Freedom of Information Act 2000 (FOIA)

Decision notice

Date: **23 March 2018**

Public Authority: **University of Leicester**
Address: **University Road**
Leicester LE1 7RH

Decision (including any steps ordered)

1. The complainant has requested information concerning the GENVASC study. The University of Leicester ('the University') released some information; directed the complainant to where other information is already published and withheld some information under section 22A (research). During the Commissioner's investigation the University voluntarily released that information – the study protocol.

2. The Commissioner's decision is that:

   - The University has released all the information it holds that falls within the scope of the complainant's request and has complied with section 1(1) of the FOIA.

   - The University was not entitled to rely on section 22A when it originally withheld some of the requested information.

3. The University has now disclosed the withheld information and the Commissioner does not require it to take any steps to ensure compliance with the legislation.

Request and response

4. The Genetics and Vascular Health Check study (GENVASC) is a large study that started in August 2012 and that is run in conjunction with Clinical Commissioning Groups (CCG) and Primary Care practices across Leicester. The purpose of GENVASC is to help determine whether the addition of genetic information can improve risk prediction of coronary artery disease.

5. On 20 May 2017, the complainant wrote to the University and requested information in the following terms:

   "I ask you to provide me with a copy, either electronically or by mail, of the project proposal as finally approved by the relevant NHS Research Ethics Committee, including any approvals of any further materials which may have been subject to delegated approval."

6. The University responded on 19 June 2017. It released some relevant information. First, a GENVASC study approval letter from East Midlands Research Ethics Committee (REC) dated 23 December 2016, which approved the current documents used in the GENVASC study. The University advised that the study was first given approval on 5 July 2012 and was given "sponsor greenlight" to begin recruitment on 2 October 2012.

7. Second, the University released a study approval letter from the Health Research Agency (HRA) dated 20 January 2017. The University advised where more information about HRA's approval process is available and where other documents and templates relating to the GENVASC study are published.

8. The University withheld the study protocol submitted to the REC under section 22A of the FOIA as it considered this to be research information, and confirmed that it considered the public interest favoured maintaining this exemption.

9. The complainant requested a review on 20 June 2017. He considered that the information provided in the materials that the University had released was inaccurate; he was dissatisfied with the information published on the University's website and disputed that section 22A could be applied to the information he had requested, namely the 'project proposal' as opposed to the 'study protocol'.

10. The University provided a review on 18 July 2017. It summarised the complainant's dissatisfaction as concerning the withholding of the

'protocol'. It maintained its position that the study protocol is exempt from release under section 22A and that the public interest favoured maintaining the exemption. The University said that the study's principal investigator was willing to meet the complainant to discuss his concerns.

Scope of the case

11. The complainant contacted the Commissioner on 6 September 2017 to complain about the way his request for information had been handled.

12. During the investigation, the University advised the Commissioner that, on 19 February 2018, it had disclosed "the study protocol" to the complainant.

13. The complainant remained dissatisfied with the University's response to his request: its interpretation of the request and its application of section 22A. He said he had requested 'the project proposal' and that the study protocol the University has released is not the same thing.

14. The Commissioner's investigation has focussed on whether the University complied with section 1(1) with regard to the request and released to the complainant all the relevant information it holds. If necessary, she has been prepared to consider whether, at the time of the request, the requested information was exempt from disclosure under section 22A, and the balance of the public interest.

Reasons for decision

Section 1 – general right of access to information held by public authorities

15. Section 1(1) of the FOIA says that anyone who requests information from a public authority is entitled (a) to be told if the authority holds the information and (b) to have the information communicated to him or her if it is held.

16. The Commissioner has reviewed the two letters the University released. The first, from the REC and dated 23 December 2016, notes 'Amendment number: 6' and 'Amendment date: 24 October 2016'. It goes on to say that this amendment was reviewed on 21 December 2016 by the Sub-Committee and gave a favourable ethical opinion of it on the basis of the amendment form and supporting documents. The

letter then lists the documents reviewed and approved at the 21 December 2016 meeting. These include advertising material, GP information sheets, a participant consent form and a 'Notice of Substantial Amendment (non-CTIMP) with regard to amendment '6' above.

17. The second letter is from the HRA to the University dated 20 January 2017. In addition to other, more general information, the letter confirms that the study has been given HRA approval. With regard to the participation of NHS organisations in England the letter goes on to say that for non-commercial studies, "*…the local document package should include an appropriate Statement of Activities and HRA Schedule of Events.*"

18. With regards to the complainant's concerns, the Commissioner has first considered the project proposal/study protocol matter. The complainant's request was for the 'project proposal' and the University has referred to, and at the time of the request applied section 22A to, the 'study protocol'. The Commissioner asked the University to clarify whether by 'study protocol' the University actually means 'project proposal' and, if not, whether it holds other information that can be categorised as a 'project proposal'.

19. On 2 March 2018 the University confirmed to the Commissioner that "*protocol/proposal is semantic and they are one of* [sic] *the same*". The Commissioner understands by this that the University does not hold separate information that could be categorised as the 'project proposal' and that the study protocol it has now released is all the information it holds that falls within the scope of this element of complainant's request. The Commissioner is prepared to accept that the University holds no further information falling within the scope of a 'project proposal'.

20. The complainant next noted that the protocol that has been released to him is dated 22 September 2016. He noted the reference in the 23 December 2016 letter to the 'substantial amendment' with the associated date of 24 October 2016 and queried why he had not received a later version of the protocol that includes the October amendment.

21. The University has confirmed that the complainant received the latest version of the protocol – version 1.3 22/09/2016 – that is, the Commissioner understands, the version that includes all approved amendments. The University explained that the reference in the REC letter to 24 October 2016 referred to the date by which the amendment

in question had to be submitted. The resulting amendment was made on 22 September 2016 (ie before the 24 October 2016 deadline) prior to the protocol being submitted for approval. Version 1.3. 22/09/2016 of the protocol was reviewed by the REC Sub-Committee on 21 December 2016 and approved.

22. The Commissioner accepts the University's explanation and is prepared to accept that the version of the protocol that the University has released satisfies the complainant's request for the study proposal/protocol "*as finally approved by the relevant NHS Research Ethics Committee"*. This version is the version the University held at the time of the request, and, the Commissioner understands, remains the current version. Although it is not expressed completely clearly, in correspondence to her dated 26 February 2018, the University explained that the latest approved version of a document supersedes all earlier versions of the document and is the version used until permission is given for it to be superseded by a new version.

23. The Commissioner has gone on to consider the complainant's remaining concerns about information he considers the University may hold that it has not released. In his request, as well as the study proposal/protocol, the complainant also requested "*any approvals of any further materials* [used in the study] *which may have been subject to delegated approval*".

24. The complainant has noted the assurance the University gave to him and the Commissioner on 2 March 2018 that the list of approved documents contained in the REC letter of 23 December 2016 is the full list of documents reviewed and approved by the HRA as part of the process of approving amendment 6, and that any documents required or requested by the HRA would have appeared in this list. The complainant seems to be suggesting that he has not received copies of the documents in that list.

25. The list is as follows:

    (i) Copies of advertisement materials for research participants v2.0 - poster
    (ii) GP/consultation information sheets or letters v1.0 – Practice pack
    (iii) Notice of Substantial Amendment 6
    (iv) Other [Withdrawal form] v1.0
    (v) Other [CV – Azhar]
    (vi) Other [CV – Heer]
    (vii) Other [Information for addition to NHS HC invite letters] v1
    (viii) Participant consent form [Un-witnessed] v1.1

(ix) Participant consent form v4.2
(x) Participant information sheet (PIS) [abbreviated] v3.0
(xi) Participant information sheet (PIS) v4.0
(xii) Research protocol or project proposal v1.3

26. The Commissioner has reviewed the University's website where it advised the complainant that some of the information he has requested is published. It appears to her that documents (i) (a poster), (ii) (a 'Practice Pack'), (iv), (viii), (ix), (x) and (xi) are available from that website (and are therefore exempt from release under section 21 of the FOIA). The University has also now released document (xii) to the complainant – the research protocol. The complainant therefore has access to these eight documents. The documents outstanding appear to be (iii), (v), (vi) and (vii).

27. The Commissioner questioned the University about these four documents. In response, the University told her that it does not consider these four documents fall within the scope of the complainant's request. Based on its correspondence with him, the University considers that the complainant wants to know whether the GENVASC study had ethics research committee approval and he wanted to know how personal data collected from research subjects would be processed. Its interpretation of the request, therefore, was for all documents where the content refers to the study protocol.

28. Document (iii), above, is the 'Notice of Substantial Amendment (6)', a copy of which the University has provided to the Commissioner. The University has explained that this document is a form that gives notice of what changes are being made to a document. The research study team and Sponsor complete the form and submit it to the REC and HRA for their approval.

29. In this case, the University says that the amendment in question was to extend the recruitment end date of the study and to add the areas of Nene and Corby as study sites, along with minor clarifications of the un-witnessed consent process and site of sample receipt. It says this information was updated and contained within the current research protocol now disclosed to the complainant, as verified by the approval from the REC and HRA committees. The University considers that this particular information falls outside the scope of the complainant's request.

30. The complainant's request was for the version of study protocol that had been finally approved, and "…*any approvals of any further materials which may have been subject to delegated approval*". The Commissioner

understands this to mean approvals of any material associated with the study but *other* than the approved protocol itself. Having reviewed the Notice of Substantial Amendment (6), she agrees that it concerns the protocol, the approved version of which the complainant has requested and received, and as such it is not relevant to the request.

31. The University has explained that documents (v) and (vi) – copies of which it has provided to the Commissioner – are the CVs of the co-investigators of the GENVASC study in Nene and Corby CCGs. As such the University considers these are outside the scope of the complainant's request and the Commissioner agrees. The 23 December 2016 letter addresses the complainant's request for '*…approvals of any further materials*' such as the CVs; the request was not for the materials themselves.

32. Document (vii) is not a complete document. The University has explained that it is simply a paragraph that is inserted into a routine 'Health Check' letter that GP practices send to patients. In the University's view, this information does not fall within the scope of the complainant's request as it does not directly relate to the study protocol but acts as more of a signpost to the study for potential participants. The Commissioner has reviewed the paragraph and agrees that it cannot be categorised as an element of the finally approved study protocol or an approval of other material associated with the study. She therefore finds it does not fall within the scope of the complainant's request and that, again, the 23 December 2016 letter addresses the second element of the complainant's request.

33. While some of the University's explanations are not completely clear, the Commissioner understands, and is prepared to accept the following:

    - The 22 September 2016 version of the study protocol that the University has released is the version that had been approved at the time of the complainant's request and this information satisfies the first element of the complainant's request.

    - The University has released all the approval material that it holds that is relevant to the second element of the complainant's request; namely the REC letter dated 23 December 2016 letter and the HRA letter dated 20 January 2017. Some associated information – listed in the 23 December 2016 letter - is already published on the University's website; the remaining information is not relevant to the request.

- That the University holds no other information that concerns the approval of *'further materials'* associated with the study.

34. The Commissioner therefore finds that the University has complied with its obligations under section 1(1) of the FOIA.

Section 22A – information derived from a programme of research

35. On 19 February 2018 the University disclosed the study protocol to the complainant that it had originally withheld under section 22A. The University has explained that it was always its intention to be entirely open. After further consideration, and taking into consideration subsequent HRA recommendations in November 2017, the University considered that, at the point it released the information, on balance the public interest in disclosing the information outweighed the public interest in withholding it. The University nonetheless considers it was correct to apply the section 22A exemption at the time of the request.

36. The complainant, however, considers the University had incorrectly applied section 22A when it responded to his request.

37. The protocol is a document that provides a background to the study, the hypothesis underpinning it and the study's objectives. It also details how the study will be run and how the resulting data will be managed.

38. Section 22A, which is subject to the public interest test, provides that:

"(1) Information obtained in the course of, or derived from, a programme of research is exempt information if—

(a) the programme is continuing with a view to the publication, by a public authority or any other person, of a report of the research (whether or not including a statement of that information), and

(b) disclosure of the information under this Act before the date of publication would, or would be likely to, prejudice—

(i) the programme,
(ii) the interests of any individual participating in the programme,
(iii) the interests of the authority which holds the information, or
(iv) the interests of the authority mentioned in paragraph (a) (if it is a different authority from that which holds the information)."

39. In a submission to the Commissioner, the University has provided the following, further, background to the GENVASC study. The principal purpose of the study is to investigate whether adding genetic information can improve the prediction of coronary artery disease (CAD). GENVASC is a cohort study; this means researchers will recruit subjects and their data and observe the study group over a period of time which could be many years.

40. The research will not provide individuals with results of the findings on a routine basis. This is because the clinical relevance of some of the research findings may take several years to realise and require further validation. Therefore, GENVASC research subjects are unlikely to personally or directly benefit from taking part in the project. Nonetheless, the information researchers get from this project will help in the future to improve the healthcare of people at risk of cardiovascular diseases.

41. With regards to section 22A(1)(a), the University has told the Commissioner that GENVASC, as a health research and cohort study, aims to publish its findings in the future. The reasoning for this study is that improving the accuracy of risk categorisation of CAD is a high public health and clinical priority.

42. The University has confirmed that the study protocol was going to be published at the time that any report from GENVASC was first published. It says there was, therefore, a settled intention for this information to be published prior to the complainant's request being received.

43. At this point no publication date has been determined. The University has explained that, as a cohort study, GENVASC is observational and the researchers will simply collect information on participants (including information from their DNA) and observe what happens, without applying any intervention to participants. At the time of the request and currently, the study is still ongoing with recruitment planned till at least March 2021.

44. The power to accurately determine whether adding genetic information will improve how accurately the risk of CAD can be predicted depends on the number of subjects recruited and the number of "cardiovascular outcome events" that happen during follow-up. As such, the University says that the timing of the study's principal publication will depend on when there is sufficient information to make this scientifically and clinically worthwhile. The value of cohorts increases the longer the follow-up period and further publications, including those of any ancillary findings, are planned.

45. The Commissioner is satisfied that the disputed information – the study protocol - was derived from a programme of research and is prepared to accept that the programme is continuing with a view to the University publishing a report of the research. She has gone on to consider whether the condition under section 22A(1)(b) – which concerns the likely prejudice to the research caused by disclosing the information – has been met.

46. In its submission the University has said that it appeared that the complainant, who was considering taking part in the study, was not satisfied with information that was contained in the Patient Information Sheet he had received, nor with information that was available online or the fact that the GENVASC study had Ethical and HRA approval. The research team had offered to meet him to resolve his queries and concerns.

47. The Commissioner understands that the complainant did not take up this invitation as the University goes on to say that the complainant's 'lack of engagement' strongly suggested to it that if it was to provide him with the protocol there would be a high possibility of him using its contents as a means to support his objections to the study. According to the University, if the complainant made incorrect assertions and these were reported in the media, these assertions could seriously undermine the long-term objectives of the study. For example, existing participants could be persuaded, based on negative media coverage, to withdraw their participation from the study and fewer people might engage with it in the future. The University says that, as it has explained above, the success of the study correlates directly with the number of individuals participating. The greater the number of participants, the more accurate the findings and the wider the public health benefit. In the University's view, at the time of the request, the prejudice it has described was likely.

48. In the Commissioner's view, the prejudice the University has described was not likely. It seems to the Commissioner that from an initial conjecture, the University has spun out a series of related conjectured outcomes that there does not seem to be any firm evidence to support. The Commissioner has reviewed the complainant's correspondence with the University, particularly his request for an internal review. While the complainant expresses some concerns about how the study might be being managed, he does not suggest he will go to the media. His correspondence seems to be seeking answers to particular questions he personally has about the study, which, in the Commissioner's view is a reasonable thing to do.

49. However, the University appears to have hypothesised that because the complainant did not accept an invitation to meet the research team, this means that he would have used the protocol – if it had been released to him – to support his objections to the study, his 'incorrect assertions' would then be picked up by the media, and the resulting reporting would undermine the study.

50. In the Commissioner's view, the University's thinking shows a lack of confidence in the robustness of its study and the protocol; this despite the fact that, as the University has re-stated, the study has Ethical and HRA approval. She considers it is reasonable for anyone volunteering to take part in a research programme – particularly a medical research programme – to want to know as much about the programme as possible. In this case, she considers that the complainant was entitled to have his questions answered and to have access to the information he believed he needed in order to decide whether to participate in the study, which included the study protocol.

51. The Commissioner does not accept, on the basis of the information the University has provided to her, that disclosing the withheld information at the time of the request would have prejudiced the study in the way the University has described, and that the condition under section 22A(1)(b) was not met. She therefore finds that the University was not entitled to rely on section 22A when it originally withheld the disputed information and she has noted no adverse effect from its subsequent disclosure to the complainant. Because she finds that section 22A was not engaged, it has not been necessary to consider the public interest arguments associated with this exemption.

Right of appeal

52. Either party has the right to appeal against this decision notice to the First-tier Tribunal (Information Rights). Information about the appeals process may be obtained from:

    First-tier Tribunal (Information Rights)
    GRC & GRP Tribunals
    PO Box 9300
    LEICESTER
    LE1 8DJ

    Tel: 0300 1234504
    Fax: 0870 739 5836
    Email: GRC@hmcts.gsi.gov.uk
    Website: www.justice.gov.uk/tribunals/general-regulatory-chamber

53. If you wish to appeal against a decision notice, you can obtain information on how to appeal along with the relevant forms from the Information Tribunal website.

54. Any Notice of Appeal should be served on the Tribunal within 28 (calendar) days of the date on which this decision notice is sent.

Signed

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