

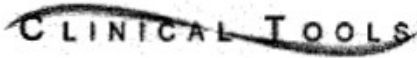
Attachment 2: IRB Letter of Approval

Supporting Statement A for

Online Skills Training for PCPs on Substance Abuse (NIDA)

January 2011

IRB LETTER OF APPROVAL FOR EXEMPT STATUS



Clinical Tools, Inc.
1506 E. Franklin Street, #200
Chapel Hill, NC 27514
919-960-8118
www.ClinicalTools.com

April 26, 2010

T Bradley Tanner, MD
Principal Investigator, Clinical Tools, Inc.

Mary P. Metcalf, PhD, MPH, CHES
Co-Principal Investigator, Clinical Tools, Inc.

Meghan Coulehan, MPH
Project Director, Clinical Tools, Inc.

Re: IRB submission for Online Skills Training for PCPs on Substance Abuse - N44DA-8-2214
IRB Protocol: New
Type of Review: Exempt

Dear Drs. Tanner and Metcalf and Ms. Coulehan,

I have completed review of your application for the project entitled, *Online Skills Training for PCPs on Substance Abuse*. This research involves minimal risks and therefore qualifies for expedited review.

The usability, pilot, and summative evaluations appear appropriate for exempt status under 45 CFR 46.101(b) (1). Clinical Tools, Inc. is considered to be an established educational setting, due to our vast experience providing online CME that is accredited, with accommodation, by the ACCME. Given the nature of the subject pool (primary care providers) and the participation experiences, I agree that there is no need for a formal informed consent process.

The recruitment methods you describe appear adequate to recruit a total of 116 primary care physicians for your studies. Your participant payment of \$75 per participant experience, in accordance with OMB guidelines, is also appropriate. Participants in the summative evaluation are involved in multiple experiences, thus 3 separate payments of \$75 per experience is justified (\$225 total).

I approve this IRB application. Please feel free to contact me with any questions.

Sincerely,

A handwritten signature in black ink that reads "Susan Wilhelm, PhD". The signature is written in a cursive, flowing style.

Susan Wilhelm, PhD
Committee for the Protection of Human Subjects in Research
Clinical Tools, Inc #01, identity IRB00002604