



FEED THE FUTURE

The U.S. Government's Global Hunger & Food Security Initiative

DESIGN AND IMPLEMENTATION OF PROSPECTIVE INTERVENTION STUDIES IN HUMAN NUTRITION

Lynne M. Ausman



USAID
FROM THE AMERICAN PEOPLE



Friedman School
of Nutrition Science
and Policy



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AGENDA

1. Greetings to all.
2. Workshop result of experience with master's and doctoral students as well as junior professionals. **MUST** be interactive and is your chance to ask questions.
3. As nutrition professionals, a common denominator is the quest to find answer to the problems that challenge us.
 - a. Best way to lose weight?
 - b. How do I deliver a supplement and make sure it is consumed by the designated person?
 - c. To improve nutritional status, is it better to provide food or cash?
4. Common denominator is that there is a pressing question.



AGENDA (CONTINUED)

6. A stumbling block is access to resources to answer your question. Few of us have eternally deep pockets. Furthermore, a successful experimental study involves buy-in from government, civilian, and staff personnel
7. Answer: Write a well defined proposal requesting resources needed to accomplish the study that will also intrigue those with the resources.
8. Thus, this workshop designed to teach you principles of writing a proposal for an experimental study.



GROUPS 1 AND 2

Groups	Participant name	Research area/theme	Group Mentors
1	<u>Alisha Karki</u>	Obesity intervention at school level - junk foods/ <u>ultra processed</u>	Dr. Eunice <u>Bonsi</u> <u>Swetha Manohar</u> Dale Davis
	<u>Durgeswori Munankarmi</u>		
	<u>Manish Choudhari</u>		
	<u>Renu Yadav</u>		
	Yangzi Sherpa		
2	<u>Dev Ram Sunuwar</u>	Maternal - Pregnancy Nutrition Pregnancy nutrition - anemia and birth outcomes	Dr. Andrew Thorne Lyman Dr. Shibani Ghosh Dr. <u>Kedar P Baral</u>
	<u>Pranil Man Singh</u>		
	<u>Kumari Twayana</u>		
	<u>Saurav Neupane</u>		
	<u>Rajani Gyawali</u>		



GROUPS 3 AND 4

Groups	Participant name	Research area/theme	Group Mentors
3	Anjana Chaudhary	Infancy, early life feeding practices Stunting, WASH, cognitive development	Dr. Patrick Webb Dr. Laurie Miller Dr. Archana Amatya
	Shankuk Bhatta		
	Vintuna Shrestha		
	Sambhavy Shrestha		
	Harihar Sharma		
4	Anju Bhatt	Diabetes lifestyle intervention - urban- clinic or non clinic	Dr. Lynne M. Ausman Dr. Robin Shrestha Dr. Ram Krishna Chandyo
	Manisha Shrestha		
	Shilpi Kumari		
	Aashma Dahal		
	Aastha Kasaju		



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MONDAY MORNING

Time	Topics	Monday March 19, 2018
		<i>Day 1</i>
Day 1: 8:15-9:45, Day 2-5: 8:00 - 9:45 Day 6: 9:00 - 11:00	Substantive 1	Inauguration and Introduction to Design and Implementation of Prospective Intervention Studies in Human Nutrition <u>L. Ausman, KP. Baral, A. Amatya</u>
9:45-10:15 am	~	Tea
10:15-12:00 noon	Substantive 2	Research Questions, Specific Aims and Hypothesis and Outcomes: Theory <u>P. Webb, A. Thorne Lyman</u>
12:00-1:00 pm	~	Lunch
1:00-2:30 pm	Application	Research question development, writing background and rationale Search engines to perform Literature Review <u>S. Ghosh, L. Ausman</u>
2:30-2:45 pm		Break



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MONDAY AFTER- NOON

2:30-2:45 pm		Break
2:45-4:15 pm	Guided Practical Work Groups	Work with Group Mentors to Refine Research question, Develop Hypothesis, Specific Aims and define Outcomes Development,
		<u>Group Mentors</u>
4:15-4:30 pm	~	Tea
4:30-6:00 pm	Guided Practical Work Groups (continued)	Work with Group Mentors to Refine Research question, Develop Hypothesis, Specific Aims and define Outcomes Development,
6:00-7:00 pm	Dinner	Dinner
7:00- 9:30 pm	Individual/Group Activity	Group work: proposal development



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DELIVERABLES END OF DAY 1

One completed PICO worksheet form

List of references

Summary table of results

Letter of Intent (LOI)



COMPONENTS OF THE PROTOCOL

- **Authors:** [*Insert names here*] [Due Day 2, March 20, 2018]
- **Title:** [*Insert proposal title here*] [Due Day 2, March 20, 2018]
- **Abstract** [*Due end of Day 5, March 23, 2018*]
- **Background** [*Due end of Day 5, March 23, 2018*]
- **Significance and rationale** [*Due end of Day 2, March 20, 2018*]
- **Specific Aims** [*Due end of day 2, March 20, 2018*]
- **Hypothesis(s)** [*Due end of day 2, March 20, 2018*]
- **Experimental design and methodology** [*Due end of Day 3, March 21, 2018*]
- **Study design and flow of study participants throughout the study** [*Due end of Day 3, March 21, 2018*] Hint: A figure helps explain the study in an easy to understand manner.



COMPONENTS OF THE PROTOCOL (CONTINUED)

Sample size determination [*Due end of Day 3, March 21, 2018*]

Analytical strategy and statistical analysis [*Due end of Day 4, March 22, 2018*] (This section should explain the general approach to the analysis including participant inclusion and exclusion criteria)

Data collection [*Due end of Day 4, March 22, 2018*]

Timeline [*Due end of Day 5, March 23, 2018*]

Budget [*Due end of Day 5, March 23, 2018*] (Be sure to include a table along with text)

Expected results [*Due end of Day 5, March 23, 2018*]

Limitations and Policy Implications [*Due end of Day 5, March 23, 2018*]

References [*Due end of Day 5, March 21, 2018*] (Use APA format for references)



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TUESDAY MORNING

Time	Topics	Tuesday March 20, 2018
		<i>Day 2</i>
Day 1: 8:15:- 9:45, Day 2-5: 8:00 - 9:45 Day 6: 9:00 - 11:00	Substantive 1	Research Design – Types of Interventions and Statistical considerations (Quantitative) <u>L. Ausman, T. Thomas</u>
9:45-10:15 am	~	Tea
10:15-12:00 noon	Substantive 2	Research Design (Formative/Pilot) <u>L. Miller, A. Thorne Lyman</u>
12:00-1:00 pm	~	Lunch
1:00-2:30 pm	Application	Research Methodology, developing the intervention and Assessment methods <u>S. Ghosh, L. Miller</u>
2:30-2:45 pm		Break



TUESDAY AFTERNOON

2:30-2:45 pm		Break	
2:45-4:15 pm	Guided Practical Work Groups	Research Methodology Developing the intervention and Assessment methods	
		<u>L. Ausman, S. Ghosh, L. Miller</u>	
4:15-4:30 pm	~	Tea	
4:30-6:00 pm	Guided Practical Work Groups (continued)	Develop Research Design, the intervention and Methodology for proposal	
6:00-7:00 pm	Dinner	Dinner	
7:00- 9:30 pm	Individual/Group Activity	Group work	



DELIVERABLES END OF DAY 2

Authors and Group #: [*Insert names here*] [Due Day 2, March 20, 2018]

Title: [*Insert proposal title here*] [Due Day 2, March 20, 2018]

Significance and rationale [*Due end of Day 2, March 20, 2018*]

Specific Aims [*Due end of day 2, March 20, 2018*]

Hypothesis(s) [*Due end of day 2, March 20, 2018*]



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WEDNESDAY MORNING

Time	Topics	Wednesday March 21, 2018
		Day 3
Day 1: 8:15:-9:45, Day 2-5: 8:00 - 9:45 Day 6: 9:00 - 11:00	Substantive 1	Sample size estimation and Sampling strategy <u>T. S. Thomas, B. Shrestha</u>
9:45-10:15 am	~	Tea
10:15-12:00 noon	Substantive 2	Statistical analysis: methods to assess intervention <u>T.S. Thomas,</u>
12:00-1:00 pm	~	Lunch
1:00-2:30 pm	Application	Writing an analysis plan <u>T.S. Thomas, S. Ghosh</u>
2:30-2:45 pm		Break



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2:30-2:45 pm		Break
2:45-4:15 pm	Guided Practical Work Groups	Sample size estimation, Sampling strategy Analysis plan
		<u>B. Shrestha, T. Thomas</u>
4:15-4:30 pm	~	Tea
4:30-6:00 pm	Guided Practical Work Groups (continued)	Day 1, 2,3 review
6:00-7:00 pm	Dinner	Dinner
7:00- 9:30 pm	Individual/Group Activity	Group Work

WEDNESDAY AFTERNOON



DELIVERABLES END OF DAY 3

Experimental design and methodology [*Due end of Day 3, March 21, 2018*]

Study design and flow of study participants throughout the study [*Due end of Day 3, March 21, 2018*] Hint: A figure helps explain the study in an easy to understand manner.

Sample size determination [*Due end of Day 3, March 21, 2018*]



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THURSDAY MORNING

Time	Topics	Thursday March 22, 2018
		Day 4
Day 1: 8:15-9:45, Day 2-5: 8:00 - 9:45 Day 6: 9:00 - 11:00	Substantive 1	Data Collection, Quality and Management <u>S. Manohar, R. Shrestha</u>
9:45-10:15 am	~	Tea
10:15-12:00 noon	Substantive 2	Data collection and management, examples <u>R. Shrestha, S. Manohar</u>
12:00-1:00 pm	~	Lunch
1:00-2:30 pm	Application	IRB, Ethical Considerations <u>P. Webb, KP Baral</u>
2:30-2:45 pm		Break



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THURSDAY AFTERNOON

2:30-2:45 pm		Break
2:45-4:15 pm	Guided Practical Work Groups	Select Data collection methods
		<u>Group Mentors</u>
4:15-4:30 pm	~	Tea
4:30-6:00 pm	Guided Practical Work Groups (continued)	Protocol for Data management and quality
6:00-7:00 pm	Dinner	Dinner
7:00- 9:30 pm	Individual/Group Activity	Group Work (presentation)



DELIVERABLES END OF DAY 4

Analytical strategy and statistical analysis [*Due end of Day 4, March 22, 2018*] (This section should explain the general approach to the analysis including participant inclusion and exclusion criteria)

Data collection [*Due end of Day 4, March 22, 2018*]



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FRIDAY MORNING

Time	Topics	Friday March 23, 2018
		<i>Day 5</i>
Day 1: 8:15-9:45, Day 2-5: 8:00 - 9:45 Day 6: 9:00 - 11:00	Substantive 1	Timeline and Budget Development <u>D. Davis, E. Bonsi</u>
9:45-10:15 am	~	Tea
10:15-12:00 noon	Substantive 2	Protocol and Grant Proposal <u>L. Ausman, S. Ghosh</u>
12:00-1:00 pm	~	Lunch
1:00-2:30 pm	Application	Funding agencies, development of proposal <u>P. Webb, D. Adhikari, M. Villanueva, S. Chitakwe</u>
2:30-2:45 pm		Break



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FRIDAY AFTERNOON

2:30-2:45 pm		Break	
2:45-4:15 pm	Guided Practical Work Groups	Finalizing protocol, timeline, Introduction to Budget and Grant Proposal	
		<u>Group Mentors</u>	
4:15-4:30 pm	~	Tea	
4:30-6:00 pm	Guided Practical Work Groups (continued)	Budget and Grant proposal	
6:00-7:00 pm	Dinner	Dinner	
7:00- 9:30 pm	Individual/Group Activity	Group work (presentation)	



DELIVERABLES END OF 5

Timeline [*Due end of Day 5, March 23, 2018*]

Budget [*Due end of Day 5, March 23, 2018*] (Be sure to include a table along with text)

Expected results [*Due end of Day 5, March 23, 2018*]

Limitations and Policy Implications [*Due end of Day 5, March 23, 2018*]

References [*Due end of Day 5, March 21, 2018*]
(Use APA format for references)



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SATURDAY MORNING

Time	Topics	Saturday March 24, 2018
		<i>Day 6</i>
Day 1: 8:15:- 9:45, Day 2-5: 8:00 - 9:45 Day 6: 9:00 - 11:00	Substantive 1	Saturday (Participant Group presentations)
9:45-10:15 am	~	Tea
10:15-12:00 noon	Substantive 2	Saturday (Conclusion and certificates distribution)
12:00-1:00 pm	~	Lunch
1:00-2:30 pm	Application	Return to KTM
2:30-2:45 pm		



PRESENTATION OF YOUR PROPOSAL

Format of Presentation:

1. 20 minutes
2. Maximum 10 slides containing:
 - Title
 - Background
 - Significance and rationale
 - Hypothesis and Specific Aims
 - Experimental design and methodology
 - Analytic strategy
 - Timeline and Budget



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