

Freedom of Information Request **6417**

Our Ref: FOI 6417/DMH/FC/CR
Date: 4th September 2020
Name: Nicholas DeVito
Via email: Nicholas DeVito <request-682980-21bc3c8f@whatdotheyknow.com>

Freedom of Information Team
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Email: foi@hey.nhs.uk

Dear Nicholas DeVito

Thank you for your Freedom of Information Request, please find the Trust's response below:

Dear Hull University Teaching Hospitals NHS Trust,

We are interested in how universities and hospital trusts manage the registration of clinical trials and the reporting of their summary results at the institutional level. For the avoidance of doubt, we are not interested in, nor asking about, trialists sharing of individual patient-level data with re-identification risks nor about specific study-level documentation. Throughout this request, we refer to clinical trials as defined by the WHO (i.e. not just CTIMPs as covered under EU law) (<https://www.who.int/news-room/q-a-detail/clinical-trials-questions-and-answers>).

- 1. Please can I request your clinical trials transparency/clinical trial registration and reporting policy or policies, standard operating procedures (SoPs), guidance given to staff, and any other overarching documentation for your institution related to the registration and reporting of clinical trials. If your institution contains sub-units (i.e. CTUs, joint research offices) with their own detailed clinical trials policies and procedures separate from any overarching institutional documentation, please provide these as well.*

If you provide more than one document can you please indicate which document(s) primarily cover which of these areas and if possible the relevant sections of the document provided (or acknowledge the absence of documentation covering these areas):

Please see the attached document - IRAS declaration to be signed by each CI/PI –which includes whether the project is being registered on a public database/registry (QA50-1).

Appendix 1.

-Requirements related to the registration of clinical trials.

Please see the attached document R&D GCP SOP 12 - End of Trial, Section 4, pages 5,6 & 7 (highlighted). R&D Policy 264 section 8.33, 8.34, 8.35 (pages 28 and 29)

Appendix 2 and Appendix 5

-Requirements for investigators to report the summary results (non-individual patient-level results) of their clinical trials in any form.

Please see the attached R&D GCP SOP 12 - End of Trial, Section 4, pages 5,6 & 7 (highlighted). R&D Policy 264 section 8.33, 8.34, 8.35 (pages 28 and 29) **Appendix 2 and Appendix 6**

-Requirements to report results, specifically, to a clinical trial registry for all clinical trials (e.g. EU Clinical Trial Register, ClinicalTrials.gov, ISRCTN or any other ICTRP approved registry).

Please see the attached IRAS application form excerpt, End of Trial SOP, Declaration of PI Responsibilities, Formal Agreement, publication working instruction 13 (W113) **Appendix 1 Appendix 2 Appendix 3 and Appendix 9**

-Processes for determining sponsorship of clinical trials, and how sponsorship responsibility is assumed/handed off when new primary investigators (PIs) join or leave the institution.

Please see the attached R&D GCP SOP 05 – Sponsorship. **Appendix 4**

-If applicable, how responsibility for registration and reporting is handled for trials with external (domestic or international) collaborators. The same procedures apply

-If applicable, how registration and reporting is handled for trials funded or co-sponsored with industry, if different from standard procedure. The same procedures apply

-Disciplinary actions that may be taken by your institution against investigators failing to comply with any of the relevant policies provided.

There have been none taken to date. However, sponsorship of future trials may be declined if there is a track record of failure to report in a timely fashion. The Director of R&D will write to PIs after escalation from the Sponsor Oversight Group (SOG) to alert them of the need to report and the potential implications of further sponsorship.

Please ensure the effective/publication date of any provided documentation is clear whenever possible.

2. *Please provide the following information on university administrative or support staff, not including the Primary Investigators of specific studies, who are explicitly tasked by their job description with oversight in ensuring trials are registered and reported at your institution:*

Within a number of academic research units in our Trust there are Clinical Trial Managers who would support the sponsor (Hull University Teaching Hospitals NHS Trust) to ensure trials are registered and reported (3.0WTE). However this is not their dedicated function and is not explicitly part of their job descriptions (some of these staff are employed via the University of Hull).

-the number of staff with any part of their job explicitly related to these activities

We have 1.82 Whole Time Equivalent (WTE) staff (centrally within the Trust R&D Team – please see above).

-Full/Whole Time Equivalents (FTE) dedicated to these activities

We have 0.2 WTE (centrally within the Trust R&D Team - please see above)

-Job titles and descriptions Quality Assurance Manager and Clinical Trials Monitor see attached **Appendix 10 and 11**

-Grades of positions QA Manager (Band 7 NHS), Clinical Trial Monitor (Band 6 NHS)

-If any of these posts are currently vacant. If these tasks are not centralised within specific individuals, please provide any documentation available which explains how staff undertake trial registration/reporting tasks or acknowledge that no specific documentation exists in this area.

Not Applicable

3. Please provide any standard operating procedures, documentation, or relevant policies detailing trials transparency monitoring at your institution either overall or for relevant trial-conducting division(s) within your institution.

If you provide more than one document, or refer to document(s) provided in another response, please indicate which document applies to which of the following criteria and if possible the relevant sections (or if no documentation exists for that criteria):

There are no specific Standard Operating Procedures for transparency monitoring. This is to be added into the Trust R&D Operating Policy (CP264) as part of its review (due November 2020).

Appendix 5

4. How trial registration and results reporting is monitored at your University.

Bi-monthly via Sponsor Oversight Group (see attached ToR- Feb 2020). Please note – we are not a University (not a Higher Education Institute). We are a hospital Trust. **Appendix 8**

5. How investigators are notified that results are due to report.

Email reminders (from Outlook calendar reminders to our QA Manager and Clinical Trial Monitor).

If there is no response or no plan of action, the issues are escalated to the SOG and the Chair will write to the PI requesting a response and plan which is then monitored.

6. Whether past registration and reporting are considered during the process of new trials being planned and approved within the institution.

Yes – new applications for sponsorship discussed at SOG meetings including any risks assessed (including previous or current non-reporting issues).

7. In addition, please provide any information on disciplinary actions taken by your institution related to clinical trial registration and/or reporting, in the last 5 years and any official audits of clinical trial registration and/or results reporting conducted at your institution in the last 5 years. If this information does not exist, please acknowledge this in your response.

As explained above there have been no disciplinary actions taken to date but a status report is given to the Sponsor Oversight Group and if necessary any disciplinary actions would be decided at that time.

At the behest of The House of Commons Science and Technology committee in May 2019, an audit was carried out to identify the Trust sponsored trials that had not been reported and to ensure that they were reported as quickly as possible.

A regular check of the EU Clinical Trials Register is carried out to ensure trials are being reported according to the legislation. Regular updates are sent to the R&D Directors and R&D Manager.

This information is also shared with the Sponsor Oversight Group. (Please find attached an example of the information shared – information available on <https://eu.trialstracker.net/>).

Please see the e mail Appendix 7.

Please note that some documents have been redacted names and telephone numbers have been removed and we are exempting these under section 40 (2) of the Freedom of Information Act 2000. The Trust considers staff names to be personal information and will only release staff names in accordance with the Trust's policy.

If the fulfillment of this request is to be delayed due to the COVID-19 pandemic, please inform me of this and the expected time in which you believe you will be able to honor the request. I am happy to allow a reasonable amount of extra time to fulfill any requests.

The information we have provided to you is copyrighted to the Hull University Teaching Hospitals NHS Trust and provided to you free of charge for your personal use or for other specific uses permitted in the Copyright Act. If, however you wish to use the information we have provided for any commercial purposes including the sale of the information to a third party then, under the Regulations on the Re-use of Public Sector Information Regulations 2005, you must ask us for permission to do so in respect of each specific piece of such information. If we do grant such permission this may involve a licensing arrangement which may attract a fee. All information provided under Freedom of Information is deemed to be in the public domain.

If you have any queries or are unhappy with the service you have received in relation to your request and wish to request a review or make a complaint on our decision, please contact us quoting the FOI reference number. If you are not content with the outcome, you may apply directly to the Information Commissioner for a decision. Generally, the ICO cannot make a decision unless you have exhausted the complaints procedure provided by the Hull University Teaching Hospitals NHS Trust. The Information Commissioner can be contacted at: The Information Commissioner's Office, Wycliffe House, Water Lane, Wilmslow, Cheshire, SK9 5AF.

Yours sincerely

Freedom of Information Team