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
Date: January 25, 2013
Re: Clinical Myth-teries: A Video Game About Clinical Studies, PIP 1418

On January 25, 2013, the IRB reviewed the new submission of the above-mentioned study, dated January 23, 2013, via Expedited Review procedures.

The IRB approved all activities as submitted, under 45 CFR 46.111. The IRB has determined that the NERI activities pose no greater than minimal risk.

This approval is for the following submitted items:

- Protocol, Version January 23, 2013
- Screening Form, Pre-Post Evaluation, Version January 23, 2013
- Guardian Consent for Participation in Research - Pre-Post Evaluation, Version January 23, 2013
- Child Assent for Participation in Research - Pre-Post Evaluation, Version January 23, 2013
- Screening Form, Qualitative Focus Group, Version January 23, 2013
- Guardian Consent for Participation in Research- Qualitative Focus Group, Version January 23, 2013
- Child Assent for Participation in Research- Qualitative Focus Group, Version January 23, 2013

Approval for the above-mentioned study is valid from January 25, 2013 and will expire on 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.

Please note this approval is specifically for the above-mentioned documents (protocol, informed consent documents, assents, and screener). All remaining subject-directed materials and the amended protocol must be forwarded to the IRB for review and approval prior to any research activities with these human subjects. At that time, the IRB will review all materials to ensure adequate procedures are in place to minimize the risks related to physical harm, psychological harm and breach of privacy and confidentiality based on this vulnerable population.

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.

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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
Date: February 7, 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 February 5, 2013, via Expedited Review procedures.

On February 7, 2013, the IRB approved the change under 45 CFR 46.110 (b) (2). At the request of the Office of Management and Budget (OMB), the responses for participant's race were revised in both Screener Forms; text in the previous paragraph was also revised. Specifically, this approval is for the following submitted items:

- Screening Form, Pre-Post Evaluation, Version February 7, 2013
- Screening Form, Qualitative Focus Group, Version February 7, 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.