

University of Bristol statement about harassment of academic staff

The University has long been aware that Professor Crawley has experienced significant harassment and personal abuse over several years. This has included but is not limited to: vexatious FOIs; cyber stalking; malicious emails; blogs/tweets and other social media posts that could be regarded as defamatory; unsubstantiated complaints to multiple institutions including Ethics Committees, The University of Bristol, The Advertising Standard Authority, the GMC and funders. The University considers this behaviour to be unacceptable.

The University has previously reviewed Professor Crawley's research projects and found they are being conducted in line with applicable research ethics and governance requirements. The University has supported Professor Crawley in dealing with the harassment and provided legal, governance and research advice and support when required.

November 2017

University of Bristol statement about the CFS/ME National Outcome Database (NOD)

The University has received queries in relation to the use of data from the CFS/ME National Outcome Database (NOD). The CFS/ME National Outcome Database (NOD) was developed to support NHS clinical care in line with Department of Health guidance. It was not set-up for the primary purpose of research but with the aim of providing important information to improve patient care. Clinicians used the assessment data and follow up data to improve treatment. The NOD also helped improve patient care by collecting this routine outcome data and using it to benchmark services. This enabled NHS services to consider how to improve service delivery. We have received confirmation from the North Somerset and South Bristol Research Ethics Committee indicating that the work Professor Crawley and her team is undertaking in relation to the database analysis is categorised as Service Evaluation. This is supported by the requirements set out in the Health Research Authority Governance Arrangements for Research Ethics Committees: 'REC review is not required for the following types of research: Research limited to secondary use of information previously collected in the course of normal care (without an intention to use it for research at the time of collection), provided that the patients or service users are not identifiable to the research team in carrying out the research'

<http://www.hra.nhs.uk/resources/research-legislation-and-governance/governancearrangements-for-research-ethics-committees/>

May 2017

University of Bristol statement about the FITNET-NHS trial

The publicity surrounding the launch of this trial on 1 November 2016 resulted in many patients coming forward wishing to take part, and many positive comments supporting the research from members of the public. A small number of people contacted us with some concerns. In line with the University's commitment to research integrity, we have undertaken a review of the research governance pathway. FITNET-NHS is a trial funded by the National Institute of Health Research Health Technology Assessment Programme. The University of Bristol is the Research Sponsor for this trial. As a Research Sponsor, the University takes primary responsibility for ensuring that the design of the study meets appropriate standards and that arrangements are in place to ensure proper

conduct and reporting. The scientific peer review process for this trial was part of the condition for funding to be awarded. In addition, the trial has been reviewed by the Health Research Authority in accordance with their standards and remit. As part of that process the trial was scrutinised and approved by an NHS Research Ethics Committee. The University's research governance review confirmed that all appropriate reviews and approvals were in place for this study to proceed; therefore we confirm continued Sponsorship for this research. In line with our quality assurance framework we will continue to monitor this study to ensure the integrity of the research. More information about the trial is available on the FITNET-NHS webpages.

[\(http://www.bristol.ac.uk/ccah/research/childdevelopmentdisability/chronic-fatigue/fitnet-nhs/\)](http://www.bristol.ac.uk/ccah/research/childdevelopmentdisability/chronic-fatigue/fitnet-nhs/)

December 2016