

Attachment A. Protocol for THAI Fluorosis Methodology Study

National Health and Nutrition Examination Survey (NHANES) THAI Fluorosis Methodology Study

OMB no. 0920-0237

Expires: 12/31/2011

Assurance of confidentiality – All information which would permit identification of an individual, a practice, or an establishment will be held confidential, will be used for statistical purposes only by NCHS staff, contractors, and agents only when required and with necessary controls, and will not be disclosed or released to other persons without the consent of the individual or establishment in accordance with section 308(d) of the Public Health Service Act (42 USC 242m) and the Confidential Information Protection and Statistical Efficiency Act (PL-107-347).

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NHANES-THAI Fluorosis Methodology Study Protocol:

Eligibility: To maximize dental conditions of interest, 150 children ages 9-15 years old will be selected for recruitment from a pre-existing study conducted jointly by the University of Manchester and Chiang Mai dental schools. All children participating in this pilot study will have participated in prior studies that have employed QLF imaging and the TF dental fluorosis exam. Therefore, all study participants will have had some prior dental fluorosis classification.

Informed Consent: This project has been approved by the NCHS Ethics Review Board. Informed Consent Form permitting participation will be obtained in writing from parent or legal guardian of their child.

Exclusion Criteria: Children not participating in an earlier THAI dental fluorosis study, children who are currently younger than 9 years or older than 15 years; children without upper six anterior teeth fully erupted; no signed informed Consent Form; no reported history of fluoride supplements; or have fixed orthodontic appliances.

Study Design: Fluorosis Assessment will be conducted at Chiang Mai University Dental School, Chiang Mai, Thailand.

Fluorosis Assessment Protocol:

A total of four assessments for each child will be undertaken during the single visit. Participants will brush their teeth with a provided toothbrush and water. The first examination will be a U.S. standard clinical examination using the NHANES method (Dean's Index protocol) to assess for dental fluorosis. The second examination will be a European and World Health Organization (WHO) endorsed clinical examination to assess for dental fluorosis.

The next assessment will require the taking of a standard white light digital photograph of the upper anterior teeth. Using newly developed technology, the final assessment will be the taking of a short series of fluorescence/polarized white light digital images of the upper anterior teeth.

Report of Findings:

If the examining dentist notices any adverse dental health conditions, a note will be sent to the parent or guardian informing them of the condition. The parent or guardian can take this letter to a dentist and they will be able to advise them further.

Findings from the overall study will be used to help determine whether this method could be incorporated into a future NHANES.