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University ordered to disclose sensitive ME clinical trial data by information rights tribunal

Queen Mary, University of London v. Information Commissioner and Mr Alem Matthees
[2016] UKFTT 2015_0269 (GRC)

Article by David Bowden

The General Regulatory Chamber of the First Tier Tribunal has handed down its majority ruling in this case. It has upheld a ruling of the ICO. The ICO had ruled that none of the exemptions in the Freedom of Information Act 2000 applied. The ICO had ordered the university to release data from one of its clinical trials. The outcome of that trial had been controversial and activists sought release of the source data to have it re-verified. The clinical trial related to 640 patients who had ME and had been collected by the university since 2002. The ICO agreed that if the trial participant's ID number was withheld the prospects of identifying a participant was remote. The decision was a majority one with a clear but short dissenting judgment provided by the only tribunal member with any medical or clinical trials experience. It seems likely the university will appeal to the Upper Tribunal.

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[2016] UKFTT 2015_0269 (GRC) 17 August 2016
First Tier Tribunal, GRC (Tribunal Judge Brian Kennedy QC, Darryl Stephenson and Nigel Watson)

What are the facts?
Mr Matthees ('the patient') requested information related to a clinical trial concerning treatments for chronic fatigue syndrome ('CFS') carried out by Queen Mary, University of London ('the University').

The clinical trial here was called **PACE** which stood for **'P**acing, graded **A**ctivity and **C**ognitive behaviour therapy: a randomised **E**valuation trial'. This was a clinical trial carried out by the University which started in 2002. It was a large scale trial to test and compare the effectiveness of 4 of the main treatments available for people suffering from chronic fatigue syndrome ('CFS') also known as myalgic encephalomyelitis ('ME').

The clinical trial required the collection of large amounts of medical baseline and treatment results over the period 2005-2010 from the 640 patients who participated in it. Results from the PACE trial had also been published in the medical journal '*The Lancet*'.

What data was the patient seeking?
The patient's letter dated 24 March 2014 to the University was very specific. He asked for this:

> *'Previous FOI requests have asked for the release of PACE Trial results according to the outcome measures laid out in the trial protocol published in 2007 but since abandoned, and for additional summary statistics on the trial participants or at least the subgroup classified as "*recovered*" after the 52-week follow up period. These requests have been denied because the information was not held in final form and the calculations required to attain them from data that is held would supposedly exceed the limit of £450 (calculated as the estimated cost of one person spending 18 hours in determining whether the information is held, then locating, retrieving and extracting the information). A few of the comments posted in response have raised doubts over whether acquiring the data and performing relatively simple calculations would really take over 18 hours to perform.*
>
> *In order to help ease the burden of staff having to perform the required calculations themselves once the relevant data is located and retrieved, I would like to request the following selection of baseline and 52-week follow up data on all 640 individual PACE Trial participants for which the data exists, in a spreadsheet or equivalent file with separate columns for each variable:*
>
> - *SF-36 physical function scores (range 0-100 points),*
> - *CFQ fatigue Likert scores (range 0-33 points),*
> - *CFQ fatigue bimodal scores (range 0-11 points),*
> - *Oxford criteria CFS caseness (does participant meet criteria, yes or no),*
> - *Participant-rated CGI scores (range 1-7),*
> - *Doctor-rated CGI scores (range 1-7),*
> - *6MWT walking distances (in meters), and*
> - *The group which each participant was allocated to after randomisation (i.e. either to APT, CBT, GET, or SMC).*
>
> *If granted, please make sure that each individual row only contains values from the same participant, as is common practice for such data in spreadsheets, so that more than one variable can be analysed at a time. To clarify, I am requesting only 'anonymised' data, I am not requesting any information which can identify individual participants (not even the participant ID numbers if those are deemed to be inappropriate to include, so long as each individual row only contains values from the same participant).'*

What does the Data Protection Act 1998 say about medical data?
This falls within the definition of '*sensitive personal data'* which s2 defines as '*personal data consisting of information as to…(e) his physical or mental health or condition'*. Schedule 3 of the DPA prescribes

special conditions under which such sensitive personal data can be processed. The relevant parts say:

> *'1. The data subject has given his explicit consent to the processing of the personal data.*
> *……*
> *3. The processing is necessary—*
> *(a) in order to protect the vital interests of the data subject or another person, in a case where—*
> *(i) consent cannot be given by or on behalf of the data subject, or*
> *(ii) the data controller cannot reasonably be expected to obtain the consent of the data subject, or*
> *(b) in order to protect the vital interests of another person, in a case where consent by or on behalf of the data subject has been unreasonably withheld.*
> *4. The processing—*
> *(a) is carried out in the course of its legitimate activities by any body or association which—*
> *(i) is not established or conducted for profit, and*
> *(ii) exists for political, philosophical, religious or trade-union purposes,*
> *(b) is carried out with appropriate safeguards for the rights and freedoms of data subjects,*
> *(c) relates only to individuals who either are members of the body or association or have regular contact with it in connection with its purposes, and*
> *(d) does not involve disclosure of the personal data to a third party without the consent of the data subject.*
> *…*
> *8. (1) The processing is necessary for medical purposes and is undertaken by—*
> *(a) a health professional, or*
> *(b) a person who in the circumstances owes a duty of confidentiality which is equivalent to that which would arise if that person were a health professional.*
> *(2) In this paragraph "medical purposes" includes the purposes of preventative medicine, medical diagnosis, medical research, the provision of care and treatment and the management of healthcare services.'*

As to what is '*personal data'* the Data Protection Directive (**95/46/EC**) states in Article 2(a) that this '*shall mean any information relating to an identified or identifiable natural person* ("data subject"); *an identifiable person is one who can be identified, directly or indirectly, in particular by reference to an identification number or to one or more factors specific to his physical, physiological, mental, economic, cultural or social identity*'.

How was the patient able to use the Freedom of Information Act 2000?
Queen Mary College is part of the federal University of London. It is caught by the provisions of the Freedom of Information Act 2000 ('FoIA') because paragraph 53 of Schedule 1 part IV applies its provisions to '*the governing body of (a) an institution within the further education sector, (b) a university receiving financial support under s65 of the Further and Higher Education Act 1992*'.

What exemptions could public body rely on here when faced with this FoIA request?
Here the University sought to rely on 4 FoIA exemptions:

- s22A Information intended for future publication,
- s40(2) Personal information,
- s41 Information provided in confidence, and
- s43(2) Commercial interests.

What did the university do?
On 22 April 2014 the university refused to supply the data relating to the PACE trial to the patient based on these 4 FoIA exemptions. Although the university held an internal review at the patient's request, this did not change anything.

What ruling did the Information Commissioner's Office make on the patient's appeal?
By a written 30 page decision notice dated 27 October 2015 (**FS50565190**) the ICO ordered the university to release the PACE clinical trial data to the patient. The University claimed that it did not believe that the data could be safely anonymised. The ICO said it recognised:

> '*the need for a great deal of caution in this area. He acknowledges the sensitivities over the release of a significant amount of data connected with people's health in to the public domain and the care that needs to be taken to try to ensure that it is not possible to link any of that data to specific individuals*.'

However the ICO said the patient had:

> '*specifically stated in his request that he did not require the University to provide the participant's ID numbers if it deemed it inappropriate to disclose this information'.*

The ICO referred to its own *'Code of Practice on Anonymisation*' and '*decided that the withheld information does not constitute personal data and that the exemption in section 40(2) is not applicable*'.

As to breach of confidence the ICO decided that:

> '*in such circumstances he does not consider that there can be an expectation of confidence or that disclosure would cause detriment by way of an invasion of privacy. Therefore it follows that there can be no breach of confidence to action and section 41 does not apply*.'

The ICO decided that the commercial interests' exemption was not engaged.

What were the issues the First Tier Tribunal was asked to consider?
The University appealed the ICO's decision ordering it to release the clinical trial data to the patient. In the end this boiled down to the FTT determining these 3 questions:

- Should a FoIA exemption be applied retrospectively?
- Is the clinical trial data '*personal information*'? If so, is there evidence that participants could be identified from the requested information?
- Would disclosing the clinical trial data cause sufficient prejudice to the university's research programmes or reputation or funding streams if the university refused to disclose it?

Who acted in this case in the FTT?
The university spared no expense at all in fighting this appeal. It engaged the services of the country's top specialist in information rights law, Mr Timothy Pitt-Payne QC from the leading barristers chambers in this field, 11 Kings Bench Walk in London. Mr Rupert Paines from the same chambers represented the ICO. This was a 'David and Goliath' struggle as the patient was forced to represent himself at a 3 day hearing in which a number of witnesses and experts attended to try and shore up the university's position.

Why did the university say the clinical trial data should not be released?
On personal information, it made these 5 submissions:

- The data is sensitive personal data derived from living individuals,
- It is not satisfactory to anonymise the data because of a '*motivated intruder risk'*,
- It has no permission from trial participants to publish their data,
- Although most responses were self-responses rather than objectively measured ones, there was still a potential for harm, and
- NHS guidance says that the boundary between personal but anonymised data and non-personal data is unclear and even the lowest risk to the public carries significant risks.

As to the point about information provided in confidence, it made these 2 points:

- The data was not supplied under a traditional doctor-patient relationship but under a clinical trial which required the patient's explicit consent, and
- Disclosure would cause particular damage or distress and compromise ability in the future to raise research funding.

On the university's commercial interests, it had these 5 submissions to make:

- It might affect its ability to attract funding in the future for further research,
- It would affect the recruitment for future clinical trials,
- The failure to honour the agreement with the trial participant would undermine trust,
- Publicity would cause anxiety to participants, and
- 2 participants had already withdrawn from the clinical trial.

What were the ICO's submissions on the clinical trial data?
As to whether the anonymised data was '*personal information'* or not, the ICO made 3 submissions:

- It is unclear why satisfactory anonymization is impossible when the patient requested that the personalised PIN reference be excluded from the data supplied,
- There is no evidence that a '*motivated intruder*' could identify participants, and
- Identification is more than making an educated guess about the identity.

On whether the information was provided in confidence or not, the ICO submitted that the university had not explained how data could lead to identifications of individuals. There would be no invasion of privacy in disclosure and therefore no breach of confidence.

Finally as to whether this would damage the university's commercial interests or not, the ICO had these 3 submissions to make:

- The potential prejudice to commercial interests is not trivial or insignificant,
- Disclosure could deter future participants, and
- There is insufficient evidence that trial participants could be identified.

Why did the patient say the clinical trial data should be released?
The patient provided an open letter to 'The Lancet' from scientists and clinicians raising concerns about the methodology and conclusion of the PACE clinical trial. He said that trial participants had shared their experiences online and had not received harassment or negative responses. He rejected the university's claim that he was using FoIA to harass its researchers. He submitted that he sought the bare minimum data to allow for '*meaningful re-analysis'*. He submitted that anonymization can be sufficiently carried out to allow the trial data to be disclosed. He disagrees with some of Professor Anderson's expert evidence to the contrary on this as '*highly emotive and without foundation*'. Finally he says there is a public interest in disclosure of the clinical trial data.

Was there any evidence or expert evidence?
Both the university and the patients relied on 4 witnesses each. Whilst most of the witnesses had a number of professional qualifications, other than Professor Anderson, it is not entirely clear that they were providing expert evidence as such.

The patient gave evidence and produced a petition with 12,000 names calling for release of the clinical trial data. In addition, he called evidence from:

- Associate Professor Kenneth Friedman, a retired professor of pharmacology at New Jersey Medical School,
- Emeritus Professor Jonathan Edwards, the chair in connective tissue medicine at UCL, and
- Dr Lily Chu.

The university pulled out all the stops and the following gave witness statements and/or attended the tribunal for cross-examination:

- Professor Chalder from the department of Psychological Medicine at Kings College London,
- Professor Thornton, the vice-principal of Barts medical school (which it is connected with),
- Dr Frances Rand, Head of corporate governance and policy at the Medical Research Council, and
- Professor Ross Anderson, the holder of the chair in Information Security Engineering at the University of Cambridge.

What had the Court of Appeal previously ruled in *Source Informatics*?
The Court of Appeal had looked at the anonymization of data by pharmacists previously in 1999. In its ruling in *Re Source Informatics* **[1999] EWCA Civ 3011** it had to decide what duty of confidence is owed by pharmacists to patients to whom they dispense prescribed drugs? In particular, provided always that the patient's anonymity was fully protected, does their duty of confidence to patients prevent pharmacists from using the material contained in the GP's prescription forms for whatever purposes they wish?

This was a fully argued judicial review appeal in which the Department of Health, the General Medical Council, the Medical Research Council and the National Pharmacy Association were represented. Lord Justice Simon Brown (as he then was) gave the judgment of the Court of Appeal with which Lords Justices Aldous and Schiemann agreed. His ruling was that:

> '55*….Participation in Source's scheme by doctors and pharmacists would not in my judgment expose them to any serious risk of successful breach of confidence proceedings by a patient (any more than were a prescribing doctor, asked by a manufacturer's representative what medicine he ordinarily prescribes for a given condition, to answer candidly on the basis of his current practice….The law of confidence cannot be distorted for the purpose*.'

In particular Simon Brown LJ ruled that:

- The patients had given implied consent for their data to be used in this way,

- No breach of confidence is involved in pharmacists using the information contained in prescription forms for their own stock-keeping purposes - the patient's privacy is thereby neither invaded nor imperiled, and
- Whilst it was not '*necessary to decide on this appeal'* he thought that there appeared no reason to doubt that it was acceptable for '*thorough research and management depend in part upon the possibility of others checking that anonymised and aggregated information does correspond to the real world, by audit procedures which must inevitably involve checking identifiable cases*'. But he cautioned that '*the use of such identifiable data'* had to be '*very strictly controlled'*.

What was the gist of Professor Anderson's evidence?
He is the BMA's adviser on safety and privacy of clinical information systems. He describes the ICO code on data anonymization as a '*hopeful view'* and blasts it a being '*mistaken and obsolete'*.
He says that a postcode and date of birth are sufficient to identify 98-99% of the UK population. Where 2 disputed data sets are linked, anonymization can fail. Two walking test scores in the PACE clinical trial would be sufficient here to identify a participant. He opines that there is an '*emerging scientific consensus that anonymization does not eliminate the risks of re-identification*' and that there is a real risks from a '*motivated intruder'*. However he says it is extremely difficult to identify individuals even from collective information.

What was the majority view of the tribunal on the clinical trial data?
It has to be said that the judgment is put together in an unusual way and is difficult to follow. It seems clear that insufficient time has been allowed to put something of sufficient standard together.

The majority ruling was given by the Tribunal Chair (Brian Kennedy QC) along with lay member Mr Darryl Stephenson. Mr Kennedy is a member of the Northern Ireland bar, acted as counsel for families on the Bloody Sunday public enquiry and was only recently appointed to the FTT. Mr Stephenson is a retired chief executive of a small rural local authority in Yorkshire (East Riding). He is now a visiting professor at Hull University. Neither the chair nor Mr Kennedy have any obvious prior expertise in clinical trials.

On the simple issue under FoIA s22A (on information intended for future publication) and whether an exemption should be applied retrospectively, the majority ruled that: '*we find there are no exceptional circumstances whereby the Commissioners ought to have exercises his discretion to apply s22A retrospectively on the facts before us*.'

On the main personal data issue as to whether individuals can be identified from disclosure of the clinical trial data, the FTT are agreed that the '*test is whether there is a risk that such disclosure would lead to identification of an individual that is more than remote'*. On this, the majority concluder at page 39 that:

> '*..we accept and adopt the Commissioner's wider submissions and reasoning….In all the circumstances and on the evidence before us we are satisfied that the risk of identification has been anonymized to the extent that the risk of identification is remote*.'

The majority then highlight 13 matters from the evidence and submissions that lead them to this result. This includes:

- There was no fixed or direct identifiers in the information,
- Professor Anderson said that 3rd parties could not identify participants from that information alone,
- Even if identification could take place of trial participants '*there would have to be a breach of medical ethics and the law*',
- Only the 'walking scores' were likely to lead to identification of trial participants,
- The university had since obtained funding for other trials and its commercial interests arguments were therefore not accepted,
- There is strong public interest in releasing the data given '*given the continued academic interest so long after the research was published*',
- There is insufficient evidence to persuade the FTT the disclosure would cause the university prejudice,
- The patient identities are encrypted,
- It did not accept the speculation that a 'determined person with specialist skills could make the link' and marry up the anonymised data with the name of a trial participant, and

- The ICO had applied himself correctly, his decision was properly arrived at and there was no reason to set it aside.

What was the minority view of the tribunal on the clinical trial data?
Mr Nigel Watson issued a short dissenting judgment. It is instructive to note that Mr Watson was formerly the Chief Executive of the Wessex Local Medical Committee and clearly has some real expert insight in this area. He seems to have a feel for how clinical trial data is obtained, the expectations of trial users and, no doubt, what would happen to trust in clinical trials if the confidentiality of the process became broken.

In his dissent he says:

> '*Each row in the spreadsheet is unique and refers to one person in the trial. The information necessary to link this data to an individual is available to a large number of people due to the way security has been implemented in the NHS and the quantity and nature of information that is now available on social media. I believe Professor Anderson is correct when he gave evidence that the chance that a determined person with specialist skills could make the link, whilst less than probable, is more than remote. For this reason the information contained in the spreadsheet is personal data and should not be disclosed*.'

Will there be an appeal?
It seems inevitable that this case will now (unless the university changes its mind) have to go on appeal to the Upper Tribunal. In some ways that may be fruitless because it will be bound by the decision of the Court of Appeal in *Source Informatics*. The provisions on transferring appeals to the Court of Appeal under CPR 52.14 only refer to transferring appeals from a court (not a tribunal).

Will the GDPR change anything?
The new EU General Data Protection Regulation (**EU/2016/679)** comes into force on 25 May 2018. In Recital 10 it says that:

> *'This Regulation also provides a margin of manoeuvre for Member States to specify its rules, including for the processing of special categories of personal data (*"sensitive data"*).'*

Article 9.4 deals with '*Processing of special categories of personal data'* and says that '*Member States may maintain or introduce further conditions, including limitations, with regard to the processing of genetic data, biometric data or data concerning health*.'

It has yet to be seen what the UK will do given the invitation to make exemptions in Recital 50:

> '(50) *Derogating from the prohibition on processing special categories of personal data should also be allowed when provided for in Union or Member State law and subject to suitable safeguards, so as to protect personal data and other fundamental rights, where it is in the public interest to do so, in particular processing personal ….for health security, monitoring and alert purposes, the prevention or control of communicable diseases and other serious threats to health. Such a derogation may be made for health purposes, including public health and the management of health-care services, especially in order to ensure the quality and cost-effectiveness of the procedures used for settling claims for benefits and services in the health insurance system, or for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes. A derogation should also allow the processing of such personal data where necessary for the establishment, exercise or defence of legal claims, whether in court proceedings or in an administrative or out-of-court procedure.*'

Are there any comments on this ruling?
There were some words of reservation in *Source Informatics* which was given in 1999 in a time when digitisation and access to information was not as advanced as it is now. An appeal court will have to grapple with how much further it is prepared to allow anonymised medical data to be released to researchers and others. We are waiting for the Supreme Court as well to hear the *Vidal-Hall v. Google* **UKSC 2015/097** appeal.

This case has the potential to go all the way to the European Court of Human Rights in Strasbourg as it raises fundamental issues on the convention particularly on Article 8 (the right to respect for private and family life).

17th August 2016