Witness Name: John Iredale

Statement No.: WITN7531001

Exhibits: WITN7531002 - 027

Dated: 09 December 2022

INFECTED BLOOD INQUIRY

WRITTEN STATEMENT OF JOHN IREDALE ON BEHALF OF THE MEDICAL RESEARCH COUNCIL

I provide this statement in response to a request under Rule 9 Request of the Inquiry Rules 2006 dated 21st September 2022.

I am Professor John Iredale, the Interim Executive Chair of the Medical Research Council (**MRC**). I have held this post since January 2022, and have been a member of the MRC Council since 2016. The questions set out in the request cover a period of time during which I was not a member of the Council nor the Interim Executive Chair of MRC. The information on which this statement is based is drawn from MRC's records.

I, John Iredale, will say as follows: -

Section 1: Introduction

1. The Medical Research Council was a non-departmental public body (**NDPB**), as is the organisation of which it is now a part, United Kingdom Research Innovation (**UKRI**). NDPBs are publicly-funded bodies, but not part of government departments and operate to a greater or lesser extent at arm's length from ministers. Their

functions and responsibilities are laid out in individual charters or by statute. Sponsoring departments, and their Ministers, are responsible for their administration

and performance, working to align their activities to larger government strategies while also ensuring they remain independent.

2. By way of background, the origins of the MRC date back to the work of the Royal Commission into tuberculosis between 1901 and 1911, which recommended the creation of a permanent medical research body in 1908. The Medical Research Committee was established in 1913 to examine research proposals and provide opinions to assist the National Health Insurance Joint Committee with decisions concerning whether or not to approve research proposals.

3. The MRC succeeded the Medical Research Committee and was established as a corporate body by Royal Charter in 1920 to provide a mechanism for promoting and supporting medical and related biological research that did not originate in specific government departments. This core purpose remained the same through a number of successive charters and supplements, although additional emphasis on research into public health, producing skilled research scientists and promoting a dialogue with the public were added to the mission in later years.

4. This remained the position until 1 April 2018 when formal responsibility for MRC activities passed to the newly formed body UKRI. UKRI was established by the Higher Education and Research Act 2017 to bring together the seven research councils, including MRC, Innovate UK and the Research and Knowledge exchange functions of the Higher Education Funding Council for England. Its purpose is to invest in and facilitate research and innovation activities across the UK, and through Research England, directly support higher education providers in England to carry out research and knowledge exchange activities. MRC's part in this endeavour is to improve human health through world-class medical research, from fundamental science to early clinical trials and preventive medicine.

In short, the MRC has invested, and continues to invest, in medical research on behalf of the UK taxpayer.

Until 1965, oversight of MRC lay with the Privy Council Medical Research Committee. With the passage of the Science and Technology Act in that

year, these responsibilities were transferred to the Secretary of State for Education and Science, passing successively to the newly formed Office of Public Service and Science within the Cabinet Department (1992), the Department of Trade and Industry's Office of Science and Technology (1995), the Department for Innovation, Universities and Skills (2007), the Department of Business, Innovation and Skills (2009) and the Department of Business, Energy and Industrial Strategy (2016). UKRI is sponsored by the Department for Business Energy and Industrial Strategy (BEIS).

5. The MRC is funded mainly by the UK taxpayer, through its sponsoring department, BEIS, and as part of the overarching UKRI budget.

   Prior to any spending review, each of UKRI's nine components, including MRC, make a case for support as a contribution to the overarching UKRI budget proposals. After Treasury sign-off for the spending review and departmental allocations the Secretary of State for BEIS makes a budget allocation for UKRI and each of its nine constituent bodies for a multi-year period, taking advice from the UKRI board on strategic priorities and on the balance of funding between disciplines. The plans for utilising this budget are detailed in the strategic delivery plans published by UKRI and each of its nine constituent bodies.

   Prior to 1 April 2019, and the formation of UKRI, MRC was funded directly through a similar process.

   The Permanent Secretary of BEIS is responsible for the UKRI budget, and the CEO of UKRI as Accounting Officer of UKRI is responsible for safeguarding public funds to ensure that they are used following the requirements for value for money, propriety, regularity and feasibility.

6. Through UKRI the MRC acts as the Government's principle public funder in biomedical and health research. We are positioned alongside the National Institute of Health Research, the Research and Development funding arm of the Department of Health and Social Care. This funds research focussed at the more applied end of human health. In addition to working closely with the Health Departments of the UK, MRC also works with the Office for Life Sciences, the other UK research councils and

Innovate UK, industry and other stakeholders to identify and respond to the UK's health needs.

The MRC is independent in its choice of which research to support. However, underlying the relationship between MRC and government is the Haldane principle, which originates in a 1918 report on the machinery of government. The key concept developed since 1918 is that decisions on individual research proposals are best taken by researchers themselves through peer review. This involves evaluating the quality, excellence and likely impact of science and research programmes and ensuring subsidiarity in decision making. It is accepted that there must be ministerial input into high level allocations between research themes, for national infrastructure and broader sector sustainability but that more granular decisions, for example the awarding of grants to specific research activities, should not be taken by Ministers or central government.

As UKRI's sponsor, BEIS is the primary central government point of contact for UKRI, championing UKRI in government and supporting and challenging UKRI to deliver its mission effectively. UKRI's primary contact at BEIS is the Director for Science, Research and Innovation within the Business and Science Group. MRC no longer has direct contact with BEIS as a sponsor, but previous to the formation of UKRI, MRC had similar relationships with its previous sponsoring departments.

Section 2: Direct Detection Assay (DDA)

7. I understand that MRC set-up a Unit focused on Transmissible Spongiform Encephalopathies (**TSE**) research in 1998, now the MRC Prion Unit. As an indication of the unit's overall level of funding, from the correspondence from Dr Catherine Elliott, Director Clinical Research Interests and Head of Theme Neurosciences and Mental Health to Professor Collinge in January 2014 (PRIU0000068), I understand that from 2008 to 2013 the Unit received approximately £6m per annum for 'core-funded' Prion Unit activities, i.e. an integrated programme of research activities funded for a 5-year, quinquennial period.

8. As noted in the information provided below about how the MRC funds science, the MRC undertakes scientific reviews of each of its units every five years to be assured of the strategic justification, scientific excellence and value for money of the work being carried out. These reviews are known as quinquennial reviews (**QQRs**). The process is designed to assess the Unit overall through an evaluation of the quality of its individual scientific programmes, MRC procedures entail that Units such as the Prion Unit are reviewed by the MRC subcommittee that is most relevant to its remit, albeit drawing on expertise from other sections as needed.

9. I understand that between 2007 and 2017, MRC provided significant amounts of funding to Dr Graham Jackson to pursue a programme of work including development of the DDA as part of the core funding provided to the Prion Unit. I am aware that in February 2007 Dr Graham Jackson and two other colleagues who had been studying the structure of prion proteins under one of the Unit's Programmes formed a new programme to accelerate work on molecule diagnostics including development of a blood test. From 2007 to 2009 the funding for Dr. Graham Jackson's work was funded as part of this programme, in which it was an embedded component and not as a programme in its own right.

10. At the Unit's next review in 2009, a sub-committee of the Neuroscience and Mental Health Board of the MRC (**NMHB**) responsible for making an assessment of the Unit proposed £2,995,000 funding for Dr Jackson's work to be delivered as its own programme of work over the coming five years (WITN7531002). The funding was approved by the NMHB in November 2009 (WITN7531003).

11. In the Unit's 2015 review (WITN7531004), however, I understand that the review subcommittee was not persuaded that the Unit's proposals for the extension of working of Prion tests by combining PMCA and QUIC tests with DDAs was sufficiently novel or of high enough quality to justify funding for another full quinquennium. The subcommittee also noted that it had not seen any preliminary evidence that the sensitivity of the blood test could be improved. The subcommittee referred the review to the Management Board, which decided that core funding could be used by the Unit for another 12 months, that is, through 2016, however requests for further funding would need to be submitted to the NMHB in competition with other applications for support from the scientific community.

12. I understand from the draft minutes of a meeting held by the MRC Council on 1 October 2015 (WITN7531005) that the MRC Council considered the NMHB sub-committee report. As part of this review it was agreed that the molecular diagnostics programme led by Jackson was not of sufficient quality to be competitive for long-term funding and was awarded transitional funding final year to end 31st March 2017. Drawing on the expert feedback Jackson was invited to submit a research grant to the MRC, outside of unit funding, with a revised focus on sensitivity and biomarker qualification, rather than population surveillance.

13. In addition to this core funding for Graham Jackson's programme, I understand that three applications were submitted by the Prion Unit for supplementary grants to investigate DDA specificity between 2011 and 2016 and that although the earliest of these, in 2011, was successful, two subsequent applications were declined.

14. I understand that MRC provided a supplementary grant to the Prion Unit for investigation of DDA specificity in 2011. This was shortly after an article entitled 'Detection of Prion Infection in variant Creutzfeldt-Jakob disease: a blood based assay', based in part of the Unit's core-funded work, was published in the Lancet.

15. MRC records include a copy of the article, published on 5 February (NHBT0033626) as well as correspondence dated 18 March 2011 between Marc Turner, on behalf of the Prion Working Group, and Mark Noterman of the CJD and Branch Coordination, Infectious Diseases and Blood Policy at the Department of Health (to which Professor Collinge is in copy) (WITN7531026). I understand from this correspondence that Professor Collinge met with a member of the UK Blood Services Prion Working Group and NHS Blood and Transplant in February 2011 to discuss the potential suitability of prototype blood test as a blood screening assay. Professor Collinge was informed that the sensitivity of such a test needed to be studied in more detail and was given contacts in the American Red Cross for sourcing potential samples. The correspondence highlights that the "critical factor to the utility of any screening assay for vCJD is that it meets the specificity and sensitivity requirements in the CTS", and that a prevalence study of UK blood samples (as opposed to tonsils) would eventually be needed to assess necessity and cost-effectiveness. I also understand that Professor Collinge was also in correspondence with the Health Protection Agency and Department for Environment Food & Rural Affairs and the Department of Health in regards to a potential DDA around February 2011.

16. I understand that the email trail between Dr. Rob Buckle, Dr. Declan Mulkeen, Dr. Christopher Watkins and Professor Collinge (WITN7531006) records that Professor Collinge met with the MRC's Professor Sir John Savill, the CEO at that time, prior to 3 March 2011 to discuss the possibility that MRC might fund the sample study discussed with UK Blood Services Prion Working Group and NHS Blood and Transplant to assess the false negative rate of the DDA. On the advice of UK Blood Services Prion Working Group and NHS Blood and Transplant, the size of the study was proposed to be 5000 samples. The MRC CEO accordingly invited Professor Collinge to make an application to MRC Strategy Board as a supplementary Unit award.

17. I am aware that on 1 April 2011 Professor John Collinge met with the Parliamentary Under Secretary for Public Health, Ann Milton MP, and the Chief Medical Officer, Professor Dame Sally Davies. They advised that they were not in a position to fund further evaluation or prevalence screening, and that no commercial interest in the DDA had materialised.

18. I understand the email trail between Dr. Rob Buckle, Dr. Declan Mulkeen, Dr. Christopher Watkins and Professor Collinge also records that Professor Collinge submitted a bid for the 5000 sample study to be considered by the MRC Strategy Board. The application was made for £525,472. Further correspondence between Dr. Rob Buckle and Professor Collinge (WITN7531007) records that on 1 June 2011 the MRC notified Professor Collinge that his bid had been successful, capped at £200,000, and that the Unit should absorb the full costs of improving the assay robustness and development of a confirmatory test, through its 5-year core budget. The grant was made contingent on submission of a project plan and timeline and the provision of quarterly updates to the MRC. The project plan submitted by Professor Collinge shows that the project was intended to run from 27 June 2011 to 17 December 2012 (WITN7531008).

19. I am aware that the results of the 5000 sample study to initially assess the sensitivity and specificity of the vCJD assay developed at the Unit were published in the British Medical Journal on 3 March 2014 (WITN3093010) and understand the study was designed to assess whether there may be justification for a larger trial.

20. I understand that the MRC declined to fund a further supplementary award in 2012, as discussed below in answer to question 5, although Professor Jackson's programme continued to receive unit core funding.

21. I am aware that on 12 and 13 October 2016 the Molecular and Cellular Medicine Board (MCMB) of the MRC declined a request for a supplementary Council award to fund a proposed research project to refine the DDA (WITN7531009). The MCMB cited the lack of preliminary evidence that the proposed approach might work, the fact that others were already pursuing the proposed approach and questions over clinical need and lack of justification for level of funding as reasons for its refusal.

22. The MCMB October feedback document (WITN7531010) relating to the MCMB's decision contains a list of the funding decisions in relation to 40 proposals, including Graham Jackson's proposal for the development of enhanced methods for the screening and diagnosis of prion disease. The document confirms that the proposal, intended to start on 1 April 2017, has been declined, and that the proposal was related to the UK Government's interest in prevalence screening for prionaemia. The documents cite the following as concerns and weaknesses of the proposal: -

    1. lack of feasibility data and a lack of evidence that the two methods of assay discussed would work synergistically together;
    2. Protein Misfolding Cyclic Amplification carried a risk of introducing significant false positives with such low levels of abnormal prion protein;
    3. given the low prevalence of prion diseases, the positive predictive value of the test may not be acceptable if false positives become a problem;
    4. significant uncertainty over the likely success of the work planned without further preliminary evidence;
    5. other leading groups in the field were using similar approaches, or recently optimised alternative approaches, and the proposed approach was not novel enough to clearly position this as the leading assay; and
    6. the case for improved screening approaches was not considered strong.

23. The report noted that many of the concerns and issues raised at the peer review stage were not successfully rebutted by the applicants.

24. I understand that Dr Jackson was informed that his application had been declined on 14 October 2016 in an email from Megan Dowie at the MCMB (WITN7531027)

Medical Research Council Technology (MRCT) involvement in patenting and commercialisation of the DDA

25. I understand that MRC also indirectly funded the development of the Direct Detection Assay through the activities of Medical Research Council Technology (MRCT) during the early stages of its development.

26. Medical Research Council Technology (now LifeArc) was established in 1999 as a charity and a charitable company, limited by guarantee. Its original remit was to manage the intellectual property (IP) arising from research in MRC's Units and Institutes. During the period of the activities outlined below, there were three members of the company, all MRC employees or ex-MRC, who broadly had the same rights and powers as shareholders in public companies. The relationship between MRC and MRCT was managed through the MRCT Board (chaired by the MRC's Chief Operating Officer) and a Service Level Agreement. MRC provided MRCT with approximately a quarter of its funding through performance of the SLA. In addition, MRCT managed the MRC Development Gap Fund. This fund was to allow MRCT staff to make rapid decisions on small investments to add commercial value to MRC-owned IP from Units and Institutes.

Work on patents in respect of the vCJD blood assays were managed by MRCT.

27. I understand an excerpt from the MRCT file plan (WITN7531011) which records that on 24 September 2007 MRC filed a patent to protect the work done by Dr. Jackson and Professor Collinge on the new vCJD blood assay. I understand from the excerpt that the initial patent was abandoned at Patent Cooperation Treaty stage.

28. On 13 September 2011 MRC assigned the rights for the Blood Assay for vCJD to D-Gen as evidenced by the Assignment to D-Gen for Blood Assay Patents (WITN7531012) and D-Gen subsequently completed an international patent filing.

D-Gen's international patent PCT/GB2011/001341 was published on 22 March 2012.

29. The Unit also received a MRCT Development Gap Fund award of £98,000 to develop a sensitive blood-based diagnostic test for vCJD. The award was to run from 1 July 2008 to 30 June 2010.

30. To provide context to the rejection of supplementary funding, on 11 July 2012 during the first phase of DDA studies which was funded by MRC, Professor Collinge wrote to the Chair of the ACDP TSE Sub group to get feedback on whether a proposal to test their new vCJD blood test as a prevalence screen would be well received (WITN3093008).

31. I understand that correspondence between Professor Collinge and Dr. Catherine Elliott (WITN7531013) shows that Professor Collinge sought interim support on 20 September 2012 to keep on technical support from the first grant for six months, pending an outcome of a funding proposal for a larger study of 20,000 samples.

32. It is my understanding, with reference to an application to MRC for supplementary funding (DHSC5149643) and correspondence from Professor Sir Rory Collins of UK Biobank (WITN3093011) in November 2012, that UK Biobank confirmed it might have a resource of whole blood samples which could be used in the proposed Unit study to estimate prion infection prevalence in the UK population.

33. The application for supplementary funding, proposing blood testing to estimate UK vCJD prion infection prevalence was submitted circa January 2013. The total estimated cost over three years, starting 1 April 2013, was £1,264,529.

34. The proposal was considered in a Strategy Board paper on 12 March 2013 (WITN7531014) and the corresponding minutes of the Strategy Board (WITN7531015) document the consideration of the proposal and the decision to decline funding. From Professor Collinge's witness statement, I understand that the MRC also sought opinions from a number of public health bodies and Department of Health officials.

The peer review process leading to this decision provided the opportunity for the applicants of the grant, Professor Collinge and others, to respond to questions posed by the peer review. The key concerns highlighted by the peer review were:

1. concerns around the sensitivity of the test, and therefore how its development will result in a viable blood test;
2. concern that the development of the test would not lead to a blood test sensitive enough to allow safeguards, such as leucodepletion, exclusion of transfusion recipients, to be removed, and as such whether there would be any take up from blood transfusion services;
3. concerns as to the validation of the test as initial validation had been on vCJD cases and not on pre-symptomatic known carriers, thus raising the issue of detection of true positives;
4. concerns around commercialisation of the test as the commercial sector finds development of a vCJD blood test unattractive in the absence of a degree of further validation in a larger sample set; and
5. ethical issues raised as to whether it is appropriate that UK Biobank participants who screen positive will not be notified of a positive result.

35. From the proposal presented to the Strategy Board, I understand that Professor Collinge responded to questions surrounding the sensitivity of the test by highlighting how it could still be effective. I also note from Professor Collinge's witness statement (WITN3093002) he responded in detail to the concern that the test should first be able to detect pre-symptomatic vCJD cases by study of such cases by explaining that there were no such examples available to test hence the rationale for the comparative study between the US and UK samples.

36. With reference to the peer review, on 12 March 2013 the MRC Strategy Board declined to fund the proposal from the Unit to develop the DDA towards a screening test to provide further information on UK prevalence. The Strategy Board minutes provide further detail as to the reasons why the funding was declined; namely, the insufficient test sensitivity, impacts of commercialisation and potential ethics issues which would arise from using the UK Biobank resource for blood samples.

37. I understand that Dr. Catherine Elliott as Director of Clinical Research Interests wrote to Professor Collinge on 13 March 2013 informing him that the Strategy Board had declined his application (WITN3093013). Dr. Elliott's letter gave details on the decision and provided feedback to Professor Collinge as to how the proposal could be improved.

    I understand that in Professor Collinge's response dated 17 April 2013 (PRIU00000074), which responded to the MRC Strategy Board's decision, he challenged the decision and attempted to demonstrate why the Board misunderstood certain parts of the proposal. I note that the letter also asks Dr. Elliott to confirm next steps for the proposal. Dr. Elliott's response on 8 May 2013 (WITN3093014) suggested that a small expert group be brought together to work with Professor Collinge to take the project forward.

    I understand, from Professor Collinge's witness statement that in previous correspondence on 4 March 2013, MRC asked if the Unit could support the project if funding was provided by the MRC Strategy Board; however, in light of the above decision, this was not possible. Further, the Business Director at the Unit had previously been specifically told by MRC Finance not to include any funding of this project in the Unit budget submission, i.e. any funding for this needed to come from separate funding and through a peer review route that would allow appropriate scrutiny of the DDA proposal.

38. I understand that MRC focussed its efforts on reviewing proposals relating to development of the DDA and to testing its performance and utility in targeted sample studies (first 5,000 and then 20,000), as outlined above in our responses to questions 4 and 5. Progression of these studies into the larger group was not supported because of the reasons already outlined.

39. The MRC was not in a position to support the ambitions of a prevalence study. It is my understanding that MRC was content to fund the previous studies which effectively demonstrated the robustness and suitability of the DDA. This is a natural extension of the assay development work, testing refinements and validation. The considerations at play for a large prevalence study (such as one with 20,000 samples) are very different. The purpose of a large prevalence study is to calculate the number of cases across the UK from a representative sample. This is not a research question in its self, rather a mechanism to look at public health risk,

protection and security. This is a matter for the Department of Health and Social Care and its health protection agent, which was at the time Public Health England and now, the UK Health Security Agency.

40. I understand that Professor Collinge wrote to the CEO of the MRC, Professor Sir John Savill in July 2014 referring to the Science and Technology report that recommended a vCJD prevalence study be conducted in the next 12 months (WITN3093016), and he responded by advising the Department of Health should consider this matter, and that progress would most likely come by waiting to see how the government would respond before the MRC took action.

41. I note correspondence from the Chief Medical Officer, Professor Dame Sally Davies to Professor Collinge (WITN3093018), correspondence from Laura Williamson, Research Director NHS Blood and Transplant, and Philip Minor, Deputy Director NIBSC, to Bernard Jolles, Director of D-Gen, (WITN3093019) and correspondence from Bernard Jolles, Director of D-Gen, to Laura Williamson of NHS Blood and Transplant (WITN3093020), From this correspondence, I understand that after the publication of the report, Professor Collinge attended a meeting and was in correspondence with various individuals in roles at Public Health England, NHS Blood and Transplant, the Advisory Committee on the Safety of Blood, Tissue and Organs Prions Group, and the UK Blood Services Prion Group.

42. From correspondence from the Chief Medical Officer, Professor Dame Sally Davies, to Professor Collinge (WITN3093018), I am aware that Professor Turner as the Chair of the Advisory Committee on the Safety of Bloody, Tissue and Organs Prions Group and Professor Gill of Public Health England presented a paper on the DDA to the Advisory Committee on Dangerous Pathogens TSE Subgroup on 13 November 2014, and that discussions took place as to how the DDA could be developed to ascertain validity and reliability of identifying asymptomatic infection.

43. I am also aware that Professor Collinge corresponded with the Chief Medical Officer regarding the prototype of the vCJD blood test in December 2014 and January 2015, during which Professor Collinge suggested that further discussion on the matter should be with Bernard Jolles of D-Gen instead of himself. MRC was not party to this correspondence nor a part of any subsequent discussions with Bernard Jolles of D-Gen.

I also understand that correspondence continued between Dr Williamson and Bernard Jolles from March to August 2015.

44. As previously stated, MRC was not in a position to support a large scale vCJD blood prevalence study as recommended by the House of Commons Science and Technology Committee in their 2014 report. However, I understand that we continued to support Dr. Jackson's core programme through investment in the Prion Unit until 2017, as outlined in our response to question 4. This programme was well placed to evolve the direct detection assay and address concerns around sensitivity.

The application referenced in the question was not made to the MRC, but to the Department of Health.

I understand from correspondence provided by the Inquiry between Farheen Shafiq, Programme Manager, Policy Research Programme Central Commissioning Facility, to Graham Jackson, Institute of Neurology, UCL which is dated 12 December, and from context, assume 12 December 2016, (WITN3093023) that Dr Graham Jackson made a research grant proposal to the Department of Health for the development of enhanced methods for screening and diagnosis of Prion disease.

I note that the Department of Health declined to take forward this proposal, providing limited feedback for Dr Jackson. In his letter, Farheen Shafiq noted that the panel agreed the proposal addressed an important policy priority, but felt that preclinical work to fully and independently validate the DDA test was necessary before committing significant financial resources to undertake this study. There were also some concerns about the lack of details regarding US human blood samples.

I have no further knowledge about this proposal as it was not a proposal submitted to MRC and therefore MRC has no independent record.

Section 3: Other Issues

Please explain in broad terms how the MRC funds research

45. Based on priorities set out in the MRC strategic plan and the ideas submitted by the nation's leading biomedical research teams, the MRC invests in research on behalf of the UK taxpayer. It supports a broad and fertile research environment, including supporting world-leading institutions such as the MRC Laboratory of Molecular Biology (LMB) and the Francis Crick Institute through international collaborations to address health challenges at the global level.

MRC employs robust competitive peer review processes to assess and make funding decisions about research proposals. These largely fall into two, equivalent, processes, for consideration of either individual proposals/applications, or of entire units and institutes.

Individual proposals are peer reviewed and considered by the relevant scientific Board or Panel. A number of criteria are considered: is the science fundamentally sound? Is the project as proposed deliverable? Does it represent 'value for money' (i.e., could it be done more cost-effectively in another way and / or are the costings reasonable or inflated?) What contribution would successful completion of the project make to the public good? Applications can meet basic criteria in all areas, but still be uncompetitive in the context of others being considered during a particular board round.

More information on our funding decision is available on UKRI's website (WITN7531016).

For units and institutes, the MRC undertakes scientific reviews to be assured of the strategic justification, scientific excellence and value for money of the work being carried out. These reviews take place every five years and are known as QQRs. The process is designed to assess the Unit overall through an evaluation of the quality of its individual scientific programmes, Unit-wide research-related activities, and the added value of the whole. The process enables clear and strategic decisions to be taken about the value of the MRC investments within the national and international landscape. The process of the scientific review is undertaken by a review Subcommittee, which includes appropriate internationally-leading scientists.

If subsequent to a quinquennial review, MRC agrees to fund the activities proposed for a unit or institute's programmes, the amount agreed is called 'core-funding'. Units and Institutes are encouraged to seek additional funding from other sources to support additional research, including submission of individual proposals to MRC Boards. Any such applications are considered in 'open competition',i.e. without any preferential treatment, and like other applications, would be bound by the requirement that the funding is not being requested for research that has already been funded elsewhere (including through a unit's core funding).

Statement of Truth

I believe that the facts stated in this witness statement are true.

Signed _ GRO-C

Dated _____09/12/2022____

Table of MRC exhibits referred to in the statement:

Date	Exhibit number	Notes/ Description
29-30 June 2009	WITN7531002	Neurosciences and Mental Health Board (NMHB) Scientific (QQR) Review of the Unit, London. Director: Professor John Collinge. Report of the NMHB Visiting Subcommittee. Subcommittee Visit 29th and 30th June 2009. [Item 21 presented to the NMHB 12-13 November 2009.]
12-13 November 2009	WITN7531003	Minutes of the Neurosciences and Mental Health Board.
18 March 2011	WITN7531026	Correspondence between Marc Turner, on behalf of the Prion Working Group, and Mark Noterman, Infectious Diseases and Blood Policy, Department of Health.
12 April 2011	WITN7531006	Correspondence from Dr. Rob Buckle to Dr. Declan Mulkeen and Dr. Christopher Watkins. Includes WITN7531026 and A1523318 as attachments, as well as an email trail dated 03/03/2011-12/04/2011. Email trail includes correspondence with Professor John Collinge, Director of the Unit.
1 June 2011	WITN7531007	Correspondence between Dr. Rob Buckle and John Collinge.
28 June 2011	WITN7531008	Project plan submitted by the Prion Unit for a Supplementary Award to investigate specificity of prion blood assay.
13 September 2011	WITN7531012	Assignment to D-Gen for Blood Assay Patents, 13 September 2011 (part of MRCT file plan).

20 September 2012	WITN7531013	Correspondence between Professor John Collinge and Dr. Catherine Elliott, (part of email trail ending 17 October 2012).
12 March 2013	WITN7531015	MRC Minutes of the Strategy Board meeting.
12 March 2013	WITN7531014	Item 6: Blood testing to estimate UK vCJD prion infection prevalence, presented to Strategy Board.
20 January 2015	WITN3093018	Correspondence from the Chief Medical Officer, Sally Davies, to John Collinge.
11 March 2015	WITN3093019	Correspondence from Laura Williamson, Research Director NHS Blood and Transplant, and Philip Minor, Deputy Director NIBSC, to Bernard Jolles, Director of D- Gen,
19-20 March 2015	WITN7531004	Neurosciences and Mental Health Board (NMHB) Scientific (QQR) Review of the Unit, London. Director: Professor John Collinge. Report of the NMHB Visiting Subcommittee. Subcommittee Visit 19th & 20th March 2015. Annex 6 to Board Paper 15, presented at Council 1 October 2015.
13 May 2015	WITN3093019	Correspondence from Bernard Jolles, Director of D-Gen, to Laura Williamson, NHS Blood and Transplant,
1 October 2015	WITN7531005	Draft minutes of a meeting of the Medical Research Council, 1 October 2015.
12-13 October 2016	WITN7531009	Minutes of the Molecular and Cellular Medicine Board, 12-13 October 2016.
Not dated	WITN7531010	October feedback document
14 October 2016	WITN7531027	Email from Megan Dowie to Dr Graham Jackson

Not dated	WITN7531011	A Blood Based Assay for the Detection of vCJD Infection (part of MRCT file plan).

Table of MRC exhibits reviewed to formulate the statement:

Date	**Exhibit number**	**Notes/ Description**
Not dated	WITN7531017	UKRI Framework Document
Not dated	WITN7531018	MRC History from 2018 appraisal report to UKRI Report setting out the history of MRC and its functions and activities.
Not dated	WITN7531019	Publication of patent – WIPO – WO2012035296 Assay for Prions..
7 October 2004	WITN7531020	Development Gap Fund - background
7 October 2004	WITN7531021	Development Gap Fund - FAQs
3 February 2011	NHBT0033626	Detection of Prion Infection in variant Creutzfeldt-Jakob disease: a blood based assay'
Not dated	WITN7531022	Excerpt from archived copy of MRC website as at 14 November 2009
Not dated	WITN7531016	Excerpt from UKRI website as at 11 November 2022.
27 August 2015	WITN7531023	Correspondence from Bernard Jolles, Director of D- Gen, to Roland Salmon,

October 2016	WITN7531024	MCMB meeting outcome spreadsheet
October 2016	WITN7531025	Post-board panel report