Epidemiology 340.715

Problems in the Design of Epidemiologic

Studies

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Session 1 and 2
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COURSE OUTLINE:

Part I: Introduction

A. Course Overview

B. Group Organization

C. Review of the Website

Part II: Principles of Research Design

Part III: Sources of Research Support

A. PHS/NIH

B. PHS Form 398

C. RO1, RFA, RFP, PA and other research jargon

D. Private Foundations

Course Outline

I. Introduction
Course Overview

II. Principles of Research Design

III. Sources of Research Support

IV. Parts of the NIH Grant Application
Form PHS 398

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B. The Research Plan

1. **Specific Aims**
2. **Background and Significance**
3. **Preliminary Studies/Progress Report**
4. **Research Design and Methods**
5. **Human Subjects**
6. **Vertebrate Animals**
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10. **Consultants**

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c. Budgets Pertaining to Consortium/ Contractual Arrangements

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B. Writing the Research Protocol
C. Completing the Research Protocol
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A. Study Section
B. Conflict of Interest
C. Summary Statements
D. Advisory Committee and Funding Decisions

VIII. Course Review

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Glossary

This glossary defines terms and phrases most commonly used in the award and administration of NIH grants.

Application A formal request for financial assistance for a project/activity submitted to NIH on the appropriate application form:

Form PHS 398, except as shown in the table below, is used for all new competing applications (Type 1) or competing continuation applications (Type 2). This same form is used for a competing supplemental application (Type 3) when requesting additional funds for a change of scope or expansion to meet the needs of a project.

Most of the competing application forms have corresponding forms to be used when applying for non-competing continuation support during an approved competitive segment. The form corresponding to PHS 398 is Form PHS 2590. Some of these forms may be accessed from one of the following web sites:

(http://www.nih.gov/grants/forms.htm) and (http://www.nih.gov/grants/oer.htm).

APPLICATION FORMS USE FORM NUMBER

Small Business Innovation Research ProgramPhase I..... PHS 6246-1
Small Business Innovation Research ProgramPhase II ..... PHS 6246-2
Small Business Technology Transfer ProgramPhase I ..... PHS 6246-3
Small Business Technology Transfer ProgramPhase II..... PHS 6246-4
Individual National Research Service Award
or Senior International Fellowship Award ..... PHS 416-1
Health Services Project..... PHS 5161-1
Construction Grant.....PHS 424

Assistance The award of money, property, services, or anything of value to a recipient to support or stimulate a public purpose authorized by Federal statute. Assistance relationships are expressed in less detail than are acquisition relationships, and responsibilities for ensuring performance rest largely with the recipient or are shared with the NCI.

Award The provision of funds by NCI, based on an approved application and budget, to an organization or an individual to carry out an activity or project.

Budget A categorical or non-categorical request for funds required to support the

proposed activity.

Budget Period The interval of time (usually 12 months) into which the grant project period is divided for funding and reporting purposes.

Catalog of Federal Domestic Assistance (CFDA) (http://aspe.os.dhhs.gov/cfda/index.htm) or (http://www.cfda.gov/default.htm) The CFDA is a government-wide compendium of Federal programs and activities that provides assistance or benefits to State and local governments; public, quasi-public, profit, and nonprofit institutions; and specialized groups and individuals. The catalog is compiled and published annually by the General Services Administration.

Competitive Segment The initial project period recommended for support (usually one to five years) or each extension of the prior project resulting from the award of a competing continuation grant.

Consortium Agreement A collaborative arrangement in support of a research project in which some portion of the programmatic activity is carried out through a formalized agreement between the grantee and one or more other organizations that are separate legal entities administratively independent of the grantee.

Contract (R&D) An instrument used by NCI to procure cancer research services and other resources needed by the Federal Government. Contracts are legally binding

documents and used when the principal purpose of the transaction is to acquire a specific service or end product for the direct benefit of, or use by, the NCI.

Contract (under a grant) A written agreement between a grantee and a third party to acquire routine goods or services.

Cooperative Agreement An award instrument reflecting an assistance relationship between the NCI and a recipient in which substantial NCI programmatic involvement is anticipated during performance of the activity.

Direct Costs Costs that can be specifically identified with a particular activity or project.

Expedited Board Concurrence and Early Award
Initiative This NCI initiative focuses on that part of the grant review and award cycle in which NCI has the most influence, the award negotiation and issuance, which accounts for two months of the 10-12 month grant review and award process.

Facilities and Administrative (F&A) Costs Costs (previously known as indirect costs) that are incurred by a grantee for common or joint objectives and which, therefore, cannot be identified specifically with a particular

projector
program.

Federal Register
(http://www.access.gpo.gov/su_docs/aces/aces140.html)
An official daily publication that provides a uniform system for communicating proposed and final regulations and legal notices issued by Federal agencies, including announcements of the availability of funds for financial assistance programs. The Code of Federal Regulations is an annually-revised codification of the general and permanent rules published in the Federal Register.

Financial Status Report (FSR) A financial report due no later than 90 days after the end of each budget period or, for grants in the SNAP population, excluding those awards to Federal institutions or foreign organizations, no later than 90 days after the end of each competitive segment. The FSR shows the status of awarded funds for the competitive segment as maintained in the official accounting records of the grantee institution. Grantees are required to submit FSRs for continued funding of their grant(s).

Grant A financial assistance mechanism providing money, property, or both to an eligible entity to carry out an approved project or activity. Performance responsibility rests primarily with the recipient and there is little or no Federal involvement or participation in the

Federal involvement or participation in the performance of activities

Grantee The organization or individual awarded a grant or cooperative agreement by NCI that assumes legal, financial, and scientific responsibility and accountability both for the awarded funds and for the performance of the grant-supported activity. A grantee organization can be public or private, nonprofit or for-profit, educational institution, hospital, corporation, domestic or foreign agency, or other legally accountable entity.

Grants Management Officer (GMO) The individual designated by an awarding component to be responsible for ensuring that both the granting agency and grantees meet all requirements of laws, regulations, and formally established policies.

Grants Management Specialist An individual selected by the Grants Management Officer to serve as the focal point of the awarding component for all business/management activities associated with the negotiation, award, and administration of a grant or cooperative agreement. He/she also interprets grant administration policy and provisions.

Indirect Costs See Facilities and Administrative (F&A) Costs.

Institute/Center (IC) The NIH organizational component responsible for a particular grant program(s) or set of activities. NCI is an IC.

Initial Review Group (IRG) A group of study sections or peer review committees that are arrayed by scientific discipline. Study sections or peer review committees of scientists advise on the scientific and technical merit of research applications submitted for support.

Institutional Animal Care and Use Committee (IACUC) A committee set up by an institution to review at least once every six months the institutions program for humane care and use of animals. The IACUC reviews research protocols involving the care and use of animals at the institution and makes recommendations to the Institutional Official regarding any aspect of the institution's animal program, facilities, or personnel training.

Institutional Review Board (IRB) A board or committee set up by a research institution to ensure the protection of rights and welfare of human research subjects participating in research conducted under its auspices. The IRB makes an independent determination to approve, require modifications in, or disapprove research protocols based on whether human subjects are adequately protected, as required by federal regulations and local institutional policy.

Modular Grants An initiative that expands the existing reinvention initiatives that are designed to concentrate the focus of investigators, their respective institutions, peer reviewers, and NIH staff on the science NIH

than on the details of budgets. Under modular budget proposals, applicants are instructed to prepare the budget request in direct cost modules of $25,000 up to a maximum direct cost level of $250,000. (Budget requests beyond this level follow traditional application instructions.) This process eliminates the need for much of the budget detail, thereby relieving administrative burdens on both NIH staff and grantee organizations and simplifying cost management for NIH program staff.

Monitoring A process whereby the programmatic and business management performance aspects of a grant are reviewed by assessing information gathered from various required reports, audits, site visits, and other sources.

Notice of Grant Award The legally binding document that notifies the grantee and others that an award has been made. This document contains or references all terms and conditions or the award, and documents the obligation of Federal funds. The award notice may be in letter format and may be issued electronically.

Peer Review (42 CFR Part 52h) A system of review of research applications that utilizes reviewers who are the professional peers of the principal investigator responsible for directing or conducting the proposed project.

Percentile Score A score that represents the relative position or rank of each priority score among

position or rank of each priority score among the scores assigned by that particular study section at its last three meetings. The lower the numerical value of the percentile score, the better. The range is from .1 to 99.9.

Preapplication A statement in summary form of the intent of the applicant to request funds. Preapplications are requested for all construction projects for which the need for Federal funding exists. It is used to determine the applicants eligibility; determine how well the proposed project can compete with other similar applications; and eliminate any proposals for which there is little or no chance for funding before applicants incur significant expenditures for preparing an application.

Principal Investigator (PI) An individual designated by the recipient organization to direct the project or activity being supported by the grant. He or she is responsible and accountable to recipient organization officials for the proper conduct of the project or program. The organization is, in turn, legally responsible and accountable to NCI for the performance and financial aspects of the grant-supported activity.

Prior Approval Written approval from NCIs Grants Management Officer required for specified postaward changes in the approved project or budget. Such approval must be obtained prior to undertaking the proposed activity or spending NCI funds.

Priority Score The score determined by averaging the individual ratings given by each voting member of the IRG. Each IRG member assigns to the application a numerical rating that ranges from 1.0 (outstanding) to 5.0 (acceptable) that reflects his/her opinion of the scientific merit of the application. A composite score is then expressed on a scale of 100 to 499.

Procurement The acquisition by purchase, lease, or barter of property or service for the direct benefit or use of the NCI or other Government agency. The procurement instrument most often used is a contract. A contract details the rights, duties, and obligations of each of the parties involved.

Program Announcement (PA) A formal statement that describes and gives notice to the grantee community of the existence of an NIH-wide or individual Institute/Center extramural research activity/interest or announces the initiation of a new or modified activity/interest or mechanism of support and invites applications for grant or cooperative agreement support. NCI uses RFAs to announce cooperative agreements. PAs are published in the NIH Guide for Grants and Contracts (http://www.nih.gov/grants/guide/index.html). Funds may or may not be set-aside for PAs.

Program Official The NCI official responsible for the programmatic, scientific and/or technical oversight and monitoring of a grant. The program official works closely with grants management staff.

Project Period The total time for which support of a discretionary project has been programmatically approved. A project period may consist of one or more budget periods. The total project period is comprised of the initial competitive segment and extensions.

Recipient The organizational entity or individual receiving a grant or cooperative agreement. See Grantee.

Recommended Levels of Future Support The funding level recommended for each of the future years approved by the IRG and the NCAB. These amounts are subject to availability of funds each year and evaluation of the scientific progress of the project. In addition, the recommended funding level may be subject to correction of arithmetic errors and to adjustments made in accordance with applicable grant policies, as appropriate.

Request for Application (RFA) A formal announcement that invites grant or cooperative agreement applications in a well-defined scientific area to support specific program initiatives, indicating the amount of funds set aside for the competition and the estimated number of

awards to be made. RFAs are published in the NIH Guide for Grants and Contracts (http://www.nih.gov/grants/guide/index.html).

Research Project Grant (RPG) Award for an investigator-initiated research proposal.

Scientific Review Administrator (SRA) A Federal scientist who presides over an Initial Review Group and is responsible for coordinating and reporting the review of each application assigned to his/her committee, thereby serving as an intermediary between the applicant institution and the reviewers of the application. The SRA prepares a summary statement for each application reviewed by his/her IRG.

Small Business A business, including its affiliates, that is independently owned and operated and not dominant in its field of operation; has its principal place of business in the United States and is organized for profit; is at least 51 percent owned, or in the case of a publicly owned business, at least 51 percent of its voting stock is owned by U.S. citizens or lawfully admitted permanent resident aliens; has no more than 500 employees; and meets other regulatory requirements established by the Small Business Administration at 13 CFR Part 121.

Stipend A payment made to an individual under a fellowship or training grant in accordance with pre-established levels to provide for the

established levels to provide for the individual's living expenses during the period of training. A stipend is not considered compensation for the services expected of an employee.

Streamlined Non-Competing Award Process (SNAP)

A streamlined process that eliminated two of the financial documents that were part of the non-competing application: a categorical budget for the next budget period and an estimated report of expenditures for the current budget period. Under SNAP, the GMO negotiates the direct costs for the entire competitive segment at the time of the competing award or, in the case of modular awards, determines the applicable number of modules for each
budget period within the competitive segment. This eliminates the need for annual budget submissions and negotiations, if applicable, and reduces the information NIH requires to review and approve noncompeting continuation applications and to monitor these awards. As a result, for awards under SNAP, grantees are required to submit only limited portions of the PHS-2590, including an annual progress report. As part of the progress report, grantees

must answer questions pertaining to other support, unobligated balances, and change in the level of effort of key personnel. If there is a change in performance site and/or if there is anticipated program income, grantees also must submit the PHS-2590 checklist and, if program income is anticipated, must include the estimated amount and source of the income. Grantees (other than foreign grantees and Federal institutions) also are required to submit a quarterly Federal Cash Transactions Report (FCTR) (SF-272) to the Payment Management System (PMS). For awards under SNAP (other than awards to foreign organizations or Federal institutions), a Financial Status Report (FSR) is required only at the end of a competitive segment rather than annually. This FSR must be submitted within 90 days after the end of the competitive segment and must report on the cumulative support awarded for the entire segment. An FSR must be submitted at this time whether or not a competing continuation award is made. If no further award is made, this report will serve as the final FSR

Study SectionThe component part of an Initial Review Group that advises on the scientific and technical merit of research applications.

Substantial Foreign ComponentUnder a grant to a domestic institution, the performance of any significant element or segment of the project outside of the United States, either by the grantee or by a researcher employed by a foreign institution, with or without grant funds.

Success RateThe number of funded applications divided by the number of applications reviewed by Initial Review Groups.

Technical Assistance ReviewAn

evaluation by NCI grants management staff to assess an institutions business and financial management systems to ensure that applicable regulations and policies are being followed.

Terms and Conditions of Award All legal requirements imposed on a grant, whether based on statute, regulation, policy, other referenced document, or the grant award document itself. The Notice of Grant Award may include both standard and special provisions that are considered necessary to attain the grants objectives, facilitate postaward administration of the grant, conserve grant funds, or otherwise protect the interests of the Federal Government.

Total Project Costs The total allowable costs (both direct costs and facilities and administrative costs) incurred by the grantee to carry out a grant-supported project or activity. Total project costs include costs charged to the NCI grant and costs borne by the grantee to satisfy a matching or cost-sharing requirement.

http://www3.cancer.gov/admin/gab/02gpb/nci_grants_bk.pdf

Research Design and Methods

- **Some generic sections**
  - **overview**
  - **population selection**
  - **data collection**
  - **data management**

quality assurance/quality control

project administration

data analysis

limitations

- **Overview section**
  - **what design and why**
  - **what population and why**
  - **what will be done**
  - **how will it be done**

- Key elements
  - what is the study design
  - location
  - schedule

Case-Control Studies

- **Population selection**
  - how is the population defined
- **Case selection**
  - criteria

- ascertainment mechanism
- recruitment mechanism

- **Control selection**
  - rationale
  - criteria
  - ascertainment mechanism
  - recruitment mechanism

Cohort Studies

- **Subject Selection**
  - criteria
  - exposure classification
- **Exposure Assessment**
  - fixed

exposures
time-dependent exposures

- **Subject Follow-Up**
  - follow-up strategy
  - tracking losses to follow-up

Limitations

- **Bias**
  - **selection bias**
    - **potential sources and consequences**
  - **information bias**
    -

- how
- minimize
- validation studies
- adjustment methods

confounding

- potential confounders
- strategies for addressing (restriction, matching, stratification and modeling)

- **Power**
  - **assumptions**
  - **adequacy of power**
  - **consequences of error**
- **External validity**
  - **barriers to generalizability**

- **Feasibility**
  - **population identification**
  - **data collection**
  - **costs**
  - **alternative approaches**

QA/QC

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

PI
review

- Laboratory protocols
  - GLP
  - QA/QC
- Data management
  - entry and edit procedures
  - audit trails

- **Project management**
- **Analyses**
  - **analytic plan**
  - **review of analytic code**
  - **documentation**

# of results

Data Analysis

- **Data description**
  - **participants vs non-participants**
- **Analytic strategy**
- **Simple**

- Simple measures of association
- Modeling approaches
- Controlling for confounding
- Statistical software

Data Management

- **Hard copy**
  - handling paper
  - tracking
- **Data**

- Hardware and software management
- Documentation
- Security
- Archiving

Project Management

- **Management structure**
  - organizational structure
  - roles
- **Project tracking**
  - reporting

- **Project communications**
  - staff meetings
- **Advisory committees**
  - internal
  - external

Gender and Minority Inclusion

- Composition of proposed study group
- Rationale for selection
- Why exceptions

- **How recruit**
  - **cost cannot be deterrent but promises must be met**
- **Consider hypotheses to be tested**

Human Subjects

- **Involvement of human subjects**
  - **rationale for selection**
  - **Inclusion/exclusion characteristics**

- Sources of material
- Recruitment/consent plans
- Potential risks
- Protecting against risks
- Risks vs benefits

The Rest of the Stuff

- Consortium/Contractual arrangements
- Consultants
- Appendix

Literature cited

Sources of Research Support

Most common mechanism is the grant, which is a form of assistance

RO1 Investigator initiated research grant

R03 Small investigator initiated research grant

R21 Exploratory investigator initiated grant

P01 Program Project grant supports a set of research projects conducted by several collaborating investigators

P50 Center grant an institutional grant used to fund multidisciplinary programs of medical research

K series individual career awards

T series institutional training

T series institutional training grants
Contract - mechanism of procurement of site

UO1 Cooperative Agreement a form of research assistance where government is a partner in the research

Grant Application: Form is called PHS 398 and is available online:
http://grants.nih.gov/grants/funding/phs398/phs398.html

Mechanism whereby NIH solicits applications include:

Program Announcements (PAs)

Request for Applications (RFAs)

Request for Proposals (RFPs)
list of NIH Guide to Grants and Contacts list PA, RFAs & RFP

The NCI Grants Process

General Information

Abbreviations and Acronyms

CFR = Code of Federal Regulations
CSR = Center for Scientific Review (formerly DRG)
DCB = Division of Cancer Biology
DCCPS = Division of Cancer Control and Population Science
DCP = Division of Cancer Prevention
DCTD = Division of Cancer Treatment and Diagnosis
DEA = Division of Extramural Activities
DHHS = Department of Health and Human Services
DRG = Division of Research Grants (renamed CSR)
EAB = Extramural Advisory Board
FSR = Financial Status Report
FY = Fiscal Year
GAB = Grants Administration Branch
GMO = Grants Management Officer
GMS = Grants Management Specialist
ICD =

ICD = Institute, Center, Division
IRG = Initial Review Group
MIS = Minority Investigator Supplement
NCAB = National Cancer Advisory Board
NCI = National Cancer Institute
NIH = National Institutes of Health
ODDES = Office of the Deputy Director for Extramural Science
OFM = Office of Financial Management
0MB = Office of Management and Budget
PA = Program Announcement
PHS = Public Health Service
R&D = Research and Development
RFA = Request for Applications
RPG = Research Project Grant
SBIR = Small Business Innovative Research
SNAP = Streamlined Noncompeting Award Process
SRA = Scientific Review Administrator
STTR = Small Business Technology Transfer
USC = United States Code

NIH Organization

NIH: National Institutes of Health
supports 1/3 of biomedical research in the US

NCI: National Cancer Institute (CA)
NEI: National Eye Institute (EY)
NHLBI: National Heart, Lung and Blood Institute (HL)
NIA: National Institute on Aging (AG)
NIAAA: National Institute for Alcohol Abuse and Alcoholism (AA)
NIAID: National Institute of Allergy and Infectious Diseases (AL)
NIAMS: National Institute of Arthritis and Musculoskeletal and Skin Diseases (AR)
NICHD: National Institute of Child Health and Human Development (HD)
NIDA: National Institute on Drug Abuse (DA)
NIDDK: National Institute of Diabetes and Digestive

NIDDK: National Institute of Diabetes and Digestive and Kidney Diseases (DK)
NIDR: National Institute of Dental Research (DE)
NIERS: National Institute of Environmental Health Sciences (EH)
NIGMS: National Institute of General Medical Sciences (GM)
NIMH: National Institute of Mental Health (MH)
NINDS: National Institute of Neurological Disorders and Stroke (NS)
NCHGR: National Center for Human Genome Research (HG)
NINR: National Institute for Nursing Research (NR)
NCRR: National Center for Research Resources (RR)

Fogarty International Center (TW)
National Library of Medicine (NLM)

National Centers for Disease Contro and Prevenitonl (CDC)
Occupational Health and Safety Administration (OSHA)
Agency for Health Care Policy and Research (AHCPR)

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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 spacedo 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.**

BB Principal Investigator/Program Director (*Last, first, middle*): Jacobson, Lisa P.

DESCRIPTION. State the application's broad, long-term objectives and specific aims, making reference to the health-related areas 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.**

The goal of this study 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). A historical cohort study nested within the Multicenter AIDS Cohort Study (MACS), a longitudinal prospective study of the natural history of HIV-1 infection in homosexual/bisexual men, will address these specific aims: 1) determine the prevalence and incidence of KSHV infection in this population; 2) determine the KSHV route of transmission and the concordance of characteristics found to be associated with the virus to risk factors for KS; 3) determine rates and biological markers of progression to KS among KSHV seropositive, HIV-1 infected homosexual men and factors which may modify disease progression; 4) examine the effect of anti-retroviral and anti-herpetic treatments on KS disease progression; and 5) examine the health effects of KSHV in the absence of HIV-1 and the effect of KSHV on HIV-1 progression independent of its role in KS disease. Behaviors to be examined as risk factors include numbers of male sexual partners and types of sexual activities (e.g., anal/genital intercourse, anal/oral intercourse, anal/oral intercourse) and recreational drug use (e.g., nitrite inhalants). Host characteristics including age, race and immune status will be examined as effect modifiers for viral acquisition and disease progression. The effects of other environmental factors such as geographic location and co-infections also will be studied. KSHV serological testing will be performed on selected visits for 414 HIV-1 seroconverters with known dates of seroconversion within 1 year and a stratified random sample of 400 HIV-1 seroprevalent and 100 seronegative men. KSHV seroprevalence also will be determined in a sample of injecting drug users from a cohort study with protocols similar as the MACS.

Establishing the epidemiology of the KS Herpes virus, consistent with principles of causality, will provide direction for developing behavioral and therapeutic interventions against the development of Kaposi's sarcoma and will guide virological and biological investigations determining the pathogenesis of this disease.

description is meant to serve as a substitute and accurate description
this description, as is, will become public information. Therefore, do not include proprietary/confidential information. DO NOT EXCEED THE SPACE PROVIDED.

An intervention that delayed onset of Alzheimer's disease (AD) by several years would yield huge public health benefits. Several studies suggest that non-steroidal anti-inflammatory drugs (NSAIDs) may produce such a delay. NSAIDs may also attenuate progressive age-related cognitive decline (ARCD) when this condition represents a prodrome of AD. Both prevention strategies can be evaluated definitively only in randomized trials. Such trials can also examine attendant risks of long-term NSAID use in the moderate doses that appear to afford protection against AD and ARCD. Improved safety may be available with selective cyclooxygenase-2 (COX-2) inhibitors, but it is not clear that COX-2 inhibition offers the protective effect apparent with conventional NSAIDs. We therefore propose a parallel trial of the common NSAID ibuprofen and the selective COX-2 inhibitor celecoxib vs. placebo for prevention of AD and for attenuation of ARCD. The trial will involve four sites and enroll 2625 dementia-free subjects aged 72 - 88 with a history of Alzheimer-like dementia in a first degree relative. Thereafter, a conspicuous decline in periodic cognitive screening test results will identify subjects with suspected incident dementia. We will evaluate these subjects clinically using structured, standardized methods of assessment and diagnosis. The proposed sample presumes 7 years of observation, with realistic estimates of attrition through mortality and other causes, and of treatment "drop-outs" and "drop-ins." It should provide 80% power (2-tailed a =0.05) to detect a 30% reduction in incidence among the treated groups. In this application we propose the first 42 - 54 months of treatment, with an interim analysis of efficacy after the last-enrolled subject has completed 30 months. At that point, the study will have 80% power to detect a 50% reduction in AD incidence with either agent, in which case the trial can be stopped. The trial should also be stopped if there is no apparent benefit of treatment, or if safety issues mandate. Otherwise, the interim estimate of treatment effects will dictate the shape of a competing renewal application an additional 0.25 to 4 years of observation and a final analysis. As a secondary outcome, we will examine the trajectory of cognitive scores to assess ARCD.

PERFORMANCE SITE(S) *(organization, city, state)*

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

(f success) to likelihood

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)

Feasiblity

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 Kaposis 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 Kaposis 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)
- Dont use unnecessary jargon
- Handle controversies with care (be

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

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

Append reprints of submitted papers in an appendix

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Epidemiology 340.715 Problems in the Design of Epidemiologic Studies

Session 4 and 5

Part II: The Research Plan - cont.

Part III: Review of Submitted Abstracts

D. Research Design and Methods

(remainder of the 25 pages - usually 13-16, including tables and figures)

- **The WHAT and HOW Section**
- **This section is used to tell the reviewers how you will do each specific aim**
- **It is important to distinguish the overall research design and the specific methods**
- **Need to state why your approach was chosen to address the problem**
- **Be focused and very clear - lead the reviewer**
- **Show that you really understand the methods you**

are proposing including the shortcoming of selected techniques

How to Write the Research Design and Methods Section

- Summarize specific aims
- Provide research design for each aim - dont repeat. Use general research design if it umbrellas all aims
  - What will be done to accomplish the specific aims
  - In what population
  - How many participants
- Indicate why study design was chosen - match to

match to specific aim

- Describe and/or reference methods
- How the participants will be ascertained and recruited
- How the data will be collected (reference known protocols):
  - Exposures and outcomes
  - Tools - questionnaires, examinations, use of registries
  - How often
  - By whom

- **How the data will be analyzed and interpreted**
  - **Match to specific aims**
  - **Dont leap to most sophisticated statistics**
  - **Show understanding of process**
  - **Indicate how you will assess for and address confounding**
  - **Provide what findings would show the association being studied**
- **Include quality assurance methods**
  - **Data collection - training, validation studies, laboratory**

Data management and analysis

- **Include a power/sample size section**
  - **For each aim - show that your proposed study will have the power to address each aim (see association if one exists)**
- **If proposing new methods - explain why they are better than existing methods**
- **Discuss potential problems and limitations of the proposed procedures and alternative approaches to achieve the aims -**
  - **State possible problems and how you will deal with them**
  - **What are limitations of your design and/or methods - not a**

- not a shopping list

Dont provide ammunition to kill your project

- **Provide a summarized timetable of project (timeline or table with a paragraph is sufficient)**

E. Human Subjects See new rules

- No page limit but be brief
- Need approval from IRB (Institutional Review Board) before receiving award
- Shows the risks and benefits to participants
- Reiterate the number of participants to be studied and the power this yields to address your aims
- Use decision table to determine Human Subjects category and what needs to be addressed
- Most epidemiologic studies will use Scenario D: Clinical Research
- Use subheadings:

  Protection of Human Subjects: Address all 4 points on NIH application form

  Inclusion of

Women and Minorities

Inclusion of Children

Link to Decision Table for Human Subject Research, Protection and the Inclusion of Women, Minorities, and Children

1. Risks to the subjects

Characteristics of subject population

- How the human subjects will be involved
- Number, ages, health status, gender, race
- Rationale for including any specific vulnerable group - fetuses, pregnant women, children, prisoners, other institutionalized individuals
- List collaborating sites where human subjects research will be performed, and describe the role of those sites

Sources of materials

- Identify sources of material obtained from individually identifiable living human subjects specimens, records, or data
- Specify whether existing material or will gather new material for this research
- Describe the data that will be recorded on human subjects
- Describe linkages to subjects, and who will have access to identities
- State how the specimens, records or data are collected and whether they will be collected specifically

for your project

Potential Risks

- Physical, psychological, social, legal, other
- Assess likelihood and seriousness
- Dont give impression that risks exist if not serious
- Dont repeat the statements from informed consent
- this study does not involve unusual physical or mental risks to subjects
- If appropriate, describe alternative treatments and procedures, including their risks and benefits

2. Adequacy of protection against risks

Recruitment and consent procedures

Briefly describe how subjects will be recruited and consented (parental permission and child assent)

Circumstances under which consent will be sought and obtained

Who will seek consent

Nature of information provided to prospective subjects

Method of documenting consent

State whether IRB has authorized a modification or waiver of the consent elements or the requirements for documentation of consent

No need to

No need to include consent form

Protection against risks

- Procedures to protect against or minimize potential risks, including risks to confidentiality, and assess their likely effectiveness
- Procedures for monitoring data collected to ensure subject safety
- All data and patient records will be confidential
- If no serious risks are involved every effort will be made to minimize risks due to according to established medical practices (see Methods section) and procedures developed by our Institutional Review Board
- If great risk is involved, provide details for prevention and treatment

prevention and treatment in Methods section

3. Potential benefits of proposed research to the subjects

What are the potential benefits to subjects and others

Why risks are reasonable in relation to benefits

4. Importance of knowledge to be gained (benefit to society)

Discuss importance of the knowledge to be gained

Be concise in stating that the risk/benefit ratio for this study

for this study
is appropriate

Inclusion of Women and Minorities

- NIH policy is that women and members of minority groups must be included in all of their sponsored research which involves humans
- State whether women and minorities will be included and to what extent
  - How many or what proportion
  - Use NIH Targeted/Planned Enrollment table
  - Recruitment process and rationale in terms of the scientific objectives and proposed study design
  - If excluded - provide convincing rationale
    - See examples on pages 15 and 16 of Supplemental Instructions for Preparing Human Subjects Section of

Research Plan
(http://grants.nih.gov/grants/funding/phs398/HumanSubjects.pdf)

Inclusion of Children

- NIH policy is that children (defined as people under 21) must be included in all of their sponsored research which involves humans.
- Create section called Inclusion of Children
  - State whether children will be included or if not, why not (see examples)
  - Why certain age ranges are included or excluded
  - If included -
    - Expertise of personnel to work with children
    - Methods appropriate to children (forms, etc.)
    - Number sufficient to

Number sufficient to make meaningful contribution

Principal Investigator/Program Director (Last, First, Middle):

Targeted/Planned Enrollment Table

This report format should NOT be used for data collection from study participants.

Study Title: _____

Total Planned Enrollment: _____

TARGETED/PLANNED ENROLLMENT: Number of Subjects			
	Sex/Gender		
Ethnic Category	**Females**	**Males**	**Total**
Hispanic or Latino			
Not Hispanic or Latino			
Ethnic Category: Total of All Subjects *			
Racial Categories			
American Indian/Alaska Native			
Asian			
Native Hawaiian or Other Pacific Islander			
Black or African American			

White			
Racial Categories: Total of All Subjects *			

* The "Ethnic Category: Total of All Subjects" must be equal to the "Racial Categories: Total of All Subjects."

F. Vertebrate Animals

- No page limit but be brief
- State whether any of the research involves vertebrate animals - not usually in most epidemiologic studies
- If it does, needs approval from Institutional Animal Care and Use Committee (IACUC)

Address the 5 points:

1. **Detailed description of the proposed use of animals species, strains, ages, gender, number (use general terms)**

2. **Justify**

   Use of animals, choice of species, number to be used

   Best justification is that particular study cannot be done in vitro or simulated by computer model

   Use scientific, not economic reasons for choice of animal

3. **Describe veterinary care of animals**

4. **Describe procedures to minimize animals discomfort, distress, pain and injury (Discuss use of analgesics, anesthetics, tranquilizers, comfortable restraining devices)**

5. **Describe euthanasia methods**

   Give reasons for selection

   State whether methods are consistent with recommendations of the Panel on Euthanasia of the American Veterinary Medical Association. If not, justify.

G. Literature Cited

(6 pages although no page limit)

- Contains all cited references
- No more than about 75
- Minimize references used to support statement but without critical comment
- Cite current literature - shows that you are familiar with current work in field
- Dont just read abstracts - read entire manuscript (abstracts may be

misleading)

- **Need to include:**
  - **Full title of paper**
  - **Names of all authors**
  - **Book or journal, volume number, page numbers and year of publication**
- **Check to make sure complete correspondence**
  - **Every citation in text is in list**
  - **Every citation in list mentioned in text**

H. Consortium/Contractual Arrangements

- Involves two or more institutions and investigations
- Detail the arrangement between you and collaborating organization - - programmatic, fiscal and administrative
- Be clear that the consortium arrangement satisfies a specific need and supports research otherwise impossible to complete
- If the contracted work is a significant portion (i.e., majority) of the overall project, you will need to explain why the monies should be granted to you and not the other investigator. If not obvious, assure reviewer that you will have a major

assure reviewer that you will have a major role in the project

- State that the administrative personnel of each organization are aware of the Public Health Service (PHS) consortium grant policy and are prepared to establish the necessary interinstitutional agreements consistent with that policy.
- Provide copies of written agreements or letters (signed by PI and authorized official of collaborating organization)

I. Consultants

- List all consultants and collaborators, whether or not you are paying them
- Here is where you put letter from each person, confirming his/her role in project
- Dont forget to put biographical sketches with the others

Appendices

- **Samples:**
  - **Questionnaires**
  - **Relevant manuscripts (≤10 reprints, accepted papers, abstracts)**
  - **Established experimental protocol**
- **Make sure that:**
  - **Publication is of good quality (dont hand draw figure)**
  - **Mentioned in text**

Important contribution

- Dont use it as an extension of the 25 page limit
- Keep in mind that only assigned readers will get the appendices - need to submit 5 copies
- Nice to add cover sheet to each appendix summarizing content and reason for its inclusion

Common Mistakes and More Tips on Abstract

- Too much background
- Add a statistic re: significance of problem
- Lack of specificity in methods
  - Study design
  - Numbers of participants
  - No statement of how exposures or outcomes will be ascertained
  - Analysis not driven by aims

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Session 6

Proposal Organization

Organizing Your Proposal

Other than the proposal itself, the following are forms/components that you need to get DONE EARLY

1. ***JHU Information Sheet (not for course)***
2. **Sub-contract applications**
3. **Face page of the PHS 398 form (need to get appropriate signatures)**
4. **Biosketch (for all**

4. Biosketch (for all investigators, make dummy ones for other key personnel)
5. Resources Page
6. Appendices
7. Budget
8. Budget Justification
9. CHR/IRB Application
10. Personal Data on PI
11. Table of Contents
12. Checklist

eIS ID:

JHBSPH BLANK Information Sheet - FOR INTERNAL DEPARTMENTAL USE ONLY.
TO OBTAIN COMPLIANCE INFO. FROM PI OR INTERNAL DEPT. PROPOSAL, etc.

Personnel **NOT ACCEPTABLE FOR SUBMISSION TO ORA.** for ORA submission, PDF must be generated after choosing "Circulate" from the online eIS system.

Participant	Name	HS Training	CUFS Area	Phone	Salary/ Effort%
Principal Investigator					

General Information

Application to:

Prime Sponsor:

Sponsor Type: Sponsor Address:

Program Announcement No.: Due Date at Sponsor's Office:

CFDA No: Project Department Code:

Project Title:

Type of Proposal: Type of Project:

Project Purpose: _____ Sponsor Grant/Contract No.: _____

Master/Previous ReSource#: Current CUFS No.: (area) (orgn)

Type of Activity: Population Served:

Project Location(s)

Location	Description	Country

Budget

Will you need multiple accounts?

Is there any cost sharing involved?

First budget period: from _____ to _____ direct costs $_____ F&A costs $_____ total costs $_____
Total budget period: from _____ to _____ direct costs $_____ F&A costs $_____ total costs $_____

F&A Base: | F&A rate: On-campus % Off-campus %

Compliance

Will the project involve or require any of following?

1.To the best of your knowledge, do any participating personnel, or their spouse or dependents, have any financial interest in the sponsor or other entities having a financial interest in any intellectual property, product or service which is a subject of the proposed research?

2.Use of human subjects via contact and/or survey, use of human tissue, serum, or other fluids?

Status	IRB	Protocol #	Protocol Title	Senior PI	Approval Date (Or)Exemption #

3. Does this project involve disclosure of protected health information to sponsor or third parties?

4. Use of live, vertebrate animals?

Status	Protocol#	Senior PI	Approval Date

5. Use of infectious agents or bio-hazardous materials?

Status	Approval#	Approval Date

6. Use of radioactive materials?

Status	Approval#	Approval Date

7. Use of hazardous and highly-toxic chemicals (e.g., carcinogens, mutagens, chemicals NIOSH IDLH level)?

Status	Approval#	Approval Date

8. Use of recombinant DNA?

Status	Approval#	Approval Date

9. Need for alterations, renovations, additional electrical or steam service?

Location	Facility cost estimated acquired?	Cost in budget?	Explanation

10. Equipment cost over $5,000 for the proposed project?

11. Are any administrative costs included in the budget?

12. Do you anticipate that program income will be generated under this project?

Identify income: _____

13. Subawards or subcontracted efforts to other organization?

14. In this project, will you be utilizing information provided under a Confidentiality Agreement?

The name of company or institution: _____

15. In this project, will you be utilizing materials provided under a Material Transfer Agreement?

The name of company or institution: _____

16. Do you anticipate that this project will involve an existing JHU invention (Yours or another investigator's) or other intellectual property?

JHU reference number: _____
Disclosed to the Division of Licensing and Technology Development? _____

17. Additional space in any project location?

Institutional approvalacquired?	Description

18. Will you require a federal license to export information or technology (either to a non-US location or to a non-US citizenregardless of location)?

19. Will you need a license because you or a member of your research team may by traveling to or sponsoring an activity (e.g. a conference or meeting) in a country on the US Embargoed Nationa list?

Comments

Contact Information

Proposal questions, contact: Name: _____ Phone: _____ Email: _____
Approval notification, contact: Name: _____ Phone: _____ Email: _____

home.cd3wd.ar.cn.de.en.es.fr.id.it.ph.po.ru.sw

Arial, Helvetica, Palatino, Linotype, or Georgia typeface and a font size of 11 points or larger

Form Approved Through 09/30/2007 OMB No. 0925-0001

Department of Health and Human Services Public Health Services **Grant Application** *Do not exceed character length restrictions indicated.*	LEAVE BLANK—FOR PHS USE ONLY.		
	Type	Activity	Number
	Review Group:		Formerly
	Council/Board (Month Year)		Date Received

1. TITLE OF PROJECT *(Do not exceed 81 characters, including spaces and punctuation.)*

81 characters, (PI - title) - unique

2. RESPONSE TO SPECIFIC REQUEST FOR APPLICATIONS OR PROGRAM ANNOUNCEMENT OR SOLICITATION ☐ NO ☐ YES
(If "Yes," state number and title)
Number: Title:

3. PRINCIPAL INVESTIGATOR/PROGRAM DIRECTOR	New Investigator ☐ No ☐ Yes	
3a. NAME (Last, first, middle)	3b. DEGREE(S) = 3	3c. eRA Commons User Name
3e. POSITION TITLE	3d. MAILING ADDRESS *(Street, city, state, zip code)*	
3e. DEPARTMENT, SERVICE, LABORATORY, OR EQUIVALENT		
3f. MAJOR SUBDIVISION		
3g. TELEPHONE AND FAX *(Area code, number and extension)* TEL: FAX:	E-MAIL ADDRESS:	

4. HUMAN SUBJECTS RESEARCH No ☐ Yes ☐	4b. Human Subjects Assurance No.		5. VERTEBRATE ANIMALS ☐ No ☐ Yes		
	4c. Clinical Trial ☐ No ☐ Yes	4d. NIH-defined Phase III Clinical Trial ☐ No ☐ Yes	5a. If "Yes," IACUC approval Date:	5b. Animal welfare assurance no.	
4a. Research Exempt No ☐ Yes ☐	If "Yes," Exemption No.				

6. DATES OF PROPOSED PERIOD OF SUPPORT *(month, day, year MM/DD/YY)*	7. COSTS REQUESTED FOR INITIAL BUDGET PERIOD	8. COSTS REQUESTED FOR PROPOSED PERIOD OF SUPPORT

From	Through ≤ 5 years	7a. Direct Costs ($)	7b. Total Costs ($)	8a. Direct Costs ($)	8b. Total Costs ($)

9. APPLICANT ORGANIZATION Name Address	10. TYPE OF ORGANIZATION Public: → ☐ Federal ☐ State ☐ Local Private: → ☐ Private Nonprofit For-profit: → ☐ General ☐ Small Business ☐ Woman-owned ☐ Socially and Economically Disadvantaged 11. ENTITY IDENTIFICATION NUMBER DUNS NO. Cong. District
12. ADMINISTRATIVE OFFICIAL TO BE NOTIFIED IF AWARD IS MADE Name Title Address Tel: FAX: E-Mail:	13. OFFICIAL SIGNING FOR APPLICANT ORGANIZATION Name Title Address Tel: FAX: E-Mail:
14. PRINCIPAL INVESTIGATOR/PROGRAM DIRECTOR ASSURANCE: 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 responsibility for the scientific conduct of the project and to provide the required progress reports if a grant is awarded as a result of this application.	SIGNATURE OF PI/PD NAMED IN 3a. *(In ink. "Per" signature not acceptable.)* DATE
15. APPLICANT ORGANIZATION CERTIFICATION AND ACCEPTANCE: I certify that the statements herein are true, complete and accurate to the best of my knowledge, and accept the obligation to comply with Public Health Services terms and conditions if a grant is awarded as a result of this application. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties.	SIGNATURE OF OFFICIAL NAMED IN 13 *(In ink. "Per" signature not acceptable.)* DATE

PHS 398 (Rev. 05/04) Face Page Form Page 1

Print all forms actual size to meet formatting specifications. Make sure "Shrink oversized pages to paper size" is NOT checked on Print window.
(This reminder will not appear on the printed form.)

Dont include unnumbered pages & dont use suffixes (5a, 5b, etc)

Principal Investigator/Program Director (Last, First, Middle):

The name of the principal investigator/program director must be provided at the top of each printed page and each continuation page.

RESEARCH GRANT
TABLE OF CONTENTS

E. Human Subjects Research

Protection of Human Subjects (Required if Item 4 on the Face Page is marked 'Yes').

Data and Safety Monitoring Plan (Required if Item 4 on the Face Page is marked 'Yes' ***and*** a Phase I, II, or III clinical trial is proposed)

Inclusion of Women and Minorities (Required if Item 4 on the Face Page is marked 'Yes' and is Clinical Research)

Targeted/Planned Enrollment Table (for new and continuing clinical research studies)

Inclusion of Children (Required if Item 4 on the Face Page is marked 'Yes')

F. Vertebrate Animals

G. Literature Cited

H. Consortium/Contractual Arrangements

I. Resource Sharing

J. Letters of Support (e.g., Consultants)

Commercialization Plan (SBIR/STTR Phase II and Fast-Track ONLY)

Checklist

Appendix *(Five collated sets. No page numbering necessary for Appendix.)*

Appendices NOT PERMITTED for Phase I SBIR/STTR unless specifically solicited ☐ Check if Appendix is Included

Number of publications and manuscripts accepted for publication *(not to exceed 10)*

Other Items (list):

Budget Justification

- Purpose: Helps answer the question: Is the bang worth the buck.
- What is it. This section provides the rationale for all budget requests in terms of on and off-campus personnel, equipment, supplies, travel

supplies, travel,
rent, etc.

NOTE: Most NIH budgets are reduced by 10% regardless of the reviewers recommendations.

No page limit, therefore justify everything

Must be credible in the experience of the reviewers

Tips for Writing a Strong Biosketch

- Use PHS 398 form
- Biosketches are 4 pages maximum (per investigator)
- A biosketch must be included for each investigator (on-campus personnel), and

personnel), and consultant use

order of key personnel

- Purpose: to establish the credentials and capability of the PI and the research team
- Think of the biosketch as a brief scientific resume

- **What reviewers are looking for:**
  - **Appropriate training**
  - **Consistent and impressive publication record in a relevant field**
  - **Related research**

Related research experience

Track record for previous grants held

Evidence of solid collaborations (especially for multi-center studies)

Biosketch

- **Dos**
  - **Provide full background**
  - **List relevant publications**
  - **List review committees**
  - **List honors**

Donts

- Dont turn abstract into papers
- Dont list in preparation
- Dont make anything up

Research Support Section

- **Purpose:**
  - To indicate the funding support that is currently held by the PI and other co-investigators
  - To indicate indicate completed projects (last 3 years)
  - To ensure that there is no overlap between currently held awards and the proposed submission (unless extremely well

justified)

To show that the investigative team has a track record of previous awards (that have led to publications listed in the Biosketch)

- **Includes:**

  List of currently held grants (PI name, title, brief sentence describing study aims, responsibilities of key person on biosketch, funding period)

  Same for completed projects (in last 3 years)

Principal Investigator/Program Director (Last, First, Middle): PI Name

BIOGRAPHICAL SKETCH

Provide the following information for the key personnel and other significant contributors in the order listed on Form Page 2.
Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME	POSITION TITLE
Carlucci, Joseph Louis	Professor of Microbiology
eRA COMMONS USER NAME Carluccij	

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	YEAR(s)	FIELD OF STUDY
Stanford University	Ph.D.	1964	Infectious Diseases
Harvard Medical School	M.D.	1972	Medicine/Parasitology

A. Positions and Honors.

Positions and Employment

1969-1971	Medical Residency, Internal Medicine, Harvard Medical School
1971-1973	EIS Officer, Hospital Infection Section, Bacterial Diseases Branch, CDC, Atlanta, GA
1973-1974	Instructor and Fellow in Medicine, Hematology, Massachusetts General Hospital, Boston, MA
1974-1975	Instructor in Infectious Diseases, Massachusetts General Hospital, Boston, MA
1978-	Senior Associate in Infectious Diseases, Children's Hospital, Boston, MA

1978-1984	Assistant Professor of Pediatrics, Harvard Medical School
1985-1998	Chief, Hemostasis Laboratory, Children's Hospital, Boston, MA
1993-	Professor of Pediatrics, Harvard Medical School, Boston, MA
1998-	Professor, Dept. of Infectious Diseases, Harvard School of Public Health

Other Experience and Professional Memberships

1972-1973	Acting Chief, National Mucosal Infections Study
1975-2000	Director of Infectious Diseases Laboratory
1975-present	Hospital Epidemiologist (Medical Director Infection Control 2000-present), Children's Hospital, Boston
1981-1982	President, Society of Hospital Epidemiologists of America
1988	Member, Society for Pediatric Research
1989-present	Medical Director Quality Assurance, Children's Hospital, Boston, MA
1991-1993	Director, American Society for Microbiology, Division F
1991-1997	Hospital Infection Control Practices Advisory Committee, Centers for Disease Control
1998-present	Vice-Chair for Health Outcomes, Dept. of Medicine, Children's Hospital
1998-2001	Steering Committee, NACI IRI/CDC Pediatric Prevention Network

Honors

1982	SERC Advanced Research Scholarship, Infectious Disease Society of America
2001	Anthony Steinway Award for Excellence in Teaching (Children's Hospital)

B. Selected peer-reviewed publications (in chronological order).

(Publications selected from 133 peer-reviewed publications)

Principal Investigator/Program Director (Last, First, Middle): PI Name

1. Luciani JM, Casper J. Goodman BF, Shaw CM. Carlucci JL. Prevention of respiratory virus infections through compliance with frequent hand-washing routines. N Engl J Med 1988 ;318:389-394.
2. Gussmann J, Pratt R, Sideway DG, Sinclair JM, Emmerson MF, Carlucci JL. Coagulase-negative staphylococcal bacteremia in the changing neonatal intensive care unit population. Is there an epidemic? JAMA. 1988;158:1548-1552.
3. Gussmann J, Carlucci JL, McGovern JE, Jr., Methodologic issues in nursing home epidemiology. Rev Infect Dis 1989;11:1119-1141.
4. Gussmann J, Emmerson MF. Smyth NE. Platt RI. Sidebottom DG. Carlucci JL. Early hospital release and antibiotic usage with nosocomial staphylococcal bacteremia in two neonatal intensive care unit populations. Amer J Dis Child 1991;149:325-339.
5. Murphy JA, Black RW, Schroeder LC, Weissman ST, Gussman JM, Carlucci JL, Short CJ. Quality of care for children with asthma: the role of social factors and practice setting. Pediatrics 1996;98:379-84.
6. Gussmann J, Carlucci JL, McGovern JE, Jr. Incidence of Staphylococcus epidermidis catheter-related bacteremia by infusions. J Infect Dis 1996;172:320 4.
7. Carlucci JL, Huskins WC. Control of nosocomial antimicrobial-resistant bacteria A strategic priority for hospitals worldwide. Clin Infect Dis 1997;S139-S145.
8. Corning WC, Saylor BM, O'Steen C, Gulapagos L, O'Reilly CJ, Carlucci JL. Hospital infection prevention and control: A model for improving the quality of hospital care in low income countries. Infect Control Hosp Epi. 1999;13:123-35.
9. Handler CJ, Marriott B, Clearwater PT, Carlucci JI . Quality of care at a children's hospital: the child's perspective. Arch Pediatr Adolesc Med. 1999;143:1120-7.
10. McKinney D, Poulet KL, Wong Y, Murphy V, Ulright M, Dorling G, Long JC, Carlucci JL, Piper GB. Protective vaccine for Staphylococcus aureus. Science 1999;214:1421-7.
11. Gulazzii I , Kispert 7T, Carlucci JI , Corning WC. Risk-adjusted mortality rates in surgery: a model for outcome measurement in hospitals developing new quality improvement programs. J Hosp Infect 2000;24:33 42.

12. Huebner J, Quirk A, Krueger WA, Carlucci JL, Pier GB. Prophylactic and therapeutic efficacy of antibodies to a capsular polysaccharide shared among vancomycin-sensitive and resistant enterococci. Infect Immun 2000; 68:4631-6.
13. Levitan O, Sissy RB, Kenney J, Buchwald E, Maccharone AB, Carlucci JL. Enhancement of neonatal innate defense: Effects of adding an recombinant fragment of bactericidal protein on growth and tumor necrosis factor-inducing activity of gram-positive bacteria tested in vivo. Immun 2000;38:3120-25.
14. Garletti JS, Harrison MC, Collin PA, Miller CD, Otter D, Shaker C, Wren M, Carlucci JL, Makato DG. A randomized trial comparing iodine to a alcohol impregnated dressing for prevention of catheter infections in neonates. Pediatrics. 2001;127:1461-6.
15. Corning WC, Barillo K, Festival MR, Lingonberry S, Lumbar P, Peters A, Pursons M, Carlucci JL. Tella JE. A national survey of practice variation in the use of antibiotic prophylaxis in heart surgery. J I losp Infect. 2001;33:121-5.
16. Hoboken S, Peterson D, Graveldy L, Carlucci JL. Compliance with hand hygiene practice in pediatric intensive care. Pediatric Crit Care Med. 2001;12:211-214.
17. Hasker S, Pittoui D, Gray L. Zaruccii A, Potter G, Seemore MH, Carlucci JL. Interventional study to evaluate the impact of an antibiotic-infused hand gel in improving hand hygiene compliance. Perliatr Infect Dis J. Accepted for publication.
18. Lander C, Summers R. Murray S. Hummer CJ. Carlucci JL. Pediatrics: Is hospital food more nutritional than mom's cooking? Pediatrics 2001;11: 140-145.

C. Research Support

Ongoing Research Support

R01 HS35793 Carlucci (PI) 9/01/99-8/30/04
AHRQ
Reducing Antimicrobial Resistance in Low-Income Communities: A Randomized Trial.

Principal Investigator/Program Director (Last, First, Middle): PI Narrie

This study is a randomized trial of interventions to reduce antimicrobial usage and resistance in low-income communities.
Role: PI

2 R01 AI12345-05 Carlucci (PI) 4/01/01-3/31/06
NIH/NIAID
Bacteriology and Mycology Study of ICU Patients at Risk for Antimicrobial Resistant Bacterial Infections.
The study will perform clinical trials of interventions to reduce antimicrobial resistant infections.
Role: PI

R01 AI24680 04 Peterson (PI) 3/01/01 2/28/06
NIH/NIAID
Virulence and Immunity to Staphylococci.
This study investigates the production of polysaccharide by *Staphylococcus aureus* and its role in virulence as measured in animal models of infection and its ability to function as a target for protective antibody.
Role: Paid consultant.

2 R01 HL 00000-13 Anderson (PI) 3/01/01-2/28/06
NIH/NHLBI
Chloride and Sodium Transport in Airway Epithelial Cells
The major goals of this project are to define the biochemistry of chloride and sodium transport in airway epithelial cells and clone the gene(s) involved in transport.
Role: Co-Investigator

5 R01 HL 00000-07 Baker (PI) 4/1/01 – 3/31/04
NIH/NHLBI
Ion Transport in Lungs

Ion Transport in Lungs
The major goal of this project is to study chloride and sodium transport in normal and diseased lungs.
Role: Co-Investigator

1 R01 AI12826 01 Hoffman (PI) 9/28/01 9/27/03
NIH/NIAID
Intermountain Child Health Services Research Consortium
This consortium will seek to build pediatric health services research capacity and training in the Intermountain Region.
Role: Co-Investigator

Completed Research Support

5 R01 AI10011-05 Herman (PI) 10/01/99 – 11/30/01
NIH/NIAID
Evaluating Quality Improvement Strategies (EQUIS)
The goal of this study was to evaluate quality improvement and collaborative learning to improve asthma care in office-based pediatrics.
Role: Co-Investigator

5 R01 AI098765 Spielman (PI) 7/01/96 -6/30/01
NIH/NIAID
Epidemiology of Emerging Infections #1 T32 AI07654
The goal of this project was to study emerging infections in high risk populations who are treated in emergency room situations.
Role: Co-Investigator

Resources

- **Purpose:**

  To demonstrate that the institutional and field setting provides an adequate infrastructure to conduct the proposed research

  To provide relevant background for the setting of a foreign grant

- **Includes:**
  - **Description of office and laboratory space**
  - **Description of laboratory equipment**
  - **Computer equipment, clinical equipment, etc.**

HINTS

This section will be scrutinized under the following circumstances:

1. **New investigator**
2. **Foreign grant**

3. **Non-academic institution for a PI**

Do not include equipment here that will be requested in the proposed grant!!

What to put in an Appendix

- *Informed consent form (tailored to your project)*
- *CHR approval notice*
- Relevant questionnaires (mark drafts appropriately; reference standard scales)
- Relevant manuscripts (≤10 reprints, accepted papers, abstracts)
- Competing renewals: list project teams

published papers and abstracts

- Letters of support
- List of members/agencies participating in Community Advisory Boards
- List of memberships on project working groups or subcommittees (e.g., for multicenter projects)
- *Graphs, tables, charts, photographs in glossy format*
- Detailed laboratory protocols
- Patents, invention reports

Tips for Organizing Your Appendices

- Copy everything ahead of time (youll be glad you did!)
- Reference each of your appendices (or no one will read them)

- Include title of each appendix in Table of Contents
- Include cover sheets for each appendix
- Label your appendix pages with the name of the PI (or it might get lost in the shuffle)

Letters of Support

- **Purpose:**

  To show that the collaborators/ consultants that are mentioned in the proposal have agreed to their stated roles in the project

  To indicate the

To indicate the public health significance of your research in the opinions of public health figures, politicians and community stakeholders

Who should write you a letter of support for your proposal.

- Consultants (include role on project and fee)
- Collaborators
- Subcontracted investigators (one per

subcontract)

- Community stakeholders*
- Public Health Officials* (critical for foreign grants; optional otherwise)
- Politicians*

*optional

Principal Investigator/Program Director (last, First, Middle):

CHECKLIST

TYPE OF APPLICATION *(Check all that apply.)*

☐ NEW application. *(This application is being submitted to the PHS for the first time.)*

☐ REVISION of application number:
(This application replaces a prior unfunded version of a new, competing continuation, or supplemental application.)

☐ COMPETING CONTINUATION of grant number: _____
(This application is to extend a funded grant beyond its current project period.)

INVENTIONS AND PATENTS
(Competing continuation appl. and Phase II only)
☐ No ☐ Previously reported
☐ Yes. If "Yes," ☐ Not previously reported

☐ SUPPLEMENT to grant number: _____
(This application is for additional funds to supplement a currently funded grant.)

☐ CHANGE of principal investigator/program director
Name of former principal investigator/program director:

☐ CHANGE of Grantee Institution. Name of former institution:

☐ FOREIGN application ☐ Domestic Grant with foreign involvement List Country(ies) Involved: _____

☐ SBIR Phase I ☐ SBIR Phase II: SBIR Phase I Grant No. _____ ☐ SBIR Fast Track
☐ STTR Phase I ☐ STTR Phase II: STTR Phase I Grant No. ☐ STTR Fast Track

1. PROGRAM INCOME ***(See instructions.)***
All applications must indicate whether program income is anticipated during the period(s) for which grant support is request. If program income is anticipated, use the format below to reflect the amount and source(s).

Budget Period	Anticipated Amount	Source(s)

2. ASSURANCES/CERTIFICATIONS ***(See instructions.)***
In signing the application Face Page, the authorized organizational representative agrees to comply with the following policies, assurances

•Debarment and Suspension; •Drug- Free Workplace *(applicable to new [Type 1] or revised [Type 1] applications only)*; •Lobbying; •Non-Delinquency on Federal Debt; •Research Misconduct; •Civil Rights

and/or certifications when applicable. Descriptions of individual assurances/certifications are provided in Part III. If unable to certify compliance, where applicable, provide an explanation and place it after this page.
•Human Subjects; •Research Using Human Embryonic Stem Cells• •Research on Transplantation of Human Fetal Tissue •Women and Minority Inclusion Policy •Inclusion of Children Policy• Vertebrate Animals• (Form HHS 441 or HHS 690); •Handicapped Individuals (Form HHS 641 or HHS 690); •Sex Discrimination (Form HHS 639 A or HHS 690); •Age Discrimination (Form HHS 680 or HHS 690); •Recombinant DNA Research, Including Human Gene Transfer Research; •Financial Conflict of Interest (except Phase I SBIR/STTR) •Smoke Free Workplace; •Prohibited Research; •Select Agents •STTR ONLY: Certification of Research Institution Participation.

3. FACILITIES AND ADMINSTRATIVE COSTS (F&A)/ INDIRECT COSTS. See specific instructions.

☐ DHHS Agreement dated: ☐ No Facilities And Administrative Costs Requested.

☐ DHHS Agreement being negotiated with _____ Regional Office

☐ No DHHS Agreement, but rate established with Date

CALCULATION* *(The entire grant application, including the Checklist, will be reproduced and provided to peer reviewers as confidential information.)*

a. Initial budget period:	Amount of base $		x Rate applied	0.00%	% = F&A costs	$
b. 02 year	Amount of base $		x Rate applied	0.00%	% = F&A costs	$
c. 03 year	Amount of base $		x Rate applied	0.00%	% = F&A costs	$
d. 04 year	Amount of base $		x Rate applied	0.00%	% = F&A costs	$
e. 05 year	Amount of base $		x Rate applied	0.00%	% = F&A costs	$
	Enter Rate above as a decimal (e.g., 0.25 for 25%, 0.495 for 49.5%)				TOTAL F&A Costs	$

*Check appropriate box(es):

☐ Salary and wages base ☐ Modified total direct cost base ☐ Other base *(Explain)*

☐ Off-site, other special rate, or more than one rate involved *(Explain)*

Explanation *(Attach separate sheet, if necessary.)*:

Print all forms actual size to meet formatting specifications. Make sure "Shrink oversized pages to paper size" is NOT checked on Print window. (Red reminders will not appear on the printed form.)

Principal Investigator/Program Director (last, First, Middle):

CHECKLIST

TYPE OF APPLICATION *(Check all that apply.)*

☐ NEW application *(This application is being submitted to the PHS for the first time.)*

☐ REVISION of application number:
(This application replaces a prior unfunded version of a new, competing continuation, or supplemental application.)

☐ COMPETING CONTINUATION of grant number: _____
(This application is to extend a funded grant beyond its current project period.)

INVENTIONS AND PATENTS
(Competing continuation appl. and Phase II only)
☐ No ☐ Previously reported
☐ Yes. If "Yes," ☐ Not previously reported

☐ SUPPLEMENT to grant number: _____
(This application is for additional funds to supplement a currently funded grant.)

☐ CHANGE of principal investigator/program director.
Name of former principal investigator/program director:

☐ CHANGE of Grantee Institution. Name of former institution:

☐ FOREIGN application ☐ Domestic Grant with foreign involvement List Country(ies) involved:

☐ SBIR Phase I ☐ SBIR Phase II: SBIR Phase I Grant No. ☐ SBIR Fast Track
☐ STTR Phase I ☐ STTR Phase II: STTR Phase I Grant No. ☐ STTR Fast Track

1. PROGRAM INCOME *(See instructions.)*
All applications must indicate whether program income is anticipated during the period(s) for which grant support is requested. If program income is anticipated, use the format below to reflect the amount and source(s).

Budget Period	Anticipated Amount	Source(s)

2. ASSURANCES/CERTIFICATIONS *(See instructions.)*
In signing the application Face Page, the authorized organizational representative agrees to comply with the following policies, assurances •Debarment and Suspension; •Drug-Free Workplace *(applicable to new [Type 1] or revised [Type 1] applications only)*; •Lobbying; •Non-Delinquency on Federal Debt; •Research Misconduct; •Civil Rights

and/or certifications when applicable. Descriptions of individual assurances/certifications are provided in Part III. If unable to certify compliance, where applicable, provide an explanation and place it after this page.
•Human Subjects •Research Using Human Embryonic Stem Cells• •Research on Transplantation of Human Fetal Tissue •Women and Minority Inclusion Policy •Inclusion of Children Policy• Vertebrate Animals• (Form HHS 441 or HHS 690); •Handicapped Individuals (Form HHS 641 or HHS 690); •Sex Discrimination (Form HHS 639-A or HHS 690); •Age Discrimination (Form HHS 680 or HHS 690); •Recombinant DNA Research, Including Human Gene Transfer Research; •Financial Conflict of Interest (except Phase I SBIR/STTR); •Smoke Free Workplace; •Prohibited Research: •Select Agents •STTR ONLY: Certification of Research Institution Participation.

3. FACILITIES AND ADMINSTRATIVE COSTS (F&A)/ INDIRECT COSTS. See specific instructions.

☒ DHHS Agreement dated: 7/2/96 ☐ No Facilities And Administrative Costs Requested

☐ DHHS Agreement being negotiated with _____ Regional Office

☐ No DHHS Agreement, but rate established with _____ Date

CALCULATION* *(The entire grant application, including the Checklist, will be reproduced and provided to peer reviewers as confidential information.)*

a. Initial budget period:	Amount of base $	125,875	x Rate applied	64.50%	% = F&A costs	$	81,060
b. 02 year	Amount of base $	450,965	x Rate applied	62.00%	% = F&A costs	$	279,598
c. 03 year	Amount of base $		x Rate applied	0.00%	% = F&A costs	$	
d. 04 year	Amount of base $		x Rate applied	0.00%	% = F&A costs	$	
e. 05 year	Amount of base $		x Rate applied	0.00%	% = F&A costs	$	
	Enter Rate above as a decimal (e.g., 0.25 for 25%, 0.495 for 49.5%)				TOTAL F&A Costs	$	360,659

*Check appropriate box(es):

☐ Salary and wages base ☐ Modified total direct cost base ☐ Other base *(Explain)*

☐ Off-site, other special rate, or more than one rate involved *(Explain)*

Explanation *(Attach separate sheet, if necessary.)*

Print all forms actual size to meet formatting specifications. Make sure "Shrink oversized pages to paper size" is NOT checked on Print window. (Red reminders will not appear on the printed form.)

Principal Investigator/Program Director (Last, First, Middle):

Place this form at the end of the signed original copy of the application.
Do not duplicate.

PERSONAL DATA ON PRINCIPAL INVESTIGATOR/PROGRAM DIRECTOR

The Public Health Service has a continuing commitment to monitor the operation of its review and award processes to detect—and deal appropriately with—any instances of real or apparent inequities with respect to age, sex, race, or ethnicity of the proposed principal investigator/program director.

To provide the PHS with the information it needs for this important task, complete the form below and attach it to the signed original of the application after the Checklist. **Do not attach copies of this form to the duplicated copies of the application.**

Upon receipt of the application by the PHS, this form will be separated from the application. This form will **not** be duplicated, and it will **not** be a part of the review process. Data will be confidential, and will be maintained in Privacy Act record system 09-25-0036 "Grants: IMPAC (Grant/Contract Information)." The PHS requests the last four digits of the Social Security Number for accurate identification, referral, and review of applications and for management of PHS grant programs. Although the provision of this portion of the Social Security Number is voluntary, providing this information may improve both the accuracy and speed of processing the application. Please be aware that no individual will be denied any right, benefit, or privilege provided by law because of refusal to disclose this section of the Social Security Number. The PHS requests the last four digits of the Social Security Number under Sections 301(a) and 487 of the PHS Acts as amended (42 U.S.C 241a and U.S.C. 288). All analyses conducted on the date of birth, gender, race and/or ethnic origin data will report aggregate statistical findings only and will not identify individuals. If you decline to provide this information, it will in no way affect consideration of your application. Your cooperation will be appreciated.

DATE OF BIRTH (MM/DD/YY)

SEX/GENDER

SOCIAL SECURITY NUMBER (last 4 digits only) XXX-XX-

☐ Female ☐ Male

ETHNICITY

1. Do you consider yourself to be Hispanic or Latino? (See definition below.) Select one.

Hispanic or Latino. A person of Mexican, Puerto Rican, Cuban, South or Central American or other Spanish culture or origin, regardless of race. The term, "Spanish origin," can be used in addition to "Hispanic or Latino."

☐ **Hispanic or Latino**

☐ **Not Hispanic or Latino**

RACE

2. What race do you consider yourself to be? Select one or more of the following.

☐ ***American Indian or Alaska Native.*** A person having origins in any of the original peoples of North, Central, or South America, and who maintains tribal affiliation or community attachment.

☐ ***Asian.*** A person having origins in any of the original peoples of the Far East, Southeast Asia, or the Indian **subcontinent**, including, for example, Cambodia, China, India, Japan, Korea, Malaysia, Pakistan, the Philippine Islands, Thailand, and Vietnam. (Note: Individuals from the Philippine Islands have been recorded as Pacific Islanders in previous data collection strategies.)

☐ ***Black or African American.*** A person having origins in any of the black racial groups of Africa. Terms such as "Haitian" or "Negro" can be used in addition to "Black" or African American."

☐ ***Native Hawaiian or Other Pacific Islander.*** A person having origins in any of the original peoples of Hawaii, Guam, Samoa, or other Pacific Islands.

☐ ***White.*** A person having origins in any of the original peoples of Europe, the Middle East, or North Africa.

☐ Check here if you do not wish to provide some or all of the above information.

Print all forms actual size to meet formatting specifications. Make sure "Shrink oversized pages to paper size" is NOT checked on Print window. (This reminder will not appear on the printed form.)

JOHNS HOPKINS
BLOOMBERG
SCHOOL of PUBLIC HEALTH


Problems

Overview of Budget Development

- Budget should reflect funding needed to conduct proposed research
- Dont over-estimate OR under-estimate
- Project Director or Principal Investigator has primary responsibility
- Involve department administration early in process

The Budget Process
Determine Needs

- Should flow logically with proposals research
- Accurately fit the research proposed
- An estimate and firm offer
- Dollar limits, if any, should comply with sponsor
- Anticipated Costs


Use current Fringe Benefit and F&A rates

The Budget Process

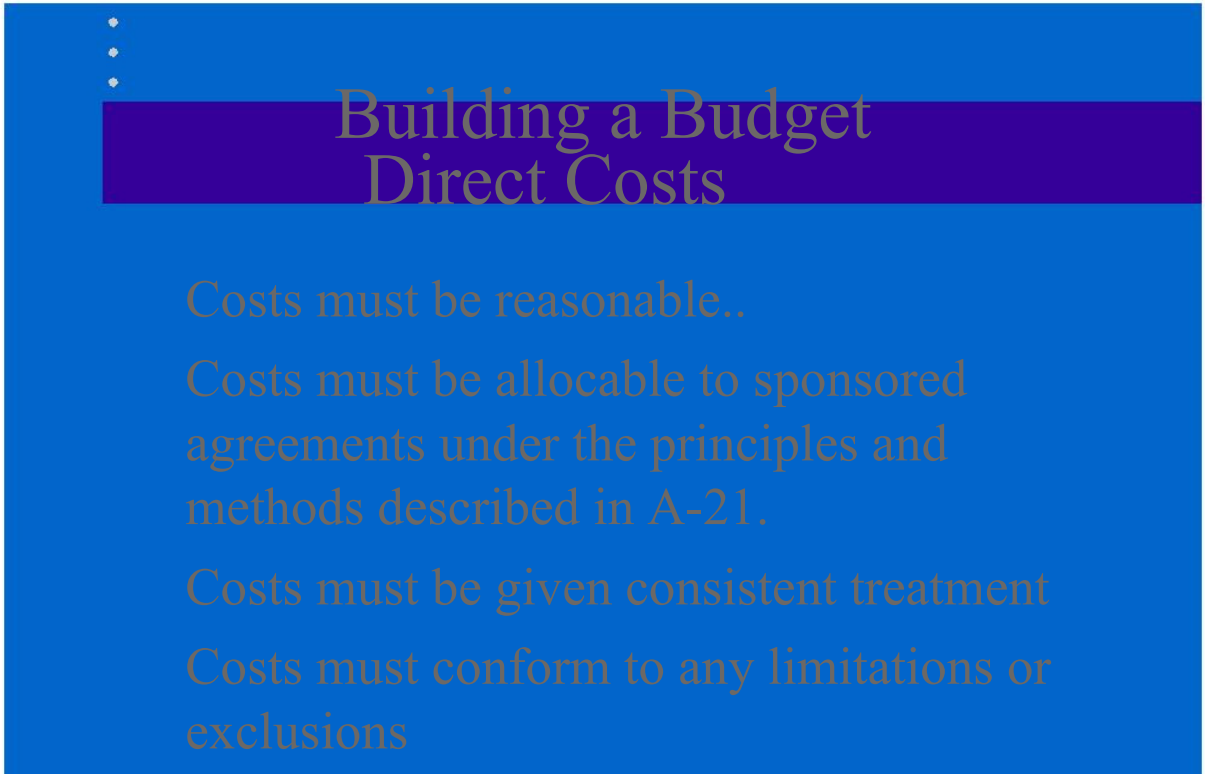
Questions to Ask

Who is the sponsor.

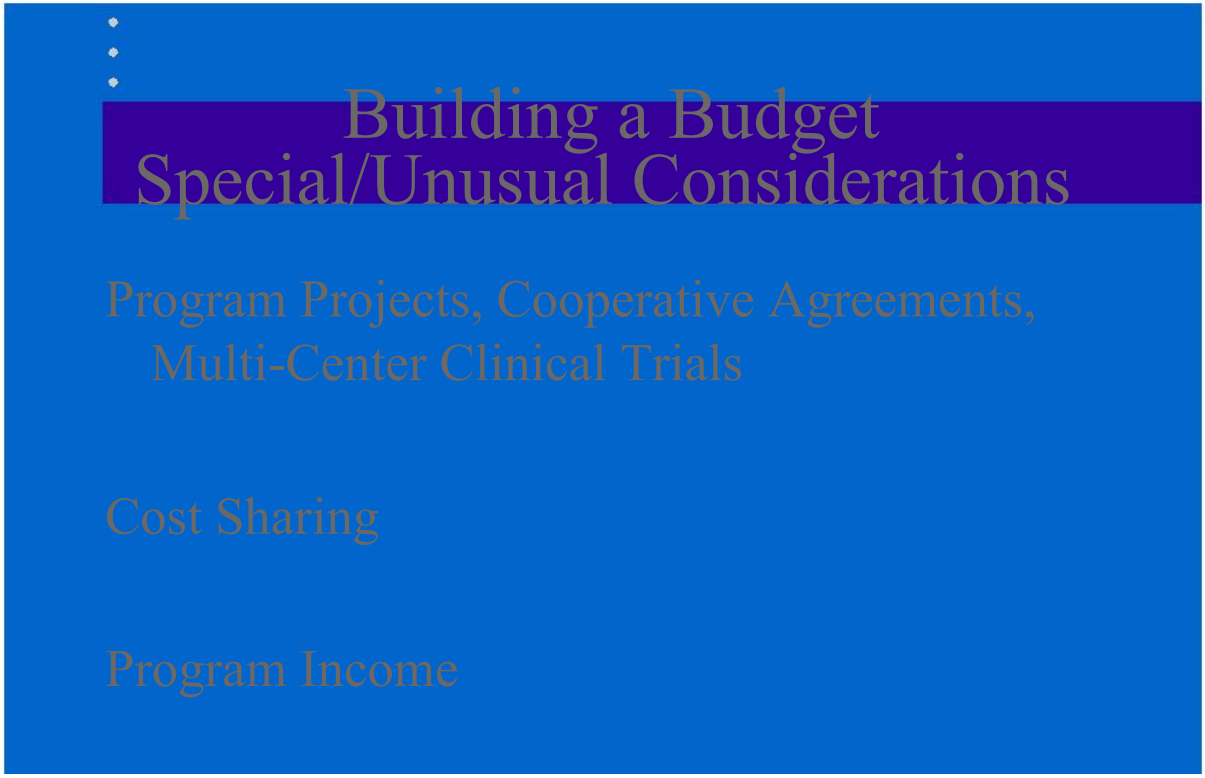
When is the proposal due to the sponsor.

Are there budget instructions.

- Provides budget period
- Provides project period
- Allowable costs
- Sponsor forms (font size, page limitations)




costs)



Building a Budget
Budget Justification

- Personnel
- Fringe Benefit Rates
- Travel (destinations, durations)
- Equipment
- Subcontracts
- F&A cost rates and base

JOHNS HOPKINS
BLOOMBERG
SCHOOL of PUBLIC HEALTH

Reviewing and Writing Grants

Jonathan M. Samet

Department of Epidemiology

Specific Aims Section

- Critical section
- Trailer for the grant
- Includes
  - Statement of scientific problem
  - Overview of scientific approach
  - Specific hypotheses to be tested
- The most read section

Specific Aims Dos

State what will be done

Give specific study design

Provide an overview of scientific issues and questions

State specific hypotheses

Describe public health significance

Specific Aims Donts

Make priority claims

Promise too much

Offer descriptive goals

Just summarize the grant

Specific Aims W atch out

Little is known about x, therefore we

This will be the first study of x, using the unique resource afforded by y.

In spite of decades of research, questions remain unanswered concerning x

The findings of this study will guide the development of preventive approaches for disease x.

Background and Significance

- Not just a review
- Critical to highlight what is known and the open questions in the face of available evidence
- Needs to be synthetic not exhaustive
- Interesting not boring
- Sets up the scientific basis for the grant

Background and Significance Going Wrong

Limited reviewLittle is known about x

Misrepresenting findings

Not synthesizing

Too long and too boring

Not citing the reviewers

Preliminary Studies/Progress Report

Highlight expertise

Provide relevant preliminary data

Document feasibility

Cover the entire team

Preliminary Studies/Progress Report Going Wrong

- Excessive claims of excellence
- Too much information
- Showing that too much work has been done
- Not establishing feasibility

Methods 1

- Useful to start with an overview to orient reviewers
  - Good spot for diagrams
- The details
  - Study design
  - Population selection
  - Data collection
  - Data management
  - Data analysis
- Other stuff
  - Human subjects

Methods 2

- Overview
- Give study design in relation to study questions
- Describe population and stuty qestions
- Justify what will follow

Methods 3
Population Selection

Why was the population selected.

- External validity.
- Feasibility.
- Prior investigation.

How will the population be seleced.

- Potential for selection bias.
- Representative of the population.

Methods 4
Data Collection

What are the items to be collected.

How will they be collected.

Does the grant build from standard approaches.

How will instruments be validated; measurement error assessed.

Methods 5
Data Management QA/QC

- Critical!
- Give plan for data management with details
- Set out systematic QA/QC approach
- Conspicuous by absence

Methods 6
Data Analysis

- Needs to match data collected and hypotheses
- Not a biostatistics tutorial
- Be specificgive models
- Specify variables
- Do not be generic

Methods 7--Power

- Always a game with assumptionjs
  - Document basis for all assumptions
- Do not exaggerate power
- Provide a range of calculations and assumptions
- Provide for major scientific question

Methods 8
Limitations

Describe potential limitations

Frameworkconfounding, selection bias, information bias, and power and precision

Anticipate and dont hold back

Be honest and not dismissive

Reviewing a Grant--1

Start with Specific Aims

Then to Methods

And then to Preliminary Studies/Progress Report

And then to remaining sections

Initial questionis the science at an acceptable

acceptable
level.

Reviewing a Grant 2
Good scientific question.

Study novel or repetitive.

Independent contribution or me too

Old questionnew twist.

Pass the well so what test.

Reviewing a Grant 3
Design Issues

Appropriate design.

Population with reasonable external validity.

Feasibility established.

What kind of approach to population selection.

Reviewing a Grant 4
Data Collection

- Use of standard instruments. The right instruments.
- Approach to data collection standardized. Interviewer training.
- Approach to QA/QCadequate. Set out.
- Data management system
- Data manager

Reviewing a Grant 5
Data Analysis

Right methods.

Textbook or tailored.

Linked to hypotheses and specific aims.

Expertise available.

Methods development needed.

Reviewing a Grant 5
Power

How calculated.

Assumptions stated and reasonable.

Measurement error issues considered.

Power given for all main hypotheses or selected.

Reviewing a Grant 6
Strengths and Limitations

Recognizing weaknesses is not a solution

Reasonable solutions proposed to problems.

Are strengths exaggerated.

Priority claims.

Study Section-1

- In Epi, cover broad areascancer, CVD, for example
- Broadly multidisciplinary
- Butexpertise on any particular specific topic is limited to two or three persons
- Study Sections have a SRA and a Chair
- Usually three primary reviewers and 2-3 discussants

Study Section-2
Triaging

Initially, grants are reviewed and those with reviewers in consensus that funding range not likely to be reached are triaged

About 40% of grants are triaged

A grant may also be NRFedNot Recommended for Fundinggroup does not want to see the application again

Study Section-3 Operations

Begin with scores from the reviewers

Then hear critiques from primary reviewers

Then any additional comments from discussants

Then open discussion

Then return to scores of initial reviewers and discussants

Then statement of anyone planning to vote outside the range

Study Section-4 Disagreements

- Novelty of work
- Feasibility
- Lack of scientific hypotheses
- Inadequate or inappropriate methods
- Cross-disciplinary conflictse.g., lab vs population perspective
- Public health importance

Study Section-5
Funding Level

- Funding itself is not a criterion for judgmentcant use the F-word
- Can make general comments about budget for NIH consideration
- Can make specific budgetary recommendations

Study Section-6
Scoring

- Everyone knows the payline approximately
- Scoring tends (too often to be dichotomous) Fnot F
- Encouragement to use the full range
- I push for giving good scores and bad scores

Study Section-7
Revised Applications

- Large proportion of applications are resubmittedtwo revisions allowed
- Investigators offer a response to each point of criticism and indicate changes in the text
- The response should be respectful and accomodating
- Combative responses can seek a grant

Grantsmanship-1

- Good questions/focused testable hypotheses
- Clarity of presentation
- Consistency across grantsfrom hypotheses to analyses
- Honesty not subterfuge
- Make scientific/public health contribution clear

Grantsmanship-2

- Focused Background and Significance section with concluding section
- Give relevant Preliminary Results only
- Begin Methods with an overview
- End with consideration of limitations
- Do not exaggerate anything, but power in particular

Grantsmanship-3
Avoid

Unique opportunity

First ever

Largest ever

important

And other exaggerations

Remember Good grants are always funded

Frank Speizer

JOHNS HOPKINS
BLOOMBERG
SCHOOL of PUBLIC HEALTH

Reviewing and Writing Grants

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Specific Aims Section

- Critical section
- Trailer for the grant
- Includes
  - Statement of scientific problem
  - Overview of scientific approach
  - Specific hypotheses to be tested
- The most read section

Specific Aims Dos

State what will be done

Give specific study design

Provide an overview of scientific issues and questions

State specific hypotheses

Describe public health significance

Specific Aims Donts

Make priority claims

Promise too much

Offer descriptive goals

Just summarize the grant

Specific Aims W atch out

Little is known about x, therefore we

This will be the first study of x, using the unique resource afforded by y.

In spite of decades of research, questions remain unanswered concerning x

The findings of this study will guide the development of preventive approaches for disease x.

Background and Significance

- Not just a review
- Critical to highlight what is known and the open questions in the face of available evidence
- Needs to be synthetic not exhaustive
- Interesting not boring
- Sets up the scientific basis for the grant

Background and Significance Going Wrong

Limited reviewLittle is known about x

Misrepresenting findings

Not synthesizing

Too long and too boring

Not citing the reviewers

Preliminary Studies/Progress Report

Highlight expertise

Provide relevant preliminary data

Document feasibility

Cover the entire team

Preliminary Studies/Progress Report Going Wrong

- Excessive claims of excellence
- Too much information
- Showing that too much work has been done
- Not establishing feasibility

Methods 1

- Useful to start with an overview to orient reviewers
  - Good spot for diagrams
- The details
  - Study design
  - Population selection
  - Data collection
  - Data management
  - Data analysis
- Other stuff
  - Human subjects

Methods 2

- Overview
- Give study design in relation to study questions
- Describe population and stuty qestions
- Justify what will follow

Methods 3
Population Selection

Why was the population selected.

- External validity.
- Feasibility.
- Prior investigation.

How will the population be seleced.

- Potential for selection bias.
- Representative of the population.

Methods 4
Data Collection

What are the items to be collected.

How will they be collected.

Does the grant build from standard approaches.

How will instruments be validated; measurement error assessed.

Methods 5
Data Management QA/QC

- Critical!
- Give plan for data management with details
- Set out systematic QA/QC approach
- Conspicuous by absence

Methods 6
Data Analysis

- Needs to match data collected and hypotheses
- Not a biostatistics tutorial
- Be specificgive models
- Specify variables
- Do not be generic

Methods 7--Power

- Always a game with assumptionjs
  - Document basis for all assumptions
- Do not exaggerate power
- Provide a range of calculations and assumptions
- Provide for major scientific question

Methods 8
Limitations

Describe potential limitations

Frameworkconfounding, selection bias, information bias, and power and precision

Anticipate and dont hold back

Be honest and not dismissive

Reviewing a Grant--1

Start with Specific Aims

Then to Methods

And then to Preliminary Studies/Progress Report

And then to remaining sections

Initial questionis the science at an acceptable

acceptable
level.

Reviewing a Grant 2
Good scientific question.

Study novel or repetitive.

Independent contribution or me too

Old questionnew twist.

Pass the well so what test.

Reviewing a Grant 3
Design Issues

Appropriate design.

Population with reasonable external validity.

Feasibility established.

What kind of approach to population selection.

Reviewing a Grant 4
Data Collection

- Use of standard instruments. The right instruments.
- Approach to data collection standardized. Interviewer training.
- Approach to QA/QCadequate. Set out.
- Data management system
- Data manager

Reviewing a Grant 5
Data Analysis

Right methods.

Textbook or tailored.

Linked to hypotheses and specific aims.

Expertise available.

Methods development needed.

Reviewing a Grant 5
Power

How calculated.

Assumptions stated and reasonable.

Measurement error issues considered.

Power given for all main hypotheses or selected.

Reviewing a Grant 6
Strengths and Limitations

Recognizing weaknesses is not a solution

Reasonable solutions proposed to problems.

Are strengths exaggerated.

Priority claims.

Study Section-1

- In Epi, cover broad areascancer, CVD, for example
- Broadly multidisciplinary
- Butexpertise on any particular specific topic is limited to two or three persons
- Study Sections have a SRA and a Chair
- Usually three primary reviewers and 2-3 discussants

Study Section-2
Triaging

Initially, grants are reviewed and those with reviewers in consensus that funding range not likely to be reached are triaged

About 40% of grants are triaged

A grant may also be NRFedNot Recommended for Fundinggroup does not want to see the application again

Study Section-3 Operations

Begin with scores from the reviewers

Then hear critiques from primary reviewers

Then any additional comments from discussants

Then open discussion

Then return to scores of initial reviewers and discussants

Then statement of anyone planning to vote outside the range

Study Section-4 Disagreements

- Novelty of work
- Feasibility
- Lack of scientific hypotheses
- Inadequate or inappropriate methods
- Cross-disciplinary conflictse.g., lab vs population perspective
- Public health importance

Study Section-5
Funding Level

- Funding itself is not a criterion for judgmentcant use the F-word
- Can make general comments about budget for NIH consideration
- Can make specific budgetary recommendations

Study Section-6
Scoring

- Everyone knows the payline approximately
- Scoring tends (too often to be dichotomous) Fnot F
- Encouragement to use the full range
- I push for giving good scores and bad scores

Study Section-7
Revised Applications

- Large proportion of applications are resubmittedtwo revisions allowed
- Investigators offer a response to each point of criticism and indicate changes in the text
- The response should be respectful and accomodating
- Combative responses can seek a grant

Grantsmanship-1

- Good questions/focused testable hypotheses
- Clarity of presentation
- Consistency across grantsfrom hypotheses to analyses
- Honesty not subterfuge
- Make scientific/public health contribution clear

Grantsmanship-2

- Focused Background and Significance section with concluding section
- Give relevant Preliminary Results only
- Begin Methods with an overview
- End with consideration of limitations
- Do not exaggerate anything, but power in particular

Grantsmanship-3
Avoid

Unique opportunity

First ever

Largest ever

important

And other exaggerations

Remember Good grants are always funded

Frank Speizer