

Freedom of Information Act 2000 (FOIA) Decision notice

Date: 28 January 2019

Public Authority: Address: The Council University College London Gower Street London WC1E 6BT

Decision (including any steps ordered)

- The complainant has requested from University College London (UCL) the transcript of Professor Martin Birchall's oral evidence and a copy of his written evidence to the Special Inquiry into Regenerative Medicine. UCL refused to provide the requested information, citing section 41(1) of the FOIA – information provided in confidence.
- 2. The Commissioner's decision is that UCL correctly withheld this information under section 41(1).
- 3. The Commissioner requires no steps to be taken by the public authority.

Request and response

4. On 8 May 2018 the complainant made the following request for information under the FOIA:

"In 2017, UCL undertook a Special Inquiry into Regenerative Medicine. A report was published in September 2017. I would like to request the



transcript of Prof Martin Birchall's oral evidence and a copy of the written evidence he provided to the Inquiry."

- 5. UCL responded on 5 June 2018 and refused to provide the requested information citing section 41 of the FOIA information provided in confidence.
- 6. Following an internal review, UCL wrote to the complainant on 4 July 2018. It maintained its original position that section 41 applied to the information it had withheld.

Background

7. In June 2016 the Vice-Provost (Research) at UCL instigated a Special Inquiry into Regenerative Medicine Research.¹ Professor Stephen Wigmore was appointed to lead this Inquiry. The rest of the Inquiry team was appointed by Professor Wigmore in consultation with the Vice-Provost (Research) and the Vice-Provost (Health) from UCL. The purpose of the Inquiry,

"...was to provide an independent investigation of the involvement of UCL and its personnel in regenerative medicine research with a particular focus on tracheal and large airway tissue engineering and UCL's relationship with Professor Paolo Macchiarini and the Karolinska Institute. It was determined that the Special Inquiry should be separate from UCL's procedures for investigating and resolving allegations of misconduct. It was, however, acknowledged that the outcomes of the Inquiry might result in such procedures being instigated."(p.1)²

8. The witness statements were voluntary and the requested information was provided by Professor Birchall who is employed by UCL as Professor of Laryngology.

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https://www.ucl.ac.uk/drupal/site news/sites/news/files/Special Inquiry Final Report 6051 09702 7 .pdf

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 The Commissioner understands that RegenVox is a stem cell based tissue engineered partial laryngeal implant and INSPIRE is a stem cell based tissue engineered tracheal replacement.

Scope of the case

- The complainant contacted the Commissioner on 5 July 2018 to complain about the way her request for information had been handled. She disputed that the information provided to the Inquiry was confidential and expressed the view that the public interest in the information being released took precedence.
- 11. The Commissioner has considered whether UCL was entitled to rely on section 41 to withhold this information.

Reasons for decision

Section 41

12. Section 41(1) of FOIA provides that -

"(a) Information is exempt information if it was obtained by the public authority from any other person (including another public authority); and, (b) the disclosure of the information to the public (otherwise than under this Act) by the public authority holding it would constitute a breach of confidence actionable by that or any other person".

- 13. The Commissioner's advice on section 41 states that "information will be covered by Section 41 if -
 - *it was obtained by the authority from any other person,*
 - *its disclosure would constitute a breach of confidence.*
 - a legal person could bring a court action for that breach of confidence, and



• that court action would be likely to succeed." ³

Was the information obtained from any other person?

- 14. Section 41(1)(a) states that the information must have been obtained from "any other person". In this case, the individual providing testimony to the Inquiry was also employed by UCL. UCL's view is that the third party who provided the requested information was Professor Birchall.
- 15. UCL further contended that the information was not generated by UCL and covers information provided in confidence by a third party in line with section 41(1)(a). The public authority quoted the Commissioner's advice on section 41 as follows:

"...the exemption won't cover information the authority has generated itself, although it may cover documents (or parts of documents) generated by the public authority if these record information provided in confidence by another person, for example:

- A transcript of the verbal testimony given by an employee at an internal disciplinary hearing." (paragraph 13)

- 16. The Commissioner has considered whether an Inquiry set up by UCL itself "generated" the requested information. It could be argued that UCL brought about the report by instigating the Inquiry and it would be true to say that it would not have existed in the form it does otherwise. However, UCL states that the information was not generated by itself but is third party information provided to the Inquiry by Professor Birchall.
- 17. Whether or not UCL can be said to have generated the requested information, the verbal evidence is verbatim from Professor Birchall and the members of the Panel posing questions (save for a few inaudible words that could not be reproduced). The Commissioner has also been provided with the written evidence which is directly from the Professor himself. The Commissioner's advice provides the scenario where even if an authority has generated the information itself, that information may

³ <u>https://ico.org.uk/media/for-organisations/documents/1432163/information-provided-in-</u> <u>confidence-section-41.pdf</u>



be exempt in the case of a transcript of the verbal testimony given by an employee at an internal disciplinary hearing.

- 18. Although the withheld information was not an internal disciplinary procedure, the Special Inquiry can be considered to have similarities. UCL has argued that individuals giving statements have the same expectations around how information should be treated in terms of confidentiality and that the parties are broadly equivalent. The scope of the Inquiry makes it clear (see 'Background') that it was "separate from UCL's procedures for investigating and resolving allegations of misconduct." Nonetheless it is acknowledged that the outcome of the Inquiry might have resulted in the instigation of such procedures.
- 19. The requested information is for the written and verbal evidence provided by Professor Birchall. Although he is employed by UCL, within the context of the Inquiry the Commissioner accepts that the Professor is "another person".
- 20. Having established that the withheld information was obtained from another person, the Commissioner must next consider whether or not its disclosure to the public (otherwise than under FOIA), would constitute a breach of confidence 'actionable' by that or any other person.

Would disclosure constitute an actionable claim for breach of confidence

- 21. The usual test for section 41 cases is set out in the case of *Coco v Clark* [1969] *RPC 41* which sets out three elements which must be present in order that a claim can be made. According to the decision in this case a breach of confidence will be actionable if:
 - the information has the necessary quality of confidence;
 - the information was imparted in circumstances importing an obligation of confidence; and
 - there was an unauthorised use of the information to the detriment of the confider.

However, for that claim to be 'actionable' within the meaning of section 41(1)(b) of FOIA, a public authority must establish that an action for breach of confidence would, on the balance of probabilities, succeed.

Does the information have the necessary quality of confidence?

22. In order for information to have the necessary quality of confidence, it must be more than trivial and not otherwise accessible. The Commissioner has read the withheld information which consists of



information about medical techniques, details of past research and ongoing research, details of specific patient treatment, the relationships between researchers and matters surrounding UCL's involvement with regenerative medicine. The information is clearly more than trivial, dealing as it does with serious medical conditions and death.

23. The Commissioner has considered whether the information is otherwise accessible. Having carried out internet searches, the testimony from Professor Birchall in its entire and unedited form is not accessible. His testimony is only as it appears in an edited, third person form in the Inquiry Report. There are media reports concerning UCL's relationship with Paolo Macchiarini, allegations of professional misconduct and criticisms of past treatment or proposed research into the use of donor/synthetic tracheas. UCL has confirmed that Professor Birchall's statements have not been made accessible to the wider public. The Commissioner accepts that the withheld information therefore has the necessary quality of confidence.

Was the information imparted in circumstances importing an obligation of confidence?

24. The Call for Evidence from the Inquiry Panel included the following statement:

"Important Information – Please Read Carefully Please be aware that evidence provided to the Inquiry is not protected by any form of privilege. Accordingly, you must not defame any person, breach any obligation of confidentiality that you may owe to a third party or incriminate yourself in any way.

The Inquiry does not intend to publish written statements received and oral evidence will be heard in private. You should be aware, however, that the Inquiry reserves the right to:

- name all (or any) of those individuals and organisations who have provided statements, information or other evidence to it; and
- refer to, attribute and quote from written statements and evidence provided to it in its Report.

In addition the Inquiry and/or UCL may be required by law, or either or both may choose, to disclose information it holds to third parties including regulatory bodies and/or law enforcement agencies in the United Kingdom and/or elsewhere. In short, the Inquiry and UCL cannot, and they do not, guarantee that information provided by you will be kept confidential.

If you have any concerns about the evidence that you wish to share



with the Inquiry you should take legal advice before doing so."

- 25. UCL argues that the requested information has been tightly controlled as the expectation from those providing testimony was that it would be kept confidential by UCL, apart from the proviso that individuals would be named and certain evidence disclosed in the Report that followed. It makes it clear that it did not intend to publish these statements or disclose them to anyone unless required to do so by regulatory or law enforcement agencies. The final sentence explicitly does not guarantee confidentiality to those giving testimony. Notwithstanding the various provisos, the Call for Evidence provides an assurance that the testimony will not be disclosed unless UCL is required to do so by law.
- 26. The complainant is convinced that the Call for Evidence and its provisos mean that anyone providing testimony would have no expectation of confidentiality. The Commissioner understands this viewpoint because the statement is qualified both by the Inquiry's own need to use evidence in the Report and by the knowledge that it might be obliged to pass on information that emerged from it to the necessary authorities. UCL accepted that it could not guarantee confidentiality in its review response but only in the sense that confidentiality can never be guaranteed. It further contended that it amounted to a statement of law because it could always be compelled to provide statements to regulatory or law enforcement bodies. The fact that the verbal evidence was in private and that written statements would not be published gave a qualified assurance of confidentiality.
- 27. UCL has provided evidence that Professor Birchall had the expectation that his testimony would be kept confidential. The public authority considers that the disclosure of the information would be an invasion of the professor's privacy due to the frankness of the testimony and the expectations under which it was made and would be tantamount to an actionable breach of confidence if it was disclosed.

Would disclosure be detrimental to the confider?

- 28. The nature of the information is professional rather than personal. Any disclosure has to be assessed against the detriment to the confider's professional life and reputation.
- 29. UCL suggests that disclosing the information would be detrimental to the confider as it would be an invasion of Professor Birchall's privacy due to the frankness with which he gave his testimony. The Commissioner accepts that there is likely to be detriment to his professional life and reputation by publicly disclosing information that was provided to the Inquiry in the belief that it was confidential.



30. Although section 41 is an absolute exemption and is not subject to consideration of the public interest test under the FOIA, there exists a recognised defence to an actionable breach of confidence which requires the public interest to be considered. The Commissioner has therefore gone on to consider this below.

Is there a public interest defence for disclosure?

- 31. UCL's view is that the public interest is satisfied by publication of the Report itself and it outlined what it believed to be the potential consequences of releasing this information:
 - It would undermine UCL's ability to conduct such Inquiries in the future as individuals called to give evidence would know that their evidence would not be confidential. This could lead to a situation where testimony is neither frank nor full and volunteers of their testimony might view UCL as untrustworthy.
 - Special Inquiries are important mechanisms for establishing facts around allegations of misconduct or public concern over research integrity. This requires a safe space to be able to reach conclusions, both at the time and following completion of the work, in order that UCL is held to account for its actions.
 - The disclosure of confidential evidence provided to the Special Inquiry would harm relationships between all parties jeopardising further research which, UCL argues, is not in the public interest.
- 32. The complainant has an interest in whether other trachea transplant patients were mentioned than those in the published Report and whether there had been discussion about the testing of trachea transplants on pigs.
- 33. The complainant argues that the Inquiry which published its report in September 2017 claimed to have documented the clinical cases of trachea transplantation in which employees of UCL had been involved. She believes that the Inquiry failed to do this accurately because the leader of UCL's trachea transplant team, Professor Birchall, indicated in a presentation he gave in 2010 that he had been involved in five adult cases that were not mentioned in the Inquiry's report. She explains that UCL issued a press release in 2010 announcing that their researchers had saved the lives of two adults, but only one is mentioned in the Inquiry's report. The complainant wishes to establish whether these additional cases were discussed during the Inquiry. She points out that a presentation given in 2014 by another member of the team indicated that, by then, only two out of ten trachea transplant patients had survived, suggesting that the five unaccounted for patients were likely to be dead. She is concerned that the statistics do not support the



Special Inquiry's view that UCL's airway transplant trials (INSPIRE and RegenVox) should proceed and describes it as "inexplicable". She claims that the Inquiry panel was only critical of transplants involving plastic tracheas performed by Paolo Macchiarini who has now been discredited. She states that the Inquiry panel appeared to overlook the negative opinion on cadaveric tracheal transplants published in February 2016 by Alessandro Nanni Costa, the Director of Italy's National Transplant Centre. In short, the complainant wants to know if Professor Birchall discussed all the patients and whether the Inquiry chose not to include them.

- 34. The complainant's view is that patient outcomes have not been disclosed in applications to funding bodies, regulatory authorities and ethics committees by the UCL's trachea transplant team. She states that the unfavourable results of pig experiments were not documented in the Inquiry and her view is that this information needs to be disclosed in the public interest.
- 35. Detailed supporting argument and documentation were provided by the complainant which can only be outlined in this decision notice. She believes that the Inquiry relied on information from the Research Ethics Committee (REC) for approval to conduct the RegenVox trial, some of it verbatim. According to the complainant it contains false information about patient outcomes which she states is a serious failing by the Panel Inquiry. She provides in detail what she believes is the false reporting of patient outcomes in the RegenVox proposal. Her primary concern is that the Inquiry report sent out a message that the procedure was safe. She believes that UCL has ambitions to continue with the trials, though the INSPIRE and RegenVox trials are currently suspended. Overall the complainant is concerned that clinicians and vulnerable patients and their relatives will be under a misapprehension that UCL trachea transplant by affiliated physician-researchers would be in their interest.
- 36. The complainant's view is that any actionable breach of confidence should be overridden. Her argument rests on her belief that incorrect information has been provided to funding bodies, regulatory authorities and ethics committees in order to conduct clinical trials. She does not accept that the conclusions reached by the Special Inquiry are consistent with trustworthy REC and grant applications that are in the public domain. In essence, she would like to see what questions were posed and the answers given to assess if the Inquiry's account is a true one. If not, the report could be rescinded and another investigation by an independent panel of experts that had not been appointed by UCL set up.



- 37. The Commissioner has been presented with a detailed and persuasive argument from the complainant as to why she considers it to be in the public interest to disclose the requested information. She has provided research in support of her view. It is not part of the Commissioner's role to assess the medical research that has already occurred or the proposals regarding future research that underpin the complainant's view that it is in the public interest to release this information. However, the Commissioner is able to consider the complainant's own opinion and broader arguments in relation to section 41 as set out in the paragraphs above.
- 38. The requested information would provide further context for researchers, patients and a section of the wider public. However, the Call for Evidence gave Professor Birchall the assurance that there was no intention to publish the whole of his evidence. He provided his statement voluntarily on that basis. The Commissioner is also mindful of the wider public interest in preserving the principle of confidentiality.
- 39. During the writing of the Inquiry report consideration was able to be given to what should be disclosed regarding confidential medical matters, whether personal or related to the research. The context within which the Inquiry was instigated is in the public domain as is the composition of the Panel and the terms of reference. Whatever an individual's view regarding the medical ethics of the proposed research and the Inquiry report, there would have to be a compelling reason to defend the overturning of a confidential statement. The Commissioner does not consider the public interest to be sufficient to provide a defence in court should this information be disclosed. The Inquiry Report has been published. In doing so, UCL has satisfied public interest by providing the material for a challenge to both its content and recommendations.

Other matters

40. Having seen the withheld information, The Commissioner is of the opinion that, although UCL solely claimed section 41, much of the content is also third party personal data.



Right of appeal

41. 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: <u>GRC@hmcts.gsi.gov.uk</u> Website: <u>www.justice.gov.uk/tribunals/general-regulatory-</u> <u>chamber</u>

- 42. 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.
- 43. 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

Pamela Clements Group Manager Information Commissioner's Office Wycliffe House Water Lane Wilmslow Cheshire SK9 5AF