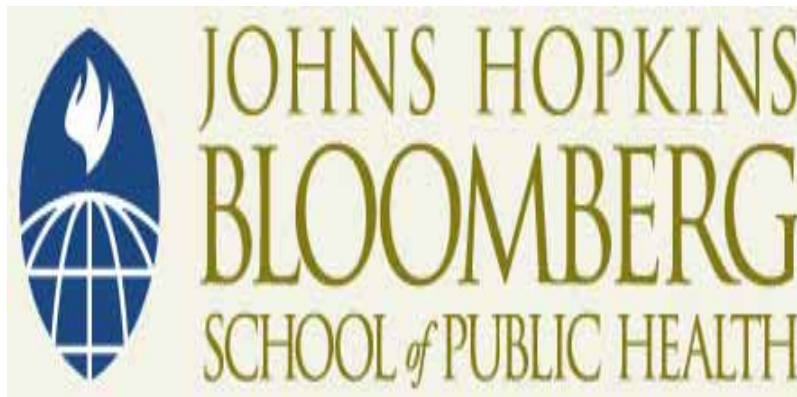


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Session 3

Part I: Abstract

Part II: The Research Plan

Grantmanship: Abstract

- ▶ **Outside of this class, the abstract is best written last (but make sure you have reserved plenty of time to do this properly!)**

- ▶ **Why?**
 - **Helps the center for scientific review (CSR) officials decide which study section should receive your grant for review**
 - **Often the first thing (and perhaps the only thing!) the Scientific Review Administrator reads when deciding which reviewers have the expertise (or not) to review your grant. (If no study section members are deemed to have the expertise required, outside reviewers may be sought).**
 - **Often the first thing the reviewer reads, so make the first impression your best one.**
 - **The rest of the study section who votes on your grant may only read the abstract as your grant is being discussed.**
 - **Abstracts for grants that have been awarded are in the public domain and are accessible by ANYONE on the Internet.**

Tips for Writing a Successful Abstract

- ▶ **Read the instructions on the PHS 398 abstract form and follow them exactly!! (i.e., Use the correct font size, do not go outside the box!)**
- ▶ **Avoid first person (ok to use first person elsewhere in the body of the grant)**
- ▶ **Include statement of problem/public health significance.**
- ▶ **Include specific aims (may want to bold or underline these or indent if you have space—do not shade!!)**
- ▶ **Include brief description of the methods you will use to address your aims, including a brief description of the analysis.**
- ▶ **Use simple language. Avoid jargon and acronyms.**
- ▶ **End with a statement of how your project is anticipated to impact the field or prevent disease.**

DESCRIPTION: State the application's broad, long-term objectives and specific aims, making reference to the health relatedness of the project. Describe concisely the research design and methods for achieving these goals. Avoid summaries of past accomplishments and the use of the first person. This description is meant to serve as a succinct and accurate description of the proposed work when separated from the application. If the application is funded, this description, as is, will become public information. Therefore, do not include proprietary/confidential information. DO NOT EXCEED THE SPACE PROVIDED.

Methamphetamine (MA), a central nervous system stimulant, has become the leading drug of abuse in Thailand over the past three years. The United Nations' Drug Control Program reported that the most significant increase of illicit drug use worldwide in 1990s was in the consumption of amphetamine-type stimulants (ATS). The WHO estimates more than 35 million regular users of MA worldwide, making it the second most commonly used illicit drug after marijuana. With recent drought and subsequent reduced poppy production in Burma, the Burmese military junta in power has responded to declining foreign reserves by encouraging the production and shipment of massive quantities of methamphetamine into Thailand during the past two years. These mobile factories are very difficult to locate and the MA tablets are easily concealed and smuggled, resulting in easy access and low price in Thailand. There are a range of social and medical consequences of MA abuse: poor performance in schools among students; anxiety; convulsion; brain damage; MA psychosis, characterized by violent behavior, repetitive activity, memory loss and paranoia; and acquiring HIV and other blood-borne infections from administering MA by injection. In Thailand, youth are the leading age-group initiating MA use.

A recent Thai national survey estimated that 12.4% of students between 12 and 20 years used illicit drugs in 1999, of whom 57% reportedly have used MA. Thus, there is a compelling public health need to address the issue of MA abuse among adolescents and young adults in northern Thailand. Preventing escalation of drug use practices, particularly with respect to route of drug administration, may prove effective in preventing the spread of HIV among those who have not yet begun injecting; HIV prevalence among injectors in northern Thailand is currently over 30%. In response to this public health emergency, we are proposing a randomized, controlled peer-outreach intervention trial targeting methamphetamine users (n=258) and their drug and sexual networks (n= 1032) in northern Thailand. We will adapt Latkin's intervention that has been demonstrated effective in the USA in reducing HIV-related risk behaviors among IDUs. The primary study endpoint would be reduction in transition to injection drug use among MA users who currently deny any history of injection.

The *primary objective* of this RCT is to assess the efficacy of a peer educator intervention versus HIV voluntary counseling and testing (VCT) on transition to injection drug use among MA users and their peer networks. The intervention addresses reduction of HIV risk behaviors. A series of behavioral measures for HIV risk, level of MA abuse (including overdose and psychiatric morbidity) and injection use among the index and network members will be used to evaluate the efficacy of the intervention. *Secondary objectives* include: (1) To compare the incidence of sexually transmitted infections (C trachomatis, N gonorrhoeae, and, for women, T vaginalis) and Hepatitis C Virus in each study condition; (2) To compare changes in HIV and sexual risk behaviors in each study condition for index participants and network members; and (3) To compare perceived changes in substance use network norms for drug and sexual risk practices in each study condition. This study builds on an active NIDA study (DA11133) of our Thai collaboration, is an appropriate extension of our work on HIV and drug use epidemiology and is responsive to a public health problem of central concern to our host country.

Research Plan

Answer these questions:

- ▶ **What do you intend to do?**
- ▶ **Why is the work important?**
- ▶ **What has already been done?**
- ▶ **How are you going to do the work?**

Write for the reviewers:

- ▶ **Significance** (important, advances science, effect on field)
- ▶ **Approach** (organized, well-developed conceptual framework, appropriate methods)
- ▶ **Innovation** (new, novel approaches, original aims, pushes science)
- ▶ **Investigator** (well-trained and experienced research team)
- ▶ **Environment** (contributes to likelihood of success)

The Research Plan

- A. Specific Aims**
- B. Background and Significance**
- C. Preliminary Studies / Progress Report**
- D. Research Design and Methods**
- E. Human Subjects**
- F. Vertebrate Animals**
- G. Literature Cited**
- H. Consortium/Contractual Arrangements**
- I. Resource Sharing**
- J. Consultants/Collaborators**
- K. Appendix**

Research Grant Application

Title - Use 81 characters maximum

Specific Aims

1 page

Background and Significance

3 pages

Preliminary Studies

Methods

Total

25 pages

A. Specific Aims – purpose of study.

- The purpose of the study is to:

1.

2.

3.

B. Background and Significance

- Overview
- Literature review in same sequence as the specific aims
- Impact of the study

C. Preliminary Studies (pilots)

- Feasibility
- Estimates

D. METHODS

- **Overview (Timetable and project administration)**
- **Population selection**
- **Data collection**
- **Data management**
- **Quality assurance/quality control**
 - **assurance – “how good is the data”**
 - **control – checks and edits**
- **Project administration**
- **Data analysis**
- **Limitations (bias, confounding, power)**

D.1 OVERVIEW

- **Design and why**
- **Population and why**
- **What will be done**
- **How will it be done**
- **Schedule**

D.2 STUDY DESIGN

- **Location**
- **Schedule**

D.3 POPULATION SELECTION

- **Definition of population**
- **Case selection**
 - **criteria**
 - **ascertainment**
 - **recruitment**
- **Control selection**
 - **rationale**
 - **criteria**
 - **ascertainment**
 - **recruitment**

D.4 PROJECT MANAGEMENT

- **Organizational structure**
- **Roles**

D.5 PROJECT TRACKING

- **Reporting**

D.6 PROJECT COMMUNICATIONS

- **Staff management**

D.7 ADVISORY COMMITTEES

- **Internal**
- **External**

D.8 QUALITY ASSURANCE/QUALITY CONTROL

- **Data collection**
 - **standardized protocols**
 - **standardized training**
 - **standardized review**
 - **standardized supervisor edit**
 - **standardized PI review**

D.9 LAB PROTOCOLS

- **QLP**
- **QA/QC**
- **NB: Put lengthy protocols in Appendix**

D.10 DATA MANAGEMENT

- **Entry and edit**
- **Audits**
- **Hard copy**
- **Data mgt hardware and software**
- **Documentation**
- **Security**
- **Archiving**

D11 SAMPLE SIZE/POWER

- **Link back to specific aims**

D.12 DATA ANALYSIS

- **Data description**
- **Analytic strategy**
- **simple measures of association**
- **Modeling approaches**
- **Control for confounding**
- **Statistical software**

D.13 TIME LINE

D.14 GENDER AND MINORITY INCLUSION AND PARTICIPATION OF CHILDREN

- **Report expected numbers/proportions of males, females, minorities etc.**
- **If one group is not included must provide a justification**

E. Human Subjects

F. Vertebrate Animals

G. Literature Cited Appendix

**H. Consortium/Contractual
Arrangements**

I. Consultants/Collaborators

Appendix

Grantmanship: The Research Plan

A. Specific Aims

- ▶ **This is the MOST important page of the entire research plan.**
- ▶ **This section should not exceed one page as a rule.**
- ▶ **Keep in mind that many reviewers base their first impression on the Specific Aims page.**
- ▶ **Begin with a preamble paragraph that states the broad long term objective of the proposed research, and the research gap(s) that your project will hope to fill.**

- ▶ **Give the reviewer the impression that you and your research team are well positioned to address your specific aims (e.g. “Our research team has been investigating the relationship between X and Y for several years, having published XXX peer-reviewed manuscripts on this topic” or “preliminary studies by our group and others support the hypothesis that X is an important factor associated with disease Y”).**
- ▶ **Write out your specific aims (usually a minimum of two and a maximum of 5 specific aims).**

- ▶ **Leave a space between each aim to draw attention to their importance.**
- ▶ **List any hypotheses that you will test, in relation to these aims.**
- ▶ **Avoid describing methods in detail at this stage, unless they are inherently related to the aim (e.g. evaluating a new research method).**
- ▶ **End with a statement emphasizing the public health significance of your study.**

A. Specific Aims (EXAMPLE)

The goal of this research project is to elucidate the epidemiology of human immunodeficiency virus type 1 (HIV-1) related Kaposi's sarcoma (KS) as it relates to the involvement of the putative KS herpes virus (KSHV). This information, will provide valuable insight into the natural history of KS. Such knowledge is essential for designing and implementing effective measures to prevent KSHV transmission and disease manifestation. Longitudinal data and specimens collected by the Multicenter AIDS Cohort Study (MACS), a well characterized cohort of homosexual men established for the study of the natural history of HIV-1 infection and AIDS, will be used to address the following specific aims:

(1) Prevalence and incidence of KSHV

Determine the prevalence of infection by KSHV in a large cohort of homosexual men with a high incidence of HIV infection and Kaposi's sarcoma. Compare to the prevalence of KSHV infection in a cohort of injecting drug users with high incidence of HIV and very low occurrence of KS. Specimens collected longitudinally over a 10 year span in the MACS will be the basis for determining the incidence of KSHV among those testing negative at study entry.

(2) Risk factors for KSHV infection

Determine the factors associated with KSHV infection in order to elucidate the most likely route of transmission and examine the consistency of risk factors for KSHV infection with the known epidemiologic patterns of KS. Behaviors (e.g., nitrite use and other drugs) which may modify risk of viral infection will be studied, as will host characteristics such as level of immunosuppression.

To address these aims in an economical and timely manner, a historical cohort study nested within the MACS is proposed. Unbiased estimates of incidence rates of KSHV among homosexual/bisexual men will be obtained by examining a stratified random sample of the cohort. Longitudinal data and testing of specimens that have already been collected from HIV-1 seroconverters before and after seroconversion in the MACS provide a basis for determining health effects of KSHV and biological markers of disease progression, independently of HIV-1 and of the interaction of the two viruses.

B. Background and Significance (2 - 3 pages)

Purpose of this section:

- ▶ **To demonstrate your mastery of the subject area as the PI.**
- ▶ **To provide a critical review of the literature (do not just regurgitate what others have shown, provide insight into what has been done and what has YET to be done).**
- ▶ **To identify gaps in the literature that your study will attempt to fill.**

How to write the Background and Significance section:

- ▶ **Make an outline of topic areas that link back to your specific aims**
- ▶ **Use subheadings to identify topic areas (e.g. risk factors you propose to study, descriptive epidemiology of the disease)**
- ▶ **Differentiate between research you have conducted vs. others (and refer to details in Section C, Preliminary Results)**
- ▶ **Where appropriate, introduce new methods with a section describing their relevance and utility to meet the specific aims of your project (e.g., ACASI, genotypic assays, etc)**
- ▶ **Don't use unnecessary jargon**
- ▶ **Handle controversies with care (be respectful to the viewpoint of potential reviewers)**

C. Preliminary Results/Progress Report (6-8 pages)

The preliminary results section is used to:

- ▶ **Describe pilot data (e.g lab data, ethnographic research, needs assessments, preliminary analyses)**
- ▶ **Describe an overview of the research team (assign roles to specific investigators who will provide oversight in key areas)**
- ▶ **Describe research infrastructure for completing the proposed work (e.g., background data from an established cohort study)**
- ▶ **Describe development of a new method (e.g. questionnaire item validity and reliability, lab test sensitivity and specificity)**

For *competitive renewal and supplemental applications*, this section is also used to:

- ▶ **Report progress of research during funding period to date;**
- ▶ **Review original specific aims and the extent to which they have been met or opened new areas for research;**
- ▶ **Introduce new members of the research team;**
- ▶ **Report list of published, submitted manuscripts and presentations at scholarly meetings, as well as mentoring of students and collaborations.**

How to write the Preliminary Results section:

- ▶ **Use an outline to order your preliminary results according to subheadings, in sequence according to the order of your specific aims and the importance of your data**
- ▶ **Link data presented back to the specific aims; do not present irrelevant data**
- ▶ **Stress public health significance of current research, and extent to which data have generated new hypotheses**
- ▶ **If an original aim could not be fulfilled, be honest and defend your stance accordingly.**
- ▶ **Append reprints or submitted papers in an appendix.**