



November 7, 2014

NAMI Comments to PCORI on Proposal for Peer Review of Primary Research and Public Release of Research Findings

On behalf of the National Alliance on Mental Illness (NAMI), I am pleased to submit the following comments to PCORI on proposed guidelines for peer review of research findings. NAMI is the nation's largest organization representing people living with serious mental illness and their families. As a patient advocacy organization, NAMI supports the work of PCORI to undertake patient-centered comparative effectiveness research that can better inform clinical care decision-making. NAMI is especially supportive of the efforts that the PCORI board and staff have made over the past few years to ensure meaningful patient engagement that drives the development of research priorities, the review of research findings and dissemination of results.

The Proposed Process for Peer Review Strikes a Careful Balance Between Speed and Scientific Integrity

NAMI believes that the proposed timeline and process for review strikes an appropriate and careful balance between making sure that important results are published quickly, while ensuring that research meets the highest standard of scientific integrity, trustworthiness and credibility. As the narrative in the proposal indicates, these are the twin goals articulated by Congress in the legislation authorizing PCORI.

NAMI supports the requirements in the timeline for registration of PCORI funded studies at [clinicaltrials.gov](http://clinicaltrials.gov) and Registries of Patient Registries (RoPR). This is an important step in ensuring that studies meet all relevant eligibility requirements.

NAMI also supports the requirements for extensive review of the draft final report from Awardee Institutions. It is important that development of the 500-word abstract is developed before peer review is undertaken by PCORI. Further, the

peer review process set forth by PCORI has a number of steps to ensure appropriate scrutiny of the research methods and findings – including adherence to the PCORI Methodology Committee standards. NAMI is satisfied that this multistep process can avoid the pitfalls associated with premature release of findings that have not been properly vetted and reviewed.

### Making Sure that Lay Abstracts are Both Understandable and Accurate

One area of concern that NAMI would like to raise relates to the requirement for translation of findings for patients and the general public. NAMI certainly supports inclusion of this critical step in the process. Clearly, in the statute Congress demanded that PCORI disseminate findings in a way that is understandable for patients and is useful for frontline clinicians. NAMI's concern is that the requirement to reduce complex findings down to a 500-word lay abstract that is readable at an 8<sup>th</sup> grade level creates additional complications. This is especially the case with what are likely to be extensive qualifications on conclusions drawn from patient-centered comparative effectiveness research.

PCORI has thus far adhered to requirements in the law ensuring that its research take into account the complexities of real world treatment settings, particularly with respect to comorbid medical conditions and patient diversity based on gender and racial and ethnic differences. It will be critical for these lay abstracts to point out how findings differ based on these critical factors that are of tremendous importance to patients and their providers. NAMI urges PCORI to ensure that lay abstracts are carefully scrutinized to ensure that all research findings and conclusions reflect these realities. Along those lines, NAMI recommends that PCORI develop additional standards to ensure additional patient in the development of these abstracts.

Finally, NAMI would like to draw out an important distinction between comprehension and usefulness in development of lay abstracts. While it may be clear as to whether or not the language in an abstract is understandable to individuals at an 8<sup>th</sup> grade level, it is a different calculation as to whether or not this same information is useful to patients and their providers in the context of real world treatment situations, i.e. for patients on an individual basis, with complex medical comorbidities, individual and family medical history, etc. NAMI urges

PCORI to continue efforts to ensure that the development of lay abstracts meet with complementary goal.

### Conclusion

Again, NAMI supports the careful balance that PCORI has achieved with these standards for peer review. In the end, this peer review process will be critical in ensuring that PCORI funded research has the integrity and credibility that will be needed to be useful for patients and their providers.

Respectfully Submitted,

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