UNIVERSITIES UK
CONCORDAT TO SUPPORT RESEARCH INTEGRITY

2019 CONSULTATION ON REVISED CONCORDAT

In April 2019, the UKCRC Registered CTU Network responded to a Universities UK consultation on revisions to the Concordat to Support Research Integrity.

The Network is very supportive of the aims of the Concordat and endorses the need for a framework to support integrity in clinical research.

Our response to this consultation follows.

Research Integrity Concordat Consultation

Page 1: Introduction

1. Introduction

1.1 A report into research integrity published by the Commons Science and Technology Committee recognised the value of the concordat to support research integrity but concluded that *the concordat to support research integrity should be tightened so that compliance can be more easily assessed, with a timetabled route-map to securing 100% compliance.*

1.2 Since the publication of the report in July 2018, the signatories of the concordat have met to consider how to clarify the existing principles and commitments of the concordat

1.3 A key weakness of the existing concordat is the sector's inability to demonstrate that it has met the requirements of the concordat. The revised concordat makes expectations clearer and requires institutions to submit information to the secretariat. Going forward, implementation of the commitments will be monitored. The commitments of the concordat are intended to be proportionate, addressing legitimate concerns about transparency while recognising that universities are operating in an increasingly challenging environment. The commitments are suitable to a range of institutions of different sizes and level of resource.

1.4 We are asking researchers, employers of researchers and funders of research to respond to this questionnaire, which is focused on whether the expectations of the revised concordat are clear and whether they are proportionate.

1.5 We are asking respondents to identify themselves and their affiliation, so that as signatories we can assess how broad the response to the consultation has been. We do not intend to publish the responses to this questionnaire, but we will present and may publish information at an aggregate level.

1.6 Responses to this questionnaire will be shared between the signatories of the concordat. The signatories of the concordat are: UK Research and Innovation, the

Wellcome Trust, the Scottish Funding Council, the National Institute for Health Research, the Department for the Economy Northern Ireland, the Higher Education Funding Council for Wales, Universities UK and the Government Office for Science. As stated in 1.4, the signatories will present and may publish aggregate responses to the call for evidence which will not be personally identifiable. However, information provided in response to this call for information may be subject to disclosure in accordance with the Freedom of Information Act 2000 (FOIA) or the Freedom of Information (Scotland) Act 2002 (FOISA). In some circumstances this may include personal information. If you believe any of the information you provide in your response is confidential, please advise us why you believe this to be the case. If we receive a request for disclosure of the information we will take full account of your explanation, however we may still have to release the information if required by FOIA or FOISA. An automatic confidentiality disclaimer generated by your IT system will not, of itself, be regarded as binding on this.

1.7 All personal data collected in the responses will be handled in accordance with the Data Protection Act 2018 and EU General Data Protection Regulation 2016/679. The information provided to the signatories in the call for evidence will be used for the purposes outlined above, and for no other purposes. Personally identifiable information will not be shared with any third parties.

1.8 Universities UK is managing this questionnaire on behalf of the signatories. The estimated time for completion is 30 minutes.

1.9 The consultation will close **on Friday 5 April 2019.**

1.10 If you have any questions or concerns about this consultation, please email Leonie Shanks: leonie.shanks@universitiesuk.ac.uk.

Page 2: Identifiers

1. Position

2. Organisation

UKCRC CTU Network

3. Please indicate whether you are responding on behalf of your organisation.

YES

Page 3: Overview

4. Is the summary of the commitments set out on page five of the draft concordat clear? For ease of reference, the summary is copied out below.

- [x] Yes
- [ ] No

4.a. If you answered no, please explain your answer

Summary of commitments

This concordat seeks to provide a national framework for good research conduct and its governance. As signatories to and supporters of the concordat to support research integrity, we are committed to:

1. upholding the highest standards of rigour and integrity in all aspects of research

2. ensuring that research is conducted according to appropriate ethical, legal and professional frameworks, obligations and standards

3. supporting a research environment that is underpinned by a culture of integrity and based on good governance, best practice and support for the development of researchers

4. using transparent, timely, robust and fair processes to deal with allegations of research misconduct should they arise

5. working together to strengthen the integrity of research and to review progress regularly and openly

The ways in which researchers, employers of researchers and funders of research are expected to meet these commitments is set out in relevant sections of this concordat.

5. The final version of the concordat will include a checklist that sets out the expectations

of researchers, funders of research and employers of research. Are there other materials that would help you or your organisation meet the commitments of the concordat?

The UKCRC CTU network would welcome further clarity on the information expected from Institution submissions with regards to Clinical Trials. Training or guidance documentation may be helpful depending on the specifics required.

Page 4: Maintaining the highest standards of research integrity

This section asks you to provide feedback on commitment one of the research integrity concordat, **Maintaining the highest standards of research integrity**, which is set out on pages 10-11.

6. The concordat identifies honesty, rigour, transparency and open communication, and care and respect, as the four core elements of research integrity. Are there other elements that should be identified?

The UKCRC CTU Network supports these four core elements. We believe in developing and sharing best practice and would therfore like to see refelction and learning represented as core values to reflect the importance for researchers to ensure they are following best practice.

7. The requirements in this section of the concordat have been updated to clarify the different responsibilities of researchers, employers of researchers and funders of research. Are the expectations of the concordat clear? (Use the free text box below if you have additional comments).

Yes the requirements for researchers, funders and employers are clear and supported by the UK CRC CTU Network

7.a. For researchers?

- [x] Yes
- [ ] No

7.a.i. If you answered no, please explain your answer

7.b. For employers of researchers?

x Yes ○ No

7.b.i. If you answered no, please explain your answer

7.c. For funders of research?

x Yes ○ No

7.c.i. If you answered no, please explain your answer

8. Are the revised expectations proportionate? (Use the free text box below if you have additional comments).

Proportionality will depend on how it is envisaged that these are measured in terms of the submission required from institutions. We would welcome clarity on the information and process involved.

8.a. For researchers?

- Yes
- No
- I don't know

8.a.i. If you answered no, please explain your answer.

8.b. For employers of research?

- Yes
- No
- I don't know

8.b.i. If you answered no, please explain your answer

8.c. For funders of research?

- Yes
- No
- I don't know

8.c.i. If you answered no, please explain your answer

9. Are you confident that your organisation will be able to implement commitment one of

the concordat?

x ○ Yes ○ No

9.a. If you answered no, please explain your answer.

10. If you have have further comments on this section of the concordat to support research integrity, please use the free text box provided.

n/a

Page 5: Ethical, legal and professional frameworks

This section asks you to provide feedback on commitment two of the research integrity concordat, **Ethical, legal and professional frameworks**, which is set out on pages 12 - 13.

11. The expectations in this section of the concordat have been updated to clarify the different responsibilities of researchers, employers of researchers and funders of research. Are the expectations of the concordat clear? (Use the free text box below if you have additional comments).

Yes the UKCRC CTU Network supports these expectations

11.a. For researchers?

x ○ Yes ○ No

11.a.i. If you answered no, please explain your answer

11.b. For employers of research?

x ○ Yes ○ No

11.b.i. If you answered no, please explain your answer

11.c. For funders of research?

x ○ Yes ○ No

11.c.i. If you answered no, please explain your answer

12. Are the revised expectations proportionate? (Use the free text box below if you have additional comments).

See comment for Qn 8

12.a. For researchers?

○ Yes ○ No ○ I don't know

12.a.i. If you answered no, please explain your answer

12.b. For employers of research?

- Yes
- No
- I don't know

12.b.i. If you answered no, please explain your answer

12.c. For funders of research?

- Yes
- No
- I don't know

12.c.i. If you answered no, please explain your answer

13. Are you confident that your organisation will be able to implement commitment two of the concordat?

x

- Yes
- No
- I don't know

13.a. If you answered no, please explain your answer

14. If you have further comments on this section of the concordat to support research integrity, please use the free text box provided.

Page 6: Embedding a culture of research integrity

This section asks you to provide feedback on commitment three of the research integrity concordat, **Embedding a culture of research integrity**, which is set out on pages 14-15.

15. The expectations in this section of the concordat have been updated to clarify the different responsibilities of employers of researchers and funders of research. Are the expectations of the concordat clear? (Use the free text box below if you have additional comments).

Yes, the UKCRC CTU Network supports these expectations

15.a. For employers of research?

x ○ Yes ○ No

15.a.i. If you answered no, please explain your answer

15.b. For funders of research?

x ○ Yes ○ No

15.b.i. If you answered no, please explain your answer

16. Are the revised expectations proportionate? (Use the free text box below if you have additional comments).

See comment Qn 8

16.a. For employers of research?

- Yes
- No
- I don't know

16.a.i. If you answered no, please explain your answer

16.b. For funders of research?

- Yes
- No
- I don't know

16.b.i. If you answered no, please explain your answer

17. Are you confident that your organisation will be able to implement commitment three of the concordat?

x
- Yes
- No
- I don't know

17.a. If you answered no, please explain your answer

18. If you have further comments on this section of the concordat, please use the free text box provided.

Page 7: Dealing with allegations of research misconduct

This section asks you to provide feedback on commitment four of the research integrity concordat, **Dealing with allegations of research misconduct**, which is set out on pages 16-17.

19. The expectations in this section of the concordat have been updated to clarify the different responsibilities of researchers, employers of researchers and funders of research. Are the expectations of the concordat clear? (Use the free text box below if you have additional comments).

The UKCRC CTU Network supports this commitment

19.a. For researchers?

x ○ Yes ○ No

19.a.i. If you answered no, please explain your answer

19.b. For employers of research?

x ○ Yes ○ No

19.b.i. If you answered no, please explain your answer

19.c. For funders of research?

x
Yes No

19.c.i. If you answered no, please explain your answer

20. Are the revised expectations proportionate? (Use the free text box below if you have additional comments).

See comment Qn 8

20.a. For researchers?

Yes No I don't know

20.a.i. If you answered no, please explain your answer

20.b. For employers of research?

- ○ Yes
- ○ No
- ○ I don't know

20.b.i. If you answered no, please explain your answer

20.c. For funders of research?

- ○ Yes
- ○ No
- ○ I don't know

20.c.i. If you answered no, please explain your answer

21. Are you confident that your organisation will be able to implement commitment four of the concordat?

x
- ☐ Yes
- ☐ No
- ☐ I don't know

21.a. If you answered no, please explain your answer

22. If you have further comments on this section of the concordat to support research integrity, please use the free text box provided.

Page 8: A commitment to strengthening research integrity

This section asks you to provide feedback on commitment five of the research integrity concordat, **A commitment to strengthening research integrity**, which is set out on pages 19 -20.

23. The expectations in this section of the concordat have been updated to clarify the different responsibilities of the of employers of researchers and funders of research. Are the expectations of the concordat clear? (Use the free text box below if you have additional comments).

Yes

23.a. For employers of researchers?

x ○ Yes ○ No

23.a.i. If you answered no, please explain your answer

23.b. For funders of research?

x ○ Yes ○ No

23.b.i. If you answered no, please explain your answer

24. Are the revised expectations proportionate? (Use the free text box below if you have additional comments).

See comment Qn 8

24.a. For employers of researchers?

- Yes
- No
- I don't know

24.a.i. If you answered no, please explain your answer

24.b. For funders of research?

- Yes
- No
- I don't know

24.b.i. If you answered no, please explain your answer.

25. Are you confident that your organisation will be able to implement commitment four of the concordat?

x

- ○ Yes
- ○ No
- ○ I don't know

25.a. If you answered no, please explain your answer

26. If you have further comments on this section of the concordat to support research integrity, please use the free text box provided.

The UK CRC CTU Network supports transparency in clinical trials and seeks to be transparent with all trials, but there are many challenges to overcome for academic trialists that make transaprency harder to achieve. We aim to raise these issues and challenges with appropriate regulators and stakeholders and endeavour to increase transparency in clinical trials research. for Registered Clinical Trial Units.

Page 9: Implementation of the concordat's commitments

27. Please could you provide details of any operational issues that might hinder implementation of the concordat that you have not already identified in the responses above.

There are many barriers to achieveing full transaprency for academic trials including accessibility and functionality issues with the reporting registries for academic trials that are not faced by pharma, delays in reporting due to 'publication bias' and the journal process, resource issues for clinical researchers that make prioritising reporting of results difficult and issues with historic trials that make reporting impractical.

28. How long do you think it will take your organisation to implement the commitments set out in the revised concordat?

We are already working towards increased transparency in clinical trials

29. Would your organisation value a training session on research integrity, focused on the requirements set out in this concordat?

x ○ Yes ○ No

29.a. Tell us about your training needs in the free text box provided.

We would welcome further clarity on the type of information expected to be submitted through the institutions

Page 10: Definitions

30. Are the definitions set out in Annexe I of the draft concordat fit for purpose? The definitions are set out on page 21.

x
- ○ Yes
- ○ No

30.a. If you answered no, please explain your answer.

Page 11: Useful Resources

31. The existing concordat sets out a series of resources that might be useful to researchers and employers of researchers. Are there specific resources you would identify as useful that might be included in this section of the Concordat? Where possible, please link to documents or web pages.

n/a

32. The signatories are committed to looking at the provision of information and guidance that might support the further development of research integrity in the UK. Are there any resources that you think might be useful to produce?

guidance on transparency compliance requirements (registering /reporting trial results) for clinical researchers

Page 12: Follow up

33. If you would like to hear about the outcome of this consultation, please enter your email in the boxprovided.

Please enter a valid email address.

regctus@leeds.ac.uk

Page 13: Final page

You have now reached the end of the research integrity concordat consultation. Many thanks for taking the time to share your views. Please contact Leonie Shanks if you have any further questions or concerns: leonie.shanks@universitiesuk.ac.uk