### RESEARCH PROTOCOL
**NUMBER: PR-09029**

<table>
<thead>
<tr>
<th>Name of IRB:</th>
<th>Protocol Title: Beliefs, attitudes and practices towards nutrition supplementation programs in Bangladeshi women</th>
</tr>
</thead>
<tbody>
<tr>
<td>ERC Approval:</td>
<td>Yes / No</td>
</tr>
<tr>
<td>Date:</td>
<td>June 2, 2009</td>
</tr>
<tr>
<td>AEEC Approval:</td>
<td>Yes / No</td>
</tr>
<tr>
<td>Date:</td>
<td></td>
</tr>
<tr>
<td>External IRB Approval:</td>
<td>Yes / No</td>
</tr>
<tr>
<td>Date:</td>
<td></td>
</tr>
</tbody>
</table>

**Short title (in 50 characters including space):** Culture and dietary supplement use during pregnancy

**Theme:** (Check all that apply)
- Nutrition
- Emerging and Re-emerging Infectious Diseases
- Population Dynamics
- Reproductive Health
- Vaccine Evaluation
- HIV/AIDS
- Environmental Health

**Key words:** Pregnant women, nutrition supplementation, beliefs, attitudes, practices

**Relevance of the Protocol:**
For deeper understanding of women’s motivation for participating in MINIMat

**Centre’s Priority (as per Strategic Plan, to be imported from the attached Separate Word Sheet):**

**Programmes:**
- Child Health Programme
- Nutrition Programme
- Programme on Infectious Diseases & Vaccine Science
- Poverty and Health Programme
- Health and Family Planning Systems Programme

**Principal Investigator (Should be a Centre’s staff)**
**Dr. Ruchira T. Naved**
Address (including e-mail address): SBSU, PHSD, ICDDR,B, Email: ruchira@icddrb.org

**Co-Principal Investigator(s):** Internal
**Co-Principal Investigator(s): External:**
(Provide full official address including e-mail address and Gender)
**Dr. Kathleen M. Rasmussen, ScD, RD** (kmr5@cornell.edu, female)
Professor; Division of Nutritional Sciences
111 Savage Hall
Cornell University
Ithaca, NY, 14853-6301, USA

**Division:**
- CSD
- LSD
- HSID
- PHSD

**Co-Investigator(s): Internal:**
Co-Investigator(s): External  
(Please provide full official address including e-mail address and Gender)  
Dr. Gretel Pelto PhD (gp32@cornell.edu, female)  
Professor; Division of Nutritional Sciences  
Cornell University  
Ithaca, NY, 14853-6301, USA

Student Investigator(s): Internal (Centre's staff):  

Student Investigator(s): External:  
(Please provide full address of educational institution and Gender)  
Jisung Woo, MS. MPH (jw557@cornell.edu, Female, graduate student)  
104 Savage Hall, Cornell University, Ithaca, NY, 14853-6301, USA

Collaborating Institute(s): Please Provide full address

### Institution # 1

<table>
<thead>
<tr>
<th>Country</th>
<th>USA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Contact person</td>
<td>Dr. Kathleen M. Rasmussen</td>
</tr>
<tr>
<td>Department (including Division, Centre, Unit)</td>
<td>Division of Nutritional Sciences</td>
</tr>
</tbody>
</table>
| Institution (with official address) | Cornell University  
127 Savage Hall  
Ithaca, NY 14853 |
| Directorate (in case of GoB i.e. DGHS) | Patrick J. Stover, PhD (Professor & Director) |
| Ministry (in case of GoB) | |

### Institution # 2

<table>
<thead>
<tr>
<th>Country</th>
</tr>
</thead>
<tbody>
<tr>
<td>Contact person</td>
</tr>
<tr>
<td>Department (including Division, Centre, Unit)</td>
</tr>
<tr>
<td>Institution (with official address)</td>
</tr>
<tr>
<td>Directorate (in case of GoB i.e. DGHS)</td>
</tr>
<tr>
<td>Ministry (in case of GoB)</td>
</tr>
</tbody>
</table>
### Institution # 3

<table>
<thead>
<tr>
<th>Country</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Contact person</td>
<td></td>
</tr>
<tr>
<td>Department (including Division, Centre, Unit)</td>
<td></td>
</tr>
<tr>
<td>Institution (with official address)</td>
<td></td>
</tr>
<tr>
<td>Directorate (in case of GoB i.e. DGHS)</td>
<td></td>
</tr>
<tr>
<td>Ministry (in case of GoB)</td>
<td></td>
</tr>
</tbody>
</table>

Note: If more than 3 collaborating institutions are involved in the research protocol, additional block(s) can be inserted to mention its/there particular(s).

### Population: Inclusion of special groups (Check all that apply):

<table>
<thead>
<tr>
<th>Sex</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Male</td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Age</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>0 – 4 years</td>
<td></td>
</tr>
<tr>
<td>5 – 10 years</td>
<td></td>
</tr>
<tr>
<td>11 – 17 years</td>
<td></td>
</tr>
<tr>
<td>18 – 64 years</td>
<td></td>
</tr>
<tr>
<td>65 +</td>
<td></td>
</tr>
</tbody>
</table>

- Pregnant Women
- Fetuses’
- Prisoners
- Destitutes
- Service Providers
- Cognitively Impaired
- CSW
- Others (specify )
- Animal

**NOTE** It is the policy of the Centre to include men, women, and children in all research projects involving human subjects unless a clear and compelling rationale and justification (e.g. gender specific or inappropriate with respect to the purpose of the research) is there. Justification should be provided in the ‘Sample Size’ section of the protocol in case inclusiveness of study participants is not proposed in the study.

### Project/study Site (Check all the apply):

- Dhaka Hospital
- Matlab Hospital
- Matlab DSS Area
- Matlab non-DSS Area
- Mirzapur
- Dhaka Community
- Chakaria
- Abhoynagar
- Mirsarai
- Patiya
- Other areas in Bangladesh
- Outside Bangladesh

**Name of Country:**
- Multi Centre Trial

**(Name other countries involved):**
Type of Study (Check all that apply):

- Case Control Study
- Community-based Trial/Intervention
- Program Project (Umbrella)
- Secondary Data Analysis
- Clinical Trial (Hospital/Clinic)
- Family Follow-up Study
- Cross Sectional Survey
- Longitudinal Study (cohort or follow-up)
- Record Review
- Prophylactic Trial
- Surveillance/Monitoring
- Others: Qualitative interviews

NOTE: Does the study meet the definition of clinical studies/trials given by the International Committee of Medical Journal Editors (ICMJE)?

- Yes ☐
- No ☑

Please note that the ICMJE defined clinical trial as “Any research project that prospectively assigns human subjects to intervention and comparison groups to study the cause-and-effect relationship between a medical intervention and a health outcome”.

If YES, after approval of the ERC, the PI should complete and send the relevant form to provide required information about the research protocol to the Committee Coordination Secretariat for registration of the study into websites, preferably at the [https://register.clinicaltrials.gov/](https://register.clinicaltrials.gov/). It may please be noted that the PI would require to provide subsequent updates of the research protocol for updating protocol information in the website.

Targeted Population (Check all that apply):

- No ethnic selection (Bangladeshi) ☒
- Bangalee ☐
- Tribal group ☐
- Expatriates ☐
- Immigrants ☐
- Refugee ☐

Consent Process (Check all that apply):

- Written ☐
- Oral ☒
- None ☐
- Bengali Language ☒
- English Language ☐
Proposed Sample Size:
Sub-group (Name of subgroup (e.g. Men, Women) and Number

<table>
<thead>
<tr>
<th>Name</th>
<th>Number</th>
<th>Name</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>(1) Pregnant women</td>
<td>25</td>
<td>(3)</td>
<td></td>
</tr>
<tr>
<td>(2)</td>
<td></td>
<td>(4)</td>
<td></td>
</tr>
</tbody>
</table>

Total sample size: 25

a) Will the specimen be stored for future use? Yes ☐ No ☑

b) If yes, how long the specimens be preserved? _____ years.

c) Will the consent be obtained from the study participants for the specimen be stored for future, for unrelated use, without further consent? Yes ☐ No ☑

d) What types of tests will be carried out with the preserved samples? __________________________________________  
____________________________________________________________________________________________

e) Will the samples be shipped to other country(ies)? Yes ☐ No ☑

f) If yes, name of institution(s) and country(ies): ___________________________________________________________

g) Will the surplus/unused specimen be returned to the Centre? Yes ☐ No ☑

h) Who will be the custodian of the specimen at the Centre and when shipped outside of the country(ies)?: _________________________________________________________

i) Who will be the owner(s) of the samples? : __________________________________________________________

j) Has a MoU been made for the protocol covering the specimen collection, storage, use and ownership? Yes ☐ No ☑

k) If yes, please attach a copy.

**Determination of Risk: Does the Research Involve** (Check all that apply):

- ☐ Human exposure to radioactive agents?
- ☐ Fetal tissue or abortus?
- ☐ Investigational new device? (specify: )
- ☐ Existing data available from Co-investigator
- ☐ Human exposure to infectious agents?
- ☐ Investigational new drug
- ☐ Existing data available via public archives/sources
- ☐ Pathological or diagnostic clinical specimen only
- ☐ Observation of public behaviour
- ☐ New treatment regime
Yes  No  Is the information recorded in such a manner that study participants can be identified from information provided directly or through identifiers linked to the study participants?

☐  ☒  Does the research deal with sensitive aspects of the study participants’ behaviour; sexual behaviour, alcohol use or illegal conduct such as drug use?

Could the information recorded about the individual if it became known outside of the research:

☐  ☒  Place the study participants at risk of criminal or civil liability?

Yes  No  Damage the study participants’ financial standing, reputation or employability, social rejection, lead to stigma, divorce etc.?

Do you consider this research (Check one):

☐  Greater than minimal risk  ☒  No more than minimal risk

☐  Only part of the diagnostic test

Minimal Risk is the risk when the probability and magnitude of the anticipated harm or discomfort in participating in the proposed research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical, psychological examinations or tests, e.g. the risk of drawing a small amount of blood from a healthy individual for research purposes is no greater than the risk of doing so as a part of routine physical examination.

Yes/ No

☒  ☐  Is the proposal funded?

If yes, sponsor Name: (1) Division of Nutritional Sciences Small Grant

(2)

Yes/No/NA (if the proposal is already funded, mark NA)

☐  ☐  ☒  Is the proposal being submitted for funding?

If yes, name of funding agency: (1)

(2)

Do any of the participating investigators and/or member(s) of their immediate families have an equity relationship (e.g. stockholder) with the sponsor of the project or manufacturer and/or owner of the test product or device to be studied or serve as a consultant to any of the above?

IF YES, a written statement of disclosure to be submitted to the Centre’s Executive Director.

Dates of Proposed Period of Support  Cost Required for the Budget Period ($)  
(Day, Month, Year - DD/MM/YY)

Cost Year-1  Direct Cost  Indirect Cost  Total Cost
Beginning Date : June 15, 2009
Year-1  2,472  0  2,472
End Date  : December 31, 2009
Year-2  0  0  0
Year-3  0  0  0
Year-4  0  0  0
Year-5  0  0  0
Total  2,472  0  2,472
### Certification by the Principal Investigator

I certify that the statements herein are true, complete and accurate to the best of my knowledge. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties. I agree to accept the responsibility for the scientific conduct of the project and to provide the required progress reports including updating protocol information in the SUCHONA (Form # 2) if a grant is awarded as a result of this application.

<table>
<thead>
<tr>
<th>Signature of PI</th>
<th>Date</th>
</tr>
</thead>
</table>

### Approval of the Project by the Division Director of the Applicant

The above-mentioned project has been discussed and reviewed at the Division level as well by the external reviewers. The protocol has been revised according to the reviewers’ comments and is approved.

<table>
<thead>
<tr>
<th>Name of the Division Director</th>
<th>Signature</th>
<th>Date of Approval</th>
</tr>
</thead>
</table>
**Table of Contents**

RRC APPLICATION FORM .................................................................................................................. 1
Project Summary ...................................................................................................................................... 9
Description of the Research Project ....................................................................................................... 10
   Hypothesis to be Tested: ..................................................................................................................... 10
   Specific Aims: ................................................................................................................................... 10
Background of the Project including Preliminary Observations ....................................................... 10
Research Design and Methods ........................................................................................................... 11
Sample Size Calculation and Outcome Variable(s) ........................................................................... 11
Facilities Available ............................................................................................................................ 12
Data Safety Monitoring Plan (DSMP) ............................................................................................... 12
Data Analysis ..................................................................................................................................... 12
Ethical Assurance for Protection of Human Rights ........................................................................... 13
Use of Animals .................................................................................................................................. 13
Literature Cited .................................................................................................................................. 13
Dissemination and Use of Findings .................................................................................................... 14
Collaborative Arrangements .............................................................................................................. 14
Biography of the Investigators ........................................................................................................... 15
Budget Justifications .......................................................................................................................... 21
Budget Description .............................................................................................................................. 22
Other Support ................................................................................................................................... 23
   Appendix 1: Voluntary Consent Form ............................................................................................. 24
   Appendix 2: Abstract Summary covering eight points specified by the ERC ............................... 36
Check-List ........................................................................................................................................... 38

☐ Check here if appendix is included
Project Summary
Briefly describe the hypothesis, objectives, and the relevant background of the project, and also the experimental design and research methods for achieving the objectives. This description will serve as a succinct and precise and accurate description of the proposed research is required. This summary should be stand alone, and be fully understandable and interpretable when removed from the main application.

Principal Investigator: Dr. Ruchira T. Naved

Research Protocol Title: Beliefs, attitudes and practices towards nutrition supplementation programs in Bangladeshi women

The effectiveness of nutrition supplementation program is closely linked with participation and adherence of program participants. Understanding of cultural beliefs and attitudes and consideration of local practices in intervention programs have been suggested as important factors for improving participation and adherence. Because it is expected that not only food-related beliefs but also general beliefs about pregnancy will influence behaviours of pregnant women, particularly in deciding their program participation and adherence, qualitative interviews will be conducted to identify emerging themes concerning pregnancy and pregnancy-related health risks and concerns among pregnant women. It will be also examined how these beliefs and concerns could be related to dietary change during pregnancy, attitudes toward different types of supplementation, and replacement of home diet by supplements. Inasmuch as the proposed study will only provide information about general perception of pregnancy-related concerns and their potential relationship with participation and adherence to nutrition supplementation, based on the result of this preliminary study, more extensive qualitative interviews can be followed to fill the gaps in understanding pregnant women’s behaviours.

A total of 25 women, who are currently pregnant or who are recently experienced pregnancy and who participated in the national nutrition supplementation including micronutrient pill supplementation, will be randomly selected. An in-depth interview will be conducted after obtaining oral consent from each participant. Women will be asked several open-ended exploratory questions concerning pregnancy related features: their general belief and attitude about pregnancy and health risks, about culture-bounded practices, about attitudes and actual use of nutrition supplements, and concerning their dietary intake pattern, which will provide useful information for developing more specific questions about nutrition supplement use for a future comprehensive study.

All interviews will be audio-recorded. Each interview will be transcribed then translated from Bengali into English. The analysis of these transcripts will involve the identification of emerging themes. Further text analysis will refine the themes and identify their potential importance for understanding participation, adherence, and replacement.

Based on the results of this preliminary investigation, a more comprehensive round of interviews will be designed to examine the relationship between beliefs/attitudes and pregnant women’s behaviour more thoroughly.

KEY PERSONNEL (List names of all investigators including PI and their respective specialties)

<table>
<thead>
<tr>
<th>Name</th>
<th>Professional Discipline/ Specialty</th>
<th>Role in the Project</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Dr. Ruchira T. Naved</td>
<td>Principal Investigator</td>
<td></td>
</tr>
<tr>
<td>2. Dr. Kathleen M. Rasmussen</td>
<td>Nutrition/ Maternal and child nutrition</td>
<td>External Co-Principal Investigator</td>
</tr>
<tr>
<td>3. Dr. Gretel Pelto</td>
<td>Nutrition/ Nutritional Anthropology</td>
<td>External Co-Investigator</td>
</tr>
<tr>
<td>4. Jisung Woo</td>
<td>Nutrition/ International Nutrition</td>
<td>Main investigator</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Student</td>
</tr>
<tr>
<td>5.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>6.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>7.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>8.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Description of the Research Project

Hypothesis to be Tested:

Please briefly list the Hypothesis to be tested and provide the scientific basis of the hypothesis, critically examining the observations leading to the formulation of the hypothesis.

In as much as this study will involve qualitative interviews to elicit cultural beliefs, attitudes, and practices of pregnant women and their possible relationship with nutritional supplement use, hypothesis testing is not applicable.

Specific Aims:

Describe the specific aims of the proposed study. State the specific parameters, biological functions, rates, processes etc. that will be assessed by specific methods.

Qualitative interviews will be conducted to achieve the following aims:

- **Aim 1:** To identify cultural beliefs of pregnant women in rural Bangladesh regarding pregnancy and pregnancy related health risks and concerns
- **Aim 2:** To examine the influence of general beliefs and perception about pregnancy on various behaviours including food consumption and supplement use of pregnant women
- **Aim 3:** To investigate pregnant women’s attitudes toward various forms of nutrition supplements, for example, pills or food-packages, as potential determinants of various participation and adherence behaviours

Background of the Project including Preliminary Observations

Provide relevant background of the proposed study, and discuss the previous works on the research topic by citing specific references. Describe in a logical way how the present hypothesis is supported by the relevant background observations including any preliminary results that may be available. Provide scientific validity of the hypothesis on the basis of background information Critically analyze available knowledge in the field of the proposed study and discuss the questions and gaps in the knowledge that need to be fulfilled to achieve the proposed goals. If there is no sufficient information on the subject, indicate the need to develop new knowledge. Also include the significance and rationale of the proposed work by specifically discussing how these accomplishments will bring benefit to human health in relation to biomedical, social, and environmental perspectives.

Nutrition during pregnancy influences the health of both the mother and her baby (1). Although food and micronutrient supplementation programs have been implemented as the key strategies to improve maternal nutrition status, the effectiveness of these programs in real communities has been inconsistent (1,2). Low participation in and low adherence to supplementation have been suggested as possible causes of these inconsistent results (3,4).

In the field of medicine, patient beliefs and attitudes toward medical treatment have gained attention as significant determinants of compliance (5). The impact of the individual perspectives of pregnant women on participation in and adherence to nutrition supplementation is particularly important because pregnancy itself tends to be associated with unique culture-specific beliefs and perceptions. Particularly, reducing food intake during pregnancy (“eating down”) is a widely accepted cultural practice to assure successful delivery in many countries (6). Foods are easily restricted or modified, which in turn can influence participation in
and adherence to nutrition supplementation considerably (4,6). However, relatively few studies have been undertaken to investigate the influence of these beliefs on the actual participation and adherence to nutrition supplementations among pregnant women (4).

The effectiveness of food supplementation programs also depends on the level of replacement of usual dietary intake by the supplementary foods (7). In some countries, particularly in South and Southeast Asia, where food restriction during pregnancy is prevalent, the degree of replacement is believed to be high because women often believe that large birth size will complicate delivery (6). The degree and causes of replacement and its relationship to adherence, however, have rarely been investigated.

Therefore, comprehensive qualitative studies are required to investigate culturally bound beliefs, attitudes, and practices of pregnant women and examine the relationship of these factors with the actual behaviour of participation and adherence (1, 8, 9).

The proposed study will be a preliminary study which will elicit major themes regarding cultural beliefs, attitudes, and practices concerning pregnancy and pregnancy-related risks and concerns, which in turn will provide basis to design a comprehensive study for examining the influence of these factors on the program participation and adherence of pregnant women.

**Research Design and Methods**

Describe in detail the methods and procedures to be used in accomplishing the objectives and specific aims of the project. Discuss the alternative methods that are available and justify the use of the method proposed in the study. Justify the scientific validity of the methodological approach (biomedical, social, or environmental) as an investigation tool to achieve the specific aims. Discuss the limitations and difficulties of the proposed procedures and sufficiently justify the use of them. Discuss the ethical issues related to biomedical and social research for employing special procedures, such as invasive procedures in sick children, use of isotopes or any other hazardous materials, or social questionnaires relating to individual privacy. Point out safety procedures to be observed for protection of individuals during any situations or materials that may be injurious to human health. The methodology section should be sufficiently descriptive to allow the reviewers to make valid and unambiguous assessment of the project.

The proposed study will adopt an ethnographic approach to ensure optimal ability to elicit information. A total of 25 women who are currently pregnant or who are recently experienced pregnancy and who participated in the national nutrition supplementation including micronutrient pill supplementation, will be recruited. Women will be randomly selected from the Health and Demographic Surveillance System (HDSS) database of Matlab, Bangladesh by a staff member. Identification numbers (ID) will be assigned to all selected women, and the staff and the student investigator will have access to the matching list of IDs and names of participants. Each woman will be contacted by the student investigator and the oral informed consent will be obtained. In-depth interviews will be conducted with pregnant women who agree to participate in the study. Interviews will take place at these women's houses or community nutrition centres, wherever the participants feel more comfortable. Each interview will take about two hours, and the participants will choose their preferred time for the interviews. Women will be asked several open-ended exploratory questions concerning pregnancy-related features: their general beliefs and attitudes about pregnancy and health risks, about culture-bounded practices, about attitudes and actual use of nutrition supplements, and concerning their dietary intake pattern. During the course of the interviews, informants may be re-visited by the principal investigator for clarification or further questions. Because the student investigator does not speak Bengali fluently, an interpreter who speaks both Bengali and English will be hired for this study.

No risks are anticipated to participants in this study other than those encountered in day-to-day life because interviews will involve minimal intrusion.

**Sample Size Calculation and Outcome (Primary and Secondary) Variable(s)**

Inasmuch as the proposed study will be a preliminary research which involves qualitative interviews, no sample size is calculated.
Outcome variables are main themes emerging from the interviews and they will be defined as the analysis of interview texts is continued.

---

**Facilities Available**

Describe the availability of physical facilities at site of conduction of the study. For clinical and laboratory-based studies, indicate the provision of hospital and other types of adequate patient care and laboratory support services. Identify the laboratory facilities and major equipment that will be required for the study. For field studies, describe the field area including its size, population, and means of communications.

The proposed study will be conducted in Matlab for three weeks. A total of 25 women will be recruited and 15 interviews are expected to be completed. The student investigator will execute interviews. Because she cannot speak Bengali, a translator who can speak both English and Bengali, will be hired for the study.

---

**Data Safety Monitoring Plan (DSMP)**

All clinical investigations (biomedical and behavioural intervention research protocols) should include the Data and Safety Monitoring Plan (DSMP) to provide the overall framework for the research protocol’s data and safety monitoring. It is not necessary that the DSMP covers all possible aspects of each element. When designing an appropriate DSMP, the following should be kept in mind.

a) All investigations require monitoring;

b) The benefits of the investigation should outweigh the risks;

c) The monitoring plan should commensurate with risk; and

d) Monitoring should be with the size and complexity of the investigation.

Safety monitoring is defined as any process during clinical trials that involves the review of accumulated outcome data for groups of patients to determine if any treatment procedure practiced should be altered or not.

---

**Data management**

All in-depth interviews will be recorded in an MP3 file format. After each interview, the MP3 files will be uploaded on a secure website. Only the PI and the student investigator and her academic advisers will have access to it. After each interview is transcribed in Bengali and translated into English, the text files will be uploaded to the web site as well. In the research site, all files will be saved in a separate hard drive and a USB memory stick. They will also be securely kept by the student investigator. None will remain in any laptop or desk top computers to avoid unnecessary exposure.

Safety monitoring is not applicable

---

**Data Analysis**

Describe plans for data analysis. Indicate whether data will be analysed by the investigators themselves or by other professionals. Specify what statistical software packages will be used and if the study is blinded, when the code will be opened. For clinical trials, indicate if interim data analysis will be required to determine further course of the study.

All interviews will be recorded after obtaining audio-recording release agreement from the participants. Recordings will be coded by ID numbers for each participant. No names will be recorded. Interviews will be transcribed in Bengali then translated into English during the field study period. All English transcripts will be coded with ATLAS.ti v6.0 by the principal investigator. Emerging themes will be identified based on the Grounded Theory, which will provide a basis for designing the larger and more comprehensive qualitative study. Based on the emerging themes, pregnant women's beliefs and attitudes regarding pregnancy will be specified and the potential relationship between these beliefs/attitudes and nutrition supplementation use.
will be suggested. At the same time, these emerging themes may provide the contextual and socio-cultural perspective for interpreting the results of the other parts of the dissertation of the student investigator, which could involve secondary data analysis of the Maternal and Infant Nutrition Interventions at Matlab (MINIMat), an intervention previously implemented in Matlab, Bangladesh.

**Ethical Assurance for Protection of Human Rights**

Describe the justifications for conducting this research in human participants. If the study needs observations on sick individuals, provide sufficient reasons for using them. Indicate how participants rights will be protected, and if there would be benefit or risk to each participants of the study.

Inasmuch as the proposed study aims to investigate pregnant women’s beliefs, attitudes, and practices in relation to nutrition supplement use, human participation is required.

Because the participants may not be able to read due to the low literacy rate (less than 40%) in the study area (10), an oral consent will be obtained from each participant for this study. The consent form attached to this application will be read to study participants. As an indication that they understand what has been read to them and agree to be in this study as well as they agree to record the interview, they are asked to provide their signatures or thumbprints.

All study participants will clearly understand that the participation in the study is voluntary through an oral informed consent procedure. They will be also informed that they have right not to answer specific questions and they can stop the interview whenever they wish. If they appear hesitant about answering any questions, no further efforts will be made to elicit information from the interviewee on that specific matter. To make them comfortable answering questions, examples will be used. At the same time, the investigator’s position, as a listener and learner, not an investigator, will be emphasized. They will be also informed about audio-recording of the interview and recording release form will be administered to obtain the consent from the participants. Their names will not be mentioned during the interviews for confidentiality. Pseudonyms will be used if names are used in further data presentation. Because there are no expected risks for pregnant women to participate in the interviews, no medical or professional intervention in the event of adverse effects on women in this study is planned. If the investigator finds a need for medical intervention during an interview, even though the need is not directly cause by the interview, the participant will be referred to the community health center for further care.

**Use of Animals**

Describe if and the type and species of animals to be used in the study. Justify with reasons the use of particular animal species in the experiment and the compliance of the animal ethical guidelines for conducting the proposed procedures.

None

**Literature Cited**

Identify all cited references to published literature in the text by number in parentheses. List all cited references sequentially as they appear in the text. For unpublished references, provide complete information in the text and do not include them in the list of Literature Cited. There is no page limit for this section, however, exercise judgment in assessing the “standard” length.

(7) Gillespie SR. Supplementary feeding for women and young children. 1999;Nutr Toolkit Module No. 5.

**Dissemination and Use of Findings**

Describe explicitly the plans for disseminating the accomplished results. Describe if and how the research findings would be shared with stakeholder, identifying them if known, and the mechanism to be used. Also describe what type of publication is anticipated: working papers, internal (institutional) publication, international publications, international conferences and agencies, workshops etc. Indicate, if the project is linked to the Government of the People’s Republic of Bangladesh through a training programme or a collaborative arrangement.

The study results will be mainly used for designing a more comprehensive study, which can be internationally published. It will also generate hypotheses to be tested in later study.

**Collaborative Arrangements**

Briefly describe if this study involves any scientific, administrative, fiscal, or programmatic arrangements with other national or international organizations or individuals. Indicate the nature and extent of collaboration and include a letter of agreement between the applicant or his/her organization and the collaborating organization.
Biography of the Investigators

Give biographical data in the following table for key personnel including the Principal Investigator. Use a photocopy of this page for each investigator.

(Note: Biography of the external Investigators may, however, be submitted in the format as convenient to them)

1 Name: Ruchira Tabassum Naved

2 Present Position: Scientist

3 Educational background: Ph.D in Economics
   (last degree and diploma & training relevant to the present research proposal)

4.0 List of ongoing research protocols
   (start and end dates; and percentage of time)

4.1. As Principal Investigator

<table>
<thead>
<tr>
<th>Protocol Number</th>
<th>Starting date</th>
<th>End date</th>
<th>Percentage of time</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

4.2. As Co-Principal Investigator

<table>
<thead>
<tr>
<th>Protocol Number</th>
<th>Starting date</th>
<th>End date</th>
<th>Percentage of time</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

4.3. As Co-Investigator

<table>
<thead>
<tr>
<th>Protocol Number</th>
<th>Starting date</th>
<th>End date</th>
<th>Percentage of time</th>
</tr>
</thead>
<tbody>
<tr>
<td>2005-039</td>
<td>01/01/06</td>
<td>30/09/09</td>
<td>29%</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

5 Publications

<table>
<thead>
<tr>
<th>Types of publications</th>
<th>Numbers</th>
</tr>
</thead>
<tbody>
<tr>
<td>a. Original scientific papers in peer-review journals</td>
<td>7</td>
</tr>
<tr>
<td>b. Peer reviewed articles and book chapters</td>
<td>1</td>
</tr>
<tr>
<td>c. Papers in conference proceedings</td>
<td>14</td>
</tr>
<tr>
<td>d. Letters, editorials, annotations, and abstracts in peer-reviewed journals</td>
<td></td>
</tr>
<tr>
<td>e. Working papers</td>
<td>6</td>
</tr>
<tr>
<td>f. Monographs</td>
<td></td>
</tr>
</tbody>
</table>
6 Five recent publications including publications relevant to the present research protocol


**Biography of the Investigators**

Give biographical data in the following table for key personnel including the Principal Investigator. Use a photocopy of this page for each investigator.

(Note: Biography of the external Investigators may, however, be submitted in the format as convenient to them)

1 **Name:** Jisung Woo

2 **Present Position:** Graduate Student

3 **Educational background:**

   (last degree and diploma & training relevant to the present research proposal)

   MPH, General Epidemiology, University of Michigan, 1999

4.0 **List of ongoing research protocols**

   (start and end dates; and percentage of time)

   NONE

4.4. As Principal Investigator

<table>
<thead>
<tr>
<th>Protocol Number</th>
<th>Starting date</th>
<th>End date</th>
<th>Percentage of time</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

4.5. As Co-Principal Investigator

<table>
<thead>
<tr>
<th>Protocol Number</th>
<th>Starting date</th>
<th>End date</th>
<th>Percentage of time</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
4.6. As Co-Investigator

<table>
<thead>
<tr>
<th>Protocol Number</th>
<th>Starting date</th>
<th>End date</th>
<th>Percentage of time</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

5 Publications - NONE

<table>
<thead>
<tr>
<th>Types of publications</th>
<th>Numbers</th>
</tr>
</thead>
<tbody>
<tr>
<td>a. Original scientific papers in peer-review journals</td>
<td></td>
</tr>
<tr>
<td>b. Peer reviewed articles and book chapters</td>
<td></td>
</tr>
<tr>
<td>c. Papers in conference proceedings</td>
<td></td>
</tr>
<tr>
<td>d. Letters, editorials, annotations, and abstracts in peer-reviewed journals</td>
<td></td>
</tr>
<tr>
<td>e. Working papers</td>
<td></td>
</tr>
<tr>
<td>f. Monographs</td>
<td></td>
</tr>
</tbody>
</table>

6 Five recent publications including publications relevant to the present research protocol

NONE

1)  
2)  
3)  
4)  
5)  

Biography of the Investigators

Give biographical data in the following table for key personnel including the Principal Investigator. Use a photocopy of this page for each investigator.

(Note: Biography of the external Investigators may, however, be submitted in the format as convenient to them)

1 Name: Kathleen M. Rasmussen

2 Present Position: Professor

3 Educational background:
(last degree and diploma & training relevant to the present research proposal)

    Brown University, Providence, RI, A.B, 1970, Molecular Biology
    Harvard University, Boston, MA, Sc.M., 1975, Nutrition
4.0 List of ongoing research protocols
   (start and end dates; and percentage of time)

4.7. As Principal Investigator

<table>
<thead>
<tr>
<th>Protocol Number</th>
<th>Starting date</th>
<th>End date</th>
<th>Percentage of time</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

4.8. As Co-Principal Investigator

<table>
<thead>
<tr>
<th>Protocol Number</th>
<th>Starting date</th>
<th>End date</th>
<th>Percentage of time</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

4.9. As Co-Investigator

<table>
<thead>
<tr>
<th>Protocol Number</th>
<th>Starting date</th>
<th>End date</th>
<th>Percentage of time</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

5 Publications

<table>
<thead>
<tr>
<th>Types of publications</th>
<th>Numbers</th>
</tr>
</thead>
<tbody>
<tr>
<td>g. Original scientific papers in peer-review journals</td>
<td>91</td>
</tr>
<tr>
<td>h. Peer reviewed articles and book chapters</td>
<td>14</td>
</tr>
<tr>
<td>i. Papers in conference proceedings</td>
<td>&gt;100</td>
</tr>
<tr>
<td>j. Letters, editorials, annotations, and abstracts in peer-reviewed journals</td>
<td>2</td>
</tr>
<tr>
<td>k. Working papers</td>
<td>18</td>
</tr>
<tr>
<td>l. Monographs</td>
<td>3</td>
</tr>
</tbody>
</table>

6 Five recent publications including publications relevant to the present research protocol


Biography of the Investigators

Give biographical data in the following table for key personnel including the Principal Investigator. Use a photocopy of this page for each investigator.

(Note: Biography of the external Investigators may, however, be submitted in the format as convenient to them)

1 Name: Gretel H. Pelto

2 Present Position: Graduate Professor

3 Educational background:
(last degree and diploma & training relevant to the present research proposal)

   Bennington College  1957-1960  (Literature)
   University of Minnesota, Minneapolis  (1961-1962) BA Sociology
   University of Minnesota, Minneapolis  (1964-1967) MA Anthropology
   University of Minnesota, Minneapolis (1967-1970) Ph.D Anthropology

4.0 List of ongoing research protocols

None currently
(start and end dates; and percentage of time)

4.10. As Principal Investigator

<table>
<thead>
<tr>
<th>Protocol Number</th>
<th>Starting date</th>
<th>End date</th>
<th>Percentage of time</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

4.11. As Co-Principal Investigator

<table>
<thead>
<tr>
<th>Protocol Number</th>
<th>Starting date</th>
<th>End date</th>
<th>Percentage of time</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

4.12. As Co-Investigator

<table>
<thead>
<tr>
<th>Protocol Number</th>
<th>Starting date</th>
<th>End date</th>
<th>Percentage of time</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

5 Publications

<table>
<thead>
<tr>
<th>Types of publications</th>
<th>Numbers</th>
</tr>
</thead>
<tbody>
<tr>
<td>m. Original scientific papers in peer-review journals</td>
<td>80</td>
</tr>
<tr>
<td>n. Peer reviewed articles and book chapters</td>
<td>30</td>
</tr>
</tbody>
</table>
6 Five recent publications including publications relevant to the present research protocol


Budget Justifications

Please provide one page statement justifying the budgeted amount for each major item, including the use of
human resources, major equipment, and laboratory services.

The budget includes all direct expenses for the proposed study including hiring translators and a
transcriptionist. Indirect expenses for the student investigator from the US are also added to. Since this
proposed study only involves interviews, no other equipments are listed because the student investigator
will bring her own technical equipment including MP3 players and lap-tops.
Budget description

1. **Duration**: June 16-July 6
2. **Place**: Matlab, Bangladesh
3. **Budget (Details):**

<table>
<thead>
<tr>
<th>Item</th>
<th>Content</th>
<th>Expense ($)</th>
<th>Note</th>
</tr>
</thead>
<tbody>
<tr>
<td>Translator 1</td>
<td>16 days * $20</td>
<td>320</td>
<td>For interviews</td>
</tr>
<tr>
<td>Translator 2</td>
<td>15 informants * $35</td>
<td>525</td>
<td>From Bengali to English</td>
</tr>
<tr>
<td>Transcription</td>
<td>15 informants * $20</td>
<td>300</td>
<td>From oral records to written transcripts</td>
</tr>
<tr>
<td><strong>Expense of student investigator</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Accommodations</td>
<td>(Dhaka) 3 days*$50</td>
<td>150</td>
<td>For the student investigator including meals, guest house of the research centre</td>
</tr>
<tr>
<td></td>
<td>(Matlab) 18 days*$40</td>
<td>720</td>
<td></td>
</tr>
<tr>
<td>Food</td>
<td>(Dhaka) 3 days *$20</td>
<td>60</td>
<td></td>
</tr>
<tr>
<td>Transportation</td>
<td>(Trip to Matlab) Round trip, $80</td>
<td>80</td>
<td>One-way is $40</td>
</tr>
<tr>
<td></td>
<td>(Trip to Airport) Round trip, $30</td>
<td>30</td>
<td></td>
</tr>
<tr>
<td></td>
<td>(Other transportation) 20 days* $5</td>
<td>100</td>
<td></td>
</tr>
<tr>
<td>Cell Phone</td>
<td>Rent and phone card</td>
<td>70</td>
<td></td>
</tr>
<tr>
<td>Others</td>
<td>Items for research</td>
<td>50</td>
<td>Stationery, rewards, etc.</td>
</tr>
<tr>
<td>Human resource</td>
<td>Salary for the administrative staff</td>
<td>67</td>
<td>Salary coverage for providing logistic support, raise requisition, arrange translator or transcriptionist, etc</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td></td>
<td><strong>2,472</strong></td>
<td></td>
</tr>
</tbody>
</table>
Other Support

Describe sources, amount, duration, and grant number of all other research funding currently granted to PI or under consideration.

None
CONSENT FORM

Purpose of the research

My name is Jisung Woo. I am from Korea, but now I am a student at Cornell University in the United States. I am working with a researcher at ICDDR, B as well. I am interested in learning more about the experiences and views about pregnancy of women in different places. The experiences and views of women are very important to understand how a pregnant woman behaves or make decisions during her pregnancy, particularly behaviors for good and healthy outcome of both the mother and the baby. Therefore I hope my study will provide important information in order to plan and implement programs for pregnant women, which will address the practical needs and at the same time will be acceptable to program participants. If you agree to talk with me I would like to ask you about your own experiences and ideas concerning your recent pregnancy. I’m not a medical doctor and I can’t give you advice. Actually I’m here to learn and listen.

During the interview, you will be asked questions about your thoughts and views on pregnancy itself and pregnancy related health issues. Your opinion concerning nutrition supplements use and your dietary eating practice during pregnancy will also be asked. You can stop talking with me at any point that you want or if I ask you about something you would rather not talk about you can just say so. I would like to talk about these with you in a place where you feel comfortable. It will take approximately two hours to finish our talk. Also if there is something that is not clear to me, I may come back and ask you more questions later. I don’t speak Bangla, although I understand a little, so I will need the help of my friend, (name of the interpreter) to translate what you are saying to me and what I am saying to you.

Possible Risks and Benefits

You can decide whether you want to do the talk with me or not. It is completely voluntary. If you participate, there will be no direct benefit to you. However, your experiences and views will be useful for people who are engaged in programs for pregnant women to understand pregnant women’s thought and their behavior better. Your participation or refusal to this study will not cause any further effects on you.

Confidentiality

I won’t tell your name to anyone, so that your privacy will be completely respected. A pseudonym will be given to you and used for further data presentation. Only I and the researcher from the ICDDR, B will have access to the list that links your name and your identification number but the list will be destroyed when the study is finished. Also I would like to record the interview so I can listen to it again later. It is very important for me to make sure I will understand what you will tell me in detail and correctly. So it would be really helpful if I can tape record the talk we will have. I won’t share what you tell me, except with my teacher back at Cornell. Even to my teacher, I won’t tell her your name and will only use the pseudonym. I will manage all materials related to our talk strictly. Interpreters will not know your name because I will not share your name with them either.
They will not have access to any material after the study. During study period, they will have limited access to the material if it is necessary with my permission and supervision.

**Future use of information**
If I need to use the information collected from this study, I will only share data with pseudonyms or abstracted information. I will make sure all the sharing processes will not violate the maintenance of privacy and confidentiality of information identifying participants in any way.

**Principle of compensation**
You will be given a small practical gift as appreciation of you participation. If any transportation costs are incurred for you to come to the place where we will have the talk, I will make sure you will be reimbursed.

**Offer to answer questions**
Do you have any questions?
Do you agree to do a talk with me?
Do you agree to let me voice record this session for accuracy and completeness?
Please tell me if this time and place are good to talk?
If there are any problems we can agree on a place and time of your choice.
Thank you for your cooperation

**Investigator’s statement**
I, the undersigned, have explained to the volunteer in a language she understands the procedures to be followed in the study and the risks and benefits involved.

_____________________________   ___________________
Interviewer’s signature      Date

If you agree to participate in my study, please indicate that by putting your signature or your left thumb impression at the specified space below

_____________________________   ____________________
Signature or left thumb impression of subject   Date
(Participation)

If you agree to record the voice during the talk, please indicate that by putting your signature or your left thumb impression at the specified space below

_____________________________   ____________________
Signature or left thumb impression of subject  
(Voice Recording)  

_______________________________________  ____________________  
Signature or left thumb impression of the witness  Date  

_______________________________________  ___________________  
Signature of the PI or his/her representative  Date  

If you have questions: The researchers conducting this study are Jisung Woo, Prof. Kathleen Rasmussen and Dr. Ruchira Naved. If you have questions later, you may contact Jisung Woo at jw557@cornell.edu or at 1-607-255-7547. You can reach Prof. Rasmussen at kmr5@cornell.edu/1-607-255-2290 or Dr. Ruchira Naved at ruchira@icddrb.org. If you have any questions or concerns regarding your rights as a participant in this study, you may contact the Ethical Review Committee at ICDDR, B at 2-886-0523~32 or Cornell Institutional Review Board (IRB) at 1-607-255-5138 or access their website at http://www.irb.cornell.edu. You may also report your concerns or complaints anonymously through Ethicspoint or by calling toll free at 1-866-293-3077. Ethicspoint is an independent organization that serves as a liaison between the University and the person bringing the complaint so that anonymity can be ensured.
Performance Agreement and Release

1. I, ______________________________, have been informed and understand that Jisung Woo from Cornell University is audio-taping the interview in which my voice will be included.

2. I hereby grant the researchers of this study and their organizations, Cornell University and ICDDR, B. the right to make, use and publish in whole or in part any recorded footage in which my voice will be included in MP3 file format. Cornell University shall have complete ownership of the Recordings in which I or my contribution appears.

3. I also grant Cornell University the right to distribute, display, and broadcast the recording as part of its summary statistics or finished papers.

4. I hereby waive any and all right that I may have to approve the finished product or printed matter that may be used in connection therewith.

5. I expressly release Cornell University and all persons acting under its permission or authority from any claim or liability arising out of or in any way connected with the above uses and representations including any and all claims for defamation or copyright infringement.

I am over the age of eighteen, and have read the above release, and fully understand its contents.

_______________________________________  ____________________
Signature or left thumb impression of subject   Date
(Voice Recording)

_______________________________________  ____________________
Signature or left thumb impression of the witness   Date

_______________________________________  ____________________
Signature of the PI or his/her representative     Date
Bengali consent form
(did not add it here as it was a pdf file)
Bengali consent form (Cont’d...)
Bengali consent form (Cont’d...)
Bengali consent form (Cont’d...)
Interview Guide

(For women who have already given birth)
1.1.1 I would like to start by asking about the last time you were pregnant. I understand you have a
new baby. When was he/she born?

1.1.2 Where did you give birth to him/her?

(For women who is currently pregnant)
1.2.1 I would like to start by asking you about this pregnancy. When do you expect your baby to be
born?

1.2.2 Where do you plan to give birth?

[For the following questions, tense will be modified according to the participant’s pregnancy
status; previous pregnancy or current pregnancy]

2. Do you have any other children?

3. How many children do you have?
(For women with no previous births, omit question about delivery experience.)

4. While you were pregnant, were there any special things you did to be healthy?

5. Were there any things you did for the health of your baby?

6. Did anyone else in your family or here in the community make recommendations to you about
what you should and should not do while you are pregnant?

7. Who made those recommendations and what did they tell you?

8. Did you get recommendations from a nurse or doctor? What did they tell you?

9. Was there anything you worried about regarding your pregnancy?

10. What about giving birth: was there anything you worried about?

11. You’ve already mentioned some things about eating during pregnancy, but I would like to ask
you more about this topic.

12. How was your diet during your pregnancy in general?

13. Did you eat any foods you usually don’t eat when you are not pregnant? What were they? Why
did you start eating these foods?

14. What about foods that you avoided eating; were there any foods you didn’t eat when you were
pregnant? Why is that?

15. Some women change the amount of food they eat when they are pregnant – eating more or
eating less. What is your view about that?

16. Did you make any changes in the amount you ate?

17. Did you have any special vitamins, pills or special preparations of food that you took during your pregnancy?

18. Can you tell me more about them?

19. What were they were and where did you obtain these?

20. What do you think the supplements did for you? For your baby?

21. Did you take more than one type of supplement? If so, what was the difference between them and was one easier to take than another?

22. Was one better for you than another?

23. What was your husband’s role or influence during your pregnancy?

24. Among your family members, who was the most influential about your decisions for foods, activities, and other matters related to pregnancy?

25. Finally I’d like to ask you about differences between the kind of advice you get from doctors and nurses and the kind of advice you get from older people in the community. Are there any differences in the sort of advice you get? What do you think about these differences?

26. Is it ever a problem to know what to do when advice isn’t the same? What do you think women should do if this happens?

Thank you so much for talking with me today.
1.1.1 me¶ Kav Avc wb hlb gvn tQb tmmgq wb tQb Avc wb mt_ K_v evi "K1tZ Pvb| Avc wb tQwb
G Kb evPvA Qwb, Z wb Rb ntnQtQ Kt e?

1.1.2 Avc wb evPwU Rb ntnQtQ K_v Q?

1.2.1 Avc wb GB Mf KijJohnson mgq wb tQb K_v evi "K1tZ Pvb| Avc wb evPwU Kt e Rb yK Kt e
etj Avc wb c ŸvKv Ki tQb?

1.2.2 evPwU K_v Q cÎée nte etj Avcwb c¿WÍi bvKší tQb?

2. Avc wb uK A1i v ms wb A4 Q?

3. Avcwb Kqw mš wb?

4. Mf @Z xA e ¼g Avc wb " f y i wb R b n yKt i Qyt b?

5. Avc wb Mt f ½ mš wb Gö " f y i wb R b n yKt i Qyt b?

6. Avcwb hlb Mf @Z xQt b ZLb Avcwb K1vDwPZ A_evKv K1vDwPZ bq tmmme velttq
Avcwb c¿wii A_ev vooc K tKD M tKvb ci vgk ÆwtQtQ b?

7. tK ci vgk @tj vwtQtQ b Ges K etj Qyt b?

8. Avcwb A1evb b®Gi wbKUt_tK ci vgk @cQtQtQ b? Z ùvK etj Qjt?

9. Avcwb Mf ym ym Kt wb K wb vPvZ Qyt b?

10. mš wb cÎé msu v velttq Avcwb K wb vPvZ Qyt b?

11. BvZgta" Mf ¼g Avcwb Lú ¼wO MÔy msûtK @KQvelg etj tQb s1Avg G veltq Av1v tevk
K QyR bZ Pvb|

12. mw1ev t e Mf ¼g Avcwb Lú ¼wO MÔy tKgb wQj?

13. Avcwb Kt Mf ¼g Ggb wbQylwev MÔy Kti tQb hvMf KijJohnson mgQti c te @mav ZY tÌZ b wb
rm, tj vKt? tKb rm LveW, tj vtlZ ii "K1ti tQ b?

14. tKvb LveW Avcwb GwQt tMtQb evLvb, Ggb wbQylwev K wb Qh, tj vAvcwb Mf @Z x
LAN Avcwb Ggb QyM K1t b wb? rm, tj vK?

15. Mf KijJohnson mgQti QyBú Lù gQttc LveWii c ¿gwb c ¿wZb Kt i tevk LveW MÔy Kti A_ev
Kg, GB velttq Avcwb c¿wì `v€ wb K?

16. Avcwb Kt LveW MÔYi c ¿gwbY tKvb c ¿wZb Kt i tQt b?
Beliefs, attitudes and practices towards nutrition supplementation programs in Bangladeshi women

Abstract

The effectiveness of nutrition supplementation programs is closely linked with participation and adherence of program participants. Cultural beliefs and practices are expected to influence the behaviours of pregnant women in participating in and adherence to nutrition supplements, but very few studies have been undertaken to elucidate their relationships. Therefore, a preliminary qualitative study will be conducted to identify emerging themes concerning cultural beliefs and practices concerning pregnancy and pregnancy-related health risks, attitudes toward different types of supplementation, and replacement of home diet by supplements among pregnant women in Bangladesh.

Inasmuch as the proposed study aims to investigate pregnant women’s beliefs, attitudes, and practices, human participation is critically required. A total of 25 women, who are currently pregnant or who are recently experienced pregnancy and who participated in the national nutrition supplementation including micronutrient pill supplementation, will be randomly selected based on the Health and Demographic Surveillance System (HDSS) database of Matlab, Bangladesh by a staff member. An ID number will be assigned to each woman and the list matching participants with their ID numbers will be kept in a secure place separate from the dataset.

Because a high rate of illiteracy is expected in the study area, oral informed consent will be administered. All study participants will clearly understand that the participation in the study is voluntary, they have right not to answer specific questions that they do not want, and they can stop the interview whenever they wish through the oral informed consent procedure. They will be also informed about audio-recording of the interview and recording release form will be administered to obtain the agreement from the participants.

After participants agree to join the study, in-depth interviews will be conducted. Women will be asked several open-ended exploratory questions concerning pregnancy related features: their general belief and attitude about pregnancy and health risks, about culture-bounded practices, about attitudes and actual use of nutrition supplements, and concerning their dietary intake pattern. Their names will not be mentioned during the interviews for confidentiality. Interviews will be taken place at these women's houses or community nutrition centres wherever the participants feel more comfortable. Each interview will take about two hours, and the participants will choose their preferred time for the interviews. Because women will be only involved in interviews, no risks are expected from this study. If they appear hesitant about answering any questions, no further efforts will be made to elicit information from the interviewee on that specific matter. To make them comfortable to answer questions, examples will be used. At the same time, the principal investigator’s position, as a listener and learner, not an investigator, will be emphasized.

All interviews will be audio-recorded in an MP3 file format. After each interview, the MP3 files will be saved with ID numbers and uploaded on a secure website. Only the PI and the student investigator and her academic advisers will have access to it. Each interview will be transcribed into Bengali then translated into English and . the text files will be uploaded to the web site as well. In the research site, all files will be saved in a separate hard drive and a USB memory stick. They will also be securely kept by the student investigator. None will remain in any laptop or desk top computers to avoid unnecessary exposure.

The analysis of these transcripts will involve the identification of emerging themes. Further text analysis will refine the themes and identify their potential importance for understanding participation, adherence, and replacement. All analyses will be conducted by using ATLAS.ti v6.0. Pseudonyms will be used if names are used in data presentation.

Based on the results of this preliminary investigation, a more comprehensive round of interviews will be designed to examine the relationship between beliefs/attitudes and pregnant women’s behaviour more thoroughly.

Participants will not benefit directly from participating in this study. However, some participants may utilize the interview as a chance to address their concerns and complaints regarding the use of nutrition supplements. Women may realize their practices regarding nutrition supplement use, which could positively affect their future utilization of supplements indirectly. Furthermore, for social groups or the society to which those women belong, this study will provide very important information about underlying beliefs and attitudes of pregnant women in relation to low or high adherence of nutrition supplementation. Inasmuch as
the degree of adherence can have the impact on the effectiveness of nutrition supplementation programs, the findings of this study will be useful for planning more feasible and effective nutrition programs for pregnant women in the future. Ultimately, this study is expected to contribute to the improved nutrition status of pregnant women through better participation and adherence to nutrition supplementation programs in Bangladesh and other countries where similar nutrition intervention is implemented.
## Check-List

**CHECK-LIST FOR SUBMISSION OF RESEARCH PROTOCOL FOR CONSIDERATION OF RESEARCH REVIEW COMMITTEE (RRC)**

[Please check (X) appropriate box]

<p>| | | | | | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Has the proposal been reviewed, discussed and cleared at the Division level?</td>
<td>Yes</td>
<td>☐ No</td>
<td>☐</td>
<td>If No, please clarify the reasons:</td>
<td></td>
</tr>
<tr>
<td>2.</td>
<td>Has the proposal been peer-reviewed externally?</td>
<td>Yes</td>
<td>☐ No</td>
<td>☐</td>
<td>If the answer is ‘No’, please explain the reasons:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>If yes, have the external reviews’ comments and their responses been attached</td>
<td>Yes</td>
<td>☐ No</td>
<td>☐</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3.</td>
<td>Has the budget been cleared by Finance Department?</td>
<td>Yes</td>
<td>☐ No</td>
<td>☐</td>
<td>If the answer is ‘No’, reasons thereof be indicated:</td>
<td></td>
</tr>
<tr>
<td>4.</td>
<td>Does the study involve any procedure employing hazardous materials, or equipments?</td>
<td>Yes</td>
<td>☐ No</td>
<td>☒</td>
<td>If ‘Yes’, fill the necessary form.</td>
<td></td>
</tr>
<tr>
<td>5.</td>
<td>Has the Ethics Certificate(s) been attached with the Protocol?</td>
<td>☒ Yes</td>
<td>☐ No</td>
<td>☐</td>
<td>If the answer is ‘No’, please explain the reasons:</td>
<td></td>
</tr>
</tbody>
</table>

Signature of the Principal Investigator

Date
Detailed Budget for the study titled: Pregnant women’s beliefs, attitudes, and practices toward nutrition supplementation programs in Bangladesh

Name of Principal Investigator: Dr. Ruchira T. Naved

Protocol Number: _____________

Division: _____________________________

Funding Source: Division of Nutritional Sciences Small Grant

Budget: Director: US$ 2,472 ; Indirect: US$__________; Total: US$ 2,472__

Study period: From: June 15 2009 through July 6 2009__

Strategic Priority Code(s): 

<table>
<thead>
<tr>
<th>Line Items</th>
<th>Budget</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Payroll and Benefits:</strong></td>
<td></td>
</tr>
<tr>
<td>Name of personnel/position</td>
<td>Pay level</td>
</tr>
<tr>
<td>Tapon K. Bose</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Sub-total of Payroll and benefits:</strong></td>
<td>67</td>
</tr>
<tr>
<td><strong>Travel and transport</strong></td>
<td></td>
</tr>
<tr>
<td>Trip to Matlab (1 round-trip)</td>
<td>80</td>
</tr>
<tr>
<td>Other transportation (Daily transportation and trip to airport)</td>
<td>130</td>
</tr>
<tr>
<td>Accomodation (Dhaka)</td>
<td>150</td>
</tr>
<tr>
<td>Accomodation (Matlab)</td>
<td>720</td>
</tr>
<tr>
<td>Food (Dhaka)</td>
<td>60</td>
</tr>
<tr>
<td><strong>Sub-total of Travel and Transport:</strong></td>
<td>1,140</td>
</tr>
<tr>
<td><strong>Supply and materials</strong></td>
<td></td>
</tr>
<tr>
<td>Stationery and small gifts for participants</td>
<td>50</td>
</tr>
<tr>
<td>Cell phone lease</td>
<td>70</td>
</tr>
<tr>
<td><strong>Sub-total of supply and materials:</strong></td>
<td>120</td>
</tr>
<tr>
<td><strong>Other contractual</strong></td>
<td></td>
</tr>
<tr>
<td>Interview translator</td>
<td>320</td>
</tr>
<tr>
<td>Interview script translator</td>
<td>525</td>
</tr>
<tr>
<td>Transcriptionist</td>
<td>300</td>
</tr>
<tr>
<td><strong>Sub-total of other contractual:</strong></td>
<td>1,145</td>
</tr>
<tr>
<td><strong>Total direct costs:</strong></td>
<td>2,472</td>
</tr>
<tr>
<td><strong>Total indirect cost:</strong></td>
<td>0</td>
</tr>
<tr>
<td><strong>Total costs:</strong></td>
<td>2,472</td>
</tr>
</tbody>
</table>