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| AFYA BORA CONSORTIUM GLOBAL HEALTH LEADERSHIP FELLOWSHIP PROGRAM |
| EFFECTIVE GRANT WRITING |
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**AFYA BORA CONSORTIUM**

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**MODULE OVERVIEW**

This training module provides instruction in proposal writing, a critical first step in conducting a successful research project. Topics covered during the week include: effective writing, the components of a research proposal, quantitative and qualitative study design, and the peer review process. The module emphasizes skills required to write a proposal by having trainees spend at least one-third of the time in class and out of class developing *their own proposals* with feedback from each other and the course instructors. Ethical conduct and research with human subjects are two critical areas in the responsible conduct of research that have been covered elsewhere in the Fellowship (see Responsible Conduct of Research distance learning module). Principles will be reviewed and specific cases relevant to research proposal and grant writing will be discussed in this module.

# MODULE LEARNING OBJECTIVES

On course completion the student will be able to:

1. Identify the key components of a successful grant proposal and discuss at least two “pearls” for writing each section.
2. Demonstrate knowledge of the different qualitative and quantitative approaches and use these effectively in designing a study.
3. Describe the grant application process and participate in reviewing a proposal using NIH criteria for peer review.
4. Write a competitive research proposal with input from a mentor and more senior colleagues.

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# EFFECTIVE PROPOSAL WRITING MODULE SCHEDULE

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **Day 1**  | **Day 2** | **Day 3** | **Day 4** |
| **9:00-10:00** | **Session 1**Introduction to Proposal Writing | **Session 3** Proposal Basics: Innovation & Significance  | **Session 6**Proposal Basics: Approach & Methods | **Session 9**Proposal Basics: Supporting Materials and Career Development Awards (HW #3 due) |
| **10:00-11:30** | **Session 2**Proposal Basics: Hypotheses & Specific Aims | **Session 4** Proposal Basics: Analysis/Sample Size Plans  | **Session 7**Sample Size Exercise | **Session 10**NIH Peer Review Process |
| **11:30-12:00** | **BREAK** | **BREAK** | **BREAK** | **BREAK** |
| **12:00-1:00** | **Group Exercise**Writing Skills | **Session 5**Research with Human Subjects and Ethics Case Studies | **Session 8** Writing the Qualitative Research Methods Section | **Session 11 (start at 11:30)**Expert Perspectives on Grant Submission: Local Researchers Panel Discussion |
| **1:00-2:00** | **LUNCH** | **LUNCH** | **LUNCH** | **LUNCH** |
| **2:00-3:00** | **Introduction to Small Group Discussions** | **Small Group Discussion**Specific Aims II(HW #1 due) | **Small Group Discussion**Approach & Methods I (HW #2 due) | **Final Presentations and Awards**  |
| **3:00-4:00** | **Small Group Discussion**Specific Aims I | **Small Group Discussions**Innovation & Significance I | **Small Group Discussion**Approach & Methods II |
| **4:00-4:30** | **Wrap-up Session** |

# EFFECTIVE PROPOSAL WRITING MODULE OBJECTIVES & READINGS FOR SPECIFIC SESSIONS

One of the best ways to learn how to write a grant is to read successful grants written by other researchers in the same field. We have identified 5 short proposals that will be used as the readings for the sessions below. Each session will specify which section of the grant is to be read. Trainees should read this section in **all SIX grants** and come to class prepared to discuss strengths and weaknesses of each section.

The grants are as follows:

1. Improving Uptake of Early Infant Diagnosis of HIV for PMTCT: RCT of a Text Messaging Intervention (PI Thomas Odeny)
2. HIV Testing and Educating Male Partners to Improve Maternal and Infant Outcomes (PI Carey Farquhar)
3. Human Herpesvirus-8 Replication and Kaposi Sarcoma Response to Treatment (PI Warren Phipps)
4. Overcoming Barriers to HIV/AIDS Care and ART Initiation (PI Brandon Guthrie)
5. Motivation matters! RCT of theory-based, 2-way SMS to support TASP in African FSW (PI Scott McClelland)
6. Gender Specific Prevalence of Multiple Strain HSV-2 Infection: A Global View (PI Anna Wald)

In addition to the above readings, journal articles may also be assigned or listed as optional reading. These have been carefully selected to complement material presented in class and will also be a topic of discussion (if required).

## Session 1: Introduction to Proposal Writing

**Learning Objectives:**

1. Prepare a realistic timeline for grant preparation
2. Describe the optimal composition of a proposal writing committee
3. Identify the different sections of a grant proposal
4. Name different types of funding sources and what is included in an RFA

**Readings:**

Review the overall format of the research grants provided and be prepared to identify similarities and differences in the organizational structure of these grants. Pay particular attention to headings, subheadings, use of figures and tables, and number of references.

Garcia, P. J., & Curioso, W. H. (2008). Strategies for aspiring biomedical researchers in resource-limited environments. *PLoS Neglected Tropical Diseases*, *2*(8), e274.

## Session 2: Proposal Basics: Hypotheses & Specific Aims

**Learning Objectives:**

1. Describe the importance and rationale for including your *research hypotheses*
2. Prepare a Specific Aims page following the recommended format
3. Identify key elements in the introductory paragraph and Aims and incorporate these into your proposals

**Readings:**

The **Specific Aims** pages for each of the research grants provided.

## Session 3: Proposal Basics: Innovation & Significance

**Learning Objectives:**

1. Identify domains of knowledge relevant to significance of a proposal
2. Describe components of well-written significance section
3. Understand the concept of innovation in the setting of proposal writing

**Readings:**

The *Significance* sections and the *Innovation* sections of research grants provided.

## Session 4: Proposal Basics: Analysis/Sample Size Plans

**Learning Objectives:**

1. Identify the necessary elements of an analysis plan and a monitoring and evaluation plan.
2. Understand how the analysis plan supports the rest of the proposal and how each specific aim is represented in the analysis plan.
3. Describe common weaknesses in analysis and M&E plans.
4. Explain how the scope of an analysis plans is directed by the nature of the proposal.

**Readings:**

Greenhalgh T. (1997). How to read a paper. Statistics for the non-statistician. I: Different types of data need different statistical tests. BMJ;315(7104):364-6.

Greenhalgh T. (1997). How to read a paper. Statistics for the non-statistician. II: "Significant" relations and their pitfalls. BMJ;315(7105):422-5.

##

## Session 5: Research with Human Subjects and Ethics Case Studies

**Learning Objectives:**

1. Discuss real-life issues that come up when conducting research in resource-limited settings
2. Highlight issues that are often beyond what is covered by IRB monitoring

**Readings:**

Bandewar S, Kimani J, Lavery J. (2010). The origins of a research community in the Majengo observational cohort study, Nairobi, Kenya. BMC Public Health. 10:630.

Corneli A, Sorenson J, Bentley M, et al. (2012). Improving Participant Understanding of Informed Consent in an HIV-Prevention Clinical Trial: A Comparison of Methods. AIDS Behav. 16:412-421.

Nama N, Swartz L. (2002). Ethical and Social Dilemmas in Community-based Controlled Trials in Situations of Poverty: A View from a South African Project. J. Community Appl. Soc. Psychol. 12:286-297.

Reddy P, Buchanan D, Sifunda S, et al. (2010). The role of community advisory boards in health research: Divergent views in the South African experience. SAHARA J. 7(3):2-8.

Vallely A, Lees S, Shagi C, et al. (2010). How informed is consent in vulnerable populations? Experience using a continuous consent process during the MDP301 vaginal microbicide trial in Mwanza, Tanzania. BMC Medical Ethics. 11:10.

## Session 6: Proposal Basics: Approach & Methods

**Learning Objectives:**

1. Identify key components of research design to include in a grant proposal
2. Describe strategies for outlining key aspects of research methods, including study design, eligibility criteria and study procedures.

**Readings:**

The *Approach and Methods* sections of the grants provided.

## Session 7: Writing the Qualitative Research Methods Section

**Learning Objectives:**

1. Compose qualitative research questions and recognize appropriate questions to answer with qualitative methods
2. Describe incorporation of qualitative research methods in grant writing

**Readings:**

Sandelowski M. (2000). Combining qualitative and quantitative sampling, data collection, and analysis techniques in mixed-method studies. Research in Nursing & Health. 23:246–255.

Sandelowski M, Barroso J. (2003). Writing the proposal for a qualitative research methodology project. Qualitative Health Research. 13: 6: 781-820.

## Session 8: Sample Size Exercise

**Learning Objectives:**

1. Explain why appropriate sample size/power calculations are important in the appropriate design of epidemiologic studies.
2. Define elements required to conduct a sample size/power calculation.
3. Identify the appropriate effect measure to be used in a sample size/power calculation.
4. Explain how to choose an effect size to use in a sample size/power calculation.
5. Conduct a sample size and power calculation for the comparison of a continuous and binary outcome between two groups and write an appropriate sample size/power justification appropriate for a research proposal.

**Readings:**

Moher D, Dulberg CS, Wells GA. Statistical power, sample size, and their reporting in randomized controlled trials. JAMA. 1994;272:122–124.

Whitley E, Ball J. Statistics review 4: Sample size calculations Crit Care. 2002; 6(4): 335–341.

## Session 9: Proposal Basics: Supporting Materials and Career Development Awards

**Learning Objectives:**

1. Identify supplemental components of grant proposals
2. Recognize time-sensitive elements of proposals and describe work-planning strategies to meet submission deadlines
3. Explain how each piece of supporting material complements the research portion of the proposal.
4. Describe the characteristics of a strong letter of support.
5. Outline the information that should be included in the “resources” section and how it is used by reviewers to evaluate your proposal.

**Readings:**

Review the letters, biosketches (especially the first paragraph), resources, and human subjects sections of the complete grant provided.

## Session 10: NIH Peer Review Process

**Learning Objectives:**

1. Describe the process of review that many peer-reviewed institutions employ
2. Understand the “scoring rubric” by which grants are scored

**Readings:**

Benos DJ, Bashari E, Chaves JM, et al.(2007). The ups and downs of peer review. Advances in Physiology Education. 31: 145-152.

## Session 11 : Expert Perspectives on Grant Submission

**Learning Objectives:**

1. Identify specific characteristics of a successful grant proposal
2. Provide examples of common pitfalls found in research proposals
3. Gain an understanding of challenges faced by researchers from resource-limited settings in preparing successful research proposals and develop strategies to respond to these challenges

##  Appendix 1. List of Instructors and Invited Speakers

|  |  |
| --- | --- |
| Christine McGrath, PhD, MPHAssistant ProfessorDepartment of Global Health University of Washingtonmcgrathc@uw.edu | Aliza Monroe-Wise, MD, MScActing Assistant Professor, Departments of Global Health & MedicineUniversity of Washingtonemail: alizamw@uw.edu  |
| Monisha Sharma, PhD, ScMActing Assistant ProfessorDepartment of Global HealthUniversity of Washingtonmsharma1@uw.edu  | Rose Bosire, MBChB, MPH, PhD.Senior Research Scientist, Kenya Medical Research Institute.bosirero@uw.edu |
| Carey Farquhar, MD, MPHProfessorDepartments of Global Health, Medicine, and EpidemiologyUniversity of Washingtoncfarq@uw.edu  |  |

# **Appendix 2: Critique Template**

**Application #**

**Principal Investigator(s)**

**Overall Impact**

Reviewers will provide an overall impact score to reflect their assessment of the likelihood for the project to exert a sustained, powerful influence on the research field(s) involved, in consideration of the following five-scored review criteria, and additional review criteria. An application does not need to be strong in all categories to be judged likely to have major scientific impact.

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| --- |
| [Overall Impact](http://grants.nih.gov/grants/peer/critiques/rpg.htm#rpg_overall) |
| **Strengths****Weaknesses** |

**Scored Review Criteria**

Reviewers will consider each of the five review criteria below in the determination of scientific and technical merit and give a separate score for each.

|  |
| --- |
| 1. [Significance](http://grants.nih.gov/grants/peer/critiques/rpg.htm#rpg_01) |
| **Strengths** **Weaknesses** |

|  |
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| 2. [Investigator(s)](http://grants.nih.gov/grants/peer/critiques/rpg.htm#rpg_02)  |
| **Strengths** **Weaknesses** |

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| 3. [Innovation](http://grants.nih.gov/grants/peer/critiques/rpg.htm#rpg_03) |
| **Strengths** **Weaknesses**  |

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| 4. [Approach](http://grants.nih.gov/grants/peer/critiques/rpg.htm#rpg_04) |
| **Strengths** **Weaknesses**  |

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| 5. [Environment](http://grants.nih.gov/grants/peer/critiques/rpg.htm#rpg_05) |
| **Strengths****Weaknesses**  |

**Additional Review Criteria**

As applicable for the project proposed, reviewers will consider **the following additional items in the determination of scientific and technical merit but will not give separate scores for these items.**

* Responses forProtections for Human Subjects, Vertebrate Animals, and Biohazards **are required for all applications**.
* A response for Inclusion of Women, Minorities and Children **is required** for applications proposing Human Subjects Research.

# Appendix 3: Homework Exercises

The following exercises are designed to help Fellows understand the grant writing process. Each exercise requires the Fellows to create a specific section that is required when submitting grants. The exercises build upon one another.

Exercise 1: Hypotheses and specific aims

Exercise 2: Research methods

Exercise 3: Data analysis and sample size

## Exercise #1: Hypotheses and Specific Aims

Write a short introductory paragraph followed by your specific aims and hypotheses as shown in the example below.

HIV-1 exposed infants suffer from high levels of morbidity and mortality, even in the absence of HIV-1 infection,1-6 and this significantly attenuates the benefits of interventions to prevent mother-to-child HIV-1 transmission (MTCT). Common causes of death in HIV-1 exposed children are infectious diseases such as pneumonia, diarrhea, sepsis, and other invasive bacterial and viral infections,4 conditions for which a child may receive some protection from passive immunity obtained via placental and breast milk transfer of maternal antibodies.7,8 However, if a woman’s immune system is compromised she may not be able to provide her infant with effective passive immunity. Several studies have demonstrated that low maternal CD4 count, high HIV-1 viral load, and symptomatic HIV-1 disease are associated with worse outcomes among infants.2,9-11 The effect of restoring maternal immune function on transfer of passive immunity has not been investigated.

Within a randomized clinical trial (RCT) conducted to assess the efficacy and safety of highly active antiretroviral therapy (HAART) versus short-course nevirapine (NVP)/zidovudine (ZDV) for the prevention of MTCT, we propose the following aims:

Aim 1: To determine whether mothers randomized to HAART versus those randomized to short-course NVP/ZDV have increased plasma IgG antibody levels to measles virus and rotavirus and improved placental transfer of these antibodies to their infants.

Aim 2: To determine whether mothers randomized to HAART versus those randomized to short-course NVP/ZDV have increased IgA antibody levels to measles virus and rotavirus in colostrum and breastmilk expressed at 2 and 6 weeks postpartum.

We hypothesize that by restoring maternal immune function and reducing HIV-1 viral load through maternal HAART, systemic and breast milk antibody levels and placental antibody transfer will increase. Specifically, women randomized to HAART will have greater concentrations of anti-measles virus and anti-rotavirus antibodies in plasma (IgG) and breast milk (IgA) than women randomized to short-course NVP/ZDV. In addition, the ratio of infant cord blood IgG against these pathogens to the same in maternal plasma at delivery will be greater in women randomized to HAART.

## Exercise #2: Research Methods

This exercise builds on exercise # 1.

In the following exercise, you will create a research synopsis. We have included a list of the basic elements that should be included in a grant. Others are fine to include here if you have time/space. This should be 1-2 pages in length.

Elements to include in your outline are as follows:

* Title
* Study design (e.g., cross-sectional, prospective cohort, case-control, randomized clinical trial, retrospective cohort, etc)
* Study population (include eligibility and exclusion criteria, where is it taking place?)
* Recruitment strategies and enrollment (discuss how you will perform consent or if no consent process is needed)
* Clinical procedures (follow-up schedule, what takes place at each visit?)
* Laboratory procedures (emphasize new procedures but mention all)
* Timeline

(Data analysis plan and sample size will be included in exercise #3.)

## Exercise #3: Data Analysis and Sample Size

This exercise is designed for you to create an outline of your proposed data analysis and same size.

**Data analysis:**

Restate each specific aim as one or more **questions**

For each question:

* If it is a quantitative question:
	+ List **outcome variables** and **exposure variables** with definitions as needed
		- Dummy tables may be appropriate
	+ Define **comparisons** and **statistical tests** needed to answer each question
* If it is a qualitative question, describe how you will evaluate each type of data you will be collecting. What will you do with the in-depth interviews, focus group data, etc?

**Sample size:** Describe how you arrived at the sample size you will be using.

Did you calculate the sample size? Did you use a statistical program? If so, which program and what were the assumptions?

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| Author, year | Article title | Study design, location | Findings |
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# Appendix 4: Literature Review Table

Relevant Literature for Proposal (minimum 5 articles):

# Appendix 5: List of sources

(Included on flashdrive)

**Articles**

Benos DJ, Bashari E, Chaves JM, et al. (2007). The ups and downs of peer review. Advances in Physiology Education. 31: 145-152

Garcia, P. J., & Curioso, W. H. (2008). Strategies for aspiring biomedical researchers in resource-limited environments. *PLoS neglected tropical diseases*, *2*(8), e274.

Greenhalgh T. (1997). How to read a paper. Statistics for the non-statistician. I: Different types of data need different statistical tests. BMJ;315(7104):364-6.

Greenhalgh T. (1997). How to read a paper. Statistics for the non-statistician. II: "Significant" relations and their pitfalls. BMJ;315(7105):422-5.

Haynes, Brian R. Forming research questions. Journal of Clinical Epidemiology 2006; 59: 881-886.

Sandelowski M. (2000). Combining qualitative and quantitative sampling, data collection, and analysis techniques in mixed-method studies. Research in Nursing & Health, 23:246–255.

Sandelowski M, Barroso J. (2003). Writing the proposal for a qualitative research methodology project. Qualitative Health Research. 13: 6: 781-820.

Weinberg, J. M., & Kleinman, K. P. (2003). Good study design and analysis plans as features of ethical research with humans. IRB: Ethics and Human Research, 25(5), 11-14.

Yamey, Gavin, (2008). Read, reflect, respond: How to write a research paper and get it published

**Grant examples**

1. Improving Uptake of Early Infant Diagnosis of HIV for PMTCT: RCT of a Text Messaging Intervention (PI Thomas Odeny)
2. HIV Testing and Educating Male Partners to Improve Maternal and Infant Outcomes (PI Carey Farquhar)
3. Human Herpesvirus-8 Replication and Kaposi Sarcoma Response to Treatment (PI Warren Phipps)
4. Overcoming Barriers to HIV/AIDS Care and ART Initiation (PI Brandon Guthrie)
5. Motivation matters! RCT of theory-based, 2-way SMS to support TASP in African FSW (PI Scott McClelland)
6. Gender Specific Prevalence of Multiple Strain HSV-2 Infection: A Global View (PI Anna Wald)

# NOTES

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Content created by:

Carey Farquhar, Rose Bosire, Christine McGrath, Aliza Monroe-Wise, Monisha Sharma

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