FACT SHEET

A Children's Environmental Exposure Research Study – CHEERS

Prepared by
National Exposure Research Laboratory
Office of Research and Development
November 8, 2004

SUMMARY

The Children's Environmental Exposure Research Study (CHEERS) is designed to fill critical data gaps in our understanding of children's exposure to pesticides and chemicals that can be found in typical household environments. The EPA seeks information to improve both risk assessment and risk management practices that will ultimately enable us to be more protective of children's health.

Recent news articles have mischaracterized the study and EPA is actively working to assure all interested parties that the study is designed to meet rigorous ethical and scientific standards.

Toward this end, EPA is taking the extraordinary step—because protecting the health and well-being of children is of paramount importance—of sending the study design for another external, independent review by an expert panel, made up of members of the Science Advisory Board, the Science Advisory Panel and the Children's Health Protection Advisory Committee, prior to implementation. It is anticipated that this review will be completed, and that a report will be forwarded to the Administrator, in the spring of 2005. Based on this review, the Agency may refine the study design.

To date, the study design for CHEERS has already been externally reviewed for scientific merit and ethical protections. Specifically, four Institutional Review Boards (IRBs) for the Protection of Human Subjects have reviewed and approved the study to ensure that it complies with all ethical standards. These boards include outside, independent experts in the fields of medicine, ethics and community advocacy. This study was judged according to procedures codified in 45 Code of Federal Regulations (CFR) 46 that mandates special requirements for children as research participants. The IRBs and the dates they approved the study are: Battelle Memorial Institute (August, 2004), University of North Carolina (September, 2004), Florida Department of Health (pending approval), and University of Florida (May, 2004).

Particular attention was given to ensure that the monetary compensation was appropriate for the level of participant burden. Each participant will be compensated with $100 to $200 for each monitoring event, which includes 5 days of sampling and data collection. The IRBs determined that $20 to $40/day was appropriate and would not motivate households to participate solely for monetary reasons.

The information below is provided to clarify the study design, requirements for participation, and actions that will be taken to guard against any inappropriate pesticide use.

CHEERS is a field monitoring study designed to evaluate the exposure of young children to pesticides and other chemicals as a result of normal use in their homes. Pesticides are routinely

used in household environments to address a multitude of pest and potential disease issues. EPA is committed to assuring that these products are used in ways that are both effective and safe. EPA will not ask parents to apply pesticides in their home to be a part of this study. This study does not encourage or promote the use of pesticides, but only collects data that will be used to better understand past and routine exposures around the home. This study includes both households that do not use pesticides and households where pesticides are commonly used to control bugs in the home. Once a family has been selected, routine, non-invasive monitoring will be used to determine whether and how children in the family may be exposed.

During each visit to the participant's home, the research team will perform an inventory of any pesticide use in the home, discuss with the participants the importance of following label directions, check to be sure that participants are using only pesticides that are registered for use indoors, and provide contact information for training in Integrated Pest Management (IPM). Participants who are found to have high pesticide exposures or who are inappropriately using pesticides will be contacted immediately and educated in the proper and safe use of pesticides. If any participants are found to have elevated exposures based on measurements of pesticide metabolites in urine samples, the EPA will immediately conduct further investigations and seek measures to mitigate such exposures. This intense monitoring of the participants will help ensure that this scientific investigation is being done in a way that also protects the health of the participants if concerns are identified.

ADDITIONAL INFORMATION

Study Objectives:

- To gain a better understanding of how children are exposed to pesticides and other chemicals found in homes and the factors that affect their exposure.
- To understand how children's ages and activities affect their exposure at home.
- Ensure rigorous scientific and ethical standards are used throughout the study.
- To use the data generated to improve risk assessments and to develop risk mitigation strategies.

This longitudinal field measurement study includes either five or six repeat visits to the same participating families over a two-year period. Sixty very young children will be enrolled into the study in two cohorts: (1) children who are approximately 12 months of age at the time of enrollment, and (2) children who are less than 3 months of age at the time of enrollment. Environmental, biological, personal, activity pattern, and questionnaire data will be collected during the study. The visits to the participant households will correspond to changes in the participant child's age, as outlined by the EPA's Risk Assessment Forum. The ages corresponding to monitoring visits include: 3, 6, 9, 12, 18, 24, 30, and 36 months old. Each monitoring visit will last for five days, during which samples will be collected on a daily basis.

Participant Selection:

CHEERS will be conducted in the Jacksonville, Florida area. The study will include participants who routinely use pesticides in their homes along with a group who do not use pesticides. CHEERS will study as diverse a population as possible. CHEERS is not targeting low socio-

economic status families. Advertising for CHEERS is being conducted county-wide. Places within the county where a CHEERS study brochure can be found include: private pediatrician's offices, health clinics, churches, mosques and temples and their nurseries, children's clothing stores, magnet schools, private schools, specialty stores for pregnant women, and selected hospitals in Duval County. Within the hospitals, the areas include the women's education centers, the nurseries, and the take-home care packages for new parents. In addition, the study flyer is being passed from family to family and friend to friend.

A three-step process is being used to select and enroll families into the study. We will not enroll families who suggest that they will start using pesticides to be in the study. Only at the completion of this three-step process can we determine if a family is fully eligible to participate in CHEERS. Once selected, we will monitor study participants regardless of whether or not they apply pesticides in their home throughout the course of the study.

- Step 1: An interested person calls the toll-free number or interviews in-person with an enrollment specialist and is administered an eligibility screening questionnaire. This questionnaire asks questions related to location of residence, age of child(ren), whether the child(ren) attends day care, pesticide use practices, and interest in participating in a longitudinal study. Based on the responses to the eligibility screening questionnaire, a person may then be scheduled for a home screening visit.
- Step 2: During the home screening visit, information is collected on pesticide use practices using the home pesticide inventory and use screening questionnaire. The field technician and a family member complete this inventory together. The inventory targets all products currently in the residence, all products that have been used by the family but that are out of stock, and all professional applications. If any pesticides are being used inappropriately, correct guidance will be given to ensure proper use.
- Step 3: While at the home, the field technician collects a surface wipe from the floor in two separate locations: an area where pesticides may have been previously applied and the main living area. These samples will be analyzed for presence and level of pesticides.

Compensation Package:
CHEERS participants will be given both monetary and non-monetary compensation. We are using a staggered monetary compensation approach, which has been approved by the IRBs. Compensation will be given to families based on their participation in monitoring events. Because monitoring will be conducted regardless of whether the family applies pesticides, the incentive is in no way tied to pesticide applications.

Participants will be compensated for the food samples they will be providing, electricity costs of running the monitoring equipment in their homes, and the many hours that they will spend collecting samples and information over the two-year study period. Compensation is between $20 and $40 for each day in the study. As shown in Attachment A this is a very labor-intensive project that will require a high level of interest and commitment from the families who are participating.

Table 1. Staggered monetary compensation to study participants for food samples, electricity costs, and time spent during data collection.

Activities	Amount	Remarks
Screening visit to determine eligibility	$ 20.00	
First event for the cohort	$ 100.00	Prepay $25 during pre-application visit
Second event for the cohort	$ 100.00	Prepay $25 during pre-application visit
Third event for the cohort	$ 150.00	Prepay $25 during pre-application visit
Fourth event for the cohort	$ 150.00	Prepay $25 during pre-application visit
Fifth event for the cohort	$ 200.00	Prepay $25 during pre-application visit
Sixth event for the cohort	$ 200.00	* Cohort 2 only
1 Blood sample – adult	$ 25.00	
1 Blood sample – child	$ 25.00	
Total Cohort 1	$ 770.00	If all study activities are completed
Total Cohort 2	$ 970.00	If all study activities are completed

Study Participation:

- The field team members are trained to engage the participants in the study and make them a part of the research team. While the field team members will be collecting the majority of the environmental samples, the families will be collecting the biological, personal, and activity pattern data.
- The environmental samples collected by the field team members include: air samples, wipes from various surfaces in the home, dust samples, and soil. In addition, the field team members will be administering questionnaires, answering questions, and training the participants on their sample collections.
- The samples to be collected by the families include: urine, which in most cases means that the diapers will be labeled and saved; having the participant child wear a one-piece union suit with socks, which will be chemically analyzed to determine how much chemical could get onto the skin based on that child's normal activities; collect a duplicate of all the food and beverages that the participant child eats and drinks during a 24-hour period; keeping a diary of the participant child's activities during the five-day period; having the participant child wear an activity monitor for the five-day period; videotaping the normal behavior of the participant child; and, on a monthly basis, keep logs of their pesticide use practices and cleaning habits.

A summary of the day-to-day events for each monitoring visit is given in Attachment A.

What will be done to educate study participants on pesticide control methods?

During the study, the field research team will perform inventories of pesticides in the study homes. The field team will determine if pesticides are being stored properly and in the original containers. The field team will discuss storage and use of pesticides in the home with the study participants to ensure that they understand label directions and precautions that should be taken when applying pesticides indoors. They will also provide contact information for training in Integrated Pest Management (IPM).

DCHD staff will be conducting education and outreach throughout the study to ensure that pest control methods are being used appropriately. At the end of the study DCHD staff will perform additional education on pest control methods, including integrated pest management procedures.

What will be done if the inappropriate use of pesticides is observed?
All personnel associated with this study are trained in the proper uses of pesticide products. If a member of the study team observes or collects questionnaire data that suggests the inappropriate use of pesticides, he/she will immediately discuss proper pesticide use practices with the participant. For example, during the screening phase for the pilot study, one of the field technicians was faced with just such a situation. Upon entering the potential participant's home, the potential participant showed the field technician the pesticide products that had been applied in the home that morning. One of the products was clearly labeled only for outdoor use. The field technician spent a considerable amount of time educating the participant on the proper use of pesticides. The field technician also brought the matter to the attention of the field team supervisor who made the DCHD staff aware of the situation.

What will be done if we find high pesticide exposures based on metabolites found in the urine?
During the study, urine samples will be collected from participating children during each visit to their home. Within a week, these samples will be screened for pesticide metabolites. The metabolites are indicators of the children's exposures to pesticides. The measured levels of the metabolites will be compared to the Dose Levels used for exposure risk assessments for the organophosphate and pyrethroid pesticides as reported by the Hazard Identification Assessment Review Committee of the Hazards Effects Divisions of the Office of Pesticide Programs of the U.S. Environmental Protection Agency. Dose levels for chlorpyrifos and diazinon are published in the Hazard Assessment of the Organophosphates (July 7, 1998) available at http://www.epa.gov/pesticides/op/chlorpyrifos.htm. The dose levels for the pyrethroid pesticides, although not yet published by the EPA, have been developed and are available for use by the EPA principal investigators in this study. For the purposes of this study, a10X Safety Factor will be used in addition to the conventional Uncertainty Factor (UF) of 100. This is consistent with the Food Quality Protection Act Safety Factors which are intended to provide additional protection for children. These dose levels are used by the EPA to perform the exposure risk assessments during the pesticide registration/re-registration process. Because we will compare the urine levels collected in this study with the dose levels used by the EPA for pesticide registration, we will have the same safety factor. If the levels for any of the metabolites measured in the urine of a study participant exceed the dose levels, the parent/caregiver of the study participant and Dr. Aaron Hilliard (Duval County Health Department - DCHD) will be notified. Staff from DCHD will then conduct follow-up with the study participant parent/caregiver on integrated pest management practices. Furthermore, any participants found to have exposures or urine levels of concern, the EPA will immediately conduct further investigations and seek measures to mitigate such exposures. This intense monitoring of the participants will help ensure that this scientific investigation is being done in a way that also protects the health on the participants if concerns are identified.

What has EPA done to ensure that the study meets the strictest ethical standards?
The Study adheres to all of the federal safeguards for human subjects research.

- ALL human subjects research conducted or sponsored by the federal government is subject to the Federal Policy for the Protection of Human Subjects (also known as the "Common Rule"; 45 C.F.R. part 46, available at http://ohrp.osophs.dhhs.gov/humansubjects/guidance/45cfr46.htm.) Briefly, the Common Rule establishes ethical standards to minimize the risks of human subjects research, to ensure that the benefits of the research exceed the risks, and to convey that information to prospective volunteers prior to obtaining their consent.
- The most significant element of the Common Rule is the requirement that an Institutional Review Board (IRB) assesses all ethical aspects of proposed human studies, and must conduct continuing oversight of research at intervals appropriate to the degree of risk. The Common Rule describes the requirement that the IRB have the appropriate expertise, for medical, ethical, and other study elements and that the IRB be fully independent of the study investigators. Furthermore, the IRB's themselves are monitored by the federal government and receive specific approvals before they can perform their responsibilities.
- IRBs are also required to assure compliance with another hallmark of high ethical standards for human testing: informed consent. The Common Rule generally mandates prior, documented, legally effective informed consent to ensure that the subject understands the risks involved and accepts them voluntarily
- This study was reviewed by four IRBs: from Battelle Memorial Institute (the primary contractor for the study; approved), the University of North Carolina (relative to a health survey included; approved), the Florida Dept. of Health (for enrollment in clinics, as required by Duval County Rules; pending approval), and the University of Florida (for same reason as Florida Dept of Health; approved).
- IRB reviews were carried out by institutions who are independent of the project and who are not biased towards moving the project forward without carefully scrutinizing it.
- EPA has additional safeguards in place. The study was also approved by the EPA Human Subjects Official who re-reviews ALL of the material, including the IRB approvals, before rendering an approval or disapproval decision.

Why were materials temporarily removed from the study Web site?
The only material that was temporarily removed from the study Web site was the peer-reviewed Study Design because there was concern that the disclaimer did not reflect the current status of the document. There were no changes made to the Study Design and the link to the document was re-established. It is again available on our Web site.

Revisions have been made to the study brochure (which was not on the Web site) to ensure that the wording accurately reflects our protocol that parents do not have to apply pesticides to be part of the study and to be monitored.

Attachment A: Study Activities

The protocol for this study involves intensive data collection at each home over a five-day period. The following describes the activities that the research team and the participants perform during each data collection event. The data collection events are repeated up to six times at each home over the two-year period of the study.

- **Day 1:** Two study researchers will visit the participant family's home at the appointment time to conduct the following study activities.
  1. Collect air samples: Depending on the monitoring visit, air samples will be collected from 1 or 2 rooms of the home for a 24-hour period. The air sampler will be placed in a box about the size of a lunch box. The air sampler is powered by batteries. One air sampling box will be placed in the room where the participant child spends most of the time during the day. In some cases, one air sampler box may be placed in the participant child's bedroom. A personal air sampler box will follow the child. The caregiver will be asked to carry this air sampler box and keep it near the child during the 24-hour air sampling period.
  2. Collect surface wipe samples: A field technician will use a small wipe that is moistened with rubbing alcohol to collect numerous wipe samples from floors and other surfaces in the home.
  3. Conduct an interview with the caregiver: A field technician will ask the caregiver general questions about his/her home and participant child. The field technician will also draw a floor plan of the house so that he/she can record the locations of the collected samples.
  4. Collect urine samples: The caregiver will be asked to collect two urine samples from the participant child and one urine sample from his/herself during this period. The field technician will provide all the containers and show the caregiver how to collect the urine samples. If the participant child is not toilet-trained, the caregiver will be asked to save the wet diaper after changing the participant child.
  5. Activity Monitor: One of the field technicians will outfit the participant child with a very small electronic activity monitor (which looks like a wristwatch) which will be used to collect the information on the participant child's activity levels over the five-day monitoring period. The activity monitor is specially designed for young children. It is very light weight and can fit comfortably around the waist or ankle of the participant child.
  6. Complete an Activity Time Line: The caregiver will be given detailed instructions on completing the activity time line for the participant child's activities during the five-day monitoring period.
  7. Monthly Pesticide Purchase, Inventory, and Use Log and Monthly Cleaning Products Purchase, Inventory, and Use Log: The field technician will show the caregiver how to record the information related to pesticide use patterns and cleaning habits.
  8. Videotaping Child's Activities: The caregiver will be asked to videotape about 20 minutes of the participant child while he/she is eating, sleeping, and playing during the five-day period. Training will be conducted by the field technician while at the house.
  9. Schedule an appointment for the next visit: The field technician will schedule (or confirm) the appointment with the caregiver for the next visit. They will leave a

phone number for the caregiver in case the appointment needs to be rescheduled. The field technicians will also ensure that the caregiver is comfortable with all the samples he/she has to collect today. They will also make sure that they have answered all the caregiver's questions.

- **Day 2:** The same researchers will visit the participant family's home at the appointment time to conduct the following study activities.
  1. A field technician will remove the air samplers from the home.
  2. A field technician will pick up the urine samples that were collected (2 urine samples from the participant child and 1 urine sample from the caregiver).
  3. A field technician will give the caregiver additional supplies for collecting the next urine samples, if needed. The field technician will review the instructions for the urine samples that are requested: 4 urine samples from the participant child and 1 from the caregiver during the 24-hour data collection period following the participant's scheduled pesticide application day.
  4. Videotaping Child's Activities: One of the field technicians will review the videotape that has been collected, if you have recorded some activities. The field technician will answer questions, provide instructions, and encouragement.
  5. Discuss data collection activities for the next visit: A field technician will discuss data collection activities for the next visit with the caregiver and answer questions.
  6. Schedule an appointment for the next visit: A field technician will schedule (or confirm) the appointment with the caregiver for the next visit. They will leave a phone number for the caregiver in case the appointment needs to be rescheduled. The field technicians will also ensure that the caregiver is comfortable with all the samples he/she has to collect today. They will also make sure that they have answered all the caregiver's questions. If the participant is planning to apply a pesticide during this period, the field technician will counsel the participant on following label directions and the fact that children should not be present during pesticide applications.
- **Day 3:** The field technicians will not visit the participant family on this day. However, a field technician will phone the participant family to answer questions, confirm the appointment for the next day, and remind the caregiver of the samples that should be collected.
- **Day 4:** The same researchers will visit the participant family's home at the appointment time to conduct the following study activities. Most activities are similar to those in the first visit.
  1. Collect air samples: A field technician will set-up and use the same air samplers to collect additional air samples during the next 24-hour period.
  2. Collect surface wipe samples: One of the field technicians will collect numerous wipe samples from floors, eating surfaces and toys in the home. A field technician may also collect a wipe sample from the family pet (dog or cat), if the caregiver reports that the participant child has played with the family pet.
  3. Collect urine samples: A field technician will ask to ensure that the urine samples are being collected. The field technician will check to make sure the cooler is adequate for storage of the urine samples.
  4. Activity Monitor: A field technician will ask you if there are any issues or problems about the activity monitor and make sure that the participant child has been wearing it.

5. Cotton Union Suit and Socks: A field technician will provide a new one-piece cotton union suit and socks to the caregiver with instructions. The field technician will give the caregiver on when to have the participant child wear the cotton suit and socks and how long.
6. Hand wipe sample: A field technician will collect a hand wipe sample from the participant child, using a small wipe that is moistened with rubbing alcohol. At the same time, the field technician will also provide the caregiver with materials and instructions on collecting a second hand wipe sample from the participant child immediately after the caregiver has removed the one-piece union suit.
7. Collect food samples: A field technician will ask the caregiver to collect a duplicate copy of all foods and beverages that the participant child eats and drinks during the next 24-hour period. The field technician will answer specific questions related to the participant child's exact diet and provide examples of what to collect. For example, one bottle of formula or breast milk.
8. Complete a Food Diary: A field technician will ask the caregiver to record all food items that the participant child eats and drinks, and the surfaces that these food items touch, during the next 24-hour period.
9. Videotaping Child's Activities: One of the field technicians will review the videotape that has been collected, if you have recorded some activities. The field technician will answer questions, provide instructions, and encouragement.
10. Schedule an appointment for the next visit: A field technician will schedule (or confirm) the appointment with the caregiver for the next visit. They will leave a phone number for the caregiver in case the appointment needs to be rescheduled. The field technicians will also ensure that the caregiver is comfortable with all the samples he/she has to collect today. They will also make sure that they have answered all the caregiver's questions.

- **Day 5:** The same researchers will visit the participant family's home at the appointment time to conduct the following study activities.
    1. A field technician will remove the air samplers from the home.
    2. A field technician will remove the activity monitor from the participant child.
    3. A field technician will pick up:
        a. Urine samples,
        b. Activity Time Line,
        c. Playsuit,
        d. Hand wipe sample,
        e. Food samples,
        f. Food diary, and
        g. Video tape and the camcorder.
    4. A field technician will collect soil samples from an area in the yard where the participant child plays (or may play when older). These sampling locations will be identified with the help of the caregiver.
    5. One of the field technicians will use a vacuum cleaner to collect a dust sample from the floor of the room where the participant child spends most of his/her waking hours, the child's bedroom, and sofa (if there is a sofa in the activity room).

6. One of the field technicians will ask the caregiver questions about the participant child's activities during the last few days. This interview takes about 20 - 30 minutes to complete.
7. Review Monthly Pesticide Purchase, Inventory, and Use Log and Monthly Cleaning Products Purchase, Inventory, and Use Log: One of the field technicians will review these forms with the caregiver and answer questions. A field technician will provide new logs as needed.
8. A field technician will ask the caregiver for his/her feedback about the study experience during the past few days so that the field technicians can make improvements for future visits.
9. A field technician will schedule a tentative appointment for the next monitoring visit: A field technician will discuss the schedule with you and make a tentative appointment for the next visit. A field technician will also answer any questions.

- **Day 6:** The caregiver will collect the last urine sample from the participant child (first morning void). After arranging a pick-up time with you, a field technician will come to the family home to pick up this urine sample. The field technician will give you a money order (according to the participant compensation schedule) and ask the caregiver to sign a receipt.