National Human Exposure Assessment Survey (NHEXAS)

Arizona Study

Quality Systems and Implementation Plan for Human Exposure Assessment

The University of Arizona
Tucson, Arizona 85721

Cooperative Agreement CR 821560

Standard Operating Procedure **SOP-UA-G-3.1**

Title: Assurance of Respondent Confidentiality

Source: The University of Arizona

U.S. Environmental Protection Agency
Office of Research and Development
Human Exposure & Atmospheric Sciences Division
Human Exposure Research Branch

ASSURANCE OF RESPONDENT CONFIDENTIALITY

1.0 Purpose and Applicability

The procedures described in this SOP are designed to assure respondent privacy and confidentiality for all participants of the NHEXAS, Border and other Health and Environment Projects. This SOP covers verbal, written and electronic data references to respondents.

2.0 Definitions

2.1 DATA = Classified under this word are the following definitions: DATA, ELECTRONIC; DATA, PHYSICAL.

2.1.1 DATA, ELECTRONIC = Data stored on some type of magnetic or optical medium (for example: floppy disk, hard disk, Bernoulli, tape).

2.1.2 DATA, PHYSICAL = A datum or data written on a physical data form.

2.2 DATABASE = Classified under this word are the following definitions: DATABASE, MASTER; DATABASE, WORKING.

2.2.1 DATABASE, MASTER = Accumulative database generated from validated data processing batches. Newly cleaned batches are appended to the master database. Copies of this database are used in analyses. All corrections made to copies of the master are made to the master database itself. Thus, it is the most complete and accurate database of its kind.

2.2.2 DATABASE, WORKING = A database earmarked for or in the process of cleaning that contains one or more data processing batches. When cleaned, this will be appended to the master database with the same name.

2.3 DISKETTE (OR FLOPPY DISK) = A small data storage medium used for storing or transferring small amounts of data. Diskettes used in this project are usually high density double-sided disks in two sizes: 3.5 inch (1.44MB) and 5.25 inch (1.2MB).

2.4 FILE PROTECTION = A security system designating who has access to a file either within a group or as an individual user.

2.5 FORM = Classified under this word are the following definitions: FORM, DATA ENTRY; FORM, PHYSICAL.

2.5.1 FORM, DATA ENTRY = A computer screen representation of a physical data form. The data on the physical form is entered into the

computer database via the data entry form.

2.5.2 FORM, PHYSICAL = The paper or "hard copy" version of a data form. This is also referred to as a "physical data form."

2.6 HOUSEHOLD IDENTIFICATION (HHID) NUMBER: A unique identification number assigned to a study household. An associated letter (or extension) defines any divisions of single households into multiple units.

2.7 HRP SITE: The Health Related Professions building, located at 1435 North Fremont Avenue; Tucson, AZ 85719. This is an annex of the Respiratory Sciences Center and the primary site of operations for NHEXAS Arizona.

2.8 INDIVIDUAL RESPONDENT NUMBER (IRN) = Each subject within a household is identified by a Individual Respondent Number (IRN). The combination of each HHID and IRN is unique to an individual respondent.

2.9 KEY VARIABLE(S) = A variable or set of variables in a data record whose value or combined values make a data record unique from other data records in the same table or file.

2.10 LAN = abbreviation for Local Area Network. This is any physical network technology that operates at high speed over short distances.

2.11 NODE = A computer that is attached to a network and can work from a larger "host" computer.

2.12 PACKET: A sturdy, envelope-like container that can be fully closed and is large enough to hold the physical data form(s) generated by a study household, laboratory, research site, or data processing batch. One type of packet is used for one type of physical data forms (e.g.., manila envelopes would be used for all lab forms processed at the HRP site). Packets are either color coded, labeled according to their contents, or both.

2.12.1 PACKET, HOUSEHOLD = A packet containing the physical data forms for a household containing subjects.

2.12.2 PACKET, LAB = A packet containing the physical data forms generated during laboratory evaluation of the field samples.

2.13 PC = Abbreviation for Personal Computer. This is a microcomputer based on the Intel 8088/8086 (and later models including Pentiums)instruction set. The HRP site has multiple operating PC machines (see UA-D-1.1 for details).

2.14 RESPONDENT or SUBJECT = Any subject enrolled in the NHEXAS Arizona Project.

2.14.1 Primary Respondent = Respondent selected at each home based on age and gender. Selection category will ensure representative participation by age and gender.

2.14.2 Secondary Respondent(s) = Family member(s) living in the same household as the primary respondent and participating in the study.

2.15 RESPONDENT IDENTITY FILE = Locked file cabinet in Project Field Coordinator's office containing full subject names, addresses, HHIDs and consent forms. The files will be arranged by HHID. Any correspondence or questionnaire pages containing the above personal information will be filed here.

2.16 TEAM LEADER = The team leader is the head of a field team on a series of household visits. The team leader interacts with the subjects. Other team members sample but have less subject contact.

3.0 References

Strausfield, C. Tollin, B. (eds) Human Subject Confidentiality (#32). Research Review. University of Arizona, 22(12): 7.

Woodward, B. 1995. The computer based patient record and confidentiality.. New England Journal of Medicine 333:1419-1422.

4.0 Discussion

4.1 The population for this study will be selected using a proportionate-based sample of the total population of the state of Arizona. An address file will be developed and subjects living at those addresses will first be contacted by a letter describing the study. This will be followed by a personal contact made at the residence.

4.2 During the first interview the subject's name and address will be recorded and the household will be assigned a number (HHID). Each individual will be assigned two digit individual number as a suffix (IRN). The combination number (HHID + IRN) will become the subject identification number.

4.3 Subject identity will be communicated on a need to know basis.

4.4 In most circumstances, only the Project Field Coordinator and the team leader will need to know the identity of the subjects. Other field staff accompanying the team leader will be aware of subject identity. They will be required to keep their information confidential (UA-T-1.0) Only if the household has hazardous levels of target pollutants will the principal investigator be notified of a subjects name or

address. BY LAW, he/she must report any hazardous levels to the appropriate State and Federal agencies.

4.5 Confidentiality is an overriding concern for the project. Subjects will be non-paid volunteers. The project will be cost free to the subjects. Participants will be advised that they can quit the study at any time. Their participation in the project will be completely explained. Participants will be provided contaminant information about themselves and their homes at no cost. At the request of the participant, the results will be reported to their physicians.

4.6 Subjects will be asked to complete questionnaires, allow monitoring of their indoor and outdoor home environment, allow collection of food and water samples and (requested but not required) to provide blood and urine samples. Dust from hands and personal air samples will be collected from selected participants. These procedures have not been shown to cause physical or psychological harm in any previous studies.

5.0 Responsibilities

5.1 Project Field Coordinator

The Project Field Coordinator is responsible for (1) proper field team decorum to maintain subject privacy and confidentiality, (2) controlling access to files containing full subject name, address and HHID number on both physical and electronic data, (3) maintaining subject address files, (4) making sure any written record of a subject's full name and address are maintained in a secure, locked environment, (5) removing or obliterating the last name of any subject mistakenly added to a questionnaire or field form and (6) disciplinary action including termination of any field staff member failing to follow this procedure.

5.2 Project Data Coordinator

In general, the Project Data Coordinator does not need to know the last name or address of any subject. Thus, under normal circumstances, the Project Data Coordinator will refuse to accept any written form containing such information from the Project Field Coordinator.

5.3 Cooperative Interaction

In rare cases, problems occur with the assignment of HHIDs. This can occur by marriage of two separate households in a study or in the unlikely event that two subjects have identical first names and birth dates. In that case the Project Field Coordinator will facilitate the Project Data Coordinator's resolution of the HHID numbering problems in the databases.

6.0 Materials and Equipment

6.1 Materials: Secure, locking file cabinet; Secure, locking office door; File folders; Heavy, permanent, black marking pen with a wide tip; access to a PC on LAN (UA-D-1.1) in a password secured file.

6.2 Reagents—None

7.0 Procedure

7.1 Preparations--None

7.2 Standards and Blanks--None

7.3 Written Address Records for Initial Contact

7.3.1 Census data will be used to select areas containing respondents.
7.3.2 A letter of introduction will be mailed to the addresses of all potential participants.
7.3.3 The file used to generate the addresses of potential subjects will be electronic and secured with a password.
7.3.4 Mailing labels will be generated to:
(a) be used for the initial mailing,
(b) be attached to page 7 of the descriptive questionnaire for face to face contact with the subjects by interview team,
(c) follow-up or track subjects through the course of the study.

7.4 Control of Written Name and Address Records

7.4.1 The first and last page of the Descriptive Questionnaire (Figure 1) will identify the subject by:
* Legal Guardian
* Name
* Address
* HHID and IRN of the Primary Respondent

7.4.2 The Project Field Coordinator (PFC) will maintain a locked file cabinet in his/her office that is also accessible to the Project Data Coordinator. This will be known as the Respondent Identity File. All essential paperwork with the subjects' identity will be filed here. This includes: pages 1 and 7 of the Descriptive Qx, consent forms and any specific correspondence.
7.4.3 Any hard copy of the Respondent Identity File, or the full name and address of any subject must be stamped confidential and limited to use by staff with a need-to-know authority.
7.4.4 All printed copies will be locked in the PFC file cabinets. A list of authorized users will accompany the document and use will be controlled by the PFC with a check out sheet (Figure 2).

7.4.5 Any listing of respondents will be shredded when use is complete. Documents must be destroyed and not simply discarded.

7.5 Control of Electronic Subject Identity Records

7.5.1 The PFC will follow all data protocols and enter, verify, clean and validate all subject HHID, name, address and primary respondent numbers.

7.5.2 The electronic Respondent Identity File(s) will be placed on the LAN and will be accessible through use of the PFC password account or super-user password of the LAN System Manager. Other approved project personnel may access the file(s) via the super-user password at the discretion of the On-Site Principle Investigator.

7.5.3 All data fields containing family names and addresses of the respondents are encrypted in all electronic data bases. A specific algorithm is required to dis-encrypt the information. Any attempt to dis-encrypt the information using any other algorithm results in the immediate destruction of the information.

7.6 Subject Contact Records for Field Visits

7.6.1 Field staff must have the name and address of the subjects for field visits. The subject visit form will be in the PFC Respondent Identity File.

7.6.2 After the visit is complete, a copy of the form with the name and address blocked out, will be filed with the data packet.

7.7 Verbal Reference to Subjects by Field Staff

7.7.1 Field Staff and Team Leaders must refer to homes among themselves to effectively collect samples. They will refer to homes without identifying subjects. They will reference homes only out of hearing of non-project staff. Homes will be referred to by:

* HHID
* Regional Reference (e.g. the house on 5to St.)
* A Household Characteristic (e.g. the big house on 5to St.)

7.7.2 Subjects will not be referred to by name or specific address.

7.7.3 No discussion of subjects outside of a work context will be tolerated.

7.8 Data

7.8.1 The PFC will remove or obliterate any last name or address on any forms transferred to the data section.

7.8.2 The data section will have no fields for subject family name or address in any database (working or master).
7.8.3 All computers will be locked in the Project Offices.
7.8.4 In all databases, excluding the Respondent Identity Files, subjects are referred to only by their unique HHID/IRN and first name.
7.8.5 Access to the LAN is limited to those with a user account and password.
7.8.6 Access to master databases is controlled by the Project Data Manager.
7.8.7 Access to working databases is limited to the Project Data Manager.
7.8.8 Data Student Assistants each have user names and passwords that access only their user area. No one else can alter files of this nature without a change in the file ownership (by the Project Data Manager or Project Data Coordinator).
7.8.9 Further information on file access is described in SOP UA-D-1.1.
7.8.10 Data use is limited to those purposes consented to on the Respondent Consent Form (Figure 3) and the Minor Assent Form (Figure 4).
7.8.11 When the project is concluded, all project data will be removed from the computers and stored copies will be placed in a secure, locked environment whose access is controlled by the Principal Investigator.
7.8.12 Data will be reported to the Environmental Protection Agency as required by the contract in a manner that preserves subject privacy, confidentiality and consented use.
7.8.13 If hazardous levels of target analytes are identified through laboratory analysis, these results and the respondents name and address will be revealed to the Principal Investigator. The Principal Investigator will notify the respondent and the appropriate State and Federal agencies. This is required by law.

7.9 Calculations--None

7.10 Quality Control

7.8.1 Tolerance Limits
Violation(s) of the rules and procedures outlined in this SOP will not be tolerated.
7.8.2 Detection Limits

(a) Improper access or use of the hard copy Respondent Identity File(s) can be detected via the check out sheet in most cases. Because the key to the file cabinet containing the identity file(s) is accessible to both the Field and Data Coordinators, they can and will serve as independent guardians of the file(s).

(b) Improper access or use of the electronic Respondent Identity File(s) can be detected via the LAN usage log files. These electronic files log each command executed on the LAN by a particular user, as well as the date and time of each execution. Thus, any instances of use of the identity file(s) on the LAN can be detected.

(c) It is forbidden for an employee of NHEXAS Arizona to reveal his or her LAN password to any other person (employee or non-employee). A password could be given out either intentionally or inadvertently and would be difficult to detect. A comparison between the specific times logged in the LAN usage files and the specific times spent at the HRP site, for a particular employee, could identify improper use of the identity file(s).

(d) Since any attempt to dis-encrypt the identity of subjects results in trashing the electronic file, unauthorized use will become readily detected and prevented.

7.8.3 Corrective Actions

Breach of confidentiality will be cause for dismissal and potential legal action.

8.0 Records

8.1 All paper containing subject name or address will be filed in a locked file cabinet in the Project Field Coordinator's office (Figure 1 and Figure 3).

8.2 Access to the Respondent Identity File(s) will be obtained through the Project Field Coordinator and documented on the use form (Figure 2) accompanying the files.

Figure 1: Pages from the Descriptive Questionnaire that will be processed and filed by the Project Field Coordinator.

NHEXAS Descriptive Questionnaire
February 1, 1994 12:59pm

NHEXAS Introduction

Hello. I'm (NAME) with NAME OF CONSORTIA MEMBER. We are conducting a survey for the Environmental Protection Agency on the exposures of people to environmental contaminants. We mailed a letter to this address that explains the importance of your participation. Do you remember receiving this letter? IF LETTER NOT RECEIVED, HAND COPY TO RESPONDENT. ALLOW TIME FOR READING, ANSWER ANY QUESTIONS.

A. HOUSEHOLD ELIGIBILITY

1 VERIFY ADDRESS ON LABEL. CIRCLE "1" OR RECORD CORRECTED ADDRESS BELOW.

ADDRESS ON LABEL IS CORRECT ..... 1 → GO TO QUESTION 2

NEW ADDRESS:_____
Street/RFD Apt. #

_____
City State ZIP Code

2 VERIFY THAT THE RESPONDENT IS A RESIDENT OF THE HOUSEHOLD AND IS AT LEAST 18 YEARS OLD. CIRCLE "1" OR REQUEST TO SPEAK TO SOMEONE ELIGIBLE TO ANSWER FOR THE HOUSEHOLD.

ELIGIBLE SCREENING RESPONDENT ..... 1 → GO TO 3

3. Is this property a vacation home or second home where you live less than half the year or is this your primary residence?

VACATION/SECOND HOME ..... 1 → ENTER FINAL RESULT CODE, COMPLETE PART D, AND THANK RESPONDENT

PRIMARY RESIDENCE ..... 2 → CONTINUE

NHEXAS Descriptive Questionnaire
February 1, 1994 2:38pm

D. RESPONDENT SELECTION

1. WHAT IS THE ROSTER LINE NUMBER OF THE SELECTED PARTICIPANT? ENTER "00" IF NO ONE IS SELECTED AND GO TO QUESTION 2.

a. ☐☐

IF A PARTICIPANT IS SELECTED, COMPLETE THE BASELINE INTERVIEW, EXPLAIN THE STUDY, AND OBTAIN INFORMED CONSENT, AND RECORD FULL NAME OF PARTICIPANT. IF PARTICIPANT IS UNDER 18 YEARS OF AGE, GET GUARDIAN'S CONSENT AND FULL NAME ALSO. SCHEDULE APPOINTMENTS FOR THE FIRST MONITORING APPOINTMENT.

b. FULL NAME OF PARTICIPANT_____

c. FULL NAME OF GUARDIAN_____

IF NO ONE SELECTED: My supervisor needs to call some of the people I talk with in order to verify my work.

IF PARTICIPANT SELECTED: We may need to call you to verify the appointments.

2. a. Do you have a telephone in this house or apartment?

Yes ... Y --> What is the telephone number, starting with the area code?

(___)___-____

No .... N --> Is there a telephone on which you can receive calls?

Yes .... Y --> What is the number?

(___)___-____

No .... N

ENTER FINAL RESULT CODE AND THANK RESPONDENT

Figure 2: Use of Respondent Identity File

NHEXAS
Respondent Identity File
(do not remove from Project Field Coordinator's Office)

Name of Authorized Staff	Use		Return	
	Date mo./day/yr.	Time	Date mo./day/yr.	Time
	__/__/__		__/__/__	
	__/__/__		__/__/__	
	__/__/__		__/__/__	
	__/__/__		__/__/__	
	__/__/__		__/__/__	
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	__/__/__		__/__/__	
	__/__/__		__/__/__	

Other Comments:

FORM G3-1

Figure 3: Project Consent Form (English)

SUBJECT'S CONSENT FORM
UA-G3.0-2.1
NHEXAS & Border Arizona

I AM BEING ASKED TO READ THE FOLLOWING MATERIAL TO ENSURE THAT I AM INFORMED OF THE NATURE OF THIS RESEARCH STUDY AND OF HOW I WILL PARTICIPATE IN IT, IF I CONSENT TO DO SO. SIGNING THIS FORM WILL INDICATE THAT I HAVE BEEN SO INFORMED AND THAT I GIVE MY CONSENT. FEDERAL REGULATIONS REQUIRE WRITTEN, INFORMED CONSENT PRIOR TO PARTICIPATING IN THIS RESEARCH STUDY, SO THAT I CAN KNOW THE NATURE AND THE RISKS OF MY PARTICIPATION AND CAN DECIDE TO PARTICIPATE OR NOT PARTICIPATE IN A FREE AND INFORMED MANNER.

PURPOSE

I am being invited to participate voluntarily in the Special Border Panel of the National Human Exposure Assessment Survey sponsored by the Environmental Protection Agency. This project will evaluate my exposure to certain metals, pesticides and fumes found inside and outside my home. Some of these occur naturally, like some metals in soils. Others are human-made, like some consumer products used inside my home. The investigators want to know how often and how much of these materials people are exposed to on a daily basis through ingestion (eating and drinking), inhalation (breathing) and absorption (transfer through the skin).

SELECTION CRITERIA

1800 households (an estimated 5400 people) in the State of Arizona are eligible for inclusion in this study. I am being invited to participate because my address was drawn randomly. Households were selected from all counties in the State. Selection was made regardless of participant ethnicity and household location. Group homes and military housing are not included in this study.

PROCEDURES

This study has various levels of participation called "stages." I may be asked to participate in one or several of the study stages. My participation at each stage will be completely voluntary. The number of stages I will be asked to participate in will be determined randomly. If I agree to participate, I will be asked to consent to the following:

- Completion of Questionnaires (interview and/or completed by me). I will be asked questions about myself, my home, my living conditions, the foods I eat and the things I do. Frequently, these questions are asked in terms of how much time I spend doing them. This questionnaire was carefully designed and reviewed. Sometimes it may seem like I

Figure 3 (cont.): Project Consent Form (English)

already answered a question and that it was repeated mistakenly. These questions are subtly different. Usually, they refer to an activity I may have performed during a longer or shorter time period. Each question is very important to the study. Investigators must be able to group me and my behavior with the descriptions and actions of others in the study.

- Collection of Environmental Samples by Staff. I may be asked by the study staff for permission to collect samples from inside and outside my home. These could include:

* Air Samples -- from inside and outside my home;
* Personal Air Samples -- from a small sampler attached to a belt and carried by me everywhere I go for a designated 24 hours;
* House Dust -- from floors, carpets, furniture and other surfaces;
* Soil -- from the foundation of my home, my yard and surfaces outside my home;
* Dust & Soil from the skin of my hands;
* Water Samples -- from my household water supply, and any other drinking water supply in my home.
* Insects living in or around my home.
* Unknown Pesticides – that I use or store in my home.

- Collection of Food and Beverage Samples. I may be asked to provide complete duplicates of all I eat and drink during a 24 hour period. This will include food and beverages I consume inside or outside (at work, school or elsewhere) my home. I will be reimbursed $15 for the food and beverages.

- Biological Samples. I may be asked for hair, blood and urine samples. These will include 90 ml (about 6 tablespoons) of blood collected from a vein in my arm by a medical professional if I am over 10 years old. No samples will be collected from children under the age of 3 years. 5 ml of blood (about 1 teaspoon) will be requested for children between 3 and 10 years of age. Up to 1 gram of hair will be trimmed from the nape of my neck using stainless steel scissors rinsed in isopropanol. The area collected will be not exceed 1 cm by 7.5 cm (or more than 0.5 inches up from the hairline by 3 inches across). I may be asked for a urine sample that I will collect when I awaken the morning after my food was collected.

TIME COMMITMENT REQUESTED

After the initial interview, all visits will be scheduled at my convenience. The study staff will be as prompt and efficient as possible.

- Stage 1: Questionnaires will take about .25 hours to complete at a single visit to my home.

Figure 3 (cont.): Project Consent Form (English)

- Stage 2: Questionnaires and sampling will take a total of 2 hours. On one day, the study staff will administer a questionnaire and sample my home.

- Stage 3: Questionnaires and sampling will require about 8.25 hours over the course of 1 week. My home will be visited up to three times by the study staff and I will receive up to 3 "reminder" phone calls of about 5 minutes each during that week. Study staff will install and remove sampling equipment and collect samples.

RISKS

- Questionnaires: Some questionnaires will be administered by an interviewer and others can be completed by me using paper and pen. If I wish, all questionnaires can be administered by staff. No known risks are associated with completion of these questionnaires.

- Monitoring: All of the monitoring techniques employed in this study have been used before. There are no known risks to me or my home associated with using these monitors. To ensure accuracy, the study staff will ask me and my children to avoid contact with the monitors. Some monitors operate with small motors. These will make very small amounts of noise (like a fish tank pump); they are not harmful.

- Dermal Wipe with Isopropanol (rubbing alcohol): When skin is wiped with isopropanol, many of the surface skin oils are removed. These oils protect me from solvents like cleaning products and gasoline. For a short time (1 - 2 days) following use of the dermal wipe, greater amounts of solvent can be absorbed through the skin of my hands.

- Collection of Hair: Some hair will be trimmed from the nape of the neck. The area sampled will not exceed 0.5 inches by 3 inches. The hair will be collected using alcohol washed stainless steel scissors This area was selected so that the cut patch would not show too much but the removal will be visible on inspection. There are no known risks or discomforts associated with this procedure.

- Blood draw: A routine sample of about 6 tablespoons (90 ml.) of blood will be requested from some participants. This will be collected by medical personnel using completely sterile equipment provided by the Centers for Disease Control (CDC) in Atlanta. The procedure may cause slight discomfort. Physical effects are rare and it only takes 2-3 minutes.

- Urine collection: A routine sample of 250 ml (about 1 cup) of urine will be requested from some participants. I will be provided with the specimen container and instructions for collection. There are no known risks or discomforts associated with this procedure.

Figure 3 (cont.): Project Consent Form (English)

- Clean-up of regulated contaminant: Both I and responsible agencies will be notified of any levels of contaminant known to cause health hazards. In the unlikely event such contaminant levels are identified, the property owner will be required to clean up the contaminant.

BENEFITS

Immediate Benefits: Samples collected in my home and from my body will be evaluated for certain metals, pesticides and volatile organic compounds. The study staff know that some of these compounds present health hazards; they are investigating how commonly other compounds occur in my environment. Up to 1 gram of hair will be trimmed from the nape of my neck using stainless steel scissors rinsed in isopropal alcohol. The area collected will be not exceed 1 cm by 7.5 cm or more than (.5 inches up from the hairline by 3 inches across). I will be immediately informed of the presence of any known hazardous compounds in or around my home and in my blood or urine. I will receive the results of my sampling in my home at the end of the study at no cost to me.

Long Term Benefits: Without identifying me, this data will be made available to Environmental Protection Agency staff and federal lawmakers. It will be analyzed and used to formulate realistic laws that relate to contamination in my environment. My cooperation will help make the world a safer place in which to live and lower my risk of encountering hazardous chemicals.

CONFIDENTIALITY

At the onset of this study, my household and all of the people residing in it will be assigned numbers. The consent forms and any questionnaires containing my family name and identification number will be kept in locked file cabinets in the Health and Environment Project Field Coordinator's office [phone: (520) 626-4226] in the Arizona Prevention Center. Samples and other forms are numbered so as not to reveal my identity. Project staff will handle, process and analyze the data collected from my home using the unique household and individual numbers only.

There is no way that anyone besides the key members of the research team, will be able to relate my identification numbers to me or my home. (Further information regarding details of confidentiality are covered in the Project SOP# UA-G-3.x, available upon request.) The study results will be made available to the Food and Drug Administration (FDA) and the Environmental Protection Agency, the sponsoring agency, in a manner that will not identify me.

If hazardous levels of the materials are found to be contaminating me or my home, then I will be contacted by the Principal Investigator, Michael D. Lebowitz, Ph.D. Further, BY

Figure 3 (cont.): Project Consent Form (English)

LAW, the Principal Investigator must notify the Arizona Department of Environmental Quality or the Department of Health Services and possibly other agencies that have regulatory authority.

PARTICIPATION COSTS AND PARTICIPANT COMPENSATION

There is neither monetary cost to me for my participation in this study, nor is there monetary reimbursement for my time. I will be reimbursed for food samples. I will be paid $15 for a complete duplicate of all the food and beverages I consume in a designated 24 hour period. Results of chemical analyses performed on collected samples are valued at $10,000 for participation in Stages 1-3. I will receive these results absolutely free when the study has been completed.

LIABILITY

I understand that side effects or harm are possible in any research program despite the use of high standards of care and could occur through no fault of mine or the investigator involved. Known side effects have been described in this consent form. However, unforeseeable harm may also occur and require care. I understand that money for research related side effects or harm, or for wages or time lost, is not available. I do not give up any of my legal rights by signing this form. If I become physically injured as a result of any research activity, necessary emergency medical care will be provided without cost beyond what is covered by my health insurance. If I have an adverse reaction or injury as a result of this study, or if I need further information, I should call Michael D. Lebowitz, Ph.D., at 626-6379. If I have questions concerning my rights as a research subject, I may call the Human Subjects Committee office at 626-6721.

AUTHORIZATION

BEFORE GIVING MY CONSENT BY SIGNING THIS FORM, THE METHODS, INCONVENIENCES, RISKS AND BENEFITS HAVE BEEN EXPLAINED TO ME AND MY QUESTIONS HAVE BEEN ANSWERED. I UNDERSTAND THAT I MAY ASK QUESTIONS AT ANY TIME, AND THAT I AM FREE TO WITHDRAW FROM THE PROJECT AT ANY TIME WITHOUT CAUSING BAD FEELINGS. MY PARTICIPATION IN THIS PROJECT MAY BE ENDED BY THE INVESTIGATOR OR BY THE SPONSOR FOR REASONS THAT WOULD BE EXPLAINED. NEW INFORMATION DEVELOPED DURING THE COURSE OF THIS STUDY, WHICH MAY AFFECT MY WILLINGNESS TO CONTINUE IN THIS RESEARCH PROJECT, WILL BE GIVEN TO ME AS IT BECOMES AVAILABLE. I UNDERSTAND THAT THE CONSENT FORM WILL BE FILED IN AN AREA DESIGNATED BY THE HUMAN SUBJECTS COMMITTEE WITH ACCESS RESTRICTED TO THE PRINCIPAL INVESTIGATOR, MICHAEL D. LEBOWITZ, Ph.D., OR AUTHORIZED REPRESENTATIVES OF THE ARIZONA PREVENTION CENTER. I UNDERSTAND

Figure 3 (cont.): Project Consent Form (English)

THAT I DO NOT GIVE UP ANY OF MY LEGAL RIGHTS BY SIGNING THIS FORM. A COPY OF THIS SIGNED CONSENT FORM WILL BE GIVEN TO ME.

_____ ____/____/____
Subject's Signature Date

Further, I give my consent as the legal guardian of the following minors for their participation in the Border Panel of the NHEXAS Project:

Legal Name to the Signature	Date of Birth	Relationship
_____	____/____/____	_____
_____	____/____/____	_____
_____	____/____/____	_____
_____	____/____/____	_____
_____	____/____/____	_____
_____	____/____/____	_____

_____ ____/____/____
Signature of Legal Guardian Date

INVESTIGATOR'S AFFIDAVIT

I HAVE CAREFULLY EXPLAINED THE NATURE OF THE THIS PROJECT TO THE SUBJECT. I HEREBY CERTIFY THAT TO THE BEST OF MY KNOWLEDGE THE PERSON WHO IS SIGNING THIS CONSENT FORM UNDERSTANDS CLEARLY THE NATURE, DEMANDS, BENEFITS AND RISKS INVOLVED IN HIS/HER PARTICIPATION AND HIS/HER SIGNATURE IS LEGALLY VALID. NEITHER MEDICAL PROBLEMS, LANGUAGE NOR EDUCATIONAL BARRIERS PRECLUDED THIS UNDERSTANDING.

_____ ____/____/____
Signature of Study Investigator Date

Figure 3 (cont.): **Project Consent Form (Spanish)**

FORMA DE CONSENTIMIENTO DEL PARTICIPANTE
UA-G3.0-2.1
NHEXAS & Frontera de Arizona

SE ME HA SOLICITADO QUE LEA LA SIGUIENTE INFORMACIÓN PARA ASEGURARSE QUE ESTOY INFORMADO(A) DE LA ÍNDOLE DE ESTA INVESTIGACIÓN Y DE CÓMO PARTICIPARÉ EN ELLA, SI DECIDO HACERLO. MI FIRMA EN ESTA FORMA ACREDITA QUE HE RECIBIDO DICHA INFORMACIÓN Y QUE ACEPTO TOMAR PARTE EN ESTA INVESTIGACIÓN. LAS LEYES FEDERALES REQUIEREN SER INFORMADAS POR ESCRITO DE MI CONSENTIMIENTO ANTES DE PARTICIPAR EN ESTA INVESTIGACIÓN, DE MODO QUE YO CONOZCA LA NATURALEZA DE LA MISMA Y LOS RIESGOS RELACIONADOS CON MI COLABORACIÓN EN ELLA, Y PUEDA DECIDIR PARTICIPAR O NO, DE UNA MANERA LIBRE E INFORMADA.

OBJETIVO DEL ESTUDIO

Se me está haciendo una invitación a que participe voluntariamente en la Sección Especial de la Frontera (Special Border Panel) del Estudio Nacional para la Evaluación de la Exposición Humana a Contaminantes (**National Human Exposure Assesment Survey** o **NHEXAS**), el cual es patrocinado por la Agencia de Protección Ambiental (Environmental Protection Agency). Este proyecto evaluará mi exposición a ciertos metales, pesticidas y gases, que se encuentren dentro y fuera de mi hogar. Algunas de estas exposiciones ocurren naturalmente, tal como la exposición a metales en la tierra. Otras exposiciones son producto de la acción del hombre como algunos productos que utilizo dentro de mi hogar. Los investigadores quieren descubrir con qué frecuencia y en qué cantidad la gente está en contacto con estos materiales diariamente, por medio de ingestión (comiendo y bebiendo), inhalación (respirando) y absorción (a través de la piel).

CRITERIO DE SELECCIÓN

En el estado de Arizona 1,800 hogares (alrededor de 5,400 personas) son elegibles para ser incluidos en este estudio. Estoy siendo invitado(a) a participar porque la dirección de mi casa ha sido elegida al azar. Los hogares han sido elegidos de todos los condados del Estado. La selección ha sido hecha independientemente de la etnicidad y localización de los residentes. Grupos de casas y viviendas militares no han sido incluidas en este estudio.

PROCEDIMIENTOS

Este estudio tiene varios niveles de participación llamados "etapas". Probablemente se solicite mi participación en una o varias etapas del estudio. Mi participación en cada etapa sería completamente voluntaria. El número de etapas en las que se solicite mi participación será determinado al azar. Si estoy de acuerdo en participar, se me pedirá consentimiento para lo siguiente:

- **Completar Cuestionarios** (en una entrevista y/o llenados por mí mismo(a)). Se me harán preguntas acerca de mí, mi casa, mis condiciones de vida, mi alimentación y de las cosas que hago. Frecuentemente, las preguntas se harán en términos del tiempo que requiero para realizar mis actividades. Estos cuestionarios han sido cuidadosamente diseñados y

Figure 3 (cont.): Project Consent Form (Spanish)

revisados. Algunas veces parecerá que ya he contestado una pregunta y que está siendo repetida por error. Sin embargo, estas preguntas son en cierta forma diferentes. Usualmente, se referirán a una actividad que yo haya desempeñado durante un período de tiempo, ya sea más corto o más largo. Cada pregunta es muy importante para el estudio. Los investigadores deben ser capaces de agruparme a mí y a mi comportamiento junto con las descripciones y acciones de otras personas que participen en el estudio.

- **Recolección de las Muestras del Medio Ambiente por los Miembros del Equipo Técnico.** El equipo de técnicos probablemente solicite mi permiso para recolectar muestras del interior y exterior de mi hogar. Estas muestras pueden incluir:

  * **Muestras de aire** -- del interior y exterior de mi hogar.
  * **Muestras de aire personal** -- utilizando un aparato en un cinturón que llevaría conmigo a cualquier lugar que vaya por 24 horas.
  * **Muestras del polvo de mi casa** -- de los pisos, alfombras, muebles y otras superficies.
  * **Muestras de tierra**-- del cimiento, del patio y otras superficies del exterior de mi hogar.
  * **Muestras de polvo y tierra** -- de la piel de mis manos.
  * **Muestras de agua** -- del abastecimiento de agua y de cualquier otra fuente de agua en mi casa.
  * **Insectos** -- que vivan en o alrededor de mi casa.
  * **Pesticidas desconocidos** -- que use o almacene en mi casa.

- **Recolección de Muestras de Alimentos y Bebidas.** Probablemente se me solicite que proporcione duplicados completos de todo lo que coma y beba durante 24 horas. Esto incluiría alimentos y bebidas que consuma dentro y fuera de mi hogar (en el trabajo, escuela o cualquier otro sitio). Se me reembolsarán $15 dólares por estos alimentos.

- **Muestras Biológicas**. Probablemente se me solicite consentimiento para tomar muestras de mi sangre, cabello y orina. Esto incluiría la toma de 90 ml (alrededor de 6 cucharadas) de sangre de una de las venas de mi brazo, realizada por personal médico si tengo más de 10 años de edad. No se recolectarán muestras de niños menores de 3 años. Para niños entre los 3 y 10 años de edad se solicitarían 5 ml de sangre. No más de un gramo de cabello sería cortado de mi nuca usando tijeras de acero inoxidable enjuagadas en isopropanol. El área recolectada no excederá 1 cm. por 7.5 cms. (0.5 pulgadas hacia arriba de la línea del cabello por 3 pulgadas a lo ancho). Probablemente se me solicite una muestra de la primera orina de la mañana, la cual recolectaré después de que haya proporcionado las muestras de comida.

TIEMPO REQUERIDO DE PARTICIPACIÓN EN EL ESTUDIO

Después de la entrevista inicial, se organizará un calendario de visitas a mi conveniencia. El equipo técnico será tan puntual y eficiente como sea posible.

Etapa 1: Se requerirá de un cuarto (.25) de hora, aproximadamente, para completar los cuestionarios en una sola visita a mi hogar.

Etapa 2: Los cuestionarios y el muestreo tomarán un total de 2 horas. En un día el equipo técnico me administrará un cuestionario y tomará muestras en mi hogar.

Figure 3 (cont.): Project Consent Form (Spanish)

Etapa 3: Los cuestionarios y el muestreo requerirán cerca de 8.25 horas en el transcurso de una semana. El equipo técnico visitará mi hogar hasta en tres ocasiones durante esa semana y, además, recibiré hasta tres llamadas telefónicas "de recordatorio" de 5 minutos cada una. El equipo técnico instalará y quitará equipo y recogerá muestras.

RIESGOS

- **Cuestionarios:** Algunos cuestionarios serán aplicados por un entrevistador y otros pueden ser contestados por mí mismo(a) utilizando pluma y papel. Si lo deseo, todos los cuestionarios pueden ser aplicados por el equipo técnico. No existen riesgos conocidos asociados con el llenado de estos cuestionarios.

- **Muestreo:** Todas las técnicas de muestreo empleadas en este estudio han sido usadas anteriormente. No existen riesgos conocidos para mí o mi hogar asociados con el uso del equipo de muestreo. Para mayor seguridad, el equipo técnico nos pedirá a mi familia y a mí que evitemos el contacto con el equipo de muestreo. Algunos equipos operan con pequeños motores. Estos producirán un poco de ruido (como el que produce una bomba de pecera casera) pero no son dañinos.

- **Pañuelo Dérmico con Isopropanol (alcohol para untar):** Cuando se limpia la piel con isopropanol, muchos de los aceites de la superficie de la piel son removidos. Estos aceites protegen contra solventes, tales como los productos de limpieza y la gasolina. Por un corto tiempo (de 1 a 2 días), después del uso del Pañuelo Dérmico, mayores cantidades de solventes pueden ser absorbidas por la piel de mis manos.

- **Muestra de cabello:** Un poco de cabello será recortado de mi nuca. La muestra no excederá 0.5 pulgadas por 3 pulgadas. El cabello será recolectado usando tijeras de acero inoxidable lavadas con alcohol. El área de donde se obtiene mi cabello no se notará demasiado a menos que se inspeccione con mucho cuidado. No existen riesgos conocidos ni incomodidades asociadas con este procedimiento.

- **Muestra de Sangre:** Una muestra rutinaria de aproximadamente 6 cucharadas (90 ml) de sangre será requerida de algunos participantes. Esta muestra será tomada por personal médico, usando equipo completamente esterilizado que es proporcionado por los Centros para el Control de Enfermedades (Centers for Disease Control --CDC) de Atlanta. El procedimiento probablemente haga que me sienta ligeramente incómodo. Efectos físicos son raros y el procedimiento toma sólo de 2 a 3 minutos.

- **Muestra de Orina:** Una muetsra rutinaria de 250 ml (alrededor de 1 taza) de orina será solicitada a algunos de los participantes, a los cuales se le proporcionará un recipiente y las instrucciones para la recolección. No existen riesgos conocidos ni incomodidades asociadas con este procedimiento.

- **Limpieza de Contaminante Regulado:** Se notificá a las agencias pertinentes y a mí de cualquier nivel de contaminante que sea reconocido como causante de daños a la salud. En el caso no deseado de que estos niveles de contaminantes sean identificados, se le solicitará al dueño de la propiedad que limpie estos contaminantes.

Figure 3 (cont.): Project Consent Form (Spanish)

BENEFICIOS

Beneficios inmediatos: Las muestras recolectadas de mi hogar y de mi cuerpo serán evaluadas para detectar ciertos metales, pesticidas y componentes orgánicos volátiles. El equipo técnico sabe que algunos de estos componentes representan daños a la salud; ellos están investigando con qué frecuencia otros componentes se presentan en mi medio ambiente. Se me notificará inmediatamente de la presencia de cualquier componente dañino que se identifique dentro o fuera de mi hogar, en mi sangre o en mi orina. Recibiré los resultados del muestreo de mi hogar al final del estudio sin costo para mí.

Beneficios a largo plazo: Sin dar información de mis datos personales, esta información será proporcionada a personal de la Agencia de Protección Ambiental (Environmental Protection Agency) y a los legisladores federales. La información será analizada y utilizada para elaborar leyes realistas en relación al control de los contaminantes a mi alrededor. Mi cooperación ayudará a hacer de nuestro mundo un lugar más seguro para vivir y a disminuir el riesgo de estar en contacto con químicos perjudiciales a la salud.

CONFIDENCIALIDAD

Al inicio de este estudio, se asignarán números de identificación a mi hogar y a todas las personas viviendo en ella. Las formas de consentimiento y cualquier cuestionario que contenga mi apellido y número de identificación, permanecerán en archivos cerrados con llave en la oficina del Coordinador de Trabajo en Campo del Proyecto de Salud y Medio Ambiente, en el Centro de Prevenciones de Arizona (Arizona Prevention Center) de la Universidad de Arizona [teléfono: (520) 626-4226]. Las muestras y otros formularios serán enumerados de tal forma que no revelen mi identidad. El equipo técnico manejará, procesará y analizará la información recolectada en mi hogar utilizando únicamente los números asignados a mi hogar y a cada individuo.

No hay forma alguna de que cualquier persona, además de los miembros del equipo de investigación, pueda relacionar los números de identificación conmigo o mi hogar. [Para mayor información y detalles referentes al aspecto de confidencialidad, puedo consultar el Procedimiento Estándar de Operatividad (Standard Operating Procedure, SOP # UA-G-3.x, disponible con previa solicitud)]. Los resultados del estudio se pondrán a disposición de la Administración de Alimentos y Medicamentos (Food and Drug Administration, FDA) y de la Agencia de Protección Ambiental (Environmental Protection Agency, EPA), dependencia patrocinadora de este estudio, de manera que no se me pueda identificar.

Si se detectan en mí o en mi hogar niveles dañinos de contaminantes, el investigador principal, Dr. Michael D. Lebowitz, se pondrá en contacto conmigo. Más tarde, **POR LEY**, el investigador principal deberá notificar esta situación al Departamento de Calidad del Medio Ambiente de Arizona (Arizona Department of Environmental Quality) o al Departamento de Servicios de Salud (Department of Health Services) y, posiblemente, a otras agencias que tienen autoridad legal.

COSTOS DE PARTICIPACIÓN Y COMPENSACIÓN AL PARTICIPANTE

No existe ningún tipo de costo para mí por mi participación en este estudio, así como tampoco existe ningún tipo de compensación monetaria por mi participación. Se me reembolsará una cantidad de dinero por las muestras de alimentos y bebidas. Se me pagarán $15 dólares por un duplicado completo de todos los alimentos y bebidas que consuma en un período designado de 24 horas. Los resultados de los análisis químicos que se realicen en las muestras recolectadas están

Figure 3 (cont.): Project Consent Form (Spanish)

valuados en $10,000 dólares por participar en las etapas de la 1 a la 3. Una vez que el estudio haya sido concluido, recibiré los resultados absolutamente grátis.

RESPONSABILIDADES (LIABILITY)

Doy por entendido que en cualquier investigación es posible que ocurran efectos o daños secundarios, en donde ni el investigador ni yo somos culpables, aún cuando se utilicen extrema precaución y cuidado. Los efectos secundarios conocidos han sido descritos en esta forma de consentimiento. Sin embargo, daños no previstos que requiren atención pueden ocurrir. Entiendo que no hay dinero disponible para compensar los daños o efectos secundarios de la investigación ni para compensar salarios o pérdidas de tiempo. No renuncio a mis derechos legales al firmar esta forma. Si resulto fisicamente lesionado como resultado de alguna actividad de la investigación, se me proporcionará la atención médica necesaria de emergencia, sin mayor costo que el que cubre mi seguro médico. Si presento una lesión o reacción adversa como resultado de este estudio, o si requiero de mayor información, debo llamar al Dr. Lebowitz, al (520) 626-6379. Si tengo preguntas referentes a mis derechos como participante en el estudio, puedo llamar a la oficina del Comité de Asuntos Humanos (Human Subjects Committee) al (520) 626-6721.

AUTORIZACIÓN

ANTES DE DAR MI CONSENTIMIENTO AL FIRMAR ESTA FORMA, DOY POR HECHO QUE HE COMPRENDIDO LA EXPLICACIÓN QUE SE ME HA DADO DE LOS MÉTODOS, INCONVENIENCIAS Y RIESGOS AL MOMENTO DE PARTICIPAR EN EL ESTUDIO. ASIMISMO, DOY POR HECHO QUE TODAS MIS PREGUNTAS Y DUDAS HAN SIDO RESPONDIDAS Y ACLARADAS. DOY POR ENTENDIDO QUE PUEDO FORMULAR CUALQUIER PREGUNTA EN CUALQUIER OTRO MOMENTO Y QUE SOY LIBRE DE DEJAR DE PARTICIPAR EN ESTE PROYECTO EN CUALQUIER MOMENTO, SIN PROVOCAR MALOS ENTENDIDOS. MI PARTICIPACIÓN EN ESTE PROYECTO PODRÍA SER INTERRUMPIDA POR EL INVESTIGADOR O POR EL PATROCINADOR DEBIDO A RAZONES QUE ME SERÍAN EXPLICADAS. LA NUEVA INFORMACIÓN QUE SE DESARROLLE EN EL TRANSCURSO DE ESTE ESTUDIO, LA CUAL PUEDE EN UN MOMENTO DADO AFECTAR MI DESEO DE CONTINUAR EN ESTA INVESTIGACIÓN, ME SERÁ PROPORCIONADA TAN PRONTO COMO ESTÉ DISPONIBLE. DOY POR ENTENDIDO QUE ESTA FORMA DE CONSENTIMIENTO SERÁ ARCHIVADA EN UNA ÁREA DESIGNADA POR EL COMITÉ DE ASUNTOS HUMANOS (HUMAN SUBJECTS COMMITTEE) CON ACCESO RESTRINGIDO AL INVESTIGADOR PRINCIPAL, DR. MICHAEL D. LEBOWITZ, O A CUALQUIER REPRESENTANTE AUTORIZADO POR EL CENTRO DE PREVENCIONES DE ARIZONA (ARIZONA PREVENTION CENTER). DOY POR ENTENDIDO QUE NO ESTOY RENUNCIANDO A MIS DERECHOS LEGALES SI FIRMO ESTA FORMA. UNA COPIA FIRMADA DE ESTA FORMA DE CONSENTIMIENTO ME SERÁ ENTREGADA.

_____ Firma del Participante

____/____/____ Fecha

Figure 3 (cont.): **Project Consent Form (Spanish)**

Más aún, doy mi consentimiento, como el tutor legal de los siguientes menores de edad, para que participen en la Sección de la Frontera (Border Panel) del Proyecto NHEXAS:

Nombre legal	Fecha de Nacimiento	Relación con el que firma esta forma
_____	____/____/____	_____
_____	____/____/____	_____
_____	____/____/____	_____
_____	____/____/____	_____
_____	____/____/____	_____
_____	____/____/____	_____

_____ ____/____/____
Firma del tutor legal Fecha

CERTIFICADO DE EXPLICACIÓN

HE EXPLICADO CUIDADOSAMENTE LA NATURALEZA DE ESTE PROYECTO AL PARTICIPANTE. ASIMISMO, CERTIFICO QUE, CON EL MEJOR DE MI CONOCIMIENTO, QUIEN FIRMA ESTA FORMA DE CONSENTIMIENTO HA ENTENDIO CLARAMENTE LA NATURALEZA, DEMANDAS, BENEFICIOS Y RIESGOS INVOLUCRADOS POR SU PARTICIPACIÓN Y QUE SU FIRMA ES LEGALMENTE VÁLIDA. NINGÚN PROBLEMA MÉDICO O BARRERAS DE LENGUAJE O EDUCACIÓN IMPIDEN ESTE ENTENDIMIENTO.

_____ ____/____/____
Firma del Investigador del Estudio Fecha

Figure 4: Minor Assent Form (English)

MINOR SUBJECT'S CONSENT FORM
UA-G3.0-3.1
NHEXAS & Border ARIZONA

My mother/father told me it is okay for me to save some urine for you. When I go to the bathroom tomorrow morning I need to urinate (pee, tinkle, another word choice supplied by the parent) in this container. Then the container needs to go into this bag and be kept cold in the refrigerator. The study staff want me to know why this is being done. Sometimes metals and bug spray that I cannot see can get inside my body. I need some metals to make me healthy, but other metals and bug spray can make me sick. A scientist at the laboratory will look at my urine and make sure it does not have metal or bug spray that can make me sick. If too much metal or bug spray is found in my urine, the study staff will tell my parents, and they will take me to the doctor. The doctor may need to do the same kind of test. Do I understand? Is it Okay?

Verbal Assent yes no

_____ ___/___/___
Subject's Name and Signature Date

_____ ___/___/___
Investigator's Signature Date

My mother/father told me it is okay to collect some blood from my arm using a needle. The needle stick may hurt and I may get a small bruise. The study staff want me to know why this is being done. Metals or bug spray that I cannot see can get inside my body. I need some metals to make me healthy, but other metals or bug spray can make me sick. A scientist will then look at my blood at the laboratory and make sure it does not have metals or bug spray that can make me sick. If too much metal or bug spray is in my blood, my parents will be told, and they will take me to the doctor. The doctor may need to do the same kind of blood test. Do I understand? Is it Okay?

Verbal Assent yes no

_____ ___/___/___
Subject's Name and Signature Date

_____ ___/___/___
Investigator's Signature Date

My mother/father told me it is okay to cut some hair from the back of my head near my neck using scissors. The study staff want me to know why this is being done. Metals that I cannot see can get inside my body. I need some metals to make me healthy, but other metals can make me sick. A scientist will then look at my hair in the laboratory and make sure it does not have metals that can make me sick. If too much metal is in my hair, my parents will be told, and they will take me to the doctor. The doctor may need to do the same kind of test. Do I understand? Is it Okay?

Verbal Assent yes no

_____ ___/___/___
Subject's Name and Signature Date

_____ ___/___/___
Investigator's Signature Date

Figure 3 (cont.): Project Consent Form (Spanish)

FORMA DE CONSENTIMIENTO DEL PARTICIPANTE MENOR DE EDAD
UA-G3.0-3.1
NHEXAS & Frontera de Arizona

Mi mamá/papá me ha dado permiso para entregarles una muestra de mi orina. Cuando me despierte mañana en la mañana y vaya al baño voy a orinar o a hacer pipí en este recipiente. Después, voy a meter el recipiente con mi orina en esta bolsa y, entonces, lo voy a guardar en el refrigerador para mantenerlo frío. Las personas que están trabajando en el estudio quieren que yo sepa por qué están haciendo este examen. A veces, algunos metales e insecticidas que no puedo ver a simple vista pueden meterse a mi cuerpo. Mi cuerpo necesita de unos metales para mantenerme en buena salud pero hay otros metales e insecticidas que me pueden hace daño. Un científico va a examinar mi orina en un laboratorio para asegurarse que mi cuerpo no tenga metales e insecticidas que me puedan enfermar. Si el científico encuentra demasiados metales o insecticidas en mi orina, se lo informará a mis papás y ellos me llevarán al doctor. Tal vez el doctor me haga el mismo tipo de análisis. ¿He entiendo? ¿Estoy de acuerdo?

Consentimiento verbal Sí No

_____ ___/___/___
Nombre y firma del participante Fecha

_____ ___/___/___
Firma del investigador Fecha

Mi mamá/papá me ha dado permiso para entregarles una muestra de mi sangre usando una jeringa. Tal vez el piquete de la aguja me duela un poquito y quizá me deje un moretoncito. Las personas que están trabajando en el estudio quieren que yo sepa por qué están haciendo este examen. A veces, algunos metales e insecticidas que no puedo ver a simple vista pueden meterse a mi cuerpo. Mi cuerpo necesita de unos metales para mantenerme en buena salud, pero hay otros metales o insecticidas que me pueden hacer daño. Un científico va a examinar mi sangre en un laboratorio para asegurarse que mi cuerpo no tenga metales o insecticidas que me puedan enfermar. Si el científico encuentra demasiados metales o insecticidas en mi sangre, se lo informará a mis papás y ellos me llevarán al doctor. Tal vez el doctor me haga el mismo tipo de análisis de sangre. ¿He entendido? ¿Estoy de acuerdo?

Consentimiento verbal Sí No

_____ ___/___/___
Nombre y firma del participante Fecha

_____ ___/___/___
Firma del investigador Fecha

Mi mamá/papá me ha dado permiso para que me corten con unas tijeras una muestra del cabello de la parte posterior de mi cabeza. Las personas que están trabajando en el estudio quieren que yo sepa por qué están haciendo este examen. A veces, algunos metales que no puedo ver a simple vista pueden meterse a mi cuerpo. Mi cuerpo necesita de unos metales para mantenerme en buena salud, pero hay otros metales que me pueden hacer daño. Un científico va a examinar mi sangre en un laboratorio para asegurarse que mi cuerpo no tenga metales que me puedan enfermar. Si el científico encuentra demasiados metales en mi sangre, se lo informará a mis papás y ellos me llevarán al doctor. Tal vez el doctor me haga el mismo tipo de análisis. ¿He entendido? ¿Estoy de acuerdo?

Consentimiento verbal Sí No

_____ ___/___/___
Nombre y firma del participante Fecha

_____ ___/___/___
Firma del investigador Fecha