During my evidence to the Committee’s inquiry on research integrity, I undertook to write to you on the matters outlined below.

**Occasions where research councils have imposed sanctions (Q539 - Q540)**

In the majority of cases of research misconduct, the appropriate course of action is for the employing research organisation to investigate and, where appropriate, impose sanctions in line with its own Human Resource and research integrity policies. There have, however, been three instances since 2013/14 where a research council has decided it was necessary to impose a sanction, in line with the RCUK Policy and Guidelines on Governance of Good Research Conduct. These were:

- In 2015/16, NERC temporarily withdrew a proposal from consideration for funding after a reviewer flagged that there appeared to have been plagiarism of another proposal. NERC raised the concerns with the applicant’s employer, who conducted a full review and the case was upheld. NERC then fully withdrew the proposal.

- In 2016, an investigation by a research organisation upheld an allegation that BBSRC research grant applications had been mishandled by an external reviewer employed there. BBSRC consequently enacted a one-year ban on the reviewing of BBSRC applications by the person, and a four-year ban on membership of all BBSRC committees and panels.

- In 2017/18, NERC withdrew information about a scientific publication from the Researchfish outputs system. NERC had previously been informed that there was an investigation over a claim that a researcher on a grant had moved institutions and then published a paper without the appropriate co-authors being named on the paper or involved in its submission. A full review was conducted and the case upheld. The publication was subsequently retracted and is being resubmitted to the journal with appropriate authors.

HEFCE (now Research England) has also engaged with research organisations where they found them to be non-compliant with the Concordat to Support Research Integrity (‘the Concordat’). HEFCE have highlighted the lack of compliance to the organisations and asked them to demonstrate progress against their action plans for compliance. This process continued at regular intervals until the organisations were fully compliant.

**Clinical trials and transparency (Q563 - Q565)**

The research councils have a long-standing commitment to open data and transparency, based on the principle that data resulting from publicly-funded research should be made available, with as few restrictions as possible, in a timely and responsible manner. To support this principle, the MRC provides guidance to support researchers undertaking clinical trials, including good practice principles for sharing individual participant data from publicly funded clinical trials (2015) and the MRC Policy on Open Research Data from Clinical Trials and Public Health Intervention Studies (2016). This guidance aims to support researchers and research organisations in fulfilling their obligations to participants. Specifically, these include ensuring data are managed in line with participant consent and study protocols, to avoid inadvertent or deliberate disclosure, while making data available to the research community for reuse to maximize the value of the data, and for eventual patient and public benefit.

**The PACE clinical trial**

The PACE clinical trial was a randomised, controlled trial of cognitive behavioural therapy, graded exercise, adaptive pacing and usual medical care for Chronic Fatigue Syndrome, also known as Myalgic Encephalomyelitis (CFS/ME). It aimed to inform the evidence base to determine which existing treatments were most effective for patients with CFS/ME. Funded by an MRC grant to Queen Mary University London (QMUL) the study ran from 2004 to 2011, with co-principal investigators based at QMUL, King’s College London and the University of Oxford.
Since the end of the study, its authors have received a number of requests from researchers to access the study data. Fifteen requests were approved by QMUL and data was shared as part of research collaborations and two requests were refused. Freedom of Information Act requests have also been received seeking the public release of individual participant level data, and anonymised individual-level data was released as a result of one such request.

Following my evidence to the Committee, the MRC sought clarification from QMUL concerning Ms Carol Monaghan’s comment that she thought the research team had said a lot of data had been lost. We have been assured that this is not the case, and access to the data may be requested by contacting the co-principal investigators. To support data sharing, the investigators have published guidance on the study webpage for researchers requesting access to the study data.

I note that the National Institute for Clinical Evidence is currently seeking to update its guidance on the diagnosis and management of CFS/ME. The review will take all relevant research into account and provide an opportunity for stakeholders to contribute evidence.

**The Concordat (Q567 – Q568)**

During the evidence session, you observed that there was some considerable variation in whether a research organisation chooses to involve an independent person in its process of inquiry or investigation and in the panel that hears any allegation.

The Concordat states that: ‘Employers of researchers have the primary responsibility for investigating allegations of research misconduct. It is the responsibility of employers to ensure that any person involved in investigating such allegations has the appropriate knowledge, skills, experience and authority to do so.’ I am aware that many universities will already have a policy in place around independence in their panels for formal investigations. It is my view that an investigatory panel considering significant cases of misconduct should have external representation at the stage at which formal action is taken against the individual. This is in line with the RCUK Policy and Guidelines on the Governance of Good Research Conduct and with UKRIO Procedure for the Investigation of Misconduct in Research.

This point was considered at the first forum on the Concordat, at which UK Research and Innovation was represented alongside Concordat signatories and other interested parties. I understand the forum will consider this alongside other possible changes to the Concordat.

I hope this is helpful.

*April 2018*