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Title: Questions about methodological and ethical quality of a vaccine adjuvant critical paper

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ACCEPTED MANUSCRIPT

Title: Questions about methodological and ethical quality of a vaccine adjuvant critical paper

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A recent manuscript published in Toxicology by Crepeaux and colleagues (Crepeaux et al. 2017) highlights a number of issues that have been appearing, particularly in the vaccine-critical peer-reviewed literature.

- A lack of clarity around the process undertaken for gaining ethical approval for both human and animal experiments.
- A lack of clarity in the methods undertaken, in terms of both the protocols followed and the biological relevancy of the methods used
- Funding and Conflict of Interest statements which lack clarity

RESEARCH ETHICS

There is no clear statement identifying ethics approval gained for the experiments involving mice. Whilst the article does state that "All the experiments on animals were performed in respect to the guidelines provided by the European Union (Directive 2010/63/EU)" it remains unclear as to which institutional/local ethics committee approved these experiments. Directive 2010/63/EU Article 36 states under Project authorisation "1. Member States shall ensure, without prejudice to Article 42, that projects are not carried out without prior authorisation from the competent authority" (2010). This would suggest that for animal experiments to be carried out, prior authorisation from an institutional/local ethics committee is necessary to state that experiments were "performed in respect to the guidelines".

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