

27 July 2022

21:12 GMT

Hello Elise.

Thank you again for the opportunity to review your assessment of AHA's policies related to clinical trials transparency. Thank you also for correcting the research expenditure data.

Below please find AHA's responses to the assessment of its facilitation of transparency in clinical trials.

AHA General Response: AHA fully supports transparency in research. For instance, we were a relatively early entrant as a nonprofit funder into requirements related to Open Science, with regard to both publishing and sharing of data. AHA historically has funded primarily basic research, and although growing, clinical trials has been a relatively small part of what we fund. Indeed, clinical research in total has averaged about 20% of what we fund each year for the past several years, and much of that does not meet the definition of a clinical trial.


We are, however, fully committed to optimizing transparency in all aspect of our portfolio, including clinical trials. Your assessment is helpful in seeing there are some areas in which we can improve some of our processes.

Specific Questions Posed to AHA:

1. Has our team overlooked any relevant items, links or documents?
 - **AHA Response:** no documents or links overlooked.
2. Does our team's scoring of any individual item award a score that your institution considers too low or otherwise misguided?
 - **AHA Response – Registry records up to date:** AHA requires quarterly reports of trial enrollment for clinical trials done as part of Strategically-Focused Research Networks and health Equity Research Networks – we **suggest this item should be changed to yellow**.
 - **AHA Response – Results published in journal:** "Requiring" publication is difficult for many reasons. However, AHA, like nearly all funders, fully expects awardees to publish their work; they must report on progress at least annually and publications are a key part of the required reporting. In addition, recent analysis of AHA's portfolio revealed that 98 % of AHA awards publish 1 or more publications; thus that expectation is understood fully by the scientific community. Finally, we note that the

WHO guidelines from which ratings are derived states publication is an "expectation". As "expectation" is also clearly not mandatory, and if the WHO approach would in fact result in a green rating, **we suggest the language AHA uses should similarly result in a green rating.**

3. Is your institution planning to introduce any new or additional policies or monitoring systems that are salient to this assessment? (If yes, please provide details on their content, plus the date at which the new policies/systems are expected to be put into place.)
- **AHA Response:** AHA is committed to transparency in all areas of research it supports, including clinical trials. To specifically address opportunities to optimize our policies and practices related to clinical trial transparency, AHA is forming an advisory group. AHA anticipates recommendations from this group in the coming months, and implementation of recommended changes soon thereafter.



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