EAST TENNESSEE STATE UNIVERSITY

Office for the Protection of Human Research Subjects • Box 70565 • Johnson City, Tennessee 37614-1707
Phone: (423) 439-6053 Fax: (423) 439-6060

IRB APPROVAL – Initial Exempt

December 15, 2016

Brittany Ratliff (Speech Language Pathology)

RE: Prevalence of Communication Disorders in Children with Neonatal Abstinence Syndrome on School Speech-Language Pathologists' Caseloads
IRB#: c1216.10e
ORSPA#:

On **December 15, 2016**, an exempt approval was granted in accordance with 45 CFR 46. 101(b)(). It is understood this project will be conducted in full accordance with all applicable sections of the IRB Policies. No continuing review is required. The exempt approval will be reported to the convened board on the next agenda.

- New Protocol Submission xForm; CV; Bibliography; Recruitment email; Reminder email; Survey; Informed Consent Document

Projects involving Mountain States Health Alliance must also be approved by MSHA following IRB approval prior to initiating the study.

Unanticipated Problems Involving Risks to Subjects or Others must be reported to the IRB (and VA R&D if applicable) within 10 working days.

Proposed changes in approved research cannot be initiated without IRB review and approval. The only exception to this rule is that a change can be made prior to IRB approval when necessary to eliminate apparent immediate hazards to the research subjects [21 CFR 56.108 (a)(4)]. In such a case, the IRB must be promptly informed of the change following its implementation (within 10 working days) on Form 109 (www.etsu.edu/irb). The IRB will review the change to determine that it is consistent with ensuring the subject's continued welfare.

Sincerely,
Stacey Williams, Chair
ETSU Campus IRB

Cc: