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

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| Instructors: Carey Farquhar, Brandon Guthrie, Scott McClelland, Rose Bosire, Doug Wiebe January 18-22, 2016  |



**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, study budget preparation, the peer review process, and manuscript writing. 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) and are not covered 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** | **Day 5** |
| **9-10** | **Session 1**Introduction to Proposal WritingCarey Farquhar | **Session 3** Proposal Basics: Innovation & Significance Brandon Guthrie | **Session 5** Proposal Basics: Approach & MethodsBrandon Guthrie,Carey Farquhar | **Session 8** Proposal Basics: Analysis/Sample Size Plans Brandon Guthrie | **Session 11**Revising and Resubmitting Your ApplicationScott McClelland |
| **10-11:30** | **Session 2**Proposal Basics: Hypotheses & Specific AimsBrandon Guthrie  | **Group Exercise**Specific AimsScott McClelland | **Session 6**Writing the Qualitative Research Methods SectionRose Bosire | **Session 9**Proposal Basics: Supporting Materials and Career Development AwardsScott McClelland, Alison Drake, Brandon Guthrie | **Session 12**Expert Perspectives on Grant SubmissionPanel TBDModerators: Rose Bosire, Scott McClelland |
| **11:30-12:00** | **BREAK** | **BREAK** | **BREAK** | **BREAK** | **BREAK** |
| **12-1** | **Group Exercise**Writing SkillsBrandon GuthrieCarey Farquhar | **Small Group Discussion**Specific Aims II(HW #1 due)  | **Session 7** NIH Peer Review Process Brandon Guthrie | **Session 10**Proposal Basics: Budget DevelopmentCarey Farquhar | **Final Presentations and Awards** |
| **1-2** | **LUNCH** | **LUNCH** | **LUNCH** | **LUNCH** | **LUNCH** |
| **2-3** | **Introduction to Small Group Discussions and Selected Applications**Carey Farquhar | **Session 4**Optimizing Clinical Research Study DesignsDoug Wiebe | **Small Group Discussion**Innovation & Significance II(HW #2 due) | **Small Group Discussion**Approach & Methods II(HW #3 due) | **Final Presentations and Awards**  |
| **3-4:00** | **Small Group Discussion**Specific Aims I | **Small Group Discussions**Innovation & Significance I | **Small Group Discussion**Approach & Methods I | **Small Group Discussion**Analysis/M&E Plan |
| **4-4:30** | **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

Instructor: Carey Farquhar

**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

Instructor: Brandon Guthrie

**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

Instructor: Brandon Guthrie

**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: Optimizing Clinical Research Study Designs

Instructor: Doug Wiebe

**Learning Objectives:**

1. Describe in general terms at least 4 different study designs
2. Give an example of how the research question guides the study design
3. Explain what is meant when we say that different study designs provide a different level of evidence to support an association

**Readings:**

Weinberg JM, Kleinman KP (2003). Good study design and analysis plans as features of ethical research with humans. IRB: Ethics and Human Research. Sept-Oct.

##

## Session 5: Proposal Basics: Approach & Methods

Instructor: Carey Farquhar & Brandon Guthrie

**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 6: Writing the Qualitative Research Methods Section

Instructor: Rose Bosire

**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 7: NIH Peer Review Process

Instructor: Brandon Guthrie

**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 8: Proposal Basics: Analysis/Sample Size Plans

Instructor: Brandon Guthrie

**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 9: Proposal Basics: Supporting Materials for Research Grants and Career Development Awards

Instructors: Scott McClelland, Alison Drake, Brandon Guthrie

**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: Proposal Basics: Budget Development

Instructor: Carey Farquhar

**Learning Objectives:**

1. Express an understanding of when and how to start developing a proposal budget
2. Define direct and indirect costs and how these are applied in different settings
3. Define allowable costs and give examples of costs that are usually *not* allowable
4. Describe common pitfalls when preparing a budget and budget justification

**Readings:**

Review the *Budget* portion of the one **complete grant** provided.

## Session 11: Revising and Resubmitting Your Application

Instructors: Scott McClelland

**Learning Objectives:**

1. To understand the interactions with the grantor agency prior to submission and after receipt of critique from the review section.

2. To be able to decide whether the grant should be revised and resubmitted or submitted as a new application

3. To plan a revision that results in a strengthened application and optimization of chances for funding.

**Readings:**

Coverletter from grant entitled, “Protective Cellular Immune Responses in HIV-1-discordant Couples”

## Session 12: Experiences and Perspectives on Grant Submission

Instructors: Rose Bosire & Scott McClelland

Panel TBD

**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

|  |  |
| --- | --- |
| Carey Farquhar, MD, MPHProfessorDepartments of Medicine, Epidemiology, and Global HealthUniversity of Washingtoncfarq@uw.edu  | Rose Bosire, MBChB, MPH, PhDc Senior Research OfficerCentre for Public Health ResearchKenya Medical Research Institutebosirero@yahoo.com |
| Brandon Guthrie, PhDAssistant ProfessorDepartments of Global Health and EpidemiologyUniversity of Washingtonbrguth@uw.edu  | Scott McClelland, MD, MPHProfessorDepartments of Medicine, Epidemiology and Global HealthUniversity of Washingtonmcclell@uw.edu |
| Doug Wiebe, PhDAssociate ProfessorDepartment of EpidemiologyUniversity of Pennsylvaniawiebe@exchange.upenn.edu | Alfred Osoti, MBChB, MMed, MPHLecturerDepartment of Obstetrics/GyencologyUniversity of Nairobialfredos@uw.edu |
| Alison Drake, MPH, PhDActing Assistant ProfessorDepartment of Global HealthUniversity of Washingtonadrake2@uw.edu | Rochelle Dicker, MDProfessorDepartment of Surgery and AnesthesiaUniversity of California, San FranciscoRochelle.Dicker@ucsf.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.

|  |
| --- |
| [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** |

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

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

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

|  |
| --- |
| 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 4: Budgets

## 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?

## Exercise #4: Budgets

In the following exercise, you will create a research budget.

A research budget outlines how the money requested in the proposal will be spent. The budget is a key step in the process of developing the proposal and is an import piece of supporting material to demonstrate the feasibility of the research strategy. The budget should be developed alongside the research strategy because it will directly inform the scope of the research, the sample size, and the resources available to support the project.

For this exercise, complete a research budget for your proposal. Include all costs that will be required to complete the research. If there are resources that will be required to complete the project that will be provided through other sources (e.g., parent grants, center support, institutional resources, etc.), then these items should not be include in the budget, but should be explained in the accompanying budget justification.

The template below outlines the information you will need to complete a budget. A worksheet with calculated cells is also included in the supporting material for use in completing this exercise.

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|  |  |  |  |  | **YEAR 01** |
| PERSONNEL | %FTE | Base Salary | Salary Requested | Fringe Benefits | Total |
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|  | Totals |  |  |  |  |
| **EQUIPMENT** |  |  |  |  |  |
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|  |  |  |  | Equipment Total |  |
| **CLINIC/OFFICE SUPPLIES** |  |  |  |  |  |
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|  |  |  |  | Supply Total |  |
| **TRAVEL** |  |  |  |  |  |
| Description | Detail |   |   |   |   |
|   |   | – | – | – |   |
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|  |  |  |  | Travel Total |  |
| **OTHER EXPENSES** |  |  |  |  |  |
| Description | Detail |   |   |   |   |
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|   |   | – | – | – |   |
|   |   | – | – | – |   |
|  |  |  |  | Other Total |  |
| **SUBCONTRACT** |  |  |  |  |  |
|  | Subcontract Directs | – | – | – |  |
| **TOTAL** | **DIRECTS W/O SUBC F&A** |  |
|  | Subcontract indirects | X% |  |
| **TOTAL** | **DIRECTS WITH SUBC F&A** |  |
| **Base** |  |  |  |  |  |
| Main Indirects |   |   |   | X% |  |
| **TOTAL COSTS** |   |   |   |   |  |

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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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