Abstract. The National Board of Medical Examiners (NBME) has instituted a new multiple choice examination in order to “certify” clinical and translational investigators. As experienced research educators, we argue that this certification process is unnecessary, values knowledge over competency, may be counterproductive, and is unlikely to achieve any worthwhile outcome. We lay out these arguments in the hope of stimulating a robust discussion among leaders, faculty, and learners engaged in clinical research education and training.

Second, the proposed approach to the certification warrants serious scrutiny. In an era emphasizing competency-based education and assessment, the proposed multiple-choice exam represents a step back to a bygone era. Competencies, or “specific learned abilities that the practitioner has adopted as a consequence of his or her education” [2], are assessed by determining the learner’s attainment of observable skills, rather than by assessments focused solely on knowledge. Undergraduate and graduate medical educators seek to translate this important theoretical construct into practice and strive to assess our students’ and trainees’ abilities to practice clinical medicine, despite the challenges of doing this reliably and objectively. In the case of CTS investigators, core competencies have been carefully developed through the NIH’s Clinical and Translational Science Award program [3]. Moreover, generally accepted and objective metrics already exist to assess a researcher’s competency, largely through the investigator’s publication of manuscripts, receipt of research grants, successful completion of formal training programs, employment, promotion, and retention in research. These may be imperfect metrics [4], but they are better assessments of research competency than multiple-choice examinations.

Third, this exam could create real problems. Given the NBME’s imprimatur in the medical realm, there is a real danger that funding

and benefit, we can find no evidence that there is an analogous need to “license” researchers, including no evidence of any current threat to the public’s health from inadequately certified clinical research professionals. Furthermore, NBME has not proposed how their examination will mitigate their perceived threat. We believe that no matter whether the researcher has an M.D. or a Ph.D., certification, with its attendant time and cost expenditures, is not needed.

First, what is the need that this certification is intended to address? In an email solicitation of potential exam item writers, NBME described “an immediate ethical need for this assessment,” citing the organization’s mission, “to protect the health of the public through state of the art assessment of health professionals” (Personal communication from Kathleen Short of NBME, February 6, 2015). There are several reasons why this need is neither immediate nor ethically mandated. “Clinical research professionals” are not “health professionals” in any way that is analogous to the largest group that NBME certifies: physicians (through its US Medical Licensure Examination). One can qualify to sit for this new certification exam by being “currently enrolled in, or a graduate of a Master’s or Doctoral degree program in medicine, science, at an academic institution meeting NBME criteria” [1]. An individual with an M.Sc. in Biochemistry or a Ph.D. in Molecular Genetics does not meet any definition of a “health professional.” Although an objective “competency” assessment is required in order to license physicians for the public’s safety

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Finally, even if there were evidence of a current threat to public health, this exam would not mitigate it. If NBME’s assertion of harm is based on investigators conducting and/or reporting research in an unethical or inappropriate manner (as inferred from the nature of 85% of the questions) they are ignoring that there has already been substantial attention to these issues, including NIH requirements for Responsible Conduct of Research training, Institutional Review Board regulations and oversight, and required demonstration of research ethics knowledge through existing programs such as Collaborative Institutional Training Initiative certification. While one could meaningfully ask to what extent these existing programs are efficacious, there is no reason to presume that the NBME examination will do any better. Indeed, we suggest readers look at the first “sample question” in the exam brochure [1] (see text below). The answer they consider “correct” (B; coercion) is actually incorrect (the vignette meets no reasonable definition of “coercion”), supporting our concerns about both the focus and the quality of this exam.

A 48-year-old woman with stage III breast cancer is referred to an oncologist participating in a Phase 2 clinical trial testing a novel chemotherapy agent. Based on the review of the patient’s medical history and current status, it is determined that she would likely meet entry criteria for the clinical research trial. During the initial interview the investigator tells the patient, “If my wife had a similar type of breast cancer, I would enroll her in the trial.” After hearing this information, the patient decides to enroll in the clinical trial. Which of the following best describes this investigator’s actions?

- (A) Clinical equipoise
- (B) Coercion
- (C) Enrollment of a vulnerable population
- (D) Therapeutic misconception

Answer: B

The comments above are a critique of the NBME’s “Investigator and Scientist Certification Examination,” which is directed at the investigators we train. However, they also are offering a “Monitor, Associate, and Coordinator Certification Examination.” We leave it to others to comment on this pathway, but we would like to emphasize that two highly regarded and commonly pursued certification pathways already exist for these research professionals: one offered by the Association of Clinical Research Professionals and the other offered by the Society of Clinical Research Associates.

In sum, we are concerned that this effort by the NBME attempts to solve a problem that does not exist and will undermine the already perilous prospects for promoting a robust pipeline of CTS investigators. NBME has instituted this certification without the input of the CTS community; we would like to encourage a thoughtful and robust conversation among leaders and faculty of training programs before this program is accepted. This conversation should include input from clinical investigators and students as to whether this proposed additional credential is warranted.

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**References**