

# Research Integrity Concordat Consultation

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Response ID	Completion date
445531-445522-44926215	14 Mar 2019, 16:00 (GMT)

1	Position	Founder
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2	Organisation	TranspariMED
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3	Please indicate whether you are responding on behalf of your organisation.	yes
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19	<p><b>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).</b></p>	<p>No. It is completely unclear whether "misrepresentation of data, including suppression of relevant results/data or knowingly, recklessly or by gross negligence, presenting a flawed interpretation of data" includes 'silent outcome switching' in the reporting of research results, or not. For example, if a paper reporting clinical trial results does not mention the trial's originally defined primary outcome, and instead only presents other outcomes (maybe including outcomes that were not pre-specified), is that "misrepresentation of data" according to the Concordat, or not?</p> <p>For background see:  <a href="https://trialsjournal.biomedcentral.com/articles/10.1186/s13063-019-3172-3">https://trialsjournal.biomedcentral.com/articles/10.1186/s13063-019-3172-3</a>  <a href="https://trialsjournal.biomedcentral.com/articles/10.1186/s13063-019-3173-2">https://trialsjournal.biomedcentral.com/articles/10.1186/s13063-019-3173-2</a></p> <p>The current wording of the draft fails to provide stakeholders with the clarity required to distinguish between acceptable and unacceptable research practices. As 'silent outcome switching' is a form of research malpractice that is widespread in many research areas, this is a serious shortcoming of the current draft.</p> <p>The Concordat should clearly and explicitly state whether or not the 'silent' (not flagged as such) addition, deletion, or switching of prespecified outcomes constitutes research misconduct.</p>
19.a	For researchers?	No
19.a.i	If you answered no, please explain your answer	see above
19.b	For employers of research?	No
19.b.i	If you answered no, please explain your answer	see above
19.c	For funders of research?	No
19.c.i	If you answered no, please explain your answer	see above

22	<p><b>If you have further comments on this section of the concordat to support research integrity, please use the free text box provided.</b></p>	<p>The definition of "misrepresentation of data" needs to be reworked and made less ambiguous. The Concordat can only serve to promote research integrity if draws clear lines between acceptable practices and research misconduct.</p>
31	<p><b>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.</b></p>	<p>TranspariMED has to date developed three "Transparency Tools" aimed primarily at universities. These can be downloaded here:  <a href="https://www.transparimed.org/resources">https://www.transparimed.org/resources</a>  Further tools may be added in the near future.  This item by AllTrials may also be of use:  <a href="http://www.alltrials.net/news/how-to-upload-results-and-update-entries-on-clinical-trial-registers-2/">http://www.alltrials.net/news/how-to-upload-results-and-update-entries-on-clinical-trial-registers-2/</a></p>

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<b>32</b>	<b>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?</b>	Yes, this document: <a href="https://docs.wixstatic.com/ugd/01f35d_def0082121a648529220e1d56df4b50a.pdf">https://docs.wixstatic.com/ugd/01f35d_def0082121a648529220e1d56df4b50a.pdf</a>
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<b>33</b>	<b>If you would like to hear about the outcome of this consultation, please enter your email in the box provided.</b>	tillbruckner@gmail.com
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