provide a link to the policy/policies. If the policy/policies are not publicly accessible online, please provide an electronic copy of the policy/policies.

Q2: Since the 30th of April 2018 has the university changed or created policy/policies that require the posting of the summary results of clinical trials on clinical trial registries, by the university itself and/or by university staff? If yes, please provide a link to the policy/policies. If the policy/policies are not publicly accessible online, please provide an electronic copy of the policy/policies.

Q3: Since the 30th of April 2018 has the university changed or created policy/policies that prohibit its staff from silent outcome switching when they report clinical trial outcomes in academic journals? If yes, please provide a link to the policy/policies. If the policy/policies are not publicly accessible online, please provide an electronic copy of the policy/policies.

Q4: Does the university have time-specific plans to retrospectively post missing summary results onto trial registries for university-sponsored clinical trials completed in the past? If yes, please share a link to that document. If the document is not online, please provide a copy of the document.

Q5: Since the start of 2018 has the university made public an internal audit of trial registration and/or summary results posting performance? If yes, please provide a link to that document.”

The University of Leeds holds some of this information. For your convenience we have responded to each of your questions in turn below.

Since the 30th of April 2018 has the university changed or created policy/policies regarding registration of clinical trials on clinical trial registries, by the university itself and/or by university staff? If yes, please provide a link to the policy/policies. If the policy/policies are not publicly accessible online, please provide an electronic copy of the policy/policies.
Please refer to the attached PDFs setting out the end of trial Standard Operating Procedure and the Clinical Trials Research Unit Publications Policy. Please note that we have redacted wet signatures under section 40(2) of the Freedom of Information Act in order to protect the personal information of the signatories.

Since the 30th of April 2018 has the university changed or created policy/policies that require the posting of the summary results of clinical trials on clinical trial registries, by the university itself and/or by university staff? If yes, please provide a link to the policy/policies. If the policy/policies are not publicly accessible online, please provide an electronic copy of the policy/policies.

No changes have been made to the policy, although it has been updated as part of our annual review of procedures and Standard Operating Procedures.

Since the 30th of April 2018 has the university changed or created policy/policies that prohibit its staff from silent outcome switching when they report clinical trial outcomes in academic journals? If yes, please provide a link to the policy/policies. If the policy/policies are not publicly accessible online, please provide an electronic copy of the policy/policies.

We do not have a specific policy provision for this.

Does the university have time-specific plans to retrospectively post missing summary results onto trial registries for university-sponsored clinical trials completed in the past? If yes, please share a link to that document. If the document is not online, please provide a copy of the document.

We do not have a specific policy provision for this. However, a piece of work to retrospectively publish summary results is now complete (with the exception of studies where it has been agreed with the UK regulator not to post results).

Since the start of 2018 has the university made public an internal audit of trial registration and/or summary results posting performance? If yes, please provide a link to that document.

No.

We hope this information is helpful. If you have any questions about this email, however, please do not hesitate to contact us on foi@leeds.ac.uk

If you are unhappy with the service you have received in relation to your request and wish to make a complaint or request a review of our decision, you can request an Internal Review. Requests for Internal Review should be made in writing using the following contact information:

Post: Mr D Wardle
Deputy Secretary
The University of Leeds
Requests for Internal Review should be submitted within 40 working days of receiving the University’s response to your request. Further information about how the University manages Freedom of Information requests and about our complaints procedure is also available on our website (www.leeds.ac.uk).

If you are not content with the outcome of the internal review, you have the right to apply directly to the Information Commissioner for a decision. Generally, the ICO cannot make a decision unless you have exhausted the review/complaints procedure provided by the University. The Information Commissioner can be contacted at: Information Commissioner’s Office, Wycliffe House, Water Lane, Wilmslow, Cheshire, SK9 5AF.

Kind regards

**Chloe Wilkins**
Freedom of Information Officer

Secretariat
University of Leeds