

## PEER REVIEW HISTORY

BMJ Open publishes all reviews undertaken for accepted manuscripts. Reviewers are asked to complete a checklist review form ([see an example](#)) and are provided with free text boxes to elaborate on their assessment. These free text comments are reproduced below. Some articles will have been accepted based in part or entirely on reviews undertaken for other BMJ Group journals. These will be reproduced where possible.

### ARTICLE DETAILS

<b>TITLE (PROVISIONAL)</b>	Awareness and enforcement of guidelines for publishing industry-sponsored medical research among publication professionals: the Global Publication Survey
<b>AUTHORS</b>	Wager, Elizabeth; Woolley, Karen; Adshead, Viv; Cairns, Angela; Fullam, Josh; Gonzalez, John; Grant, Tom; Tortell, Stephanie

### VERSION 1 - REVIEW

<b>REVIEWER</b>	Jackie Street The University of Adelaide, Australia
<b>REVIEW RETURNED</b>	04-Mar-2014

<b>GENERAL COMMENTS</b>	<p>This is a useful paper but I have difficulty in recommending this for publication. My main concern with this paper is the lack of ethics approval. Most of the reasons for not obtaining ethics approval are not really relevant except that they make the omission less egregious e.g. not personal medical information, not patients, not healthcare professionals, participation voluntary. None of these are sufficient reason for not needing to undergo an ethical review of the research. I can see that the authors were hampered by the fact that the research was 'not carried out by an academic institution' but I think that this is not a good enough reason. There are ways to locate an HREC or to create an equivalent process if no alternative exists. I would be concerned for a participant if they reported ethical lapses at their company and if that reporting somehow leaked back to their company then their employment may be threatened. I certainly make no aspersions against TGaS and I would assume that persons employed by TGaS are skilled at maintaining confidentiality particularly if they are a Safe Harbor certified company. I would note that I had never heard of Safe Harbor certification before reading this paper. I asked a highly experienced colleague working in health technology assessment if they had heard of Safe Harbor certification. They had but could not remember where they had heard it or what it meant. This probably reflects a non-USA bias and it is possible that all participants in the survey were aware of what this certification meant. However, in the preamble to the questionnaire, the participants are not advised of the steps which will be taken to protect the data and safely store the data nor what Safe Harbor Certification means.</p> <p>On the other hand, this is a well written paper, the limitations have been declared and it does reveal some useful insights for improvement in publication practice in industry.</p> <p>Other than these issues my only comment is that a sentence about the limitations should be included in the abstract and an explanation about TGaS should be included in the method - On first reading the paper, I did not know who TGaS advisors (page 8) were.</p> <p>I regret having to make this recommendation. My recommendation</p>
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	to reject is based entirely on the lack of ethical approval. I have wondered if it might be possible for the authors to obtain retrospective ethical approval. On the other hand, my concerns with the preamble to the questionnaire, which I have described above, would preclude me from providing such approval myself.
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<b>REVIEWER</b>	LEONARDO D. DE CASTRO  CENTRE FOR BIOMEDICAL ETHICS YLL SCHOOL OF MEDICINE NATIONAL UNIVERSITY OF SINGAPORE  I AM EDITOR-IN-CHIEF, ASIAN BIOETHICS REVIEW
<b>REVIEW RETURNED</b>	19-Mar-2014

<b>GENERAL COMMENTS</b>	With participants consisting of individuals with financial conflicts of interest because they make money by mainly working in pharmaceutical or device companies, communication agencies or contract research organizations, the responses cannot not be taken at face value. While one might not find it difficult to accept that part of the conclusion that says publication professionals working in or for industry were aware of major publication guidelines, one finds it more difficult to accept that the data supports the conclusion that those same professionals applied the guidelines just because they say so. One can only say that the respondents "reported" that they applied those guidelines.
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### VERSION 1 – AUTHOR RESPONSE

Reviewer: 1

Other than these issues my only comment is that a sentence about the limitations should be included in the abstract and an explanation about TGaS should be included in the method - On first reading the paper, I did not know who TGaS advisors (page 8) were.

\*\*\*We have added a sentence about limitations to the abstract and provided more information about TGaS Advisors in the Methods (p8).

Reviewer: 2

With participants consisting of individuals with financial conflicts of interest because they make money by mainly working in pharmaceutical or device companies, communication agencies or contract research organizations, the responses cannot not be taken at face value. While one might not find it difficult to accept that part of the conclusion that says publication professionals working in or for industry were aware of major publication guidelines, one finds it more difficult to accept that the data supports the conclusion that those same professionals applied the guidelines just because they say so. One can only say that the respondents "reported" that they applied those guidelines.

\*\*\*We have emphasized, in several places, that findings represent those reported by participants (as is the case in all surveys). Socially desirable responses are a problem in any survey, but the fact that our survey revealed problems (e.g. poor provision of training for freelancers) suggest that responses were truthful. We have now mentioned this in the Discussion (p23)