

Attachment 13.

Validation of Pubertal Maturation Self Administered Module

The purpose of the validation study is to compare the results obtained using the “gold standard” physical examination Tanner staging method to results reported by children and teens based on self-assessment. Tanner staging is part of a routine physical examination. Data collection for the validation study will coincide with clinic visits. Informed consent will be obtained at the time of the clinic visit. The study will be conducted in conjunction with and at the Children’s National Medical Center (CNMC) in Washington, D.C. as soon as it is approved. The NCHS Institutional Review Board (Ethics Review Board (ERB)) and the CNMC Institutional Review Board have approved the validation study protocol and consent materials.

Five attachments are provided describing the details of the study: The ERB protocol document (Attachment i), the study justification, protocol, and materials (Attachment ii), the consent form (Attachment iii), assent form (Attachment iv), and questionnaire (Attachment v).

The primary aim of the research is to validate a new pubertal maturation self-assessment interview methodology. For this project, each participant will answer two pubertal maturation questions. Boys will self-assess pubic hair and genital development and girls will self-assess breast and pubic hair development. After answering the pubertal maturation questions, all participants will answer one question about using the computer and one question about the ease or difficulty of answering the pubertal maturation questions. We propose to recruit 120 girls and 120 boys 8 to 19 years of age for the study. A sample plan has been developed to ensure that there are sufficient numbers of children and older adolescents. English and Spanish language versions of the module will be used for the study.

The study will be conducted at CNMC. The self-assessment module will be completed after the participants see their CNMC health care providers for their routine appointment. The self-assessment module will be completed in a private room in the out-patient clinic after parental consent and child assent are obtained. After a brief tutorial on the use of the computer, the participants will complete the module questions independently.

Information on sexual maturation status of children and adolescents is needed to interpret child growth, body composition, and laboratory data which are collected in NHANES. The recommendations of a World Health Organization Expert Committee convened in 1995 provided guidance on anthropometric data standards (WHO Expert Committee on Physical Status: the Use and Interpretation of Anthropometry., 1995) At that time, the Expert Committee recommended that maturational status be taken into account for interpreting anthropometric data based on chronologic age and gave recommendations on how to incorporate maturational status in the evaluation (de Onis & Habicht, 1996).

Recent references have also noted the importance of pubertal maturation information, particularly in the context of NHANES. A review of research on pubertal development in girls was supportive of population data collection in studies such as NHANES (Herman-Giddens, Kaplowitz, & Wasserman, 2004). An editorial published in 2005 by Charles Irwin, M.D., Editor-in-Chief of the Journal of Adolescent Health commented on the need for “collection of pubertal

status measures in the NHANES study on children as early as seven years of age; and for ongoing clinical studies to elicit the associations among obesity, under-nutrition, geographical location, and environmental toxins, and their impact on pubertal development” (Irwin, 2005). NHANES sexual maturation data have been used as national reference data to examine rates of sexual maturation, growth disorders, including hypothalamic pituitary hormone deficiencies, and primary gonadal failure (Sun et al., 2002). The lack of sexual maturation status information is a serious limitation and this has been noted in recent literature by researchers who have reported on findings from the continuous NHANES.

DHANES convened an *ad hoc* expert group in August, 2005 to advise DHANES on pubertal maturation assessment methodology. The group was unanimous in its support for the collection of pubertal maturation information in NHANES. The group was supportive of efforts to develop a non-invasive methodology for pubertal maturation assessment. Many of the suggestions offered by the panel to improve upon earlier self-assessment methods were incorporated into the design of the NHANES A-CASI module. The next step in the planning process is to validate the new methodology.

DHANES has identified a site for a validation study. Self-assessed maturation ratings will be compared to the ratings recorded by health professionals who use the “gold standard” Tanner staging method which involves a physical examination. DHANES and Children’s National Medical Center (CNMC) in Washington, DC have a contractual agreement for the validation study. CNMC investigators are very interested in the self-assessment method and they see potential for its use in settings where it is impossible or impractical to collect this information using the gold standard Tanner staging examination method.

The CNMC Institutional Review Board has approved the validation study protocol and consent materials. We plan to begin the validation study as soon as it is approved by OMB.

The participants will be paid \$15 after the completion of the exam and self assessment questionnaire.

NHANES’ respondents will not be involved in this test. The respondent burden is estimated to be 20 minutes per person including reading and signing consent documents, the examination and the self assessment questionnaire. The target number of respondents is 240 children. Therefore, the total burden is 80 hours.

References Cited:

- de Onis, M., & Habicht, J. P. (1996). Anthropometric reference data for international use: recommendations from a World Health Organization Expert Committee. *Am J Clin Nutr*, 64(4), 650-658.
- Herman-Giddens, M. E., Kaplowitz, P. B., & Wasserman, R. (2004). Navigating the recent articles on girls' puberty in Pediatrics: what do we know and where do we go from here? *Pediatrics*, 113(4), 911-917.
- Irwin, C. E., Jr. (2005). Pubertal timing: is there any new news? *J Adolesc Health*, 37(5), 343-344.

- Sun, S. S., Schubert, C. M., Chumlea, W. C., Roche, A. F., Kulin, H. E., Lee, P. A., et al. (2002). National Estimates of the Timing of Sexual Maturation and Racial Differences Among US Children. *Pediatrics*, 110(5), 911-919.
- WHO Expert Committee on Physical Status: the Use and Interpretation of Anthropometry. (1995). *Physical status: the use and interpretation of anthropometry : report of a WHO Expert Committee*. Geneva: World Health Organization.

List of Attachments:

- Attachment i: Ethics Review Board (ERB) submission
Attachment ii: Study Protocol and materials
Attachment iii: Consent materials
Attachment iv: Assent materials
Attachment v: Questionnaires

