Here are IRB excerpts from Dr. Kovelman's study (HUM00033727), which has been approved. Feel free to refer to this when filling out your own IRB and also to the study itself to support that the system has already been approved for use with human subjects.

If you have any questions about your fNIRS IRB application, please contact: fnirs-lab@umich.edu

01. General Study Information

1.8* Project Summary:

c) functional Near Infrared Spectroscopy: we will investigate the neural bases of typical and atypical language and reading development using fNIRS. Like fMRI, fNIRS assess the brain's hemodynamic response by employing optical properties of light. The advantages of fMRI are that it gives a high-resolution 3D image with detailed anatomical information. Unlike fMRI, fNIRS only collects data ~3 cm into the cortex, yet, the advantages of fNIRS are that it is small, portable, quiet, and is well suited for working with children as young as neonates, we thus hope to be using fNIRS with infants and children. The PI is highly experienced in the use of fNIRS (please see a peer-reviewed video publication of the system by the PI: http://www.jove.com/index/details.stp?ID=1268)

05. Research Design

5.1.2* Indicate the section where each of the following are covered in the attached protocol:

Background Information

fNIRS is a relatively new technology for the study of human brain. The disadvantage of, fNIRS relative to the fMRI is that it only collects data from the cortex (2-3 cm deep into the head, which makes it well suited for the study of cortical involvement in cognition. The advantages of fNIRS are that it is quiet, portable, does not require being still in a narrow tube, and can thus be used with awake and behaving infants and young children (for details about the system and it's use see our publication in video format, Shalinsky, Kovelman, 2009: http://www.jove.com/index/details.stp?ID=1268). fNIRS operates by using near infrared light emitters and detectors. Emitters emit near-infrared light, and detectors detect the light. There are no known risks associated with the use of this technology. The fNIRS system purchased by the University of Michigan is the TechEn system.

References

Shalinsky, M. S., Kovelman, I., Berens, M. S., & Petitto L. A. (2009).Exploring Cognitive Functions in Babies, Children & Adults with Near Infrared Spectroscopy. Journal of Visualized Experiments. Available in a movie format online soon at http://www.jove.com/

06. Benefits and Risks

6.5 * Benefits and Risks:

fNIRS experiment has no more than minimal risk and Techen fNIRS system has been approved by the Biomedical Engineering Unit (BEU) (Tag number: 357899)

16. Devices

16.1* For all devices to be used at the Hospital and Health Centers, has the Biomedical Engineering Unit (BEU) assessed all devices for safety and tagged or registered all devices?

(●) Yes ( ) No

16.2.1 Devices Not Approved or Not Cleared for Marketing by the FDA:

Device Not Approved by the FDA:

16.2.2* What is the generic name or descriptor of the device? Include trade names if available.

TechEn CW6 functional Near Infrared Spectroscopy

16.2.3* What is the source of the device? Include both supplier and manufacturer if different.

NIRSOptix and TechEn, Inc

16.2.4* What is the purpose of the device and how will it be used in the study? ***Include any post-manufacturing modifications to the device.***

The device will be used for measuring blood oxygenation in the brain to study….

16.2.6* Is this an in vitro diagnostic device? [WHERE ALL THE FOLLOWING STATEMENTS ARE TRUE]

( ) Yes (●) No

16.2.7* Is this a medical device being tested for safety and/or efficacy?

(●) Yes ( ) No

16.2.8* What is sponsor's risk designation for the device? ***[NOTE: if this is a sponsor-investigator study, the PI provides this designation. Complete the MIAP IDE Checklist to provide validation of the risk designation.]***

Non-significant Risk (NSR)

16.2.9.2* Describe why this device and its use, as proposed in this study, constitute a non-significant risk to the subjects involved. ***Include an evaluation of the safety risks to the subject in the event of a device failure.***

The TechEn CW6 functional Near Infrared Spectroscopy device is very similar to the FDA approved Hitachi ETG-4000 functional Near Infrared Spectroscopy device (designated non-significant risk) that we have previously used for our research here at the University of Michigan. Both systems utilize nearly identical physics to acquire data and the TechEn device will be used in the same way that the Hitachi device was when it was here on loan during 2010.

The TechEn device is currently being used at multiple research facilities such as Massachusetts General Hospital (Dr. David Boas), the University of Pittsburgh (Dr. Ted Huppert), and the University of Connecticut (Dr. Heather Bortfeld).

In the event of a device failure, there are minimal safety risks to the subject. The TechEn system is similar to a computer, so possible device failures would be on the "computer" end -- the system freezing, refusing to start, etc. In the event of such a failure, the subject would simply remove the headset and be rescheduled for another time when the device is working properly.