Appendix F. RTI Institutional Review Board Approval Notice

Full ☒, IRB Meeting Date: 11/21/2006
Expedited ☐, category: None

Type of Review *(check one)*:
☐ Preliminary review (Do not involve human subjects or data until pretest or full study is approved.)
☒ Pretest/Pilot Test
☐ Full Implementation
☐ Amendment, describe:
☐ Add study site(s):
☐ Renewal
☐ Study Closure

IRB Approval of Special Conditions *(check all that apply)*:
☐ Waiver of Signed Informed Consent/Parental Permission
☐ Participation of Pregnant Women (**Worksheet B** submitted by project team)
☐ Participation of Prisoners (**Worksheet C** submitted by project team)
☒ Participation of Minors (**Worksheet D** submitted by project team)
☐ IRB Agreement of Nonsignificant Risk Device Study Determination

Please note the following requirements:
- If **unexpected problems** or **adverse events** occur, the project team must notify the IRB.
- If there are **changes** in study procedures or protocol or any data collection materials (brochures, letters, questionnaires, etc.) the project team must notify the IRB before they are implemented.
- The project team is required to apply for **continuing review** as long as the study is active, which includes participation of human subjects or possession of human data or specimens.

Expiration Date of IRB Approval: **May 21, 2007**
(No human subjects research can occur after this date without continuing review and approval.)

Jerry VanSant

Signature - IRB Member or Chair

11-22-06
Date of IRB Approval

Jerry VanSant
Name - IRB Member or Chair (print or type)

☐ Copy sent to project leader: _____
☐ Entered into MIS

Office of Research Protection and Ethics, Institutional Review Board
3040 Cornwallis Road, Research Triangle Park, NC 27709-2194, USA
Telephone: 919-316-3358 Fax: 919-316-3897 orpe@rti.org