



*Dietary Factors Associated with Cardiovascular Disease Risk in School-age Children and their Parents  
in Mesoamerica*

**Institute of Nutrition of Central America and Panama –INCAP–, Guatemala**

**INCAP Comprehensive Center for the Prevention of Chronic Diseases**

**University of Michigan School of Public Health, USA**

**Harvard School of Public Health, Boston, USA**

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**PROTOCOL**

**Dietary Factors Associated with Cardiovascular Disease Risk in School-  
age Children and their Parents in Mesoamerica**

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Institute of Nutrition of Central America, Panama and the Dominican Republic

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**Research Protocol**

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**Title of the Study:**

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**1. Hypothesis and Objectives**

a. Hypothesis

1. Dietary risk factors including: *deficiency of  $\omega$ -3 fatty acids (in adipose tissue), vitamin B12 (in plasma), folate (in erythrocytes), vitamin B6 (in plasma), and vitamin D (in plasma), cortisol in saliva, exposure to mercury measured in hair, and high-fructose corn syrup measured in nails; a high glycemic load, a dietary pattern with high adherence to "refined grains or cereals", a high intake of sugar-sweetened beverages (SSBs), intake of trans-fatty acids, a sedentary lifestyle, and eating while watching TV* are related to cardiovascular disease (CVD) and have a high prevalence in school-age children (7-12 years old) and their parents in Mesoamerica (México, Belize, Guatemala, El Salvador, Honduras, Nicaragua, Costa Rica, Panama, and the Dominican Republic.)
2. These dietary factors are associated with early CVD risk factor such as overweight and hypertension.

b. Objectives

1. General Objective:

- i. Determine the prevalence of dietary risk factors for CVD in children and adults in 9 countries of Mesoamerica, including the deficiency of  $\omega$ -3 fatty acid (in adipose tissue), vitamin B12 (in plasma), folate (in erythrocytes), vitamin B6 (in plasma), and vitamin D (in plasma), as well as a high glycemic load, a dietary pattern with high adherence to "refined grains or cereals", a high intake of sugar-sweetened beverages (SSBs), intake of trans-fatty acids, a sedentary lifestyle, and eating while watching TV.

2. Specific Objectives:

- i. Analyze if the deficiency of  $\omega$ -3 fatty acids (measured in adipose tissue) is positively associated with: a) plasma levels of high sensitivity C-reactive protein (hs-CRP), which is a marker of systemic inflammation and independent CVD risk factor, and b) adult and child obesity in Mesoamerica.
- ii. Evaluate if the deficiencies of folate, vitamin B12 or vitamin B6 are associated with increased plasma homocysteine.
- iii. Study the association between vitamin D status and child and adult obesity.
- iv. Evaluate if a high glycemic load, a dietary pattern with high adherence to "refined grains and cereals", a high intake of SSBs and an elevated intake of trans-fatty acids are associated with: a) higher plasma triglyceride levels, b) low levels of high-



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- density lipoprotein (HDL) cholesterol, c) high fasting glucose levels, d) hyperinsulinemia, and e) metabolic syndrome.
- v. Evaluate if a high sodium concentration in urine (marker of this mineral intake) is associated with hypertension.
  - vi. Examine if exposure to mercury (measured in hair samples), to high-fructose corn syrup (measured in clipped nails) and/or cortisol (measured in saliva) are associated with: a) high blood pressure and b) metabolic syndrome.
  - vii. Examine associations between fat mass and fat-free mass determined through deuterated water method and through the hs-CPR.
  - viii. Determine the prevalence of polymorphisms in candidate genes related to obesity and genetic markers associated with CVD.

## 2. Background and Significance

Cardiovascular diseases are the leading cause of death in adults in Mesoamerica. Modifiable risk factors for CVD (lifestyle, diet, and physical activity) significantly contribute to the etiological fraction of these diseases in the region.

For instance, in a study conducted in Costa Rica, the largest contributors to population attributable risk (PAR) for non-fatal myocardial infarctions were diet-related risk factors, including abdominal obesity (29.3% PAR), physical inactivity (9.6% PAR), and inadequate food intake (6.0% PAR).<sup>1</sup>

Other diet-related specific factors that have been associated with cardiovascular disease risk in the region include alpha-linolenic acid<sup>2</sup>, low consumption of legumes<sup>3</sup>, increased use of palm oil to cook, and intake of refined grains and cereals<sup>4</sup>.

The region could also be affected by the endemic deficiency of long chain  $\omega$ -3 fatty acids, due to the insufficient intake of its food source.

On the other hand, the prevalence rates of child and adult obesity are alarmingly increasing in Mesoamerica. Although in some countries there is available data about the prevalence of nutritional factors for CVD, the load attributable to such factors is still unknown to most of the region.

In order to prioritize the possible interventions to improve diet quality and increase physical activity, it is crucial to obtain reference data about the prevalence of diet risk factors for CVD in every country of the region.



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### **3. Sample Size and Population**

The target population consists of school-age boys and girls, between the ages of 7 and 12, enrolled in elementary schools located in peri-urban areas of the capital city in each participating country. The parents of each child will also be recruited in order to have triads. Thirty triads will be recruited in each of the 9 countries of Mesoamerica, for a total of 270 triads (810 participants). Exclusion criteria will be the following: orphanhood, absence of one of the parents, pregnant students or mothers, and having a sibling already participating in the study. Since this is a pilot study, formal statistical calculations have not been included for the sample size. The number of selected participants (30 children and their parents in each country) will allow us to gather preliminary data and estimate the degree of the effect of the sample size in the 9 countries within the financial limits of this study. In order to maximize representativeness, we have planned to recruit children from several schools in each country (4 schools per country).

### **4. Study Design**

The proposed study is cross-sectional for 540 adults and 270 school-age children between the ages of 7 and 12 living in 9 countries of Mesoamerica. Thirty children will be recruited in each country and their parents will be invited to join the study. The recruitment will be carried out in 4 peri-urban schools located in the capital city of each country and an additional 10% (3 families) will be recruited in case a family fails to continue for any reason. Information will be gathered in schools and through home visits, where questionnaires will be administered, anthropometric measurements will be taken, and biological samples will be collected from children. The average dietary intake during the last months will be determined through a semi-quantitative food frequency questionnaire (FFQ). Then, researchers will identify the kind and brand of the most frequent foods that are potential sources of trans fats and sodium, in order to obtain them in the market and carry out a biochemical analysis of the concentration of those components.

### **5. Recruitment and Informed Consent Process**

In each country, the population of the study will be recruited in coordination with the Ministry of Education, who will assist in identifying schools. Four schools in the capital city of each country will be chosen as convenient, trying to represent different areas of the city. After establishing contact with the educational authorities, a list of the students will be requested in order to randomly pick 20 children from each school (for a total of 80 in each city) and they will be stratified by age and sex. Invitations will be made until we reach the required sample in each school. If the sample is not completed after choosing the group of 80 children, another group of children will be chosen taking into account the ratio of the first group.

After having the sample of 80 children randomly chosen, a verifying process of the exclusion criteria will be carried out (interview with children). Those criteria are the following: 1) If the student lives with both parents, 2) if the student or her mother is pregnant, 3) if a sibling has already been chosen. If the child is not excluded for any of these criteria, an



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invitation to participate in a briefing about the study will be handed to him/her and his/her parents. In the case of item 2, the researcher will ask the question in a private environment, trying to make the student feel comfortable. This question will only be asked if the girl has already had her menarche.

The briefing will be scheduled on a date and time suitable for both parents. In that briefing the project team members will be introduced (research fellow and professional field staff), a presentation will be carried out, information on the study will be provided, and with the aid of photographs, it will be explained in detail, and in a simple language, what does participating entails. It will also be explained that evaluations will be carried out in group, in other words, the parents will be evaluated along with their child. In order to ensure that participants have understood the procedures, there will be time for answering questions and solving doubts. To explain the amount of biological samples (blood and fatty tissue) that will be collected, a syringe and teaspoons will be used to illustrate the equivalence. Finally, researchers will hand out one informed consent to each family and will request the three members of each family to consider participating voluntarily in the study. During this process, it will be explained to families that the visit will last at least 4 hours and that they will need to fast for at least 6 hours prior to the visit. Each family will be able to return the signed consent on the same day of the briefing if they desire to do so, or they will have a week to confirm their participation in the study. During that week, families will be able to contact the research team if they have any questions about the participation. All families will require the signature of two witnesses backing the fact that the information was clearly delivered.

The families that agree to participate will be requested to return the signed consent to the child's teacher by the end of the week, and the teacher will give these to a member of the research team. If the consents are not received at school, these will be collected through home visits. Upon obtaining the signed consents, the team member will confirm the expressed consent to participate from the child before one of his/her parents. Once the consent has been signed and the child has confirmed his/her consent, the team member will make an appointment with the family for a home visit in order to carry out the evaluations.

The consent will be delivered in the local language of the country (English in Belize and Spanish in the rest of the countries).

In the case of children who return the signed informed consents at school, an evaluation appointment will be scheduled for the three family members. On that same day, the father or mother will be called to inform him/her about the appointment and to confirm his/her attendance on the scheduled date and time. Such appointment will be scheduled as convenient for the participants, and if one of the family members desires to change the date or time, the appointment will be rescheduled for the family member who was not evaluated. Home visits are foreseen to be on non-business days in order to suit the parents' work schedule.





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For parents who personally bring the informed consent signed, or those visited at home, the evaluation appointment will be scheduled on a specific date and time. In most cases, the evaluation will take place at homes. For those families who prefer not to have a home visit, the evaluation will take place at school, at a clinic, or at a health center. The parents who want to have the evaluation at home will be asked to prepare a private place with enough space to collect the samples.

### 5.1 Procedures

On the day of the evaluation, the three family members will receive the questionnaires and the samples will be collected. They will answer questionnaires that will provide information about their socio-demographic and food security characteristics, health condition, habits (nutritional habits), and food frequency intake (FFQ); biological samples will be also collected. These questionnaires will be previously validated in each participant country. If one of the family members is not present, a second visit will be scheduled on the day and time suggested by the family in order to carry out the evaluation.

#### 5.1.1 Measurements

- i. Socio-demographic Data: Each participant will provide general information about his or her living conditions, housing quality, food security, and educational level.
- ii. Dietary Intake and Physical Activity: Each participant's diet will be evaluated through a FFQ and a physical activity pattern questionnaire. Information about exposure time to TV and electronic games will be obtained from the latter. Information about glycemic load, sugar-sweetened beverages, dietary patterns, and the intake of fish and legumes will be obtained from the FFQ. Data from the FFQ and from the questionnaires on physical activity and socio-demographic characteristics will be compiled in palm-like portable digital devices that use as platform software developed in *Centro Centroamericano de Población of Universidad de Costa Rica*.
- iii. Anthropometry: In order to obtain information about the nutritional condition, measurements of body weight, height, arm, abdominal and hip circumference, triceps and subscapular skin fold will be taken. Standard protocols will be used for taking the anthropometric measurements.
- iv. Body Composition in school age children: The lean body mass and body mass index percentages will be estimated by using the deuterium dilution technique only in children. This is a well-established method for the measurement of total body amount of water in children.<sup>7</sup> This technique is safe (non-radioactive), standard, widely used in children and adults; it is also a non-invasive technique in which water enriched with deuterium (a hydrogen



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stable isotope) is ingested by each individual (12-18ml). The water used in this test is drinkable and innocuous to health. A 4-ml saliva sample will be obtained by using cotton balls before and after 3 hours of ingesting the deuterated water dose. The samples will be kept frozen until they are analyzed at INCAP using Fourier Transform Infrared Spectroscopy (FTIR).

- v. **Blood Pressure:** Through a standard procedure, blood pressure will be measured to all participants using digital sphygmomanometers. It will be measured no less than three times, after the patient has remained seated for at least five minutes, with a lapse of at least one minute between each measurement. An appropriate bracelet size will be used for each person. The average of the second and third measurements will be reported.
- vi. **Biological samples:** Samples of nails, hair, saliva, 24-hour urine, blood, and adipose tissue will be collected in each participant.
- A **toenail** will be clipped in order to analyze high-fructose corn syrup residues.
  - Approximately 50 **hair ends** will be cut from the back side of the head (occipital region, more or less 1 inch above the neck line so it is undetectable). This sample will be used to analyze mercury in hair.
  - A 3-ml sample of **saliva** will be collected in order to measure cortisol concentration. The saliva samples for the deuterated water test and for the cortisol analysis will be collected at the same time.
  - A professional from the team will collect a **blood sample** (22 ml) through venipuncture of a vein in the arm. The blood sample (a 7.5 mL EDTA aliquot and a 5 mL aliquot in a mineral trace-free tube) will be used for the analysis of micronutrients in plasma (vitamin B-12, pyridoxal 5-phosphate –PLP- the active form of vitamin B6 and 25 OH of vitamin D), homocysteine, Ultra-sensitive C-reactive protein, fasting blood glucose, serum insulin, lipid profiles, red corpuscule folate concentration and an aliquot of 8.5ml for DNA extraction. The plasma and serum samples will be kept frozen, preferably at -70°C or at least -20°C for less than 3 months until they are analyzed. The blood chemistry, vitamins, and the DNA extraction analysis will be carried out at INCAP laboratories, or at any of the participant entities.
  - The **adipose tissue** sample will be used for fatty acid analysis and for DNA extraction in fatty cells. This adipose tissue sample will be collected on a stretcher or bed, from the gluteal area (outer upper quadrant) using a 15mm needle. The needle is inserted and the piston is pulled to create a vacuum. Then, the piston is softly pulled and moved forward to obtain the adipose tissue sample. A cold, topical analgesic spray will be used before the procedure. Before and after the procedure, the area will be disinfected using 70% alcohol, and a new needle will be used with each participant. This procedure will be performed by experienced professional personnel, and in the case of children, both parents will be present.



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- **Collection of 24-hour urine sample:** The day of the evaluation, that will take place on a non-business day (Saturday in most cases), each family will receive three containers specially designed for a 24-hour urine collection. During this visit, it will be explained to them how to collect the 24-hour urine sample (if the visit is held on Saturday, they will be asked to collect the urine of Sunday). If the visit takes place on Sunday, they will be asked to collect urine from the second urine of that day until the first one of Monday. The research team will collect the samples on Monday in order to store them that same day.<sup>10</sup>

We will create a biological sample repository for future studies of DNA analysis. The recruited participants may continue in the study even if they do not authorize to store their samples for future analysis. Participants will specifically give their consent for this procedure (See Annex 3 "Informed Consent for Sample Storage". All biochemical analysis of the biological samples will be performed at INCAP laboratories. On page 18, we have included the ethical considerations about the handling and storage of biological repository samples.

- vii. **Physical Activity Pattern:** In order to measure the physical activity of each family member, in addition to the forms, where semi-quantitative data will be obtained, a pedometer will be used to obtain quantitative numbers of the steps taken in a day and the time in which moderate-strong physical activity takes place. This measurement will be made with the assistance of pedometers, which are devices widely used in researches, especially in children. These devices are placed on the waist, suspended by a belt. These devices will be placed on the same day the samples are collected and will be removed seven days later. The NL 1000 pedometer will be used (Newlifestyles Inc., Montana, US) around the waist and is validated for measuring the intensity of each step (moderate-strenuous) and the accumulated time for this physical activity in one day.
- viii. **Food samples:** In the FFQ, the family will be asked which food brands they consume from the following categories: oils or edible fats, appetizers or snacks, cookies, sausages, soups, clear soups, and breakfast cereals. The members of the study team will buy these brands and types of food in order to analyze trans-fatty acid and sodium content at INCAP laboratories. The samples collected in the countries other than Guatemala will be kept cold the same day they are collected, and will be stored inside the freezers of the institutions of each country until the collection is completed; these will be later sent to INCAP laboratories in Guatemala.



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**6. Length of the Study:**

The study is expected to last 3 years. During the first six months, the working teams of each country and the schools where the recruitment will take place will be identified. In addition, pilot research instruments, procedures, operation manuals, and questionnaire validation will be developed in each country; personnel hiring and training will also take place during this period.

Data compilation is expected to take place in three cycles of six months each, one year and a half, as of the beginning of the study. Three countries will carry out the field work simultaneously during the three six-month cycles. The biochemical analysis will be performed during the first half of the third year, and the statistical data analysis and report writing will be done during the second half of the third year.

**7. Information Sources:**

Information will be obtained at a home visit through questionnaires described in Annex 4-7. These questionnaires include questions about their socio-demographic characteristics, food intake, and physical activity habits. During the home visit, anthropometric measurements will be taken (weight, height, mid-arm and waist circumference, triceps skin fold, and shoulder blade skin fold) as well as biological samples of the child and parents. All the information will be handled by health professionals and technical assistants trained for this study. The visit will not last more than 4 hours and will be scheduled on a convenient date and time for each family. Home visits will be organized by the research team members and will be coordinated by the Local Coordinator of the study. This study consists of one home visit to each family in which the collection of biological samples and interviews with the parents and child will be carried out. All the procedures and interviews to the child will be held before his/her parents. If the family prefers not to have a home visit, carrying out the procedure at the nearest health center to the community or at the school will be considered.

**8. Statistical Methodology**

a. Definition of Exposures:

Exposures are dietary and physical activity factors associated with cardiovascular disease risk in medical literature. These include:

- Body Mass Index, abdominal obesity, and fat mass index
- Concentration of mercury in hair
- High-fructose corn syrup in nails
- Cortisol levels in saliva
- Sodium excretion in 24-hour urine
- Erythrocyte folate and plasmatic concentration of vitamin B12, pyridoxal-5'-phosphate-PLP- (vitamin B6 indicator), vitamin D, homocysteine, ultrasensitive C-reactive protein, fasting blood glucose, insulin, and lipid profile.



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- Concentrations of polyunsaturated  $\omega$ -3 and  $\omega$ -6 fatty acids, and trans-fatty acids in adipose tissue.
- Amount of hours spent eating while watching TV or playing electronic games.

b. Definition of Outcomes:

The outcomes will be factors for early CVD risk, obtained from the biological samples and questionnaires.

- Food pattern of high consumption of grains and refined cereals
- Dietary pattern with high consumption of trans fats and sodium
- Excessive use of TV and electronic games
- Overweight and obesity
- Hypertension
- Hyperglycemia
- High fasting glucose levels
- High plasma homocysteine
- High levels of systemic inflammation markers (ultra sensible C-reactive protein).
- Metabolic Syndrome<sup>8,9</sup>

- c. Data Analysis: For the first objective, prevalence rates will be calculated with confidence intervals of 95% for each risk factor by country and demographic group (parents and child).

For Objectives 2 to 5, we will compare the distribution of continuous results for the categories of each predictive factor with the use of parametric and nonparametric methods. Then, we will adjust a model of multivariable linear regression for each result by making adjustments to potential confounding factors such as age, sex, socioeconomic conditions, and others.

Dichotomy of some results such as obesity and waist circumference will be classified according to WHO standards, and blood pressure according to the guidelines of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure (JNC VII). The Metabolic Syndrome will be defined according to the American Heart Association (AHA-NHLBI) and the International Diabetes Federation (IDF). For dichotomous results, the adjusted prevalence rates will be estimated by the categories of each predictor using binomial regression. Analysis of parents and children will be performed separately.

Since this is a pilot study that will allow obtaining preliminary data of the main dietary risk factors, formal calculations of statistical power have not been included.



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**9. Potential risks**

There are no complications foreseen related to the participation in the study. Children and adults will be subject to minimum risks due to the non-interventional character of the study. Hair cutting nail clipping, anthropometric measurements, and urine and saliva collection do not cause pain. Participants may feel a slight pain during and after the blood and fat sample collection, or a minor bruise or redness may appear on the needle mark spot where the blood and the gluteus fat samples were collected but this will not have any repercussion in the participant's health.

There exists a minimum psychosocial risk, if the information of each participant is not handled confidentially. However, all the necessary precautions will be taken in order to maintain the confidentiality of each person's information and the privacy of the participants when the biological samples are collected.

**10. Adjustment of Protection against Risks.**

**10. 1. Recruitment and Informed Consent:**

Participants will be recruited randomly, based on the lists provided by the chosen schools. During the introductory briefing at each educational center, the researchers will clearly explain that the parents' and child's participation is voluntary and that the fact of not participating will not have any negative consequence. Any member of the family may retire from the study at any time, even if he/she has already signed the informed consent or has expressed consent. Likewise, if any member or the entire family wants to participate, but does not want to undergo a certain procedure; it will be possible without any negative repercussion. Each family will have one week to confirm their interest in participating in the study. In case they have doubts or questions about their participation, during this week, they may contact the research team.

Families that decide to participate will be asked to hand in the parents' consent signed to the child's teacher at the end of the week. One member of the research team will receive all the signed consents from the teacher. If the consents are not received at school, these will be collected through home visits. Parents must sign their child's consent. Additionally the child's expressed consent will be asked before his/her parents or person responsible at school or home. This process will be carried out in the local language of each country. If the visit takes place at the family home, they will be asked for a private place with enough space for the samples collection, since these will be collected in group, that is, parents and child together.

**10. 2. Protection against Risks:**

In order to guarantee the confidentiality of the information, the disclosure risk will be minimized. This will be done by assigning each participant an arbitrary identification code. Data will be stored in a locked filing cabinet, inside a restricted access office in each country, and in confidential electronic files. All computers and electronic devices



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where the data is filed will be protected with passwords and will also have restricted access.

Biological samples will be labeled only with the identification code, not with the participants' name. Only the persons involved in the study will have access to the obtained information.

None of the reports or results that are made public will include personal identification data. All the members of the research team have been trained on the protection of human subjects in research studies, and on the importance to guarantee data confidentiality.

The recruitment and consent process will be carried out in a simple language, with illustrations such as real pictures of the procedures and syringes with teaspoons in order to illustrate the equivalences of the quantities needed for each test.

On the evaluation day the researchers will try to speak with each participant in order to create a calm and trustful environment at the moment of collecting the samples to minimize the discomfort caused by any test. Researchers will be responsible for the participant, even at their homes. In case one of the members of the family does not want to undergo a procedure in the presence of other member of the team, the test will be performed in another private space inside the house.

The slight pain that participants may undergo during and after the fat sample collection will be minimized. Collecting the adipose tissue sample may cause a temporary redness. In order to reduce the risk, a cold, topical analgesic spray will be applied; this produces a soothing sensation due to the instant action of intense cold. This spray solution has been used in similar studies, since it provides a calming effect which is more intense and safer than ice, without risks or side effects.

The collection of the biological samples in children will take place in front of their parents in order to guarantee the minor's safety.

## **11. Potential Benefits for Participants of the Study**

The direct benefit for the participants will be getting to know the main indicators of their health condition, such as body mass index, glycemia, homocysteine, lipids profile, and blood pressure. Those with abnormal values in any of these indicators will receive a referral note to visit a doctor in the nearest health center of his/her community or the family doctor, if that were the case. Also, during the home visit, the family will receive nutritional advice.

Families may also have the psychological benefit of feeling satisfaction contributing to such an important research.



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This study has the potential to create useful information about the status of the dietary risk factors related to CVDs in countries in Mesoamerica and the Dominican Republic. It will have middle- and long-term benefits for the community, since the findings will allow identifying three countries of the region where interventions to improve the dietary quality should be prioritized. Additionally, main dietary recommendations will be specifically identified for each participating country.

Another long-term benefit is the use of the generated evidence in the creation of public health policies and programs oriented to the prevention and treatment of these conditions. Thus, the study will provide information that can be used by governmental authorities in order to improve the quality of nutrition and health interventions that are now taking place in the school population.

## **12. Acknowledgement**

As part of the procedure, every member of the family will receive a breakfast immediately after the blood and adipose tissue collection. This breakfast will be prepared with quality standards and served on hygienic conditions.

At the end of the home visit, the child will receive a backpack containing a meal sample to promote healthy food such as fruits and vegetables.

The family will also receive a food basket containing the portion of fruits and vegetables that a five-member family must eat in one day, and basic groceries for two days in order to compensate a possible income loss for missing work because of this study. The basket will be delivered along with a brief guidance about the importance of fruits and vegetables intake.

In addition, the family will receive a healthy life promotional video (DVD), adapted and validated for the Central American population, in order to encourage healthy life styles and family coexistence on Sundays, the day when the urine sample must be collected. These videos were created, and are currently used for the same purpose by the Ministry of Health. All of these items will be given as gratitude and recognition for the family's participation.

## **13. Importance of possible findings**

This study will help distinguish the more important CVD risk factors in early and adult life in a region where CVD are the most common cause of death and disability, and where risk factor rates are suspected to be increasing.

Findings will provide a basal line to identify the dietary recommendations that will contribute to reduce overweight, hypertension, and other risk factors. The results on this study will provide the stage for the discussion of strategies to improve the nutrition policies for school-age children of the entire region.





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**14. Other Ethics Committees**

- El Salvador: Ethics Committee of the Ministry of Health of El Salvador-
- Costa Rica: Ethics Committee of Universidad de Costa Rica –UCR (for its initials in Spanish). Research Vice-rectory, Ciudad Universitaria Rodrigo Facio.
- Chiapas, México: Ethics Committee of the Secretariat of Health of the State of Chiapas.
- Honduras: MD Denis Padgett, PhD. Biomedic Research Ethics Committee (CEIB for its initials in Spanish). Unit of Scientific Research, School of Medicine, Universidad Nacional Autónoma de Honduras. Electronic mail: ddpadgettm@hotmail.com.
- Belize: Ethics Committee of the Ministry of Health of Belize.
- Nicaragua: Ethics Committee of the Ministry of Health of Nicaragua.
- The Dominican Republic: Jorge Asjana David, PhD. Ethics Commission of the School of Health Care Sciences, Universidad Autónoma de Santo Domingo and National Bioethics Commission of Health –CONABIOS (for its initials in Spanish).
- Panama: Ruth Graciela de León, PhD. President of the National Committee on Bioethics of Research.

**15. Inclusion of Women:**

Approximately half of the study population is expected to be women, including girls from schools and mothers of all the children participating in the study.

**16. Inclusion of Minorities:**

The population of this study belongs to the Ladino ethnic group (which is the result of a tripartite racial mix: Amerindian, European, and in a small proportion, African). They belong to the Spanish-American culture.

**17. Inclusion of Children:**

A third (n=270) of the study population will be school-age boys and girls, between the ages of 7 and 12. We will recruit 30 school-age children in each of the 9 countries proposed.

**18. Problem Reporting Plan**

If any serious unfavorable event should happen, the main researcher will notify it in writing to NHLBI and the Ethics Committee of each country, within 24 hours.



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**19. Collaborators**

**19.1 International Collaborators**

The Institute of Nutrition of Central America and Panama (INCAP), Michigan School of Public Health and the Harvard School of Public Health will collaborate in this study.

The main researchers are:

- Ana Victoria Román, PHD (Nutrition). Co-PI (INCAP). She will be responsible for all the deployment aspects of the study, hiring, training and supervision of the personnel, operative manual development, and budget management.
- Eduardo Villamor, MD DrPH (Nutrition Epidemiology). Co-Pi (Michigan). He will be in charge of the study design, development of the data collection protocol, data analysis and interpretation.
- Hannia Campos, PHD (Biochemistry). Co-Researcher (Harvard): She is the Biochemistry specialist who will be the consultant for food analysis and biochemical samples.

**19.2 Local Collaborators**

INCAP will recruit and coordinate the training of 9 local coordinators, one in every participating country. Coordinators will be in charge of personnel management, supervision, field work coordination, local data collection, regular data verification, data integrity and protocol compliance. There will be a selection process for each local coordinator, research fellow and professional biological sample collector (national team). Besides, during the study, they will receive training on topics related to this study, such as: use of instruments, data collection techniques, handling, storage and delivery of both biological and food samples from the different countries to INCAP's laboratories. All the research fellows (Doctors, Nutritionists or similar) involved in the research in Guatemala, as well as in other countries, must have college degrees. Local coordinators have college degrees, most of them are Doctors and Nutritionists. The field personnel that will be in charge of collecting samples must be graduated technicians (Laboratory technicians, Medical urgencies technicians, Nursing technicians, Anthropometry technicians). If they do not have a degree, they must have proven experience in the research field and in biological and anthropometric sample collection.

On-line and face-to-face meetings of the teams from the participant countries are planned in order to discuss topics related to events and improvements of the research. These meetings will be held every two months in order to guarantee the follow-up of the proceedings. For this study, the 9 participating countries have been divided into three groups. The first group is integrated by Guatemala, El Salvador, and the Dominican Republic; the field work will take place from January to June 2011. The second group



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includes Honduras, Nicaragua, and Belize, and will carry out the field work from July to December 2011. The field work of the third group, Mexico, Panama and Costa Rica, will be carried out from January to June 2012.

On-line and face-to-face meetings will allow permanent communication with INCAP and with collaborators from Harvard University and University of Michigan.

The National Heart, Lung and Blood Institute –NHLBI-, cooperating agency, schedules monthly telephone conferences with the researchers in order to discuss the improvements and events related to the activities of the Center of Excellence, CIIPEC, their researches, and this study.

## 20. Storage of Biological Samples

A duplicate, or repository sample of the biological samples (blood, adipose tissue, hair, nails, saliva, and urine), will be stored for future analysis of genetic factors related to cardiovascular diseases. A specific consent form will be used for this matter. Sample confidentiality will be kept as described in Section 10.2 “Protection against Risks”, page 14. The participants of this study will be the source of repository biological samples, only if they accept during the informed consent process. Any participant of this study may decide whether or not to have a repository sample stored without affecting his or her participation.

The samples will be stored at INCAP’s laboratories (inside -20°C freezers) for up to 5 years, and will be under the responsibility of INCAP. After the period is due, the stored samples and/or remains will be discarded.

During the storage period the only persons that will have direct access will be from the participant institutions in this study (INCAP, University of Michigan and Harvard University). The biological samples might be analyzed by other researchers or institutions as long as they have a written authorization from the main researchers. They must make sure that the samples will be used and analyzed with the same ethical care/concern of this study; approved by Ethics Committees registered at the Office for Human Research Protection (OHRP) of the Department of Health and Human Services of the United States of America.

## 21. Cited Literature

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Factores dietéticos asociados con riesgo de enfermedades cardiovasculares en escolares y sus padres en Mesoamérica



Form No. 1

GENERAL DATA, HEALTH CONDITION  
AND PHYSICAL ACTIVITY ADDRESSED TO THE MOTHER

ID	<input type="text"/>
Starting time:	<input type="text"/>
Name (initials):	Date: <input type="text"/>
Interviewer's ID:	<input type="text"/>

FMD. General Data		
FMD1	Where were you born? Country:	<input type="text"/>
FMD11	Department or Province:	<input type="text"/>
FMD2	Age (years)	<input type="text"/>
FMD21	Date of Birth	<input type="text"/>
FMD3	Do you speak another language besides Spanish? 1. Yes 2.No	<input type="text"/>
FMD31	If the answer is YES, which one? _____	<input type="text"/>
FMD4	Are you able to read and write? 1. Yes 2. No	<input type="text"/>
FMD5	What was the last year you completed in school? <div style="display: flex; justify-content: space-around;"> <div style="text-align: center;"> <p>School</p> <p><input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/></p> <p>1 2 3 4 5 6 7 8 9 10 11 12</p> </div> <div style="text-align: center;"> <p>College</p> <p><input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/></p> <p>14 15 16 17 18 19 20 21</p> </div> </div>	<input type="text"/>
FMD6	What is your marital status? 1. Married 2. Unmarried Partner	<input type="text"/>
FMD7	Do you currently have a paying job? 1. Yes 2. No	<input type="text"/>
FMD 8	What is your current job or occupation?	<input type="text"/>
FMD9	What is your profession?	<input type="text"/>
FMD10	How many hours a day do you work?	<input type="text"/>

Factores dietéticos asociados con riesgo de enfermedades cardiovasculares en escolares y sus padres en Mesoamérica

FMC. Household Characteristics			
FMC1.	How many people live in the same household, that is, under the same roof?		
FMC2.	The house you live in is: 1. Own                    2. Rented            3. Borrowed 4. Other		
FMC3.	How many bedrooms does your house have?		
FMC4.	The roof of your house is made of: 1. Metal/Tin sheet   2. Roof tiles   3. Concrete   4. Other		
FMC5.	The floor of your house is made of: 1. Dirt floor            2. Concrete   3. Tile floor   4. Other		
FMC6.	The walls of your house are made of: 1. Cardboard          2. Adobe       3. Wood        4. Brick/Block   5. Other		
FMC7.	The water you use in your house comes from: 1. Faucet /public well/river    2. House well    3. Aqueduct /piped water		
FMC8.	In the bathroom of your house there is: 1. You do not have   2. Latrine /Septic tank    3. Toilet		
FMC9.	In the following list, mark each service you have in your house: 1. Yes                    2. No		
FMC91	Cable TV		FMC94 Natural Gas
FMC92	Sewage system		FMC95 Base phone
FMC93	Electricity		FMC96 Mobile phone
FMC10.	In the following list mark each item you own 1. Yes                    2. No		
FMC101	Car		FMC108 Microwave oven
FMC102	Bicycle		FMC109 Washing machine
FMC103	Refrigerator		FMC1010 Color TV
FMC104	Gas stove		FMC1011 Sound Equipment
FMC105	Electric stove		FMC1012 Computer
FMC 106	Blender		FMC1013 Internet Service
FMC107	Inverter		

**Factores dietéticos asociados con riesgo de enfermedades cardiovasculares en escolares y sus padres en Mesoamérica**

FMC11.	What is your family's monthly income? Dollars 1. 100 or less      2. 101-200      3. 200 -400      4. 401-600      5. 601-800 6. 801-1000      7. More than de 1000	
FMC12.	How much does your family spend on food per month? (in dollars)	
<b>FMO. Obstetric and Breastfeeding Information</b>		
FMO1	Edades de sus hijos y otros niños a su cargo: (del mayor al menor)  _____ 1      2      3      4      5      6      7      8      9      10	
FMO2	Have you been pregnant durign the last 12 months? 1. Yes      2. No      9. NR	
FM03	How many of your children have been breastfed?	
FM04	Have you breastfed your child during the last 12 months? 1. Yes      2. No      9. NR	
FM05.	Are you currently breastfeeding? 1. Yes      2. No      9. NR	
FM06	How many pregnancies have you had?	
FM07	Of all your pregnancies, how many children were born alive?	
FMC08	How many of your children are alive?	
FMC09	Ages of your children and other children under your care: (from eldest to youngest)  _____ 1      2      3      4      5      6      7      8      9      10	
FMC010	At what age (years and months) did you have your menarche? ____years ____months	
<b>FME. Health Condition and Risk Factors</b>		
FME1.	How would you describe your health? 1. Excellent    2. Very good    3. Good    4. Regular    5. Poor	
FME2.	Of the following diseases, have you ever been told by a doctor that you suffer or have suffered from? 1. Yes      2. No      9. NR	
	1. High sugar level or diabetes	
	2. Hypertension	
	3. High cholesterol	

**Factores dietéticos asociados con riesgo de enfermedades cardiovasculares en escolares y sus padres en Mesoamérica**

	<p>4. Heart attack or infarction</p> <p>5. Cancer. If the answer is affirmative, specify _____</p> <p>6. Cerebrovascular accident</p> <p>7. Asthma</p> <p>8. Bronchitis or emphysema</p> <p>9. Arthritis</p> <p>10. Other _____</p>	_____
FME3	<p>Are you currently under any medical treatment?</p> <p>1. Yes                      2. No</p>	_____
FME31	<p>If the answer is YES, specify the treatment.</p> <p>Treatment 1                      Treatment 4 _____</p> <p>Treatment 2                      Treatment 5 _____</p> <p>Treatment 3                      Treatment 6 _____</p>	_____
FME4	<p>Have you ever smoked cigarettes or cigars?</p> <p>1. Yes                      2. No (Go to section FMA)</p>	_____
FME5	<p>How old were you when you started smoking regularly?</p>	_____
FME6	<p>Do you currently smoke?    1. Yes    2. No    9. NR</p>	_____
FME7	<p>How old were you the last time you smoked tobacco?</p>	_____
FME8	<p>Approximately, how many cigarettes/cigars did you smoke in</p> <p>1. One day                      2. One week                      _____</p> <p>3. A month                      _____</p>	_____
<b>FMA. Family Disease History</b>		
FMA1.	<p>Did your father, mother, grandfather, or grandmother suffered from any of these diseases?</p> <p>1. Yes                      2. No                      9. NR</p>	_____
	<p align="center">Mother                      Father                      Grandfather M                      Grandmother M                      Grandfather F                      Grandmother F</p>	
FMA11. Diabetes	_____	_____
FMA12 Hyper-tension	_____	_____
FMA13 Heart Attack or Infarction	_____	_____
FMA 14 Cancer	_____	_____



Factores dietéticos asociados con riesgo de enfermedades cardiovasculares en escolares y sus padres en Mesoamérica

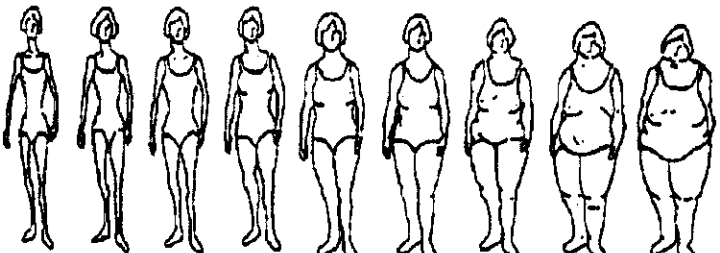
FMA15. Cerebro - vascular accident						
FMA16 Asthma						
FMA17 Chronic bronchitis	_____	_____	_____	_____	_____	_____
FMA18 Tubercu- losis	_____	_____	_____	_____	_____	_____
FMA19 Other						
<b>FMI. Food Security</b>						
Respond with a YES or a NO to the following questions:						
		1. Yes	2. No			
FMI1.	During the last 3 months, did you ever worry that food might run out at home due to the lack of money?					_____
FMI2.	During the last 3 months, did food ever run out due to the lack of money?					_____
FMI3.	During the last 3 months, did you ever run out of money or resources that allowed you to have healthy and varied nutrition?					_____
FMI4.	During the last 3 months, did you or any adult in your home have a poor variety of food due to the lack of money and resources?					_____
FMI5.	During the last 3 months, did you or any adult in your home was not able to have breakfast, lunch or supper, due to the lack of money?					_____
FMI6.	During the last 3 months, did any adult in your home eat less than what you think is necessary, due to the lack of money?					_____
FMI7.	During the last 3 months, did you or any adult in your home was hungry and did not eat due to the lack of money?					_____
FMI8.	During the last 3 months, did you or any adult in your home had only one meal or did not eat throughout the day, due to the lack of money?					_____
FMI9.	During the last 3 months and due to the lack of money, did you have to do something that you would rather not do due in order to get food?					_____
FMI10	During the last 3 months, did anyone under 18 years of age in your home not receive adequate and varied nutrition due to the lack of money?					_____
FMI11.	During the last 3 months, did anyone under 18 years of age in your home have poor nutrition variety due to the lack of money?					_____



Factores dietéticos asociados con riesgo de enfermedades cardiovasculares en escolares y sus padres en Mesoamérica

<b>FMS. Sleep and Physical Activity</b>													
Ask questions FMS1-FMS7 if the answer to FMC1010 is affirmative.													
FMS1.	How many TVs do you have at home?												
FMS2.	Do you have a TV in your bedroom or where you eat? 1. Yes                      2. No												
FMS3.	Do you have TV in your bedroom?                      1. Yes                      2.No												
FMS4.	From Monday through Friday, how many hours do you watch TV sitting or lying down?												
FMS5.	During the weekend, how many hours do you watch TV sitting or lying down?												
FMS6.	How frequently do you eat sitting in front of the TV? 1. Always                      2. Sometimes                      3. Never (go to FMS8)												
FMS7.	If the answer to the previous question is 1 or 2, how many hours do you watch TV and eat at the same time?												
FMS8.	From Monday through Friday, how many hours do you usually sleep?												
FMS9.	During weekends, how many hours do you usually sleep?												
FMS10.	Is it hard for you to fall asleep?    1. Yes                      2. No                      3. Sometimes												
FMS11.	Do you wake up during the night? 1. Si                      2.No                      3. Sometimes												
FMS12.	If the previous answer is yes, how long do you stay awake?												
FMS13.	Do you need help to eat, wash, or move around the house, due to any handicap or health difficulty? 1. Yes (ask only questions FMS15-20)                      2. No												
FMS14.	Due to any handicap or health problem, do you need help for your daily routine such as household chores, going to the bank, shopping or going out of the house for any other reason?    1. Yes                      2. No												
Please, answer if you did the following activities, and how frequently you did them last year, ON AVERAGE.													
<table style="width: 100%; border: none;"> <tr> <td style="width: 50%;">0= Never</td> <td style="width: 50%;">5= 2-4 times a week</td> </tr> <tr> <td>1= &lt; than once a month</td> <td>6= 5-6 times a week</td> </tr> <tr> <td>2= Once a month</td> <td>7= Once a day</td> </tr> <tr> <td>3= 2-3 times a month</td> <td>8= 2-3 times a day</td> </tr> <tr> <td>4= Once a week</td> <td>9= 4-5 times a day</td> </tr> <tr> <td></td> <td>10= 6 times a day</td> </tr> </table>		0= Never	5= 2-4 times a week	1= < than once a month	6= 5-6 times a week	2= Once a month	7= Once a day	3= 2-3 times a month	8= 2-3 times a day	4= Once a week	9= 4-5 times a day		10= 6 times a day
0= Never	5= 2-4 times a week												
1= < than once a month	6= 5-6 times a week												
2= Once a month	7= Once a day												
3= 2-3 times a month	8= 2-3 times a day												
4= Once a week	9= 4-5 times a day												
	10= 6 times a day												
During the last twelve months how often, on average?													

**Factores dietéticos asociados con riesgo de enfermedades cardiovasculares en escolares y sus padres en Mesoamérica**

FMS15	Did you take a nap (30 minutes)?	_____
FMS16	Did you LIE DOWN to watch TV, read, listen to music (30 minutes)?	_____
FMS17	Did you REMAIN SEATED while working, reading, eating, driving, watching TV, playing electronic games (1 hour)?	_____
FMS18	DID YOU STAND while carrying out effortless activities (1 hour)? At work (filing, photocopying, writing, customer service)? At home (i.e.: washing dishes, dusting, cooking, tidying up, etc.)	_____
FMS19	DID YOU REMAIN STANDING WHILE CLEANING (1 hour)? i.e.: sweeping, moping, washing (windows, clothes, etc.)?	_____
FMS20	DID YOU REMAIN STANDING UP AND BENDING DOWN IN GARDENING CHORES (1 hour)? (weeding, watering, pruning)	_____
FMS21	DID YOU DO LIGHT AGRICULTURAL WORK (1 hour)? Harvesting coffee, planting, watering, manuring	_____
FMS22	DID YOU WALK ON FLAT TERRAIN IN THE CITY?	_____
FMS23	DID YOU CARRY OUT TOUGH CHORES THAT MADE YOU SWEAT (1 hour)? Shoveling, plating, making ditches, cutting down trees)?	_____
FMS24	DID YOU WALK ON MOUNTAINOUS TERRAINS (30 minutes) (farms, ranch, mountains)	_____
FMS25	DID YOU CLIMB STEPS (1 floor)?	_____
FMS26	DID YOU PRACTICE TEAM SPORTS? (30 minutes) (football, basketball, volleyball)	_____
FMS27	DID YOU PRACTICE INDIVIDUAL SPORTS (30 minutes)? (Jogging, cycling, swimming, etc.)	_____
FMS28	DID YOU PRACTICE SOME OTHER SPORT (30 minutes)?	_____
FMS281	Specify _____	_____
FMS29	DID YOU MOVE OR LIFT HEAVY THINGS THAT MADE YOU SWEAT (30 minutes)? Furniture, boxes, a person, water, luggage, etc.	_____
<b>FMP. Body Perception</b>		
FMP1.	Approximately, how much do you weigh? (kg)	_____
FMP2	Approximately, how tall are you? (m)	_____
FMP3.	Of these illustrations, which one: (write the corresponding number) Display card.	_____
		_____

Factores dietéticos asociados con riesgo de enfermedades cardiovasculares en escolares y sus padres en Mesoamérica

	1	2	3	4	5	6	7	8	9	
FMP31	Do you think that looks like you at the present.									
FMP32	Is how you would like to look.									
FMP33	Do you think is the healthiest.									
FMP34	During the last 12 months, have you tried to lose weight?									
	1. Yes	2. No							9. NR	
FMP35	During the last 12 months, have you followed a food regime, or have you ever stopped eating any particular food?									
	1. Yes	2. No							9. NR	



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FND14	If you do not remember the exact date, at what age did she have her first menstruation? Years ___ months ___	
FND15	Has a doctor ever told you that your child suffers from any of these diseases? Yes 2. No 9. NR FND151. Asthma _____ FND154. Malnutrition _____ FND152. Allergies _____ FND155. Overweight and obesity _____ FND153 Pneumonia _____ FND156. Others _____	1. _____
<b>FNH</b>	<b>Dietary History of the Child</b>	
FNH1	Did you breastfeed your child? If the answer is 2, go to question FNH2 1. Yes 2. No	
FNH11	How long did you breastfeed your child? Days/weeks /months	_____ days _____ weeks _____ months
FNH2	Did you fed him/her with formula? If the answer is 2 go to question FNH3	1. Yes 2. No
FNH21	How old was the baby when you fed him/her with formula?	_____ days _____ weeks _____ months
FNH4	Do you have control over what your child eats at school? 1. Yes 2. No	
FNH5	How many proper meals does your child have while he is not at school?	
FNH6	Does he/she eat between meals? 1. Yes 2. No	
FNH7	Do you usually reward him/her with food? 1. Yes 2. No	
FNH8	How many times a week does your child eat the main meal out (restaurant, cafeteria, food posts on the street)?	
<b>FNF.</b>	<b>Physical Activity of the Child</b>	
FNF1	During the 5 school days, how does your child go to school? 1. Walking 2. Public bus 3. Car /motorcycle /school bus	
FNF2	How does your child return home more often? 1. Walking 2. Public bus 3. Car /motorcycle /school bus	
FNF3	How many blocks to and from school does your child walk each day?	
FNF4	Besides the distance he/she walks to and from school, how many blocks does he/she walk to go from one place to another (errands, visits, etc.)?	
FNF5	From Monday through Friday, how many hours, on average, does your child play outdoors?	
FNF6	During the weekend, how many hours, on average, does your child play outdoors?	
FNF7	Does your child practice any sport (football, baseball, basketball, etc.) or dances? 1. Yes 2. No (Go to FNF10)	

Factores dietéticos asociados con riesgo de enfermedades cardiovasculares en escolares y sus padres en  
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FNF8	How many times a week does he/she practice it?	
FNF9	For how many hours, on average, each day?	
FNF10	How many days a week does your child use the bicycle or skateboard? 0 = don't use (go to question FNF11)	
FNF101	For how many hours a day does he /she use it?	
FNF11	Does your child have a TV in his/her bedroom?      1. Yes      2. No	
FNF12	On how many school days does your child watch TV before leaving for school?	
FNF13	On school days, how many hours does he/she watch TV?	
FNF14	During weekends, how many hours a day does he/she watch TV?	
FNF15	How many days a week does your child eat while watching TV?	
FNF16	On average, how many hours does your child eat while watching TV?	
FNF17	How many days a week does your child play electronic games in the computer or TV?	
FNF18	On school days, how many hours, on average, does he/she play in the computer?	
FNF19	During weekends, how many hours does he play in front of a screen?	





Factores dietéticos asociados con riesgo de enfermedades cardiovasculares en escolares y sus padres en  
Mesoamérica

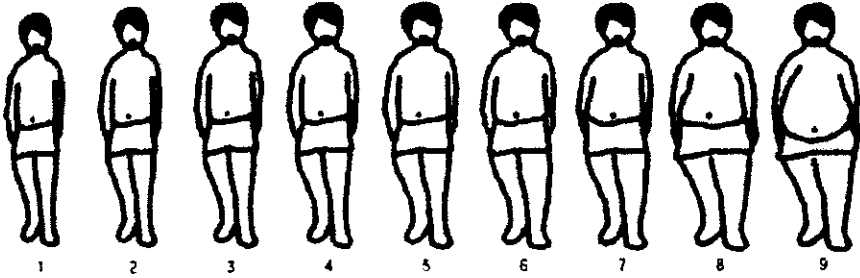
FPE. Health Condition and Risk Factors		
FPE1.	How would you describe your health? 1. Excelente 2. Very good 3. Good 4. Regular 5. Poor	
FPE2.	Of the following diseases, have you ever been told by a doctor that you suffer or have suffered from: 1. Yes 2. No	
	1. High sugar level or diabetes	
	2. Hypertension	
	3. High cholesterol	
	4. Heart attack or infarction	
	5. Cancer. If the answer is affirmative, specify _____	
	6. Cerebrovascular accident	
	7. Asthma	
	8. Bronchitis or emphysema	
	9. Arthritis	
	10. Other _____	
FPE3	Are you currently under any medical treatment? 1. Yes 2. No	
FPE31	If the answer is YES, specify the treatment. Treatment 1 _____ Treatment 4 _____ Treatment 2 _____ Treatment 5 _____ Treatment 3 _____ Treatment 6 _____	
FPE4	Have you ever smoked cigarettes or cigars? 1. Yes 2. No (Go to section FMA)	
FPE5	How old were you when you started smoking regularly?	_____
FPE6	Do you currently smoke? 1. Yes 2. No 9. NR	_____
FPE7	How old were you the last time you smoked tobacco?	_____
FPE8	Approximately, how many cigarettes/cigars did you smoke in 1. One day _____ 2. One week _____ 3. A month _____	

Factores dietéticos asociados con riesgo de enfermedades cardiovasculares en escolares y sus padres en  
Mesoamérica

<b>FPA. Family Disease History</b>							
Did your father, mother, grandfather or grandmother suffered from any of these diseases?							
1. Yes      2. No      9. NR							
		Mother	Father	Grand- father M	Grand- mother M	Grandfather F	Grandmother F
FPA1	Diabetes						
FPA2	Hypertension						
FPA3	Heart attack or Infarction						
FPA4	Cancer						
FPA5	Cerebrovascul ar accident						
FPA6	Asthma						
FPA7	Chronic bronchitis						
FPA8	Tuberculosis						
FPA9	Others						
<b>FPS. Sleep and Physical Activity</b>							
Ask questions FPS1-FPS5 if FMC1010 is positive							
FPS1	Do you have TV in your bedroom?			1. Yes	2. No	3. Dont have (go to FPS8)	
FPS2	From Monday through Friday, how many hours do you watch TV?						:
FPS3	During weekends, how many hours do you watch TV?						:
FPS4	How frequently do you eat sitting in front of the TV?						
	1. Always		2. Sometimes		3. Never (go to FMS8)		
FPS5	If the answer to the previous question is 1 or 2, how many hours do you watch TV and eat at the same time?						:
FPS6	From Monday through Friday, how many hours do you usually sleep?						
FPS7	During weekends, how many hours do you usually sleep ?						
FPS8	Is it hard for you to fall asleep?			1. Yes	2. No	3. Sometimes	
FPS9	Do you wake up during the night?			1. Yes	2.No	3. Sometimes	
FPS10	If the previous answer is yes, how long do you stay awake?						:

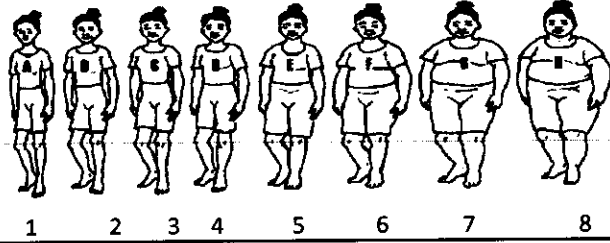


Factores dietéticos asociados con riesgo de enfermedades cardiovasculares en escolares y sus padres en Mesoamérica

FPS271	Specify	
FPS28	DID YOU MOVE OR LIFT HEAVY THINGS THAT MADE YOU SWEAT (30 minutes)? Furniture, boxes, a person, water, luggage, etc.	
<b>FPP. Body Perception</b>		
FPP1	Approximately, how much do you weigh? (kg)	
FPP2	Approximately, how tall are you? (m)	
FPP3	Of these illustrations, which one: (write the corresponding number). Display the card	
		
FPP31	Do you think that looks like you at the present	
FPP32	Is how you would like to look	
FPP33	Do you think is the healthiest	
FPP34	During the last 12 months, have you tried to lose weight? 1. Yes      2. No      9. NR	
FPP35	During the last 12 months, have you followed a food regime, or have you ever stopped eating any particular food? 1. Yes      2. No      9. NR	



Factores dietéticos asociados con riesgo de enfermedades cardiovasculares en escolares y sus padres en Mesoamérica

FNA3	How long is school recess?	_____:
FNA4	What do you do during school recess?	_____
<b>FNC</b>	<b>Body Perception</b>	
FNC1	<p>Of these illustrations, which one: (write the corresponding number indicated by the child)</p> <p>Note: Images differ in the form for boys.</p>  <p style="text-align: center;">1      2      3      4      5      6      7      8</p>	
FNC2	Do you think that looks like you at the present	_____
FNC3	Is how you would like to look	_____
FNC4	Do you think is the healthiest	_____
FNC5	<p>During the last 12 months, have you tried to lose weight?</p> <p style="text-align: center;">1. Yes      2. No      9. NR</p>	_____
FNC6	<p>During the last 12 months, have you been on a diet or have you ever stopped eating any particular food?</p> <p style="text-align: center;">1. Yes      2. No      9. NR</p>	_____

Factores dietéticos asociados con riesgo de enfermedades cardiovasculares en escolares y sus padres en Mesoamérica



Factores dietéticos asociados con riesgo de enfermedades cardiovasculares en escolares y sus padres en Mesoamérica.

Form No. 5

FOOD FREQUENCY QUESTIONNAIRE

ID	_____
Starting time:	_____
Name (Initials):	Date: ____/____/____
Technician's ID:	_____

Instructions: Now we will talk about what you have eaten in the past 12 months.

Filling instructions: Circle the number corresponding to each square.

**During the past 12 months, how frequently did you eat, on average, the following foods?**

		Never or < than once a month	1-3 times a month	Once a week	2-4 times a week	5-6 times a week	Once a day	2-3 times a day	4-5 times a day	6+ times a day
DL	<b>DAIRIES</b>									
DL1	Milk (liquid o powder, 1 glass)	1	2	3	4	5	6	7	8	9
DL2	Hard/dry cheese (1 slice)	1	2	3	4	5	6	7	8	9
DL3	Sliced American cheese (1)	1	2	3	4	5	6	7	8	9
DL4	Fresh/cottage/ cheese (1 slice)	1	2	3	4	5	6	7	8	9
DL5	Cream cheese (1 tbs)	1	2	3	4	5	6	7	8	9
DL6	Cream (1tbs)	1	2	3	4	5	6	7	8	9
DF	<b>FRUITS</b>									
DF1	Pineapple (1 slice)	1	2	3	4	5	6	7	8	9
DF2	Papaya/pawpaw (1 slice)	1	2	3	4	5	6	7	8	9
DF3	Bananas (1)	1	2	3	4	5	6	7	8	9



**Factores dietéticos asociados con riesgo de enfermedades cardiovasculares en escolares y sus padres en Mesoamérica**

DF4	Mangoes (1)	1	2	3	4	5	6	7	8	9
DF5	Oranges (1)	1	2	3	4	5	6	7	8	9
DF6	Orange juice (1 small glass)	1	2	3	4	5	6	7	8	9
DF7	Have you eaten another fruit in the past 3 months?									
	0=NO (go to VEGETABLES)									
	1=YES (Which one? Write it down.)									
DF8		1	2	3	4	5	6	7	8	9
DF9		1	2	3	4	5	6	7	8	9
DF10		1	2	3	4	5	6	7	8	9
DV	<b>VEGETABLES</b>	Never or < than once a month	1-3 times a month	Once a week	2-4 times a week	5-6 times a week	Once a day	2-3 times a day	4-5 times a day	6+ times a day
DV1	Tomato/natural sauce/chirmol (½ cup)	1	2	3	4	5	6	7	8	9
DV2	Cabbage (½ cup)	1	2	3	4	5	6	7	8	9
DV3	Lettuce (½ cup)	1	2	3	4	5	6	7	8	9
DV4	Avocado (¼ unit)	1	2	3	4	5	6	7	8	9
DV5	Carrot (½ cup)	1	2	3	4	5	6	7	8	9
DV6	Cucumber (½ cup)	1	2	3	4	5	6	7	8	9
DV7	Ayote (½ cup)	1	2	3	4	5	6	7	8	9
DV8	Güisquil/chayote (½ cup)	1	2	3	4	5	6	7	8	9
DV9	Spinach (½ cup)	1	2	3	4	5	6	7	8	9
DV10	Green beans (½ cup)	1	2	3	4	5	6	7	8	9
DV11	Cauliflower (½ cup)	1	2	3	4	5	6	7	8	9
DV12	Broccoli (½ cup)	1	2	3	4	5	6	7	8	9
DV13	Radish (½ cup)	1	2	3	4	5	6	7	8	9
DV14	White or yellow corn (1/3)	1	2	3	4	5	6	7	8	9
DV15	Herb and green leaves (½ cup)	1	2	3	4	5	6	7	8	9
DV16	Ripen, green plantains (½ cup)	1	2	3	4	5	6	7	8	9

**Factores dietéticos asociados con riesgo de enfermedades cardiovasculares en escolares y sus padres en Mesoamérica**

DV17	Potato (1)	1	2	3	4	5	6	7	8	9
DV18	Yucca/cassava/taro (1/3 unit)	1	2	3	4	5	6	7	8	9
DV19	Have you eaten another vegetable in the last 3 months?									
	0 =NO (go to Eggs-Meats)									
	1=YES (Which one? Write it down.)									
DV20		1	2	3	4	5	6	7	8	9
DV21		1	2	3	4	5	6	7	8	9
DH	<b>EGGS-MEATS</b>	Never or < than once a month	1-3 times a month	Once a week	2-4 times a week	5-6 times a week	Once a day	2-3 times a day	4-5 times a day	6+ times a day
DH1	Hard-boiled egg (1)	1	2	3	4	5	6	7	8	9
DH2	Fried/scrambled/minced egg (1)	1	2	3	4	5	6	7	8	9
DH3	Chicken meat in soups, stew, pie (1 portion)	1	2	3	4	5	6	7	8	9
DH4	Fried or roasted chicken	1	2	3	4	5	6	7	8	9
DH5	Beef, pork, or bacon in soup, minced, stew, pies (1 portion)	1	2	3	4	5	6	7	8	9
DH6	Beef or pork as main dish (1 portion)	1	2	3	4	5	6	7	8	9
DH7	Atún o sardinas enlatadas (1 porción)	1	2	3	4	5	6	7	8	9
DH8	Canned tuna fish or sardine (1 portion)	1	2	3	4	5	6	7	8	9
DH9	Pork cracklings (¼ cup)	1	2	3	4	5	6	7	8	9
DH10	Meat patty (1)	1	2	3	4	5	6	7	8	9
DH11	Entrails (beef or chicken giblets or liver)	1	2	3	4	5	6	7	8	9
DE	<b>SAUSSGES</b>	Never or < than once a month	1-3 times a month	Once a week	2-4 times a week	5-6 times a week	Once a day	2-3 times a day	4-5 times a day	6+ times a day
DE1	Ham (1 slice)	1	2	3	4	5	6	7	8	9
DE1.2	¿What brand of ham do you buy?									
DE2	Mortadella/Salami	1	2	3	4	5	6	7	8	9

**Factores dietéticos asociados con riesgo de enfermedades cardiovasculares en escolares y sus padres en Mesoamérica**

DE3	Sausage (1)	1	2	3	4	5	6	7	8	9
DE4	Pork sausage/chorizo (1)	1	2	3	4	5	6	7	8	9
DP	<b>BREADS, FLOURS, CEREALS</b>	Never or < than once a month	1-3 times a month	Once a week	2-4 times a week	5-6 times a week	Once a day	2-3 times a day	4-5 times a day	6+ times a day
DP1	Rice (2/3 cup)	1	2	3	4	5	6	7	8	9
DP2	Whole/smashed/grinded beans (1/3 cup)	1	2	3	4	5	6	7	8	9
DP3	Refried beans (1/3 cup)	1	2	3	4	5	6	7	8	9
DP4	Noodles, macaroons, spaghettis (1 cup)	1	2	3	4	5	6	7	8	9
DP5	White bread, roll, bun, baguette (1 portion)	1	2	3	4	5	6	7	8	9
DP6	Sweet bread, toasted bread (1 portion)	1	2	3	4	5	6	7	8	9
DP7	Flour tortilla (1)	1	2	3	4	5	6	7	8	9
DP8	Corn tortilla (1)	1	2	3	4	5	6	7	8	9
DP9	Atole (any type ½ cup)	1	2	3	4	5	6	7	8	9
DP10	Fortified beverages (Incaparina, Bienestarina)	1	2	3	4	5	6	7	8	9
DP11	Oats without milk (½ cup)	1	2	3	4	5	6	7	8	9
DP12	Oats with milk (½ cup)	1	2	3	4	5	6	7	8	9
DP13	Other corn products such as pastry/pies, pupusas, fried corncakes, roasted tamale (1)	1	2	3	4	5	6	7	8	9
DP14	Breakfast cereal, for example Cornflakes (1 cup)	1	2	3	4	5	6	7	8	9
DP14.1	¿What brand of breakfast cereal do you buy?									
DB	<b>BEVERAGES</b>	Never or < than once a month	1-3 times a month	Once a week	2-4 times a week	5-6 times a week	Once a day	2-3 times a day	4-5 times a day	6+ times a day
DB1	Diet soda beverages (1)	1	2	3	4	5	6	7	8	9
DB2	Regular soda beverages (1)	1	2	3	4	5	6	7	8	9

**Factores dietéticos asociados con riesgo de enfermedades cardiovasculares en escolares y sus padres en Mesoamérica**

DB3	Natural beverages (lemonade, berry, pineapple, tamarind, cas, guava, etc. (1 glass))	1	2	3	4	5	6	7	8	9
DB4	Coffee	1	2	3	4	5	6	7	8	9
DB5	Chocolate	1	2	3	4	5	6	7	8	9
DB6	Energizing beverages (Red Bull, Adrenaline, or others)	1	2	3	4	5	6	7	8	9
DB7	Beer (any type) (1 glass)	1	2	3	4	5	6	7	8	9
DB8	Liquor (rough liquor/rum/tequila) (1drink)	1	2	3	4	5	6	7	8	9
DB9	Wine (1 glass)	1	2	3	4	5	6	7	8	9
DB10	Non-alcoholic malt	1	2	3	4	5	6	7	8	9
DR	<b>FAST FOOD</b>	Never or < than once a month	1-3 times a month	Once a week	2-4 times a week	5-6 times a week	Once a day	2-3 times a day	4-5 times a day	6+ times a day
DR1	Hamburgers (1 portion)	1	2	3	4	5	6	7	8	9
DR2	Hot dog (1 portion)	1	2	3	4	5	6	7	8	9
DR3	Pizza(1 portion)	1	2	3	4	5	6	7	8	9
DR4	Sandwich/submarines (1 portion)	1	2	3	4	5	6	7	8	9
DR5	Corn toasts or tacos of any type (1 portion)	1	2	3	4	5	6	7	8	9
DD	<b>CANDIES, PASTRIES, OTHERS</b>	Never or < than once a month	1-3 times a month	Once a week	2-4 times a week	5-6 times a week	Once a day	2-3 times a day	4-5 times a day	6+ times a day
DD1	Candies, caramels (1)	1	2	3	4	5	6	7	8	9
DD2	Pound cake/sponge cake/pastries/packaged pastries (75-150g presentation)	1	2	3	4	5	6	7	8	9
DD3	Desserts such as rice pudding, three milk cake, crème caramel, jelly (1 portion)	1	2	3	4	5	6	7	8	9
DD4	Ice-cream (1 portion)	1	2	3	4	5	6	7	8	9
DD5	Fried snacks of any type, size, or brand (1 portion)	1	2	3	4	5	6	7	8	9
DD6	What brand of snacks do you buy?									
DD7	Sweet cookies with filling, such as sandwich (1 portion)	1	2	3	4	5	6	7	8	9

**Factores dietéticos asociados con riesgo de enfermedades cardiovasculares en escolares y sus padres en Mesoamérica**

DD8	Galletas saladas tipo soda	1	2	3	4	5	6	7	8	9
DD9	Salted cookies with filling, sandwich type (1 portion)	1	2	3	4	5	6	7	8	9
DD10	What brand of cookies do you usually buy?									
DD11	Peanuts (1 portion)	1	2	3	4	5	6	7	8	9
DD12	Cashew (1 portion)	1	2	3	4	5	6	7	8	9
DC	<b>SUPPLEMENTS / AGGREGATES / OTHERS</b>	Never or < than once a month	1-3 times a month	Once a week	2-4 times a week	5-6 times a week	Once a day	2-3 times a day	4-5 times a day	6+ times a day
DC1	How much sugar (tsp) do you add to coffee, tea, or chocolate?	Teaspoon   _     _								
DC2	Ketchup (¼ cup)	1	2	3	4	5	6	7	8	9
DC3	Worcester sauce (1 tbs)	1	2	3	4	5	6	7	8	9
DC4	Powder/dice beef or chicken consomme (1tsp)	1	2	3	4	5	6	7	8	9
DC5	What brand of powder consomme do you buy?									
DC6	Clear soup: noodles and chicken, rice and chicken (1 portion)	1	2	3	4	5	6	7	8	9
DC6.1	What brand of clear soup do you buy?									
DC7	Instant soup: chicken/beef/shrimp (1 portion)	1	2	3	4	5	6	7	8	9
DC7.1	What brand of instant soup do you buy?									
DG	<b>GREASES AND OILS</b>	Never or < than once a month	1-3 times a month	Once a week	2-4 times a week	5-6 times a week	Once a day	2-3 times a day	4-5 times a day	6+ times a day
DG1	Margarine or butter added to the food (1 tbs)	1	2	3	4	5	6	7	8	9
DG2	Dressings such as Thousand Islands/ranch/mustard/mayonnaise for sandwiches (1 tbs)	1	2	3	4	5	6	7	8	9
DG3	Margarine (1 tbs) (If the answer is never, go to DG5)	1	2	3	4	5	6	7	8	9















**Factores dietéticos asociados con riesgo de enfermedades cardiovasculares  
en escolares y sus padres en Mesoamérica.**

**Form No. 9.1**

**Determination of Hematocrit from the Blood Sample**

**General Information**

Starting time:	_____ : _____
Date:	____/____/____
Technician's ID:	____ ____ ____

Participant's ID	Hematocrit Value	Time		Observations
		Hour	Min	
____ ____ ____ ____ ____	_____	_____	_____	
____ ____ ____ ____ ____	_____	_____	_____	
____ ____ ____ ____ ____	_____	_____	_____	



Factores dietéticos asociados con riesgo enfermedades cardiovasculares  
en escolares y sus padres en Mesoamérica.

Form No. 10

PHYSICAL ACTIVITY PEDOMETER

1. ID: <input style="width: 100%;" type="text"/>			2. Date: <input style="width: 100%;" type="text"/>			
3. Participant's ID (initials): <input style="width: 100%;" type="text"/>						
4. Pedometer: <input style="width: 100%;" type="text"/>						
5. Starting date: <input style="width: 100%;" type="text"/> Day of the week: M T W T F S S						
6. Starting time: <input style="width: 100%;" type="text"/>						
INFORMATION OF REGISTERED STEPS AND MVPA						
Saturday steps	Sunday steps	Monday steps	Tuesday steps	Wednesday steps	Thursday steps	Friday steps
MVPA	MVPA	MVPA	MVPA	MVPA	MVPA	MVPA
7. Finishing date: <input style="width: 100%;" type="text"/> Day of the week: M T W T F S S						
8. Finishing time: <input style="width: 100%;" type="text"/>						

Observation

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Factores dietéticos asociados con riesgo de enfermedades cardiovasculares en escolares y sus padres en Mesoamérica.

Form No. 11 FOOD SAMPLE COLLECTION FORM

Country ID	
Starting time:	:
Date:	/    /
Technician's ID:	

Sample/group of food	Food Brand	Units bought	Net Weight(g)	Characteristics/Presentation

Observations:





File Name: CENTER - CTSU Enterprise Network Transaction Engine for RAVE - Windows Internet \_2012-06-04\_11-50

Time: 11:52:28

Date: 6/4/2012



## Helpdesk

[Back to Menu](#)

Please enter CTEP ID or Email Address	
CTEP ID	<input style="width: 80%;" type="text"/>
CTEP EMAIL	<input style="width: 80%;" type="text"/>
<input type="button" value="Submit Request"/>	

### Information from MetaData

First Name	Susan
Last Name	Aach
Email Address	by123@westat.com
UUID	ce0c05e0-526e-11e1-bc10-1231381b81ee

### Information from CENTER

Uls	Operation Name	Message ID	Retry Count	Status	Status Text	Status Date	Relayed
1/2	CREATE_PARTIAL_USER	Person CTEP ID :17687	0	COMPLETED		2012-01-31 09:18:00.0	YES
1/2	CREATE_PARTIAL_USER	Person CTEP ID :21809	0	COMPLETED		2012-01-31 09:48:00.0	YES
1/2	CREATE_PARTIAL_USER	Person CTEP ID :19280	0	COMPLETED		2012-01-31 11:20:00.0	YES
1/2	CREATE_PARTIAL_USER	Person CTEP ID :20949	0	COMPLETED		2012-01-31 11:26:00.0	YES
1/2	CREATE_PARTIAL_USER	Person CTEP ID :18089	0	COMPLETED		2012-01-31 11:28:00.0	YES
1/2	CREATE_SITE	Organization CTEP ID:25118	0	COMPLETED		2012-01-31 12:02:00.0	YES
1/2	CREATE_SITE	Organization CTEP ID:37010	0	COMPLETED		2012-01-31 12:02:00.0	YES
1/2	CREATE_SITE	Organization CTEP ID:DC005	0	COMPLETED		2012-01-31 12:48:00.0	YES
1/2	CREATE_SITE	Organization CTEP ID:CT038	0	COMPLETED		2012-01-31 12:48:00.0	YES
1/2	CREATE_STUDYSITE	Site Registration :DC005:E1609	0	COMPLETED		2012-01-31 16:04:00.0	YES
1/2	INVITE_STUDY_USER	Invite User to Study USR_ID:485; Person: 20949, Study: , Role: READ ONLY	0	COMPLETED		2012-01-31 17:06:00.0	YES
1/2	ASSIGN_STUDYSITE	Study Site Assignment USS_ID:584; Person: 20949, Study: , Site: DC005	1	FAILED	Invalid User/Study/StudySite UUID or Duplicate StudySite assignment for User	2012-01-31 17:06:00.0	NO
1/2	INVITE_STUDY_USER	Invite User to Study USR_ID:490; Person: 21809, Study: E1609, Role: RAVE INVESTIGATOR	0	COMPLETED		2012-01-31 19:04:00.0	YES
1/2	ASSIGN_STUDYSITE	Study Site Assignment USS_ID:589; Person: 21809, Study: E1609, Site: DC005	0	COMPLETED		2012-01-31 19:04:00.0	YES
1/2	REMOVE_STUDY_USER	Remove User from Study USR_ID:490, Person: 21809, Study: E1609	0	COMPLETED		2012-01-31 19:10:00.0	YES

Monday, June 04, 2012 11:52:28 AM