

Business Assurance  
Information Compliance

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**Till Bruckner**

By email only to: [request-494706-1184d239@whatdotheyknow.com](mailto:request-494706-1184d239@whatdotheyknow.com)

16 July 2018

Dear Till Bruckner,

**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 some of the requested information is held by the university.

**Your request**

We received your information request on 29 June 2018 and have treated it as a request for information made under section 1(1) of the Act.

You requested the following information:

**Q1. Does the university have publicly available policies and/or SOPs that require its staff to follow global best practices in clinical trial registration and registry entry maintenance?**

**Q2. Does the university have publicly available policies and/or SOPs that commit it to following global best practices in clinical trial summary results posting?**

**Q3. Has the university within the last 12 months made public an internal audit of trial registration and/or summary results posting performance? If yes, please share a link to that document.**

**Q4. Does the university have time-specific plans to retrospectively post missing summary results 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. Does the university have a publicly available policy that prohibits its staff from undeclared 'outcome switching', HARKing, p-hacking and/or similar (mal)practices when they report clinical trial outcomes?**

This FOI request is being filed on behalf of UAEM-UK and TranspariMED.

Please note that the answers to these questions will be used to determine the university's score in the forthcoming Global Health Ranking of leading UK universities by Universities Allied for Essential Medicines (UAEM) UK.

We encourage you to read this background briefing before compiling your response:

<https://emea01.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.scribd.com%2Fdocument%2F382814051%2FBackground-Briefing-Assessing-Clinical-Trial-Transparency-at-UK-Universities-v3-TB20180628&data=01%7C01%7Cinfo-compliance%40kcl.ac.uk%7C5d19fce5e0a4f61642208d5dd2fc2fc%7C8370cf1416f34c16b83c724071654356%7C0&sdata=DDaBlQlrWesKFNXyLkLQl2W%2Fqro0kCoOBzJo9P8vsFk%3D&reserved=0>

### Our response

**Q1. Does the university have publicly available policies and/or SOPs that require its staff to follow global best practices in clinical trial registration and registry entry maintenance?**

All clinical trials are required (by UK legislation) to be registered on the EU Clinical Trials Register (EU-CTR) as the first stage to obtaining Clinical Trial Authorisation in a participating Member State. The EU-CTR is a Primary Registry in the WHO Registry Network and recognised by the ICMJE.

The King's Health Partners Clinical Trials Office (KHP-CTO) SOP 12 – Application of Clinical Trial Authorisation details the requirement for all clinical trials to be registered within the EU-CTR. The KHP-CTO SOPs are publicly available. [http://khpcto.co.uk/SOPs/00\\_SOPs.php](http://khpcto.co.uk/SOPs/00_SOPs.php)

**Q2. Does the university have publicly available policies and/or SOPs that commit it to following global best practices in clinical trial summary results posting?**

Publicly accessible link to KHP-CTO Standard Operating Procedures - [http://khpcto.co.uk/SOPs/00\\_SOPs.php](http://khpcto.co.uk/SOPs/00_SOPs.php)

**Q3. Has the university within the last 12 months made public an internal audit of trial registration and/or summary results posting performance? If yes, please share a link to that document.**

No, the University has not made public an internal audit of trial registration within the past 12 months.

**Q4. Does the university have time-specific plans to retrospectively post missing summary results 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.**

No time specific plans.

**Q5. Does the university have a publicly available policy that prohibits its staff from undeclared 'outcome switching', HARKing, p-hacking and/or similar (mal)practices when they report clinical trial outcomes?**

We do not have a publicly facing policy.

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 Assistant Director of Business Assurance (Information Compliance) within 60 days of the date of this letter.

Further information about our internal complaints procedure is available at the link below:

[http://www.kcl.ac.uk/college/policyzone/assets/files/governance\\_and\\_legal/Freedom\\_of\\_Information\\_Policy\\_updated\\_Oct\\_%202011.pdf](http://www.kcl.ac.uk/college/policyzone/assets/files/governance_and_legal/Freedom_of_Information_Policy_updated_Oct_%202011.pdf)

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

Jade Roche  
Information Compliance