

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



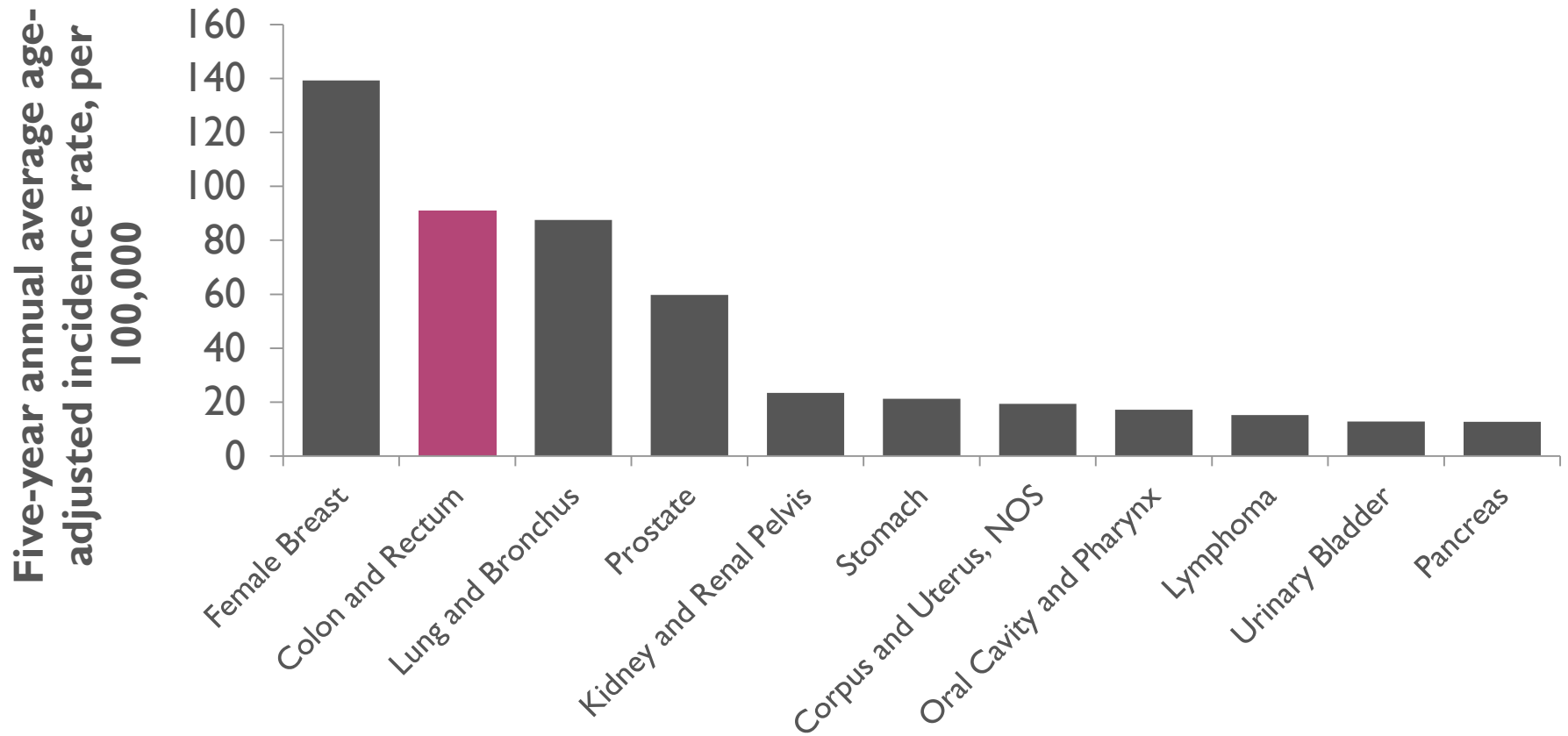
Before you get started

Select your topic

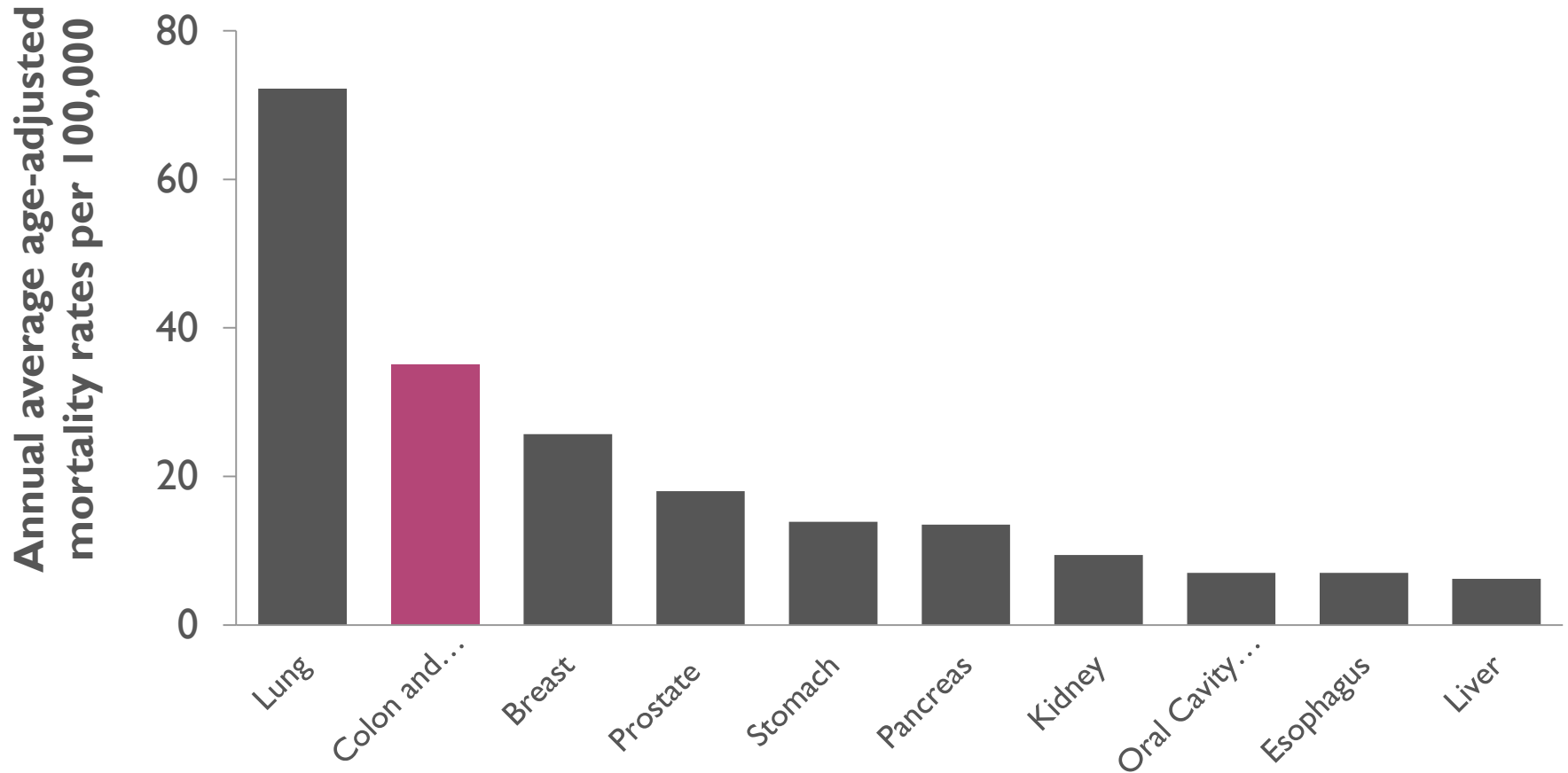


IDEA

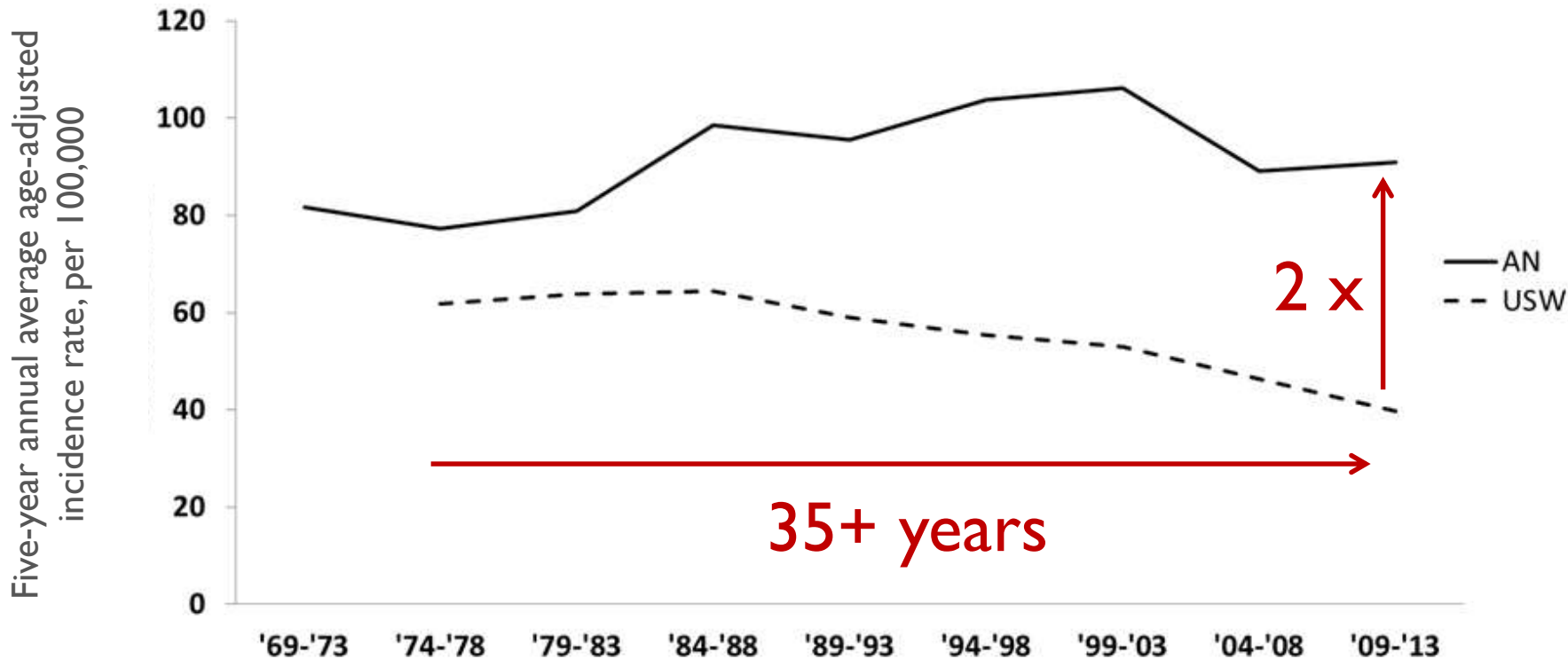
Colorectal cancer is the second most common cancer among AN people



...And the second leading cause of cancer death



Alaska Native people have among the highest incidence of colorectal cancer in the world



Before you get started

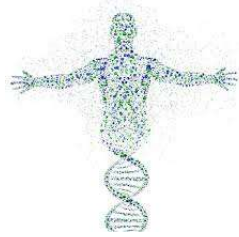
Select your topic

Perform a literature
review

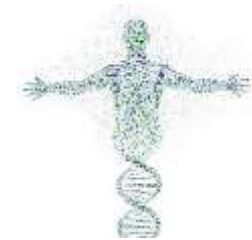


Very little is known about risk and protective factors for CRC among AN people

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



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

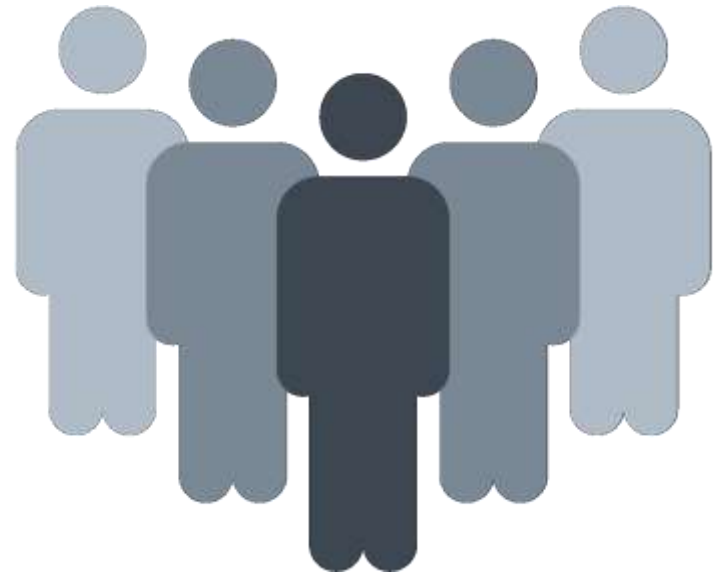


Before you get started

Select your topic

Perform a literature
review

Gather your team





Diana Redwood, PhD MPH



Rochelle Greenley, BA (AN)



Riki Peters, PhD MPH

Before you get started

Select your topic

Perform a literature
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PLAN PLAN PLAN



ANTHC Research Consultation
Committee

Scientific Advisory Group

Conversations with
tribal health leaders,
researchers, clinicians



Development and
approval of study
protocols
(IRB, Tribal approvals)



Conduct Pilot Study



Participant focus
groups



Research and clinical
staff key informant
interviews



Protocol modifications



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

Nash, Peters, Redwood. Journal of Public Health Management and Practice, in press.

Research was supported by the National Institute of General Medical Sciences of the National Institutes of Health under Award Number U54GM115371

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

Problem Statement

Additionally, as CRC risk is increasing among typically low-risk populations, 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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How this study will address the problem

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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Our methods (in brief)

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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

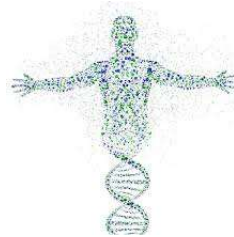
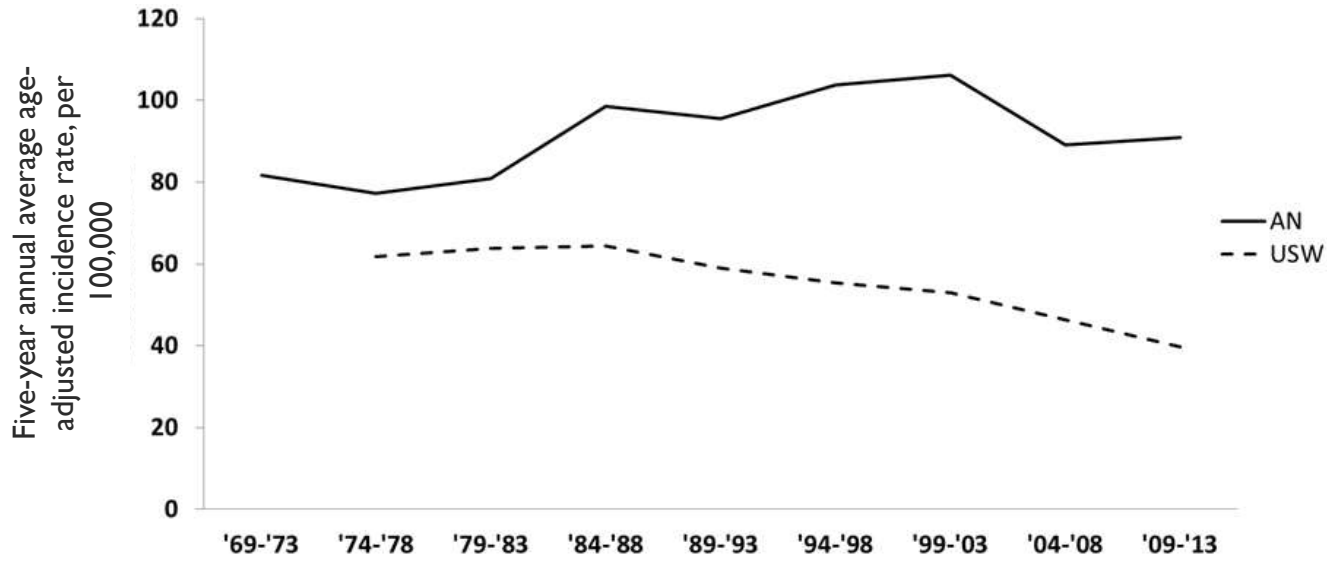


Introduction

Why this study?

What's the
relevance?

What other research
has been done?



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

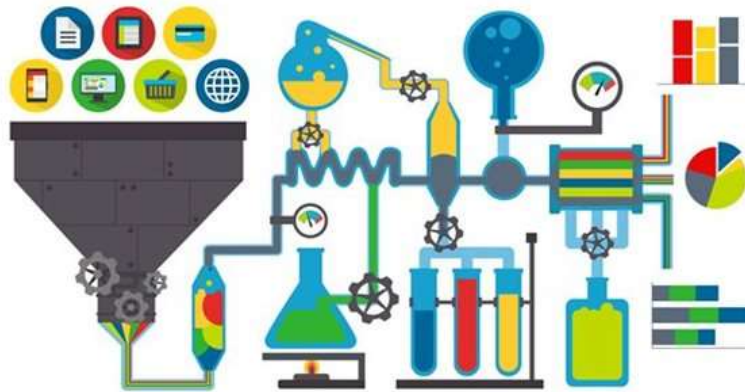
People who smoke will be at higher risk of developing CRC than those who do not

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?

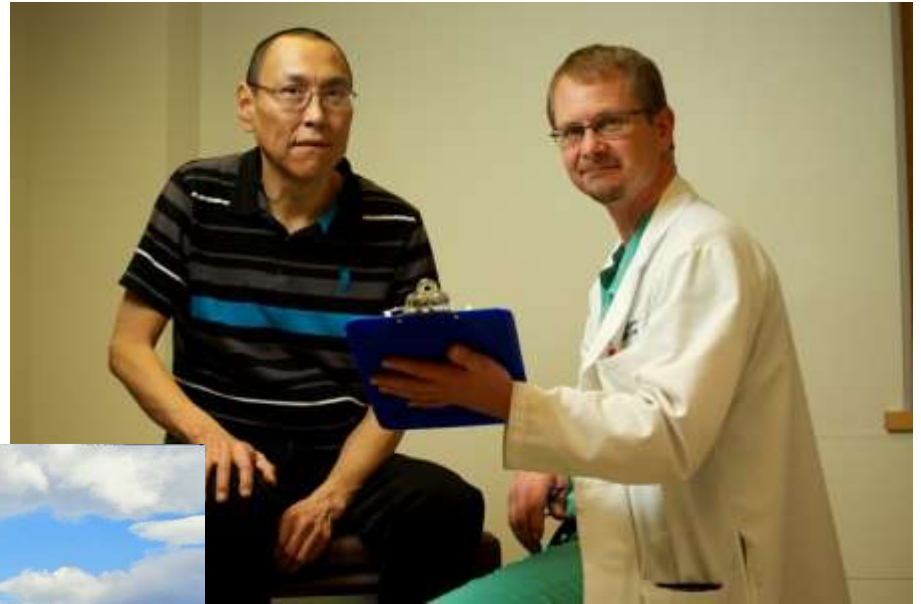
Inclusion/exclusion criteria

Comparison group

Sampling method

How do participants withdraw?

ANMC Colorectal Cancer Screening Clinic



- Over 18
- No history of cancer
- No serious medical issue

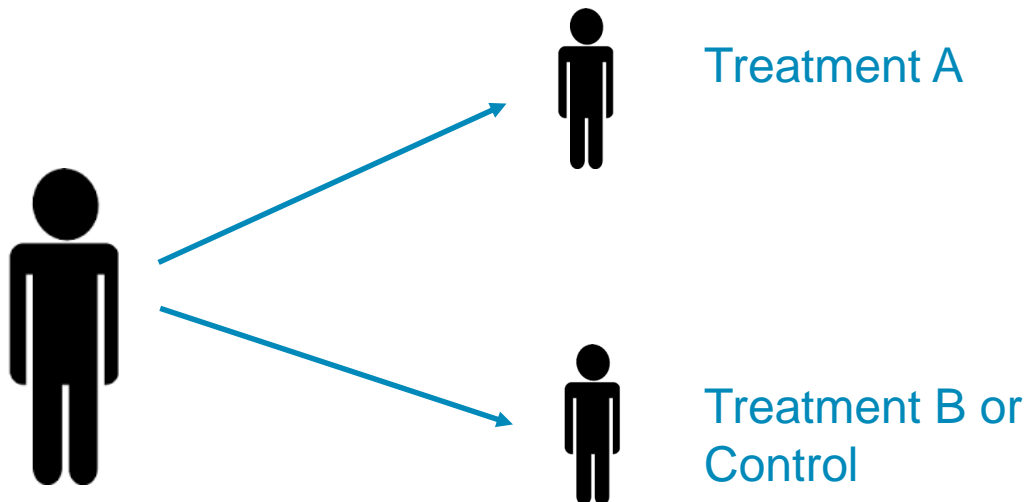
Methods: Intervention

What is the intervention?

How will it be delivered?

Who will it be delivered to?

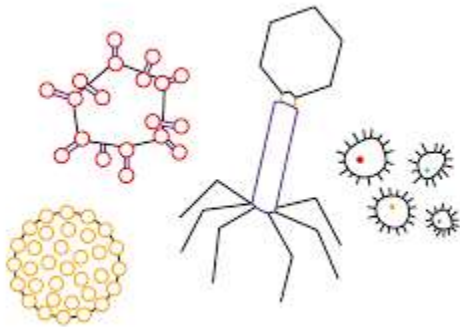
What's your control group?

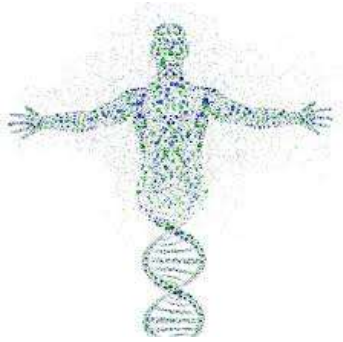


Methods: What will you measure?

Independent variables:

Exposure variables. The things you think might cause the outcome(s) of interest

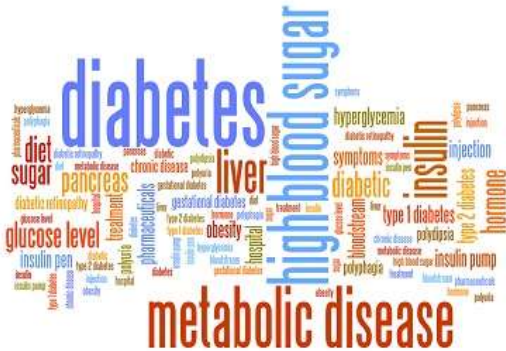




Methods: What will you measure?

Dependent variables:

The outcome(s) of interest





Methods: What will you measure?

“Background” variables:

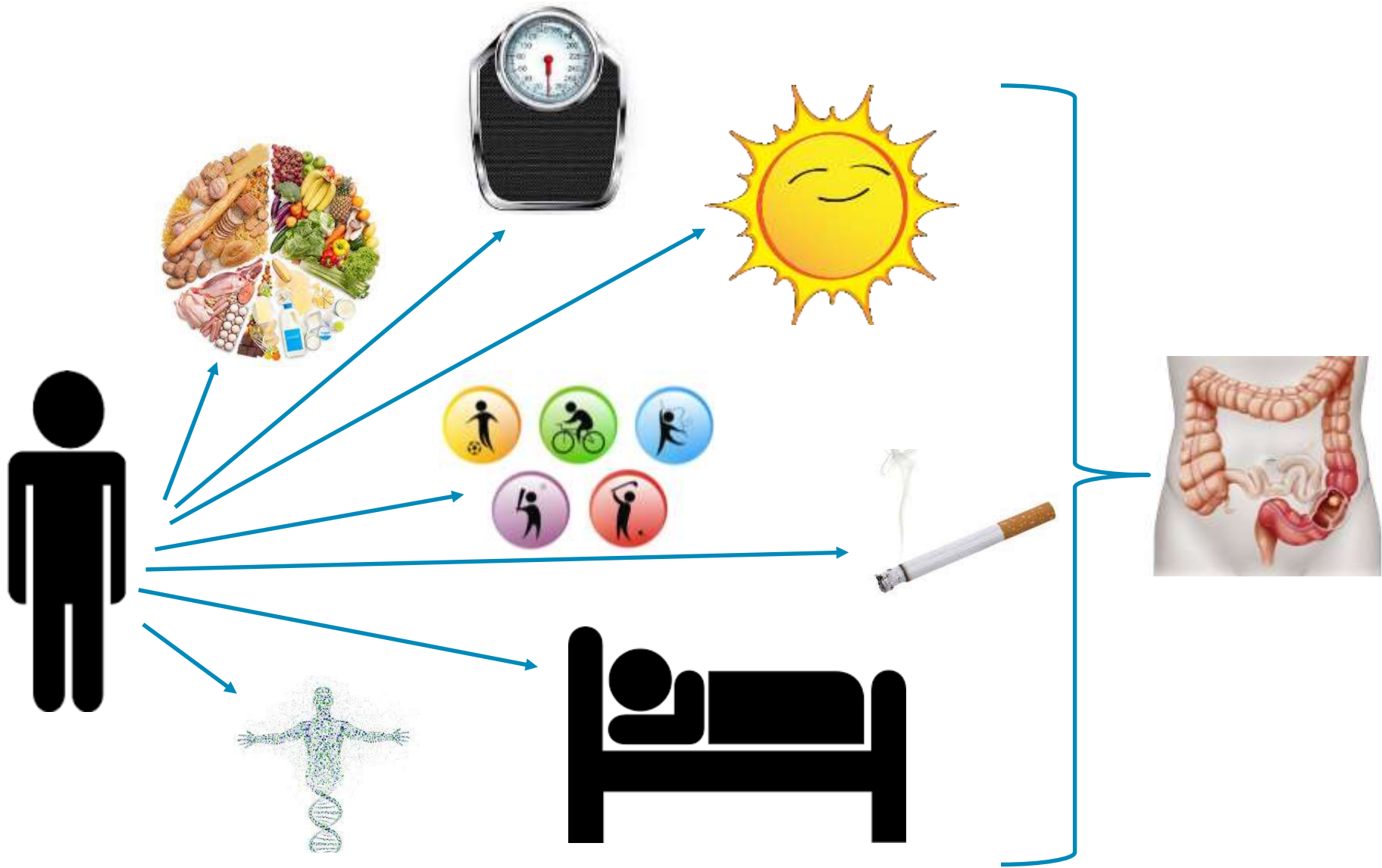
Other things that might affect the exposure or outcome



Considering context

How do the variables in your system fit together?





Methods: How will you measure it?

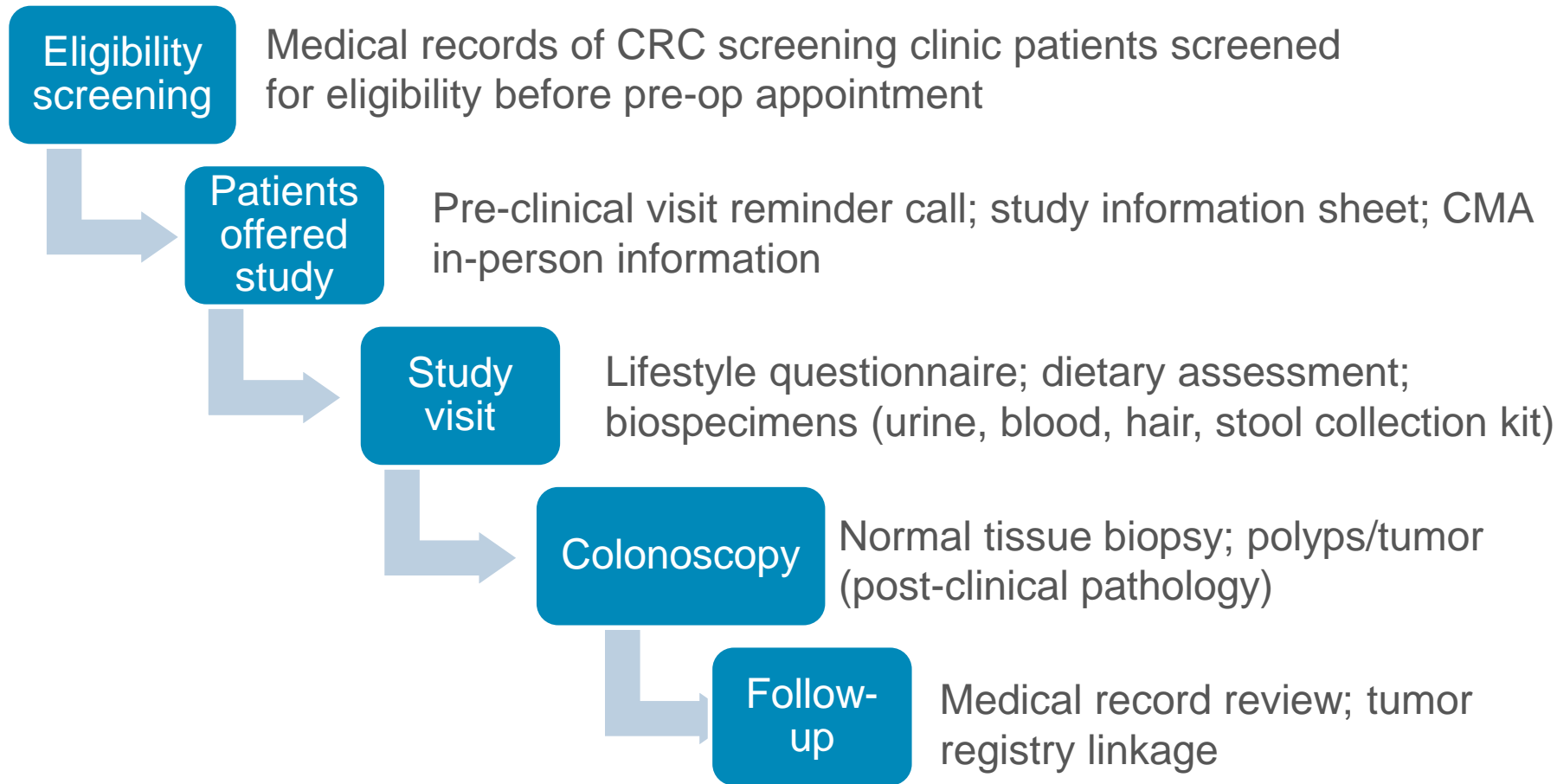


Your **Study instruments** should be included as an appendix

What will be your study process?

What will happen as part of your study?

Walk through the process, like a “dress rehearsal”



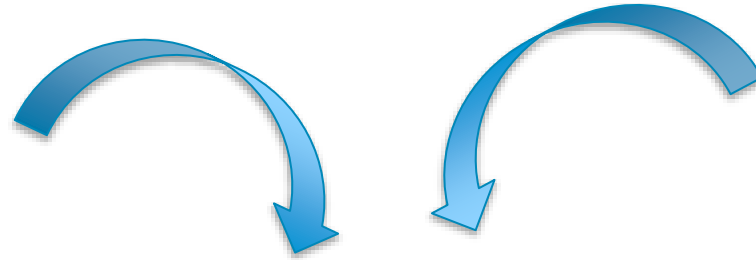
Methods: Sample size

How many participants do you need to test your hypothesis?



(A biostatistician can help with this, and many other things)

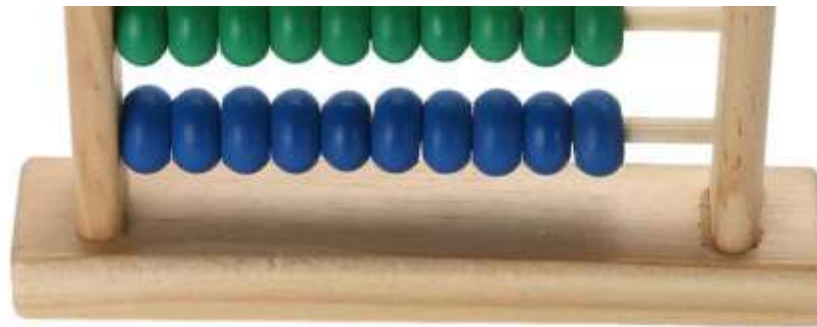
Methods: Data storage and security



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

qagaasakung • baasee' • tsin'aen • quyanaq
dogedinh • quyanaa • igamsiqanaghalek

Thank You

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

Sarah Nash, PhD, MPH • shnash@anthc.org

OUR VISION:

Alaska Native people are the healthiest people in the world.



ALASKA NATIVE
TRIBAL HEALTH
CONSORTIUM