RISK FACTORS FOR MISCARRIAGE IN ARMENIA

Master of Public Health Integrating Experience Project

Research Grant Proposal Framework

by

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ABSTRACT

Background: "*Miscarriage* is a spontaneous expulsion or extraction of an embryo or fetus weighing 500grams or less, corresponding to an expulsion prior to 20 weeks of pregnancy" (W.H.O). Miscarriage or occurs in every one in five pregnancies worldwide. Women who had in their life a miscarriage had a 45% chance to have retained tissue in their uterus, but if the required procedures are not performed a complication such as heavy bleeding can occur and without intervention there is a high probability that the woman will die. Also, women who are more predisposed to miscarriages are at risk not being able to have a full-term live birth.

Objectives: Investigation of women of reproductive age with or without miscarriage to find out the prevalence of miscarriage in Armenia, as well as highlight what are the risk factors for miscarriage and what are the interactions between different risk factors.

Methods and materials: Incidence density sampling will be used to assess the prevalence of miscarriage in Armenia. Two Yerevan tertiary maternity hospitals are going to be recruited for the study – Republic Institute of Reproductive Health, Perinatology, Obstetrics and Gynecology (RIRHPOG), as being a referral hospital and the other - "Erebuni" Medical center, as another hospital having a large number of births. Women from Yerevan and marzes that will participate in the study will receive care in the two selected hospitals. Study instrument includes interviewer administered questionnaire, data extraction form medical records with abstraction form, and laboratory analysis of blood test for identification of infections and chromosomal anomalies. The χ^2 test, simple logistic regression and multivariate logistic regression will be used to assess the relationships between study variables.

Ethical considerations: The proposal will be reviewed by the Institutional Review Board/Committee on Human Research (IRB) within College of Health Sciences at the American University of Armenia. Before starting data collection heads of maternity hospitals will be provided with a support letter. During interviews participants will be provided with oral consent form and be provided free choice to participate or not.

Team and budget: Research team will include principal investigator, interviewers, nurses and data enterers. The overall study will last for six months and two weeks. The budget needed to conduct the study is 10,916,800AMD.

Specific Aims

The purpose of the following research grant proposal is to determine the prevalence of miscarriage and identify the main risk factors and effect modifications between risk factors for miscarriage in Armenia. The main risk factors identified in the published literature for miscarriages include chromosomal anomalies, maternal/paternal age, parity, previous miscarriages, short pregnancy spacing, smoking, coffee drinking, alcohol consumption, first-trimester bleeding, BMI, uterine defects, antiphospholipid syndrome, infections, sleeping hours and trauma[1-13]. No studies were found in the literature concerning miscarriages' risk factors, rates and prevalence in Armenia. And as there was no information about the similarity of risk factors worldwide and particularly in Armenia this study will allow finding out and more deeply understand the risk factors of miscarriage in Armenia. By determining the major risk factors in Armenia we would be able to specify the most valuable one which will allow us to organize more widespread actions towards prevention of these particular risk factors. Looking at interactions between the risk factors will be another new thing done for the Armenia population.

Risk factors will be measured by questionnaire (maternal/paternal age, parity, previous miscarriages, short pregnancy spacing, smoking, coffee drinking, alcohol consumption, first-trimester bleeding, BMI, sleeping hours, trauma), and by data extraction from the medical records (uterine defects) and laboratory testing (chromosomal anomalies, antiphospholipid syndrome, infections).

For women who had in their lifetime at least one diagnosis of miscarriage had a 45% chance to have retained tissue in the uterus[14], and if the needed medical procedures are not performed a complication such as heavy bleeding can occur and as a result the woman can die. Miscarriages can also lead to infertility. This study will identify risks factors that can be

used for early identification of women at high risk for miscarriage for the prevention of complications and death. The prevention methods for miscarriages are known, but as the situation in Armenia is not known, so with exploring the risk factors in Armenia it will bring to a creation of a preventive strategy targeted to specific factors for Armenia.

This study will be the first known study of miscarriages in Armenia and the only study reviewed that will evaluate interactions between risk factors that could lead to new interventions to reduce the incidence of miscarriage.

The research questions addressed by the proposal are:

- What is the prevalence of miscarriage in Armenia?
- What are the demographic and behavioral risk factors (demographic, behavioral, genetic and medical) for miscarriage in Armenia?
- What are the interactions between risk factors associated with miscarriage in Armenia?

Background

According to the World Health Organization (W.H.O.), *miscarriage* is "a spontaneous expulsion or extraction of an embryo or fetus weighing 500 grams or less, corresponding to an expulsion prior to 20 weeks of pregnancy" [12, 15]. Miscarriage or spontaneous abortion occurs in every one in five pregnancies worldwide[13]. Miscarriage carries a substantial risk to the health and fertility of women. Women who had in their life a diagnosed miscarriage had a 45% chance to have retained tissue in the uterus[14], and if the needed medical procedures were not conducted, a complication such as heavy bleeding can occur and without intervention there is a high probability that the woman will die. Also, women who are prone to miscarriages are at risk not being able to have a full-term live birth.

The prevalence and the timing of miscarriage in Republic of Armenia are not known. In a published review of studies in other countries on miscarriages, the percentage of miscarriages in recognized pregnancies varied from 15% to 31%. In the U.S. approximately 15% to 20% of pregnancies end in miscarriage[11, 12] and more than 80% percent of these miscarriages occurred in the first 12 weeks[15]. This is important question for planning out the most effective prevalence strategies for miscarriage.

According to several studies, a quarter of pregnancies ended in miscarriage by the sixth week after a woman's last menstrual period[14, 16]. It is difficult to estimate the full count of miscarriages in a population because women miscarry earlier than a pregnancy is clinically confirmed[14,17,18]. However, 90% of all miscarriages occur between 12 and 14 week of gestation[18].

Recurrent miscarriage is defined by most researchers as a loss of three or more consecutive pregnancies before 20 weeks of gestation, with or without previous live births [15, 19- 22]. Recurrent miscarriages occur in 1%-3% of women during their reproductive years [6, 12,15, 19, 20, 23]. Several studies have shown that approximately 60% of miscarriages are due to chromosomal abnormalities [3, 12,19, 24]. One study found that the count of chromosomal anomalies decreased as the number of miscarriages increases [25].

One of the major risk factors identified for recurrent miscarriages' is antiphospholipid syndrome[10, 15, 24,26]. Antiphospholipid syndrome, another risk factor for miscarriage, is diagnosed based on several signs, which include thrombosis, one or more unexplained pregnancy losses after 10 weeks of pregnancy and three or more consecutive miscarriages before 10 weeks of pregnancy[10,15, 26].

The incidence of the risk factor chromosomal anomalies ranges from 30% to 80% [6,12, 27,28]. In the first trimester 55% of miscarriages have been shown to be associated with chromosomal

anomalies, in the second trimester these anomalies were associated with 35% of miscarriage and in the third trimester the percentage sharply decreases to 5% of all miscarriages[15].

Another risk factor for miscarriage is maternal age. Several studies have shown that with age ovarian function progressively declines and miscarriage rates increase[12,27]. In many Asian and European countries, such as Turkey, Hungary, Czech republic, maternal and paternal age, less than 20 years, have similar percentage of miscarriage occurrence – 12%, while risk of miscarriage almost doubles for women older than 20 years[6,12,24]. Risk increases to 20%for fathers older than 20 years[6,29].

Pregnancy spacing also has been shown to be associated with risk of miscarriage. Women who became pregnant within six months after a prior birth have been found to have lower rates of miscarriage than those who became pregnant more than six months after the last birth[13].

Smoking has been linked to miscarriages, both smoking by the pregnant woman and by her husband. Smoking during pregnancy has been associated with various negative outcomes, including miscarriage[4,12]. Maternal smoking is associated with approximately 15% of miscarriages[6]. Studies have also shown that for smoking couples, the risk of having a miscarriage was four times greater than that of non-smoking couples [31]. Study authors suggested that the biological pathway for a causal association might be related to nicotine's ability as a vasoconstrictor, reducing blood flow to placenta leading to carbon monoxide relocating oxygen in hemoglobin. This in turn may lead to maternal and fetal deficiencies in the amount of oxygen delivered to the tissue, causing miscarriage[12,31]. Some studies also indicate that smoking induces morphological changes in paternal sperm, decreasing its density and mobility[31]. In one study women were most likely to quit alcohol consumption during pregnancy than to quit smoking and were much less likely to quit coffee drinking[8].

A dose response association between regular maternal alcohol use and risk of miscarriage has been found associated in various studies[6,12,32] . Several studies have shown that alcohol consumption causes micronutrient deficiencies, which may lead to miscarriage[32]. Another study showed a major decrease in regular drinking by women after they knew they were pregnant[8].

First-trimester bleeding, a common complication has been shown to be a risk factor for miscarriage. Heavy bleeding during pregnancy in the first trimester has been shown to have three times higher risk of having subsequent miscarriage compared to pregnant women without bleeding, though heavy bleeding may also be a symptom of miscarriage.

Several studies have also found heavier caffeine usage was associated with miscarriage. Coffee, tea and many carbonated drinks are major sources of caffeine and are commonly consumed by women[5,12,33]. More than 95% of the adult European population reported consuming caffeine drinks at least weekly, though women consume less when they are pregnant[5,33]. The reductions of caffeine consumption during pregnancy is highly associated with "loss of taste" or vomiting and nausea[5,33]. Some studies have shown a dose-response relationship between caffeine consumption and risk of miscarriage[33]. Women who drank more than five cups of coffee daily have shown to have an increased risk of miscarriage, with a linear dose-response association with number of cups of coffee consumed daily [6].

Obesity is seen as the world's newest epidemic and as the prevalence of obesity and overweight among women has increased, miscarriage and other pregnancy complication rates have also increased[2,34]. What biological pathway obesity might use to increase miscarriage is still not clearly understood. BMI (body mass index) is defined as the weight in kilograms divided by the square of the height in meters (kg/m^2) and is a better measure of body fat than other weight measurements for adults. BMI underweight and normal weight is considered

less than 25kg/m^2, overweight as 25-29.9kg/m^2 and obesity as greater-than-or-equal-to 30kg/m^2[22,34,35]. Though several studies suggest that obesity is associated with increases in the risk of miscarriage[34,35], others found no association [35,36]. Another study has shown that sleeping less-than-or-equal-to 8 hours per day are under higher risk of having miscarriage than comparing to women that sleep ≥ 8 hours per day [37].

Uterine defects such as leiomyoma of the uterus and uterine synechiae (Asherman's syndrome) have both been shown to be associated with increased risk of pregnancy loss [12,24]. Uterine malformations such as unicornuate, bicornuate uterus, and septate uterus all lead to increased risk of miscarriage[12,24]. Infections as a risk factor for miscarriage are more controversial. Some published research has found that infections have little association with risk of miscarriage [15], while others studies have found that some specific infections are more strongly associated with risk of miscarriage; these infections include toxoplasmosis, lysteriosis, syphilis, HIV and malaria[7,20].

There are interventions currently available to prevent or reduce the likelihood of miscarriage, including treatment for antiphospholipid syndrome; haemostatic drugs; abstaining from alcohol, coffee and smoking; and bed rest. During the study we will explore other factors for protective associations against miscarriages.

Though many studies examined risk factors for miscarriage, there have been few studies that have examined interactions between these risk factors. Interactions may increase risks of miscarriage that might provide new targets for interventions to reduce the risk of miscarriage. On review of the literature and reports, there was also no published research study on risk factors for miscarriage in Armenia. Thus, this proposed project's purpose is to evaluate any interactions between risk factors and highlight major risk factors of miscarriage in Armenia

to lead to the development of more effective interventions to reduce risk of miscarriage for Armenia and internationally.

Methods

Study design

A case-control study was chosen to address the research questions, providing a more statistically efficient way to answer the research questions where cases are more accessible in maternity hospitals[38].

Study population

The study population is women from two Yerevan tertiary maternity hospitals – Republic Institute of Reproductive Health, Perinatology, Obstetrics and Gynecology (RIRHPOG), which is chosen as being a referral hospital and the other is "Erebuni" Medical center, as another hospital having a large number of births. All women that are going to be recruited for the study, both from Yerevan and marzes, will receive care in the two selected hospitals.

Cases will be women with the history of most recent pregnancy that ended in miscarriage. Inclusion criteria for *cases* will include:

- Women who were admitted to hospital because of miscarriage (the most recent pregnancy)
- Having miscarriage in RIRHPOG, "Erebuni" Medical Center
- Speaking Armenian

Controls will be women with the history of most recent pregnancy that ended in normal delivery. Inclusion criteria for *controls* will include:

- Women who were admitted to hospital for giving birth (the most recent pregnancy)

- Having live birth in RIRHPOG, "Erebuni" Medical Center
- Knowing Armenian

Exclusion criteria for *controls* will include:

- Pregnant women who received treatment against miscarriage

We will exclude women who were treated because of threatening abortion, just to have only normal pregnancies and deliveries.

Study variables

The proposed study's outcome variable is having a miscarriage in the most recent pregnancy, with independent variables including those of special interest, those which are potential confounders and those which are for testing interactions. These independent variables include the presence of chromosomal anomalies, maternal and paternal age, parity, previous miscarriages, pregnancy spacing, smoking behaviors, coffee drinking, alcohol consumption, first trimester bleeding, body mass index (BMI), relevant infections, uterine defects and sleeping hours. Information about several variables such as chromosomal anomalies, infections and uterine defects will be obtained from the medical records. Parity will be assessed on a categorical scale. Previous miscarriages are assessed with several scales provided in the questionnaire. Questions are also designed to characterize all pregnancies that women had during her lifetime. Pregnancy spacing will be calculated based on questions characterizing previous pregnancies. Smoking behaviors are assessed by questions with binary responses (yes/no) and with an ordinal scale (never, once a month or less, several days a month, several days a week, every day). Coffee drinking behaviors will be measured with similarly designed questions, questions with binary responses (yes/no) and an ordinal scale (none, less than 1 cup per day, 1-2 cups per day, 3-4 cups per day, 5-6 cups per day ,7-8 cups per day, 9 cups or more per day). Alcohol consumption will also be measured on an ordinal

scale (never, less than 1 day a week, 1-2 days a week, 3-5 days a week, 6-7 days a week) and numerically (number of shots). First-trimester bleeding is again measured with questions with yes/no responses and an ordinal scale for the duration of bleeding (one episode, 1 day, 2 days, 3 days, more than 3 days). BMI will be calculated based on the height and weight data provided during the interview. Sleeping hours of the women will be assessed with a binary scale of less-than-or-equal-to 8 hours and greater than 8 hours. Trauma during pregnancy will only be evaluated with questions that have binary responses (yes/no). A final study variable will include whether the patient resides in the marzes or in Yerevan.

Sample Size

The sample size was calculated using the standard formula for the unmatched case-control study[38]. The potential risk factor *chromosomal anomalies* for the outcome *miscarriage* was selected for sample size calculations. Based on prior published research, the prevalence among women who had miscarriage was 32.4% and prevalence in women who didn't have miscarriage but had live birth have 15% chance of having a chromosomal anomalies[30]. With the assumptions of $\alpha=0.05$ and $1-\beta=0.80$ and a 4 to 1 ratio of cases to controls, the sample size was calculated to be 300, with 60 cases and 240 controls. Adjusting this number for an assumed 20% of non-participation rate, the sample size will equal 375. This sample size is sufficient to test for individual interactions of selected factors with reasonable frequencies and distributions where associations with having a miscarriage may be feasibly modified by other covariates.

Sampling Methodology

The case-control study sampling method will be a prospective incidence density sampling of one miscarriage case and one control randomly selected within one week following the miscarriage in the same hospital. Each time a woman is admitted to the hospital for a miscarriage, four women with a normal birth will be invited to participate as a matched

control for that case. As the cases and controls will be matched, in case if the control will refuse to participate another pregnant woman will be chosen within one week period of time when the case is chosen. This particular sampling methodology is chosen to assure that for each case, the controls selected for that case are selected at the same period of time, assuring that if there are changes over time such as seasonality, it will not bias the results.

Study Instruments and testing

The study instruments will be an interviewer administered questionnaire and a medical records abstraction form (Appendix 1 and 1.1). The questionnaire was developed based on other study questionnaires and the internationally published literature in this field. This instrument was further pretested and adapted as needed for the current study. Questions about smoking, coffee drinking and alcohol consumption were adapted from study questionnaires used by the Center for Health Services Research and Development (CHSR) at the American University of Armenia. The questionnaire includes questions about participants' socio-demographic characteristics (maternal/paternal age, employment, marital status and family income) and questions about risk factors for miscarriage. Medical record abstraction forms were based on the internationally published literature in the field and adapted for acquiring the required data for the proposed study. Data about uterine defects and infections will be obtained. Genetic laboratory blood tests for parents' karyotype will be used to identify the chromosomal anomalies of the fetus. This test has been used widely in published studies. The blood samples will also be used for further analysis to identify infections and antiphospholipid syndrome that are also risk factors for miscarriage. After taking blood samples, nurses will prepare and send these samples to the laboratory for the indicated tests.

There are 38 questions and the main domains of the questionnaire are:

- Socio-demographic questions – maternal and paternal age, family income, marital and employment status.
- History of the previous pregnancies and their sequence
- Bleeding and trauma during pregnancy
- Lifestyle - this includes questions about smoking, alcohol consumption, coffee drinking, and sleeping hours.

Data collection

The study will be conducted in two Yerevan tertiary maternity hospitals – Republic Institute of Reproductive Health, Perinatology, Obstetrics and Gynecology (RIRHPOG), which is chosen as being a referral hospital and the other is "Erebuni" Medical center, as another hospital having largest numbers of births.

The interviewers and data extractors will be recruited from previous American University of Armenia MPH alumni. Before starting the data collection interviewers and data extractors will be trained for two weeks; at the end of the training session, each interviewer will practice conducting preliminary interviews, and will meet to share experiences, receive feedback and reinforcement in weak areas in their interviews. They will also practice data abstraction on data abstraction forms and be evaluated and corrected as needed. Two nurses will be needed for the whole program; one nurse in each hospital to conduct taking the blood sample tests. Nurses will be trained during one session for taking and preparing to send the blood sample of parents for genetic testing, and for testing for infections and antiphospholipid syndrome. A team manager recruited from American University of Armenia MPH alumni will monitor and assure quality of interviews, abstractions and blood samples.

After receiving permission from the maternity hospital directors, cases and controls will be identified using incidence sampling. After taking secured contact information, which means

not collecting personal identifiers, securing contact information separately, destroying it when the data collection is finished; and making contact with eligible participants, consent will be requested for the interview, for medical record abstraction and for the blood test and if consent is granted, data collection will begin. Each interview will take 15-20 minutes and blood test 5 minutes.

Personnel

A team of 9 people will conduct the study. Principle investigator, team manager and statistician will be enclosed in one person, who will train, monitor and assure quality of interviews, abstractions and blood samples, also will do the analyses and prepare explanations, tables, charts and diagrams. During the study principle investigator will periodically check interviewers and nurses for doing accurate job. Four interviewers will be recruited to conduct interviews and data extraction from medical records. Interviewers will be recruited from former AUA MPH students. Two interviewers will be in one hospital and the other two in the other hospital. Also two nurses will be recruited to assist interviewers in each hospital for assessment of infections and antiphospholipid syndrome and to take and prepare blood samples to be sent to an Armenian lab for genetic testing. Cell phones will be provided to the reception of each maternity hospital, so the nurses on duty will be able to inform interviewers about the cases of miscarriage. During each call the names of the nurses will be recorded to provide the salaries per names. Two data enterers will be recruited and trained for double data entry for checking of data errors, making corrections and further data cleaning. An accredited laboratory will be selected for genetic testing of blood samples during the hospitalization of interest for chromosomal risk factors of miscarriage, and for testing for infections and antiphospholipid syndrome.

Time frame

The overall study will last for six and a half months. During the first month the team manager will conduct recruitment of the team and training of the staff, and contact and gain consent from participating hospitals. Following the first two weeks, the next five months data collection, data entry and data cleaning will be conduction, followed by data analysis, preparation of reports and papers and finally dissemination of findings in peer-reviewed journals and international conferences. See Gannt's Chart in Appendix 3.

Analysis

Data analysis will start after completion of data collection, data entry and data cleaning. Double data entry and error checking will be performed to ensure the accuracy of the data. The software Statistical Package for Social Sciences (SPSS) 11.0 for Windows will be used for data entry, data cleaning and data management. Data entry will be performed using the statistical package for social sciences for windows (SPSS 11.0). The data will be transferred to STATA 7.0 for further data analyses. The information collected during the interviews will be held under the password in the computer, no personal identifiers will be available on the questionnaires, the ID list will be kept under the lock by principal investigator, and all information of the computer will have a stick back-up, which also will be under the control of principal investigator.

Descriptive analysis will be used for socio-demographic characteristics of the study population such as maternal, paternal age, marital status, educational level, employment status and family income and will be calculated with STATA. Descriptive analysis will be used to highlight the frequencies and distribution of variables among cases and controls. The χ^2 test and simple logistic regression will evaluate the unadjusted individual associations between each independent variable and the outcome variable whether the woman had a

miscarriage in their last pregnancy or not. Multivariate logistic regression will test the associations between the outcome variable miscarriage in the last pregnancy and the independent variables, control for confounding and also testing for interactions between these independent variables. Patient's residency, obtained from the abstraction form, will provide a means to control for confounding and an opportunity to compare miscarriage rates between patients in the marzes as compared to those in Yerevan.

Because there are feasible pathways leading to effect modification between key variables and these have not been explored in the previous literature, analyses will also include testing for interaction terms. Given feasibility of effect modifications and the limitations of sample size, interaction terms that will be tested will be limited to those potential interaction between the following variables: the number of live births and pregnancy spacing, the number of abortions and miscarriages, hours of sleeping during 24 hours, BMI, maternal and paternal ages, income of the family, related infections and chromosomal anomalies.

The variables were also selected for testing interactions because they have reasonable distributions and counts, given the sample size. Live births, miscarriages, abortions, related infections and chromosomal anomalies may feasibly have overlapping biological pathways that can lead to effect modifications, modeled in multivariate regressions as interactions. Maternal and paternal ages and BMI are frequent effect modifiers for other diseases and should also be tested. Hours of sleeping are a newly identified potential risk factor in the literature. Testing for interactions is important because synergistic or antagonistic effect modification can inform improvements in interventions to reduce the risk of miscarriages, especially for high risk women.

Ethical consideration

The proposal will be reviewed by the Institutional Review Board/Committee on Human Research (IRB) within College of Health Sciences at the American University of Armenia. After getting IRB the training of the interviewers will start. Before starting interviews, data abstraction and taking blood all heads of maternity hospitals will be provided with a support letter, and only after consent the data collection will start. During interviews participants will be provided with oral consent form (See Appendix 2) and be provided free choice to participate or not. Privacy and confidentiality of the participant will be protected by not collecting personal identifiers and securing the contact information separately, destroying it when the data collection is completed. Both questionnaire and abstraction form will have ID number, so the linkage of the information will be secured. All participants will be made aware in consent that they can stop their participation at any point of time that they wish, and they could chose to not answer to any question, refuse data abstraction from their medical records and/or refuse giving blood. Personal information of the participant will be available only for researcher and personal data will not be entered in the computer and will not be analyzed.

Strengths and Limitations

One major limitation of the study findings is that they may not be generalizable for the entire population. In rural hospital pregnancies, the importance of risk factors and interactions between risk factors for miscarriage may vary from Yerevan. More complicated cases are referred to Yerevan hospitals, which may also change results—limiting external validity of the study.

Another limitation can be information bias-during pre-test of the study questionnaire, while asking about previous pregnancies not all women were able to identify or preferred not to

share correctly the overall number of the pregnancies they had experienced; elective abortion, stillbirths and miscarriages were sometimes not considered as pregnancies.

Early miscarriages cannot be investigated because majority is considered as another menstrual cycle and woman doesn't realize that she was pregnant.

The strength of this study is that the interactions between risk factors can be evaluated, which according to the literature review have not been evaluated in previous studies. Looking at interactions and finding out the relationship between risk factors will inform the planning of more effective interventions to reduce the numbers of miscarriages. This is the first study about miscarriage risk factors conducted in Yerevan, Armenia.

Budget

The budget is calculated taking into account personnel salaries, copies, transportation of the samples, and analysis of infections (see Table 1). Personnel salaries are calculated based on the average salaries provided in international and non-governmental Armenian organizations. The team manager will receive a monthly salary. Each of five interviewers will be paid for each completed interview. All nurses will also be paid per participant. Data entry and cleaning will be paid by the hour. The cost of copying of questionnaires is included. Different costs may include cell phone costs, some devices that may be needed for blood sample taking, office space for team manager and other unintended costs. Costs of blood sample preparation materials, transportation of blood samples to an Armenian laboratory, and testing charges are included. The laboratory will be paid for each provided analysis. A driver will be hired for transportation of the samples from the hospital to the laboratory. At the end of the study a statistician will conduct analyses and support the preparation of the report. The total sum of the expenditures during the particular study is calculated to be 10,916,800AMD.

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Table 1: Budget

Required resources	**Type of payment**	**Cost of the unit (AMD)**	**Number of required units**	**Total cost (AMD)**
Salaries				
Team manager	Fixed monthly salary	100,000	6.5 months	650,000
Interviewer	Per completed interview	1,000	300	300,000
Nurse	Per patient	500	300	150,000
Lab. analysis for antiphospholipid syndrome	Per patient	7,000	300	2,100,000
Lab. analysis for infections	Per patient	10,000	300	3,000,000
Lab. analysis for chromosomal abnormalities	Per patient	15,000	300	4,500,000
Total cost			10,700,000	
Transportation, Copies				
Driver	Per km/drams	100	value	100,000
Copies	Per page	7	300	16,800
Other expenses				
Other expenses	Different types	different	Different	100,000
Total cost			216,800	
Total cost of resources in AMD				**10,916,800**

Appendices

Appendix 1. Questionnaire

Risk factors of miscarriage: a case-control study

Interviewee code: _____ **Status:** 1.Case 0.Control

Date of the interview: _ _ _ _ /_ _ _ _ /_ _ _ _

(Day) (Month) (Year)

1. **How many live births did you have?**_____
   □77. Difficult to answer
   □88. Refused to answer

2. **Mention the year/years that you had live births.**_____
   □77. Difficult to answer
   □88. Refused to answer

3. **How many elective abortions did you have?**_____
   □77. Difficult to answer
   □88. Refused to answer

4. **Mention the year/years that you had elective abortions**. _____
   □77. Difficult to answer
   □88. Refused to answer

5. **How many miscarriages did you have?**_____
   □77. Difficult to answer
   □88. Refused to answer

6. **Mention the year/years that you had miscarriage.**_____
   □77. Difficult to answer
   □88. Refused to answer

7. **Please mention the gestational age/ages when you had miscarriage.**_____
   □77. Difficult to answer
   □88. Refused to answer

8. **How many stillbirths did you have?** _____
   □77. Difficult to answer
   □88. Refused to answer

9. **Mention the year/years that you had stillbirths.**_____
   □77. Difficult to answer
   □88. Refused to answer

10. **Please mention the gestational age/ages when you had stillbirths**.
    _____
    □77. Difficult to answer

□88. Refused to answer

11. **How many total pregnancies (including live births, abortions, miscarriages, stillbirths) did you ever have? _____**

□77. Difficult to answer
□88. Refused to answer

12. Did you have bloody discharge in the first trimester of your last pregnancy?

□1. Yes
□2.No (Go to Q.14)
□77. Difficult to answer
□88. Refused to answer

13. For how long did it last?

□1. One episode
□2.1 day
□3. 2 days
□4.3 days
□5.more than 3 days
□77. Difficult to answer
□88. Refused to answer

14. Have you ever smoked cigarettes? (At least one cigarette)?

□1. Yes
□2.No (Go to Q.17)
□77. Difficult to answer
□88. Refused to answer

15. How often did you smoke before your last pregnancy?

□1. Never
□2.Once a month or less
□3. Several days a month
□4. Several days a week
□5. Every day
□77. Difficult to answer
□88. Refused to answer

16. How often did you smoke during your last pregnancy?

□1. Never
□2.Once a month or less
□3. Several days a month
□4. Several days a week
□5. Every day
□77. Difficult to answer
□88. Refused to answer

17. **How many of your household members smoked during your last pregnancy?_____**

□77. Difficult to answer
□88. Refused to answer

18. How often people smoked in the same room where you were during your last pregnancy?

□1. Every day
□2. Several days a week
□3. Once a week
□4. Several days a month
□5. Once a month or less
□6. Never
□77. Difficult to answer
□88. Refused to answer

19. Did you ever drink coffee?

□1. Yes
□2.No (Skip to Q.22)
□77. Difficult to answer
□88. Refused to answer

20. How many cups of coffee per day did you drink before your last pregnancy?

□1.None
□2.Less than 1 cup per day
□3. 1-2 cups
□4. 3-4 cups
□5. 5-6 cups
□6. 7-8 cups
□7. 9 cups or more
□77. Difficult to answer
□88. Refused to answer

21. How many cups of coffee per day did you drink during your last pregnancy?

□1.None
□2. Less than 1 cup per day
□3. 1-2 cups
□4. 3-4 cups
□5. 5-6 cups
□6. 7-8 cups
□7. 9 cups or more
□77. Difficult to answer
□88. Refused to answer

22. On the average how many days a week did you drink alcohol before your last pregnancy?

□1. Never (Go to Q.24)
□2.Less than 1 day a week
□3.1-2 days a week
□4.3-5 days a week
□5.6-7 days a week
□77. Difficult to answer
□88. Refused to answer

23. On the average, on the days before your last pregnancy when you drank alcohol how many shots or glasses of vodka, beer, wine or champagne did you drink?

□1. Vodka/cognac _____shots
□2. Beer _____can (250 gram)
□3. Wine/champagne _____glass
□4. Other _____
□77. Difficult to answer
□88. Refused to answer

24. On the average how many days a week you drink alcohol during your last pregnancy?

□1. Never (Go to Q.26)
□2.Less than 1 day a week
□3.1-2 days a week
□4.3-5 days a week
□5.6-7 days a week
□77. Difficult to answer
□88. Refused to answer

25. On the average, on the days during your last pregnancy when you drank alcohol how many shots or glasses of vodka, beer, wine or champagne did you drink?

□1. Vodka/cognac _____shots
□2. Beer _____can (250 gram)
□3. Wine/champagne _____glass
□4. Other _____
□77. Difficult to answer
□88. Refused to answer

26. On average how many hours did you sleep before your last pregnancy during 24 hours?

□1. ≤ 8 hours
□2. ≥8 hours
□77. Difficult to answer
□88. Refused to answer

27. On average how many hours did you sleep during your last pregnancy during 24 hours?

□1. ≤ 8 hours

□2. ≥8 hours
□77. Difficult to answer
□88. Refused to answer

28. Did you have traumas/accidents during your last pregnancy?

□1. Yes
□2. No
□77. Difficult to answer
□88. Refused to answer

29. What was your weight before last pregnancy? _____ (kg)

□77. Don't know
□88. Refused to answer

30. What is your height?_____ (cm)

□77. Don't know
□88. Refused to answer

31. Year of birth (dd/mm/yy) ___/___/___

32. Paternal year of birth (dd/mm/yy) ___/___/___

33. Marital status:

□1. Married
□2. Separated/Divorced
□3. Widowed
□4. Single
□88. Refused to answer

34. Education:

□1.School (less than 10 years)
□2. School (10 years)
□3. Professional technical education (10-13 years)
□4.Institute/University
□5.Postgraduate
□88. Refused to answer

35. Are you employed?

□1. Yes
□2.Yes, but on maternity/pregnancy leave
□3.No
□4.Self-employed
□5. Student
□8.Other *(specify)* _____
□88. Refused to answer

36. Is your family registered in a family poverty benefit program (e.g. PAROS)?

□1. Yes
□2.No
□77. Difficult to answer
□88. Refused to answer

37. How would you rate your family's general standard of living?

□1. Substantially below average
□2. Little below average
□3. Average
□4. Little above average
□5. Substantially above average
□77. Difficult to answer
□88. Refused to answer

38. In average, how much money does your family spend monthly?

□1. Less than 50,000 AMD
□2. From 50,000 to 100,000 AMD
□3. From 100,000 to 200,000 AMD
□4. From 200,000 to 300,000 AMD
□5. Above 300,000 AMD
□77. Difficult to answer
□88. Refused to answer

THANK YOU
for your participation!!!

Հարցաթերթիկ

Վիժումների դեմոգրաֆիկ և վարքագծային ռիսկի գործոնները Երևանում, Հայաստան. դեպք-ստուգիչ հետազոտություն

ID _____ Կարգավիճակը: 1. դեպք 0.ստուգիչ

Հարցազրույցի ամսաթիվը_ _ _ _ /_ _ _ _ /_ _ _ _

(օր) (ամիս) (տարի)

1. Քանի՞ կենդանի պտղով ծննդաբերություն եք ունեցել._____

□77.Չիհիշում
□88. Հրաժարվում է պատասխանել

2. Նշեք տարեթիվը/տարեթվերը, թե երբ եք ունեցել կենդանի պտղով ծննդաբերություն_____

□77.Չիհիշում
□88. Հրաժարվում է պատասխանել

3. Քանի՞ աբորտ եք ունեցել._____

□77.Չիհիշում
□88. Հրաժարվում է պատասխանել

4. Նշեք տարեթիվը/տարեթվերը, թե երբ եք ունեցել աբորտ._____

□77.Չիհիշում
□88. Հրաժարվում է պատասխանել

5. Քանի՞վիժում եք ունեցել. _____

□77.Չիհիշում
□88. Հրաժարվում է պատասխանել

6. Նշեք տարեթիվը/տարեթվերը, թե երբ եք ունեցել վիժում. _____

□77. Չի հիշում
□88. Հրաժարվում է պատասխանել

7. Նշեք հղիության ժամկետը, թե երբ եք ունեցել վիժում._____

□77. Չի հիշում
□88. Հրաժարվում է պատասխանել

8. Քանի՞մեռելածին եք ունեցել. _____

□77. Չի հիշում
□88. Հրաժարվում է պատասխանել

9. **Նշեք տարեթիվը/տարեթվերը, թե երբ եք ունեցել մեռելածին.**_____

□77. Չի հիշում
□88. Հրաժարվում է պատասխանել

10. **Նշեք հղիության ժամկետը, թե երբ եք ունեցել մեռելածին.**_____

□77. Չի հիշում
□88. Հրաժարվում է պատասխանել

11. **Քանի՞ հղիություն եք ունեցել(Կենդանի պտղով ծննդաբերություն, աբորտ, վիժում, մեռելածին).** _____

□77. Չի հիշում
□88. Հրաժարվում է պատասխանել

12. **Ձեր վերջին հղիության առաջին եռամսյակում արդյոք ունեցե՞լ եք արյունային արտադրություն կամ արյունահոսություն:**
□1.Այո
□2.Ոչ (Անցնել14-րդ հարցին)
□77. Չգիտեմ
□88. Հրաժարվում է պատասխանել

13. **Որքա՞ն է տևել արյունային արտադրությունը:**
□1. Ընդամենը մի դրվագէր
□2. 1 օր
□3. 2 օր
□4. 3 օր
□5. ավելի քան 3 օր
□77.Չգիտեմ
□88. Հրաժարվում է պատասխանել

14. **Դուք երբևէ ծխե՞լ եք:**
□1.Այո
□2.Ոչ (Անցնել17-րդ հարցին)
□77. Չգիտեմ
□88. Հրաժարվում է պատասխանել

15. **Որքա՞ն հաճախ եք ծխել նախքան Ձեր վերջին հղիությունը:**
□1. Երբեք
□2. Ամիսը մեկ կամ պակաս
□3. Ամիսը մի քանի անգամ
□4. Շաբաթը մի քանի անգամ
□5. Ամեն օր
□77. Չգիտեմ
□88. Հրաժարվում է պատասխանել

16. Որքա՞ն հաճախ եք ծխել Ձեր վերջին հղիության ընթացքում.
□1. Երբեք
□2. Ամիսը մեկ կամ պակաս
□3. Ամիսը մի քանի անգամ
□4. Շաբաթը մի քանի անգամ
□5. Ամեն օր
□77. Չգիտեմ
□88. Հրաժարվում է պատասխանել

17. Ձեր ընտանիքի անդամներից քանի՞սն էին ծխում Ձեր վերջին հղիության ընթացքում _____

18. Որքա՞ն հաճախ էին մարդիկ ծխում Ձեր վերջին հղիության ընթացքում Ձեր ներկայությամբ՝ նույն սենյակում:
□1. Երբեք
□2. Ամեն օր
□4. Շաբաթը մեկ անգամ
□5. Շաբաթը մի քանի անգամ
□6. Ամիսը մեկ կամ պակաս
□7. Ամիսը մի քանի անգամ
□77. Չգիտեմ
□88. Հրաժարվում է պատասխանել

19. Սուրճ խմու՞մ եք.

□1.Այո
□2.Ոչ (Անցնել22-րդ հարցին)
□77. Չգիտեմ
□88. Հրաժարվում է պատասխանել

20. Քանի՞ բաժակ սուրճ էիք խմում օրեկան նախքան Ձեր վերջին հղիությունը.

□1. Չեմ խմել
□2. Հազվադեպ
□3. 1-2 բաժակ
□4. 3-4 բաժակ
□5. 5-6 բաժակ
□6.7-8 բաժակ
□7. 9 բաժակ և ավելին
□77. Չի հիշում
□88. Հրաժարվում է պատասխանել

21. Քանի՞ բաժակ սուրճ էիք խմում օրեկան Ձեր վերջին հղիության ընթացքում.
□1. Չեմ խմել
□2. Հազվադեպ
□3. 1-2 բաժակ
□4. 3-4 բաժակ
□5. 5-6 բաժակ

□6.7-8 բաժակ
□7. 9 բաժակ և ավելին
□77. Չի հիշում
□88. Հրաժարվում է պատասխանել

22. Ձեր վերջին հղիությունից առաջ շաբաթվա ընթացքում միջինում քանի՞ օր էիք ալկոհոլ խմում.
□1. Չեմ խմում (Անցնել26-րդ հարցին)
□2. շաբաթական 1 օրից քիչ
□3. շաբաթական 1-2 օր
□4. շաբաթական 3-5 օր
□5. շաբաթական 6-7 օր
□77. Չի հիշում
□88. Հրաժարվում է պատասխանել

23. Ձեր վերջին հղիությունից առաջ միջինում քանի՞ բաժակ վոդկա, կոնյակ, գարեջուր, գինի կամ շամպայն եք խմել.
□1. Վոդկա/ կոնյակ _____ բաժակ
□2. Գարեջուր _____ շիշ (250գ)
□3. Գինի/Շամպայն _____ բաժակ
□5. Այլ _____
□77. Չի հիշում
□88. Հրաժարվում է պատասխանել

24. Ձեր վերջին հղիության ընթացքում շաբաթվա ընթացքում միջինում քանի՞ օր էիք ալկոհոլ խմում.
□1. Չեմ խմում (Անցնել26-րդ հարցին)
□2. շաբաթական 1 օրից քիչ
□3. շաբաթական 1-2 օր
□4. շաբաթական 3-5 օր
□5. շաբաթական 6-7 օր
□77. Չի հիշում
□88. Հրաժարվում է պատասխանել

25. Ձեր վերջին հղիության ընթացքում միջինում քանի՞ բաժակ վոդկա, կոնյակ, գարեջուր, գինի կամ շամպայն եք խմել.
□1. Վոդկա/ կոնյակ _____ բաժակ
□2. Գարեջուր _____ շիշ (250գ)
□3. Գինի/Շամպայն _____ բաժակ
□5. Այլ _____
□77. Չի հիշում
□88. Հրաժարվում է պատասխանել

26. Միջինում քանի՞ ժամ էիք քնում Ձեր վերջին հղիությունից առաջ.
□1. ≤ 8 ժամ
□2. ≥8 ժամ
□77. Չի հիշում

□88. Հրաժարվում է պատասխանել

27. Միջինում քանի՞ ժամ էիք քնում Ձեր վերջին հղիության ընթացքում.

□1. ≤ 8 ժամ
□2. ≥8 ժամ
□77. Չի հիշում
□88. Հրաժարվում է պատասխանել

28. Արդյո՞ք ունեցել եք պատահար/ վնասվածք Ձեր վերջին հղիության ընթացքում

□1.Այո
□2.Ոչ
□77. Չի հիշում
□88. Հրաժարվում է պատասխանել

29. **Որքա՞ն էր Ձեր քաշը վերջին հղիությունից առաջ._____ (կգ.)**

□77. Չգիտեմ
□88. Հրաժարվում եմ պատասխանել

30. Որքա՞ն է Ձեր հասակը _____ (սմ.)

□77. Չգիտեմ
□88. Հրաժարվում եմ պատասխանել

31. Ծննդյան թիվը (օր/ամիս/տարի) ___/___/___

32. Ամուսնու ծննդյան թիվը (օր/ամիս/տարի) ___/___/___

33. Ամուսնացա՞ծ եք.

□1. Ամուսնացած
□2. Չամուսնացած/ամուսնալուծված
□3. Այրի (ամուսինը մահացած)
□4. Չամուսնացած
□88. Հրաժարվում է պատասխանել

34. Ձեր կրթությունը:

□1.Թերի միջնակարգ (10 տարուց քիչ)
□ 2.Դպրոց (10 տարի)
□3.Միջին մասնագիտական (10-13 տարի)
□4.Ինստիտուտ/համալսարան
□5.Հետդիպլոմային/ասպիրանտուրա
□88. Հրաժարվում եմ պատասխանել

35. Դուք աշխատու՞մ եք:

□1. Այո
□2.Այո, բայց ֆիզ. արձակուրդում եմ
□3.Ոչ

□4.Տանն են աշխատում
□5.Ուսանող եմ
□6. Այլ *(նշեք)* _____
□88. Հրաժարվում եմ պատասխանել

36. Ձեր ընտանիքն օգտվու՞մ է Փարոսից կամ սոցիալապես անապահով ընտանիքների օգնության որևէ այլ ծրագրից:
□1.Այո
□2.Ոչ
□77. Չի հիշում
□88. Հրաժարվում է պատասխանել

37. Ընդհանուր առմամբ, ինչպե՞ս կգնահատեիք Ձեր ընտանիքի նյութական վիճակը:
□1. Միջինից բավականին ցածր
□2. Միջինից մի փոքր ցածր
□3. Միջին
□4. Միջինից մի փոքր բարձր
□5. Միջինից բավականին բարձր
□77. Չի հիշում
□88. Հրաժարվում է պատասխանել

38. Միջինում, ամսական որքա՞ն գումար է ծախսում Ձեր ընտանիքը:
□1. 50 000 դրամից քիչ
□2. 50 000 – 100 000 դրամ
□3. 100 000 – 200 000 դրամ
□4. 200 000 – 300 000 դրամ
□5. 300 000 դրամից ավելի
□77. Չի հիշում
□88. Հրաժարվում է պատասխանել

ՇՆՈՐՀԱԿԱԼՈՒԹՅՈՒՆ
մասնակցության համար

Appendix 1.1 Abstraction form

Interviewee code: _____ **Status:** 1.Case 0.Control

Residency: □Yerevan □Marzes

Date of the collection **(dd/mm/yy)** ___/___/___

LMP (last menstrual period) **(dd/mm/yy)** ___/___/___

Ultrasound data:

- Leiomyoma **Yes/No**
- Uterine synechiae **Yes/No**
- Uterine malformations (unicornuate, bicornuate, septate) **Yes/No**

Cervical cerclage operation **Yes/No**

Արտահանման ձև

ID _____ Կարգավիճակը: 1. դեպք 0.ստուգիչ

Բնակության վայրը: □ Երևան □ Մարզեր

Արտահանման տարեթիվը (օր/ամիս/տարի) ___/___/___

Վերջին դաշտանը (օր/ամիս/տարի) ___/___/___

ՈւՁՀ (ուլտրաձայնային հետազոտություն) տվյալները.

- Միոմա Այո/Ոչ
- Արգանդի սինեխիաներ Այո/Ոչ
- Արգանդի թերզարգացումներ Այո/Ոչ

Վզիկային սերկլյաժ վիրահատություն Այո/Ոչ

Appendix 2. Consent form

Oral consent form

Title of Research Project: Demographic and behavioral risk factors for miscarriage in Yerevan, Armenia: a case-control study

Explanation of Research Project (for cases)

Hello, my name is Tatevik Blbulyan. I am a second year resident in the Institute of Perinatology, Obstetrics and Gynecology in the department of Obstetrics and Gynecology and a graduate student of Master of Public Health at the American University of Armenia. The College of Health Sciences of AUA is conducting a study to investigate the role of demographic and behavioral risk factors associated with miscarriage among women who reside in Yerevan, Armenia.

Your contact information was obtained from your medical records from the hospital where you have been admitted for miscarriage. Permission to collect your contact information was received from the head of maternity home, because I work in the same maternity.

Participation involves only one interview which will last for about 10-15 minutes. You may refuse to answer any question in the interview or stop the interview at any time. Your participation in the study is voluntary and you are free to refuse participating without any negative consequences. There is no direct benefit or major risk to participating in this study, beyond helping for future prevention of miscarriages.

Your name, phone number - will be kept confidential and your name will not appear on the questionnaire. Your personal information will be coded and secured. The information you provide during this study will be kept confidential and only general findings will be presented in the report.

If you have any questions about the study you can contact Varduhi Petrosyan, the Associate Dean of the College of Health Sciences of AUA calling 512592. If you feel you have not been treated fairly, please contact Hripsime Martirosyan, AUA Human Subjects Administrator at 512561.

If you agree to participate, could we start?

Oral consent form
Title of Research Project: Demographic and behavioral risk factors for miscarriage in Yerevan, Armenia: a case-control study

Explanation of Research Project (for controls)

Hello, my name is Tatevik Blbulyan. I am a second year resident in the Institute of Perinatology, Obstetrics and Gynecology in the department of Obstetrics and Gynecology and a graduate student of Master of Public Health at the American University of Armenia. The College of Health Sciences of AUA is conducting a study to investigate the role of demographic and behavioral risk factors associated with miscarriage among women who reside in Yerevan, Armenia.

Your contact information was obtained from your medical records from the hospital where you have been admitted for delivery. Permission to collect your contact information was received from the head of maternity home, because I work in the same maternity.

Participation involves only one interview which will last for about 10-15 minutes.

You may refuse to answer any question in the interview or stop the interview at any time. Your participation in the study is voluntary and you are free to refuse participating without any negative consequences. There is no direct benefit or major risk to participating in this study, beyond helping for future prevention of miscarriages.

Your name, phone number - will be kept confidential and your name will not appear on the questionnaire. Your personal information will be coded and secured. The information you provide during this study will be kept confidential and only general findings will be presented in the report.

If you have any questions about the study you can contact Varduhi Petrosyan, the Associate Dean of the College of Health Sciences of AUA calling 512592. If you feel you have not been treated fairly, please contact Hripsime Martirosyan, AUA Human Subjects Administrator at 512561.

If you agree to participate, could we start?

Բանավոր համաձայնության ձև(դեպք)

Հետազոտության անվանումը: Վիժումների դեմոգրաֆիկ և վարքագծային ռիսկի գործոնները Երևանում, Հայաստան.դեպք-ստուգիչ հետազոտություն

Հետազոտության բացատրություն.

Բարև Ձեզ, ես Տաթևիկ Բլբուլյանն եմ: Ես Պերինատոլոգիայի, մանկաբարձության և գինեկոլոգիայի ինստիտուտիմանկաբարձության գինեկոլոգիայի ամբիոնի երկրորդ կուրսի օրդինատոր եմ և Հայաստանի ամերիկյան համալսարանի (ՀԱՀ) Հանրային առողջապահության մագիստրատուրայի վերջին կուրսի ուսանող: ՀԱՀ Առողջապահական գիտությունների ֆակուլտետն իրականացնում է հետազոտություն վիժումներին նպաստող գործոններիվերաբերյալ:Հետազոտության նպատակն է ուսումնասիրել վիժումների տարբեր ռիսկի գործոնները Երևանում:

Ձեր տվյալները վերցվել են Ձեր բժշկական քարտից ՝ այն հիվանդանոցից, որտեղ Դուք ընդունվել եք վիժման կապակցությամբ: Ձեր անձնական տվյալներից օգտվելու թուլտվությունը ստացվել է հիվանդանոցի գլխավոր բժշկից, որտեղ նաև աշխատում եմ ես:Ձեր մասնակցությունը կընդգրկի մեկ հարցազրույց, որը կտևի մոտ 10-15 րոպե: Ձեր մասնակցությունը կամավոր է: Դուք կարող եք չպատասխանել ցանկացած հարցի կամ ընդհատել հարցազրույցը ցանկացած պահի: Այս հետազոտությանը մասնակցելու դեպքում Դուքորևէ պարգևատրում չեք ստանա:Դուք ռիսկի չեք դիմում մասնակցելով այս հետազոտությանը, սակայն Ձեր անկեղծ պատասխանները կօգնեն վիժումներին նպաստողգործոնների կանխարգելմանը:

Ձեր անձնական տվյալները (անունը, հեռախոսահամարը) չեն գրանցվի հարցաթերթիկի վրա: Ձեր կողմից տրամադրած տեղեկատվությունները գաղտնի կպահվեն: Ձեր տրամադրած տեղեկատվությունը գաղտնի կպահվի և միայն ընդհանրացված տվյալները կներկայացվեն զեկույցում:

Հետազոտության հետ կապված հարցերի դեպքում կարող եք զանգահարել Հայաստանի ամերիկյան համալսարանի Հանրային առողջապահության մագիստրատուրայի փոխդեկանին՝ Վարդուհի Պետրոսյան – +37410- 51-25-92 հեռախոսահամարով:

Եթե կարծում եք, որ հետազոտության ընթացքում Ձեզ հետ լավ չեն վերաբերվել և/կամ հետազոտությունը Ձեզ վնաս է հասցրել կարող եք զանգահարել Հայաստանի ամերիկյան համալսարան էթիկայի հանձնաժողովի քարտուղար Հռիփսիմե Մարտիրոսյանին -+37410-51-25-61 հեռախոսահամարով: Եթե համաձայն եք կարո՞ղ ենք շարունակել:

Բանավոր համաձայնության ձև (ստուգիչ)

Հետազոտության անվանումը: Վիժումների դեմոգրաֆիկ և վարքագծային ռիսկի գործոնները Երևանում, Հայաստան.դեպք-ստուգիչ հետազոտություն

Հետազոտությանբացատրություն.

Բարև Ձեզ, ես Տաթևիկ Բլբուլյանն եմ: Ես Պերինատոլոգիայի, մանկաբարձության և գինեկոլոգիայի ինստիտուտիմանկաբարձության գինեկոլոգիայի ամբիոնի երկրորդ կուրսի օրդինատոր եմ և Հայաստանի ամերիկյան համալսարանի (ՀԱՀ) Հանրային առողջապահության մագիստրատուրայի վերջին կուրսի ուսանող: ՀԱՀ Առողջապահական գիտությունների ֆակուլտետն իրականացնում է հետազոտություն վիժումներին նպաստող գործոններիվերաբերյալ:Հետազոտության նպատակն է ուսումնասիրել վիժումների տարբեր ռիսկի գործոնները Երևանում:

Ձեր տվյալները վերցվել են Ձեր բժշկական քարտից ՝ այն հիվանդանոցից, որտեղ Դուք ընդունվել եք ծննդաբերության կապակցությամբ: Ձեր անձնական տվյալներից օգտվելու թուլտվությունը ստացվել է հիվանդանոցի գլխավոր բժշկից, որտեղ նաև աշխատում եմ ես:

Ձեր մասնակցությունը կընդգրկի մեկ հարցազրույց, որը կտևի մոտ 10-15 րոպե: Ձեր մասնակցությունը կամավոր է: Դուք կարող եք չպատասխանել ցանկացած հարցի կամ ընդհատել հարցազրույցը ցանկացած պահի: Այս հետազոտությանը մասնակցելու դեպքում Դուք որևէ պարգևատրում չեք ստանա:Դուք ռիսկի չեք դիմում մասնակցելով այս հետազոտությանը, սակայն Ձեր անկեղծ պատասխանները կօգնեն վիժումներին նպաստողգործոնների կանխարգելմանը:

Ձեր անձնական տվյալները (անունը, հեռախոսահամարը) չեն գրանցվի հարցաթերթիկի վրա: Ձեր կողմից տրամադրած տեղեկատվությունները գաղտնի կպահվեն: Ձեր տրամադրած տեղեկատվությունը գաղտնի կպահվի և միայն ընդհանրացված տվյալները կներկայացվեն զեկույցում:

Հետազոտության հետ կապված հարցերի դեպքում կարող եք զանգահարել Հայաստանի ամերիկյան համալսարանի Հանրային առողջապահության մագիստրատուրայի փոխդեկանին՝ Վարդուհի Պետրոսյան – +37410- 51-25-92 հեռախոսահամարով:

Եթե կարծում եք, որ հետազոտության ընթացքում Ձեզ հետ լավ չեն վերաբերվել և/կամ հետազոտությունը Ձեզ վնաս է հասցրել կարող եք զանգահարել Հայաստանի ամերիկյան համալսարան էթիկայի հանձնաժողովի քարտուղար Հռիփսիմե Մարտիրոսյանին -+37410-51-25-61 հեռախոսահամարով: Եթե համաձայն եք կարո՞ղ ենք շարունակել:

Appendix3. Gantt chart

Activities	2weeks	1m	2m	3m	4m	5m	6m
Training interviewers	X						
Training nurses	X						
Conducting int., med data extraction, taking blood tests		X	X	X	X	X	
Data entry, data cleaning		X	X	X	X	X	
Prep. of papers & reports							X
Prep. of presentation for public audience & conferences							X