



New England Research Institutes

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MEMORANDUM
Institutional Review Board

To: Lisa Marceau, MPH, PI
Cc: Michael Maurao, PM
From: Susan Hall, PhD, NERI IRB Co-Chair *Susan A. Hall*
Date: April 4, 2013
Re: Clinical Myth-teries: A Video Game About Clinical Studies, PIP 1418

The IRB reviewed the new submission of the above-mentioned study, dated April 3, 2013, via Expedited Review procedures.

On April 3, 2013, the IRB approved the change under 45 CFR 46.110 (b) (2). At the request of the Office of Management and Budget (OMB), in both Recruitment Letters, the word "confidential" was changed to "private", and in the Screening Forms, the "Confidentiality Statement" was changed to "Privacy Statement" and the word confidential" was changed to "private". Specifically, this approval is for the following submitted items:

- Recruitment Letter, Qualitative Focus Group, Version April 3, 2013
- Recruitment Letter, Pre-Post Evaluation Focus Group, Version April 3, 2013
- Screening Form, Pre-Post Evaluation, Version April 3, 2013
- Screening Form, Qualitative Focus Group, Version April 3, 2013

The IRB has determined that the NERI activities pose no greater than minimal risk.

This correspondence does not change the current study expiration date of January 24, 2014. Materials for continuing review should be submitted no later than November 2013. The IRB should be notified if the scope of the project changes in any way.

IRB member Lisa Welch, PhD, was recused from this review due to a conflict of interest; specifically, Dr. Welch's role as Qualitative Expert.

Thank you for your continued efforts in the protection of human subjects.

As Principal Investigator, you have the following obligations:

1. To give every subject a copy of the approved consent form (if applicable), and
2. To obtain approval from the IRB before instituting any change in the research protocol or the consent form.