Developing a Research Proposal

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What is a research proposal?

A detailed description of a proposed research study that you’re designing to investigate a particular problem.
Why would you write one?

For your employer/university
For IRB and tribal review
For funding
So you (and your team) know what you’re doing
So you can identify gaps in your research

Your proposal may look a little different for each audience!
Case study: colorectal cancer among Alaska Native people
Before you get started

Select your topic
Colorectal cancer is the second most common cancer among AN people.
...And the second leading cause of cancer death
Alaska Native people have among the highest incidence of colorectal cancer in the world.

Five-year annual average age-adjusted incidence rate, per 100,000

Source: Alaska Native Tumor Registry
Before you get started

Select your topic

Perform a literature review
Very little is known about risk and protective factors for CRC among AN people.

We know of factors that have been studied in other populations:

- DNA
- Diet
- Smoke

But there are other, Alaska-specific factors that have not been studied:

- Image of hands holding red objects
- Image of fish
- DNA and human biology
Before you get started

Select your topic
Perform a literature review
Gather your team
Before you get started

Select your topic
Perform a literature review
Gather your team

PLAN PLAN PLAN
Conversations with tribal health leaders, researchers, clinicians
Development and approval of study protocols (IRB, Tribal approvals)
Conduct Pilot Study

Protocol modifications
Research and clinical staff key informant interviews
Participant focus groups

ANTHC Research Consultation Committee
Scientific Advisory Group
Themes from planning conversations with tribal health leaders, researchers, clinicians

- Translational nature of research
- Community and study participant feedback
- Informed consent process
- Impact on clinical workflow
- Appropriate use of biospecimens
- Tribal ownership of data, particularly genetic data
- Incorporating plans for sharing study results with the AN community into study design


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Elements of a research proposal

Title
Abstract
Introduction
  Problem statement
  Objectives
  Hypothesis
Methods
Sharing results
Title

Should be:
Concise
Descriptive
Catchy
Comprehensible
A case-control study of colorectal cancer risk among Alaska Native people

Exploring risk and protective factors for colorectal cancer among Alaska Native people
Abstract

Brief summary, ~300 words
Summarize all the elements of the project
Stand-alone
Highlight the importance of the work
Alaska Native (AN) people experience the highest documented colorectal cancer (CRC) rates in the world. Both incidence of and mortality from CRC is twofold higher among AN people than US whites, and AN people are diagnosed at earlier ages than US whites. To address this disparity, a holistic approach to CRC control that includes both primary and secondary prevention is required. Yet, while CRC screening among AN people has been increasing, no epidemiological studies exist to help explain the high risk of CRC among the AN population. This study will be the first to identify risk and protective factors for CRC among AN people, including genetic factors, to help identify potential targets for intervention. Additionally, as CRC risk is increasing among typically low-risk groups, including the young, understanding the causes of this disease in a population that has seen dramatic increases in cancer risk over the past century may be informative. Led by the Alaska Native Tribal Health Consortium (ANTHC), in partnership with the Fred Hutchinson Cancer Research Center (FHCRC), this proposed research will establish a community-based participatory research study of CRC risk among AN people. Building on our successful pilot recruitment study, we will enroll up to 500 individuals (200 cases; 300 controls) prior to colonoscopy screening in Anchorage, the primary urban center of Alaska, as well as at three regional tribal hospitals located off the road system. Cases will be defined as incident CRC and advanced CR adenoma patients; controls will be matched by age and sex. We will collect lifestyle information using culturally appropriate and previously validated questionnaires of demographics, diet, food storage and processing, medication, occupation and tobacco use. We will also collect medical history and anthropometric information, including objective measures of physical activity and sleep. Lastly, we will collect biospecimens for analysis (saliva, hair, urine, and blood) and biobank those samples as a resource for future work. We will analyze these questionnaire, anthropometric, biomarker, and medical record data to assess associations of lifestyle risk or protective factors with CRC risk. We will perform whole genome sequencing to assess germline genetic risk factors for CRC among AN people, as well as individual variant and genome-wide association analyses. Finally, we will develop culturally respectful data communication materials that will enable sustainable translation of research findings through prevention programs to encourage healthful behavior change among AN people. These communication resources will be informed by community member perspectives on effective and appropriate data dissemination media. This study utilizes a community-based participatory research approach to address a key health disparity of community concern. By providing a better understanding of the lifestyle and genetic basis of CRC among this increased-risk population, the research will provide critical information that can be used to inform future research studies, develop risk prediction models, and design effective primary prevention strategies among AN people and other populations at high risk of this disease.
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Introduction

Gives readers background information, rationale, context
Introduction: Problem statement

The major problem of interest and significance that your study will address
Introduction

Why this study?

What’s the relevance?

What other research has been done?
Five-year annual average age-adjusted incidence rate, per 100,000.

AN

USW

'69-'73  '74-'78  '79-'83  '84-'88  '89-'93  '94-'98  '99-'03  '04-'08  '09-'13
Introduction: Objectives

What goals do you want your research to achieve?

Can be
- General/Specific
- Primary/Secondary

Do not make too many, or too ambitious
General objective:
To better understand risk and protective factors for CRC among AN people

Specific objectives:
To determine whether there are genetic mutations that affect CRC risk among AN people
To identify behaviors that, if modified, could reduce the risk of CRC among AN people
Introduction: Hypothesis

Tentative prediction of what you think you might find

For exploratory research, you may not have a hypothesis

Remember: you don’t set out to prove your hypothesis, you set out to test it
People who smoke will be at higher risk of developing CRC than those who do not.

People who regularly eat salmon will be at lower risk of developing CRC than those that do not.
Methods

Arguably the most important section

Tells your audience how you will answer the research question
Methods: Research design

What study design will you use?

Experimental
Observational

For more information about study designs, see the Coursera Course “Study Designs in Epidemiology”
Methods: Study participants

Who will your participants be?
Inclusion/exclusion criteria
Comparison group
Sampling method

How do participants withdraw?
ANMC Colorectal Cancer Screening Clinic

- Over 18
- No history of cancer
- No serious medical issue
Methods: Intervention

What is the intervention?
How will it be delivered?
Who will it be delivered to?
What’s your control group?

Treatment A
Treatment B or Control
Methods: What will you measure?

Independent variables:
Exposure variables. The things you think might cause the outcome(s) of interest.
Methods: What will you measure?

Dependent variables:
The outcome(s) of interest
Methods: What will you measure?

“Background” variables:
Other things that might affect the exposure or outcome
Considering context

How do the variables in your system fit together?
Methods: How will you measure it?

Your Study instruments should be included as an appendix.
What will be your study process?

What will happen as part of your study?

Walk through the process, like a “dress rehearsal”
Eligibility screening

Patients offered study

Pre-clinical visit reminder call; study information sheet; CMA in-person information

Study visit

Lifestyle questionnaire; dietary assessment; biospecimens (urine, blood, hair, stool collection kit)

Colonoscopy

Normal tissue biopsy; polyps/tumor (post-clinical pathology)

Follow-up

Medical record review; tumor registry linkage
Methods: Sample size

How many participants do you need to test your hypothesis?

(A biostatistician can help with this, and many other things)
Methods: Data storage and security
Methods: Data analysis

Hint: your biostatistician should write this part!
Dissemination of results

Dissemination is a critical part of community-engaged research

Plan ahead how you will share results with participants, community members, and tribal health leaders
Conclusions

Give some expected outcomes

Reiterate how your proposed study will answer the research question and provide useful information to the world

What happens next? How will your research lead to more research or programs?
Ethics of a research proposal

Describe how the study will be conducted in accordance with relevant ethical guidelines

USA: Common Rule
Reviewing your research proposal in three questions

Is the proposed study adequate to answer the research question?

Is the research feasible?

Does the proposal provide enough detail that another investigator could do the study?
Lessons learned?

Iterative process

Gather your team early (and use them!)

Involve the community early and often

Think about the end at the beginning
Resources

https://www.who.int/ethics/review-committee/emro_ethics_dsa237.pdf

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3282423/

Coursera Courses:
Study Design in Epidemiology
Understanding Clinical Research
Statistical Inference
Thank You

gunalchéesh • ‘awa’ahdah • chin’an • mahsi’
tsin’e e • way dankoo • háw’aa • quyana

qagaasakung • baasee’ • tsin’aen • quyanaq
dogedinh • quyanaa • igamsiqanaghkhalek

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OUR VISION:
Alaska Native people are the healthiest people in the world.