



BASELINE CLINIC VISIT PROCEDURES IN A PROSPECTIVE STUDY OF ENVIRONMENTAL AND GENETIC FACTORS AND PUBERTY: THE CYGNET STUDY



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INTRODUCTION

The CYGNET Study (Cohort Study of Young Girls' Nutrition, Environment, and Transitions) is a prospective study examining predictors of early puberty in young girls. As part of the Bay Area Breast Cancer and the Environment Research Center, it is one of three cooperative studies nationwide enrolling 6-8-year-old girls who are being followed longitudinally. CYGNET Study participants are members of Kaiser Permanente Northern California in the San Francisco Bay Area. Clinic visits are held at Kaiser facilities in Oakland, San Francisco, and San Rafael.

METHODS

➤ *Waiting Room.*

- **Greeting:** A CYGNET Study participant's yearly clinic experience begins the moment she and a parent or legal guardian (usually the biological mother) walk through the door. They are welcomed in English and/or Spanish, provided refreshments and meet the clinic staff.
- **Consent/Assent:** A research assistant sits down with the child and parent, explains the study and clinic procedures, and obtains informed consent from the parent and assent from the child. Both child and parent are encouraged to ask questions at this time and throughout the clinic visit.
- **Anthropometry Screening:** The parent answers screening questions about the child, verifying her fitness for bioelectrical impedance analysis.
- **Blood Draw Demonstration:** For the phlebotomist's demonstration, the child is shown the blood draw process using props, including a tourniquet and butterfly needle. The child is also shown how to identify her veins and where the needle would go in, if they choose to participate in the draw.
- **Arts & Crafts:** The waiting area is equipped with activities to occupy the girl, including activities that may result in a gift for the child, such as construction of beaded jump rope.

METHODS (CONTINUED)

➤ *Parent/Guardian Data Collection.*

- **Interviewer-Administered Questionnaire:** A standardized, structured interview is administered to the parent in a private interview room by the research assistant who performed the consent/assent.
- **Self-Administered Questionnaires:** These sections are introduced by the research assistant and given to the parent. Parents have the option to complete these in the clinic or at home. A pre-paid self-addressed envelope is provided for sections that will be mailed back.
- **Self-Administered Sections include:**
 - **Standardized Psychosocial Instruments:**
 - ✓ Behavior Assessment System for Children, 2nd Edition (BASC-2) Parental Rating Scale
 - ✓ Family Environment Scale (FES)
 - ✓ Center for Epidemiologic Studies Depression Scale (CES-D)
 - **Residential History**
 - **Contact Information**

➤ *Child Data Collection.*

- **Anthropometry:** Is usually conducted in a private exam room concurrent with the parent interview. For measurement accuracy, the child changes into a paper gown.
 - Girth (Gulick tape measure):
 - ✓ Minimum waist
 - ✓ Umbilicus waist
 - ✓ Maximum hip
 - Height (fixed stadiometer)
 - Weight (Tanita Scale 300A)
 - Body Composition (Tanita Scale 300A and RJL bioelectrical impedance analyzer)
- **Tanner Staging:** After anthropometry, the parent is brought into exam room for the Tanner Staging portion of the girl's exam. Prior to assessment, the research assistant gives a detailed description of the Tanner Staging procedure. Pubic hair is assessed visually, while palpation is conducted to assess breast development.

➤ *Biospecimen Collection.*

- All biospecimen supplies are provided by the Centers for Disease Control and Prevention.
- **Blood Sample:** If the child is willing, the phlebotomist draws a blood sample using a butterfly needle.
 - Two 10 mL red top tubes
 - One K2 EDTA purple top tube
 - An additional purple top tube is collected for DNA
- **Urine Sample:**
 - Minimum volume required 30 mL
- **Saliva/Sputum:** Oragene DNA Self-Collection Kit (collected if participant refuses blood draw)

➤ *Exit Interview Sections.*

- **Pedometer:** If the parent is willing to facilitate the pedometer portion of study, the child is fitted with a *Step Into Health* pedometer. The parent and child are instructed on how to keep a one-week log of the pedometer's recordings.
- **Diet Recall:** Instructions and directions for participating in periodic 24-hour dietary recall interviews, administered by Cincinnati researchers, are also provided.
- **Compensation:** After completion of all activities, a nominal gift certificate, canvas bags, or other items are provided to thank the participants. Other incentives are offered in the clinic visit during/after:
 - Anthropometry
 - Blood draw

CONCLUSION

Clinic activities in the CYGNET Study revolve around collecting high-quality data in a safe, supportive and fun environment for the girls and their parents/guardians. The participant's initial experiences are important for subsequent clinic visits and future involvement in the CYGNET Study.

