

Re: Response to the Stellenbosch University's Research Ethics Committee: Social, Behavioural and Education Research expression of concern

To the Editor: Thank you for the opportunity to respond to the concerns raised by the Stellenbosch University's Research Ethics Committee: Social, Behavioural and Education Research (REC: SBE) in their letter dated 4 June 2021. As we read it, the concerns raised may be divided into two categories, as detailed below.

Firstly, we did not consult the public record on the 'Nieuwoudt *et al.*' case and, especially, the public statement issued by Stellenbosch University's Deputy Vice-Chancellor: Research, Innovation and Postgraduate Studies, Prof. Eugene Cloete, issued on 12 June 2020. Nor did we approach the REC: SBE itself for comment or information.

Secondly, as a result of our failure to consult the public record, we relied on 'erroneous assumptions' about the ethical review of the research on which the Nieuwoudt *et al.* article is based. In particular, we assumed that:

- (i) the research was conducted in accordance with the protocol approved by the REC: SBE, when in fact this was not the case; and
- (ii) the REC: SBE was aware of the fact that study would be presented in terms of racial generalisations.

Regarding the first concern that we failed to consult the public record, we concede that we did not refer to Prof. Cloete's public statement. Even though our article was published in April 2021, it was accepted for publication a year earlier, in April 2020. In other words, our article was accepted for publication 2 months before Prof. Cloete issued his public statement.

The long delay between the date on which the article was accepted for publication (April 2020) and the date on which it was actually published (April 2021) arose as a result of bureaucratic issues relating to the payment of the page fees. Given this fact, we mistakenly did not think it necessary to revisit the content of the article when reviewing the final proofs.

In light of this error, we would appreciate if the journal could add an erratum to the article in the following terms:

'This article was written and accepted for publication prior to the conclusion of a formal investigation into Nieuwoudt *et al.*'s article by Stellenbosch University. That investigation has been concluded and a summary of its findings was published by the Deputy Vice-Chancellor: Research, Innovation and Postgraduate Studies, Prof. Eugene Cloete, on 12 June 2020. Prof. Cloete's summary ought to be read in conjunction with this article. It may be found at <http://www.sun.ac.za/english/Lists/news/DispForm.aspx?ID=7426>.⁽¹⁾

Finally, we would also like to point out that our article expressly states that it is based on publicly available information, and for this reason we did not feel it was necessary to seek comment or information from the REC: SBE.

Regarding the second concern, that we relied on 'erroneous assumptions' about the ethics review process, we make two responses in turn.

As indicated above, the first of these is that we assumed that the research was conducted in accordance with the protocol approved by the REC: SBE, when this was not the case. In so far as this issue is concerned, we submit that this was an appropriate and standard assumption to make given that Nieuwoudt *et al.* referred expressly in their article to the fact that their study had been granted ethics approval by the REC: SBE.

Secondly, we believed that the REC: SBE was aware of the fact that the study would be presented in terms of racial generalisations according to the study protocol, and under the assumption that deviations to the protocol would have been reported to the REC: SBE. However, this was not the case. In so far as this issue is concerned, we maintain that it was invertible that the findings would have to be reported in race-based terms for the following reasons:

- Firstly, the REC: SBE appears to have approved a methodology allowing the enrolment of only coloured women into the study. The consequences of this methodology were that it would have to be reported in racial terms, as the selection criteria required self-identification as a coloured woman, and the exclusion of other race groups.
- Secondly, we accept that Prof. Cloete is in all likelihood correct that the REC: SBE did not approve a methodology that would enable population-based findings about all coloured women being made when he states that the 'article was NOT based on the appropriate methodology to make population-based inferences about "coloured South African women"'. However, even if we accept that the REC: SBE did not foresee the researchers making population-based findings relating to all coloured women, we nevertheless submit that the REC: SBE should have foreseen that the findings would have to be presented in racial terms.

Other comments that we would like to make in relation to the public statement issued by Prof. Cloete are: (i) We do not understand how the publication of an article that was found to be not 'aligned' to a protocol approved by the REC: SBE came to be, particularly when the public statement notes that the formal investigation found there had been no 'deliberate intent to mislead the relevant role-players'. This 'finding' raises some unanswered questions, including whether this 'finding' raises some unanswered questions, including whether this unintentional non-alignment was due to a protocol deviation. Or was it because they had applied for a protocol amendment to the original ethics application? Or is there some other reason for the non-alignment? (ii) The recommendations for reform are very general, and focus on awareness-raising rather than the development of 'consensual guidelines for researchers regarding research dealing with racial categories and other social constructs'. We would have been more specific than the university and recommended a deeper consideration of structural issues by ensuring that the ethics application form clearly requests a

breakdown of the racial/ethnic categories of potential participants and a justification for inclusion/exclusion. Careful consideration of the sample is an ethical requirement, and in line with the principle of justice, which mandates fair participant selection.

In conclusion, we are pleased that Stellenbosch University took this matter seriously and investigated it. However, we feel that the outcome of the investigation was superficial and rests primarily on shifting the blame from the way the study was reviewed and carried out, to the way it was written up.

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1. Erratum. *S Afr J Bioethics Law* 2021;14(1):39. <https://doi.org/10.7196/SAJBL.2021.v14i1.780>