University Hospitals Bristol NHS
NHS Foundation Trust

Freedom of Information Request **Ref: UHB 17-204**

Date 11 April 2017

[redacted]

Dear [redacted]

Thank you for your request for information under the Freedom of Information Act 2000. The Trusts response is as follows:

1. **Does your institution have a policy requiring those conducting clinical trials in humans to register those trials on a public clinical trials registry before the first participants are recruited? If yes, please provide a link to the policy.**

   It is a condition of the Research Ethics Committee approval to register clinical trials within 6 weeks of first participant recruitment. Wording in the REC letter reads:

   > *"Registration of Clinical Trials*
   > *All clinical trials (defined as the first four categories on the IRAS filter page) must be registered on a publically accessible database within 6 weeks of recruitment of the first participant (for medical device studies, within the timeline determined by the current registration and publication trees).*
   > *There is no requirement to separately notify the REC but you should do so at the earliest opportunity e.g. when submitting an amendment. We will audit the registration details as part of the annual progress reporting process.*
   > *To ensure transparency in research, we strongly recommend that all research is registered but for non-clinical trials this is not currently mandatory"*

   This Trust has a standard operating procedure, Gaining and maintaining authorisations SOP (see attached) which states that REC approval is required for relevant research.

2. **Does your institution have a policy requiring those conducting clinical trials in humans to post the results of those trials on a public clinical trials registry within 12 months of a trial being completed? If yes, please provide a link to the policy.**

   Yes - Please see section 4.2.8 and 4.3 (Timing) in the attached document for details

   We also have a Sponsorship SOP which is publicly available on the Trust's website (see http://www.uhbristol.nhs.uk/research-innovation/information-for-researchers/setting-up-and-running-a-clinical-research-study/templates-and-sops/sops/).

3. Does your institution have a policy requiring those conducting clinical trials in humans to post the methodologies of those trials on a public clinical trials registry and/or different online platforms, and if so, within what time frame? If yes, please state the time frame and provide a link to the policy.

Please see our response to question 2. For clinical trials of an investigational medicinal products we are required to post to EudraCT, and the methodology must be included, but this is post hoc (along with results). This falls under our 'Gaining and maintaining authorisations SOP (see attached).

We do not have a policy or SOP for devices trials.

4. Does your institution audit staff and contractor compliance with the policies referred to in questions 1-3? If yes, please provide a link to a document providing the most recent audit data, or if such data exist but are not online, please provide the relevant data.

The Research and Innovation department carries out monitoring of individual studies against our SOPs, but no audit of compliance with the Health Research Authority/Research Ethics Committee requirements referred to in them has been carried out.

5. How many clinical trials sponsored by your institution were completed during the calendar year 2015?

There were 3 studies which submitted an End of Study Declaration form in 2015:

- An RCT to compare normoxic versus standard cardiopulmonary bypass in cyanotic children undergoing cardiac surgery (Oxic-2) – Eudract 2010-019713-21
- Xenon and cooling therapy in babies at high risk of brain injury following poor condition at birth: randomised pilot study (Cool Xenon 2) Eudract 2011-005397-34
- Circadian variations in cytokines and the effect of timed release tablet prednisone in polymyalgia rheumatic Eudract 2008-007315-32

6. How many clinical trials sponsored by your institution that were completed during the calendar year 2015 have been registered on a public clinical trials registry as of 24 February 2017?

All three studies are registered on a clinical trials registry.

- Oxic 2 is on the EU Clinical Trials Registry and the ISRCTN Registry.
- Cool Xenon 2 and the Circadian variations studies are both on ClinicalTrials.gov.

7. How many clinical trials sponsored by your institution that were completed during the calendar year 2015 have posted results on a public clinical trials registry as of 24 February 2017?

None.

- Oxic-2*:* In 2015 it was not a requirement to post the results on a public clinical trials registry. Consequently, the fields on EudraCT do not lend themselves to the data collected and the output of the analysis as run for this study. The End of Study report was submitted within 6 months to the MHRA and, in agreement with the MHRA, a full final report will be submitted, once the analysis (currently ongoing) is complete.

- Cool Xenon 2: This was the second phase of a larger study and the intention is not to publish the results until the next phase (Cool Xenon 3) has been completed. Cool Xenon 3 is in recruitment phase and plans to close in Dec 2018.

- Circadian variations study*:* The results have been submitted to Clinicaltrials.gov registry. Clinicaltrials.gov have asked the CI to make some changes before the information is released and made public. This is currently underway.

8. Please provide the name of each clinical trial that was sponsored by your institution and was completed during the calendar year 2015 that has not been registered on a public clinical trials registry as of 24 February 2017, together with the name and email address of the Principal Investigator (or equivalent position within the research team) of that trial.

Not applicable – please see response to question 7.

9. Please provide the name and unique identification number of each clinical trial that was sponsored by your institution and was completed during the calendar year 2015 that has not posted its results on a public clinical trials registry as of 24 February 2017, together with the name and email address of the Principal Investigator (or equivalent position within the research team) of that trial.

Not applicable – please see response to question 7.

This concludes our response. We trust that you find this helpful, but please do not hesitate to contact us directly if we can be of any further assistance.

If, after that, you are dissatisfied with the handling of your request, you have the right to ask for an internal review. Internal review requests should be submitted within two months of the date of receipt of the response to your original letter and should be addressed to:

Trust Secretary
University Hospitals Bristol NHS Foundation Trust
Trust Headquarters
Marlborough Street
Bristol
BS1 3NU

Please remember to quote the reference number above in any future communications.

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

To view the Freedom of Information Act in full please click here.

Yours sincerely,

[redacted]