

By email only to: request-671768-d8e02c5c@whatdotheyknow.com

06 July 2020

Dear Sarai Keestra,

Freedom of Information Act 2000  
Request for information: response

Date of request: 20 June 2020  
Due date: 18 July 2020  
Ref: RITM0299017

We refer to your request for information under the Freedom of Information Act 2000 ("the Act").

Below is your question with the University's corresponding response.

**Question:**

Please respond to the following questions and provide us with electronic copies of the relevant documents:

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.

Thank you for taking the time to address this and we look forward to your response. If you are expecting any delays due to the COVID-19 pandemic please do let us know. We would like to refer you to BIH QUEST's recently published clinical trial reporting manual to improve clinical trial transparency at your university: <https://eur03.safelinks.protection.outlook.com/?url=https%3A%2F%2Ftinyurl.com%2Fy8p6z5bn&data=01%7C01%7Cfoi%40soton.ac.uk%7Cfcfd94645dc4197ba7d08d814f42056%7C4a5378f929f44d3ebe89669d03ada9d8%7C0&data=XOGvI1W8xhwiKiZjz0E2ga07YH1NaxBokUeQDrs7MDg%3D&reserved=0>

Yours faithfully,  
Sarai Keestra

**Answer:**

In accordance with [section 1\(a\)](#) of the Act we confirm that the University holds information of the description specified in your request.

**Question 1/2:**

The University of Southampton does not have a separate policy for the registration or reporting of clinical trials. This is because all our studies are conducted in accordance with the requirements of HRA and the IRAS system and the Medical Research Council (MRC) which already impose a need to register clinical trials on a publicly accessible database. As a Sponsor, the University's expectation is that our clinical trials are registered on ClinicalTrials.gov (<https://clinicaltrials.gov/>).

**Please note, there have been no further changes made to policies between 30th April 2018 - 31st May 2020.**

**Question 3**

No, as these are quite specific examples of potential misconduct. Our Code of Conduct (below) emphasises good research conduct and needs to be applicable to researchers from all disciplines not just those undertaking medical research. The principles of excellence, openness, integrity and rigour outlined in the Code is applicable. In addition, such activity deemed as research misconduct, would be handled according to the University's Procedures for investigating cases of alleged misconduct in research, which is publicly available.

**Please note, there have been no further changes made to policies between 30th April 2018 - 31st May 2020.**

**Question 4:**

No we do not have such plans. However the University has oversight of monitoring activities for CTIMPs it sponsors and seeks to ensure studies are carried out in compliance with the ICH Good Clinical Practices and our funder requirements

**Please note, there have been no further changes made to policies between 30th April 2018 - 31st May 2020.**

**Question 5:**

No such audit has been undertaken nor planned to be undertaken at the current time

**Please note, there have been no further changes made to policies between 30th April 2018 - 31st May 2020.**

If you do not feel that we have dealt with your request in accordance with the requirements of [Part I](#) of the Act, you may request a review. Your request for a review should specify in what respect you consider that the requirements of [Part I](#) have not been met. Please address your request to the Chief Operating Officer at the following address: [foi@soton.ac.uk](mailto:foi@soton.ac.uk).

In accordance with section 5.3 of the [Code of Practice](#), a request for a review must be sent within 40 working days of the date of this email. The University is not obliged to accept any requests for a review beyond 40 working days.

We will endeavour to respond to your request for a review within 20 working days of receipt.

The Information Commissioner is responsible for enforcing rights of access to information and the operation of the publication scheme. You may apply to the Information Commissioner in writing (FOI/EIR Complaints Resolution, Information Commissioner's Office, Wycliffe House, Water Lane, Wilmslow, Cheshire SK9 5AF) or [electronically](#) for a decision whether, in any specified respect, your request for information has been dealt with by the University in accordance with the requirements of [Part I](#) of the Act. The Information Commissioner will not normally take action unless they are satisfied that the University's review procedure has been exhausted.

Yours sincerely,



Freedom of Information Office

email: [foi@soton.ac.uk](mailto:foi@soton.ac.uk)

FREEDOM OF INFORMATION ACT 2000  
REF: REQUEST FOR INFORMATION  
INFORMATION PROVIDED BY THE UNIVERSITY OF SOUTHAMPTON  
FOI@SOTON.AC.UK