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Colon Cancer Vaccine Study: Development of a Decision Support Intervention for Study Recruitment

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COLON CANCER VACCINE STUDY: DEVELOPMENT OF A DECISION SUPPORT INTERVENTION FOR STUDY RECRUITMENT

Evelyn Stevens

Summer Training Program in Cancer Immunotherapy

Thomas Jefferson University

Mentors: Dr. Ronald Myers and Dr. Terry Hyslop



Colorectal Cancer

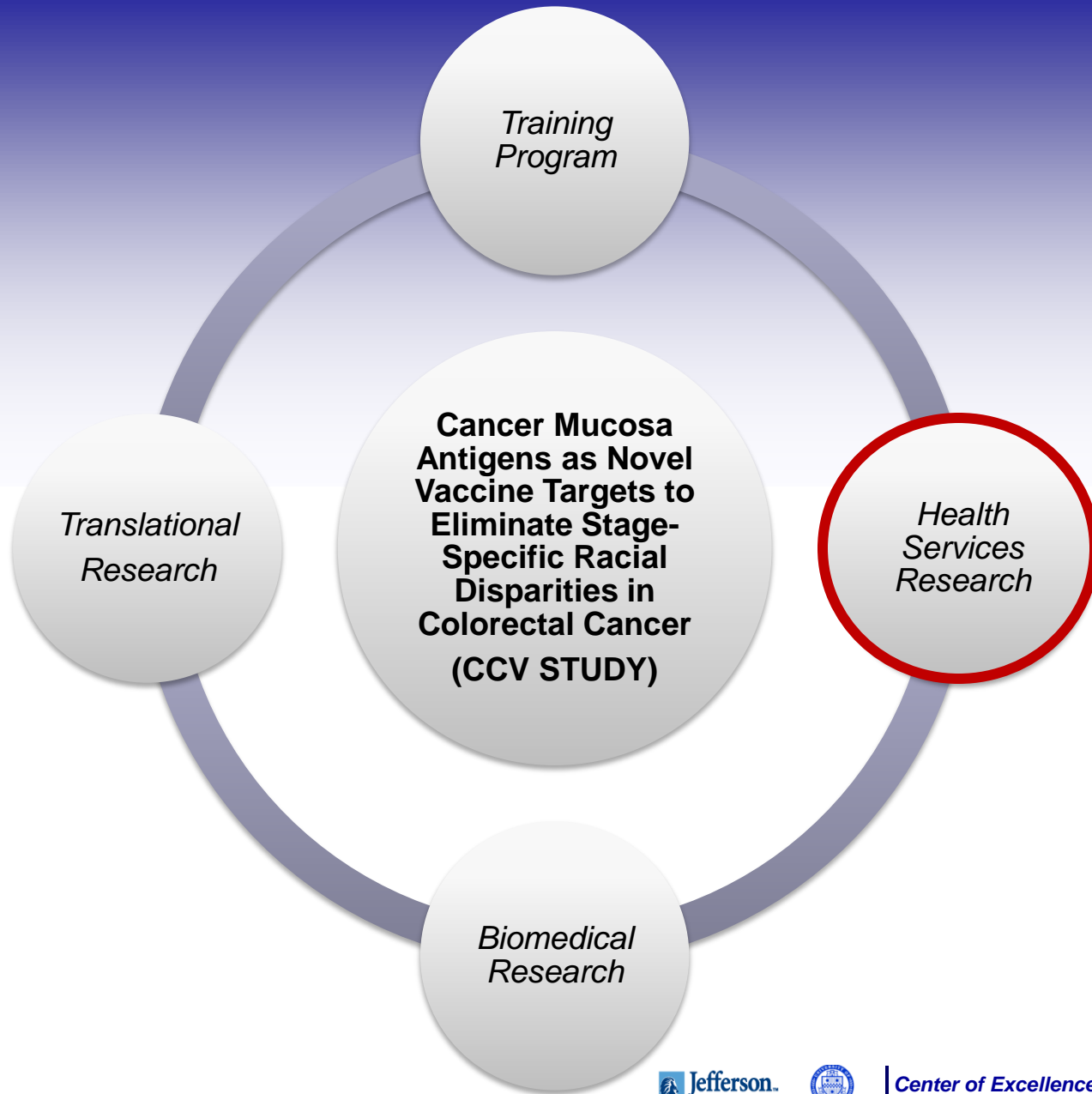
- **3rd leading cause of cancer and 2nd leading cause of cancer related deaths in the United States¹**
- **African Americans have higher rates of recurrence¹**
- **Guanylyl cyclase C (GCC) is a protein that is over expressed by metastatic colorectal tumors**
- **Cancer clinical trials^{2, 3}**
 - Participation is 3-5%
 - Recruitment (communication challenges)
 - Lower rates in African Americans

¹. *Center for Disease Control*, 2012

². Cox & McGarry, *European Journal of Cancer Care*, 2003

³. National Cancer Institute *Cancer Bulletin*, 2009.





Health Services Research

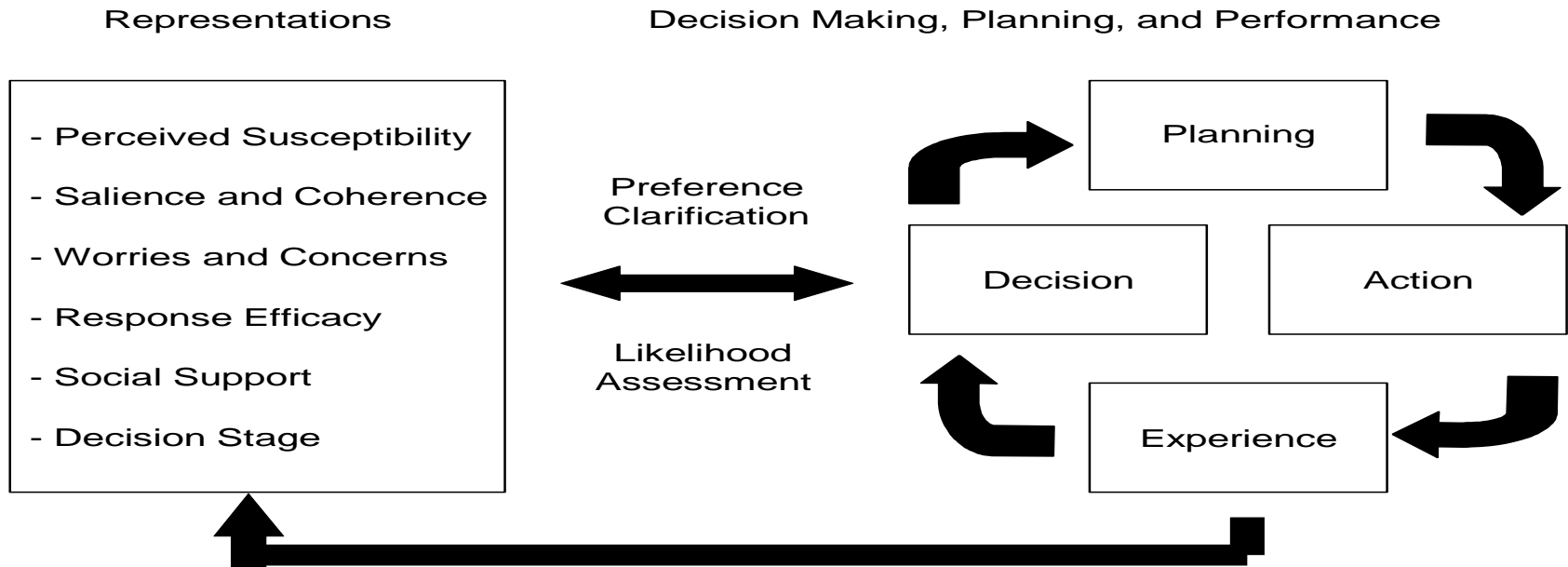
- Addresses patient access to health care and health care services as well as patient outcomes and effectiveness of health care
- Addressing racial barriers in participating in cancer vaccine trials
- Develop a decision support intervention to improve informed participation

MY
FOCUS

Identify factors that may influence trial participation

Theoretical Framework⁴

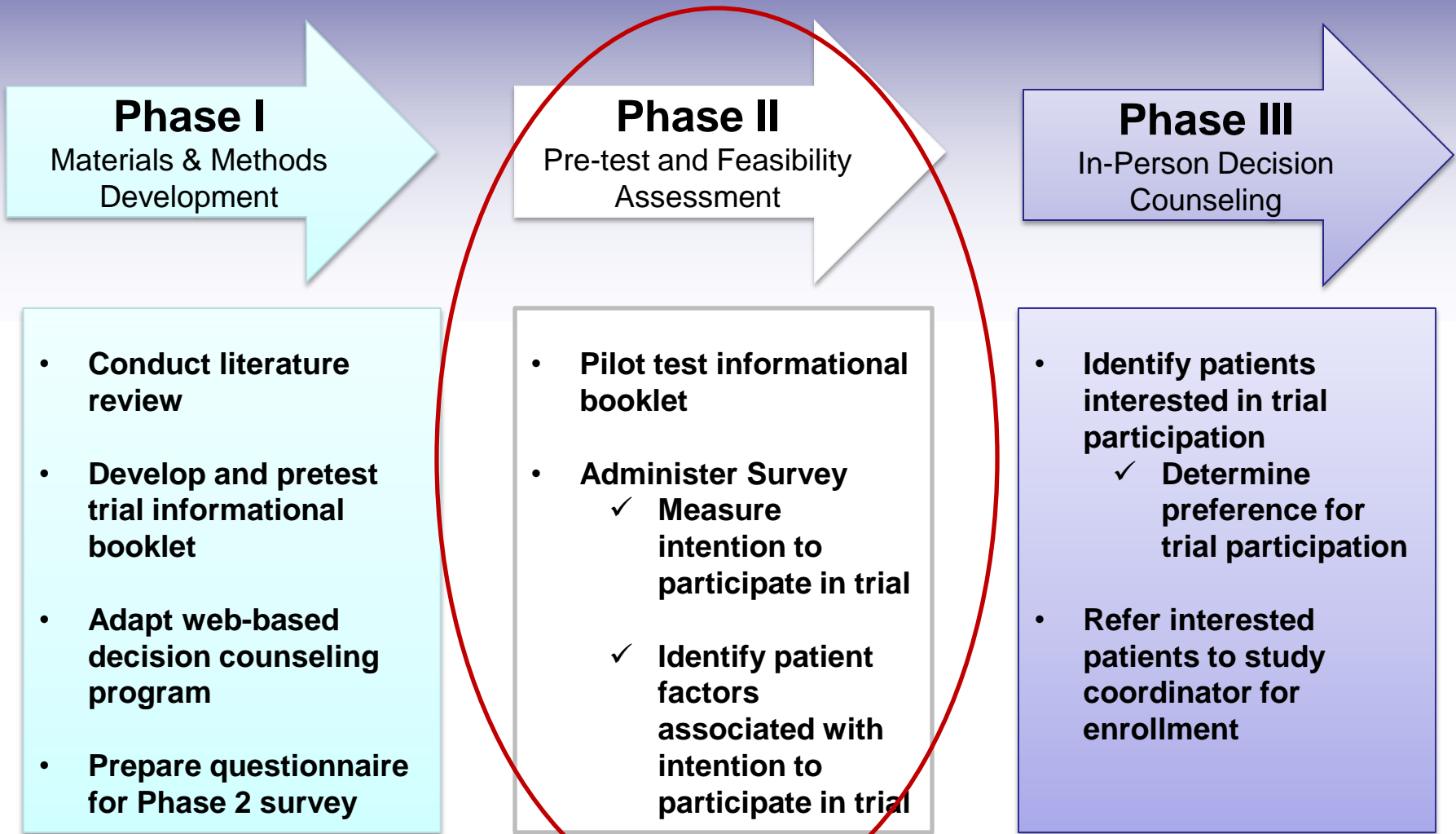
Figure 1. The PHM and AHP in Mediated Decision Support *



* PHM = Preventive Health Model, AHP = Analytic Hierarchy Process

⁴ Myers (2005) *Health Psychology*

Phases of The CCV Study

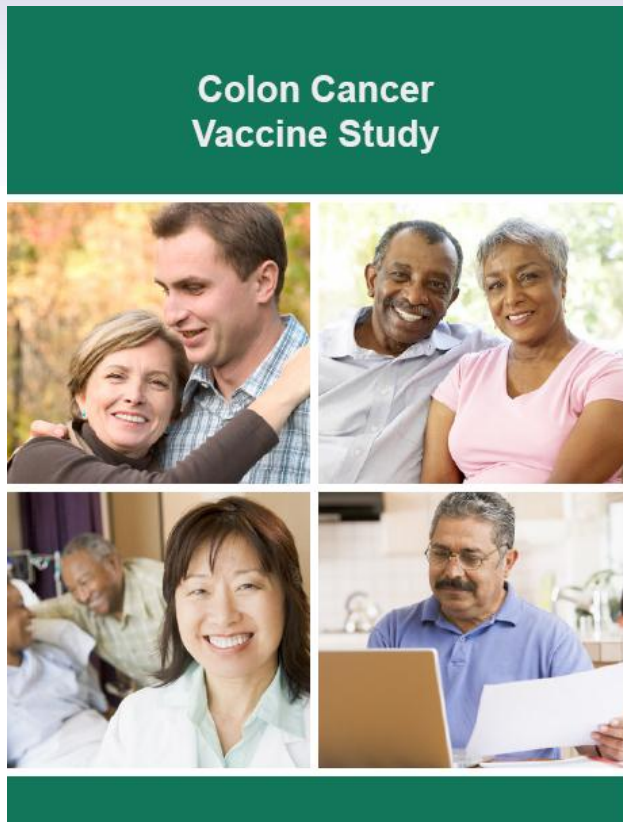


Phase I: Conclusions

- **Perceived effectiveness of the informational booklet varied by age**
 - Older patients found the booklet more challenging
- **Modifications to the booklet**
 - Large print
 - Subheadings
 - Reducing reading level from 11th grade to an 8th grade level
 - Additional information
 - clarify side effects and safety
 - participation requirements

Informational Trial Booklet

- Developed and pre-tested the Informational Booklet



About this booklet

Goals of the study

This booklet includes information about a research study on a new **vaccine** that may help prevent colon cancer from coming back (**recurrence**) for people who have been treated for early stage (stage I or II) colon cancer.

The study, referred to here as the Colon Cancer Vaccine Study, aims to:

1. Make sure the vaccine is safe, and
2. Find out if the vaccine is likely to work.

Information in the booklet is for people who may be interested in joining the study

To help you decide if you want to be a part of the Colon Cancer Vaccine Study, we encourage you to take the following steps:

- **Read.** Review information in this booklet.
- **Ask questions.** Speak with a research staff member and your doctor to learn more about the study and get your questions answered.

Medical terms and abbreviations

Some words in the booklet might not be familiar to you. These words are printed in **orange** and are defined in the Glossary.

Table of contents

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2



3

Phase II

MY
FOCUS

Identify factors that may influence trial participation

- **Began my research during the middle of phase II**
 - Recruitment at 21 patients (19 Whites and 2 Blacks)
 - Goal is 25 Blacks and 25 Whites
- **Literature review**
- **Data entry**
- **Preliminary Analyses**

Literature Review

- **Search databases were RefWorks, Scopus, and PubMed**
- **Annotated 42 articles**
- **Identified factors that influence trial participation:**
 - Decision-Making Process (9)
 - Participant – provider communication (12)
 - Decision Aids (11)
 - Recruitment Strategies (10)

Literature Review

- **Decision Making Process**
 - Shared decision making is ideal for increasing trial participation
- **Patient – Provider Communication**
 - Important to ensure participants have complete understanding of the research study
 - Test/feedback mechanisms
- **Recruitment Strategies**
 - Specific to culture and socio-demographics will increase trial participation
- **Decision Aids**
 - Enhanced informed consent, audiovisuals, and in-person interactions seem to influence trial participation

Phase II

- **Independent Variables**

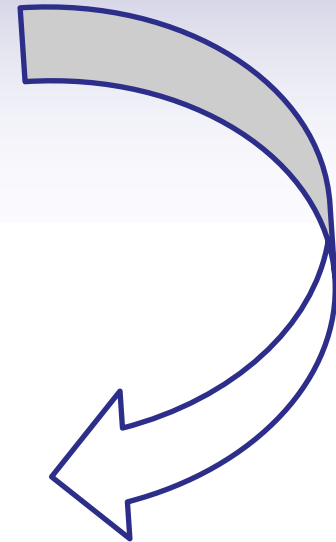
- Background Characteristics
- Knowledge about the CCV Study
- Thoughts about joining the CCV Study
- Perceptions about Religion and Health
- Perceptions about Health Care Research
- Thoughts about the CCV Informational Booklet

- **Dependent Variable**

- Intention to join the CCV Study if it were available today (hypothetical scenario)

- **Goal of recruitment**

- 25 Whites and 25 Blacks



Intention to Join CCV Study

Introduction

Colon cancer can come back (recurrence) among some people who have had early (Stage I or II) colon cancer. Currently, there is no known treatment that prevents colon cancer recurrence. This problem is the focus of a study, the Colon Cancer Vaccine Study

In the Colon Cancer Vaccine Study, work is now underway to develop a new vaccine that may help to prevent colon cancer recurrence. When the vaccine is ready, it must be evaluated to make sure it is safe and is effective in activating the body's defense (immune system). At that time, we will ask eligible patients to join a research study intended to evaluate the vaccine.

Summary of Steps in the Colon Cancer Vaccine Study

- Sign a consent form, complete blood studies, provide their medical history information, and have a physical exam.
- Visit the clinic, receive the vaccine injection in the upper arm, and remain for at least 30 minutes to make sure there are no reactions to the vaccine. (Mild flu-like symptoms are an example of a potential side effect of the vaccine)
- Receive follow up telephone calls to assess well-being
- Visit the clinic at one, three, and six months to evaluate response to the vaccine and have blood studies.



Phase II: Participant Accrual

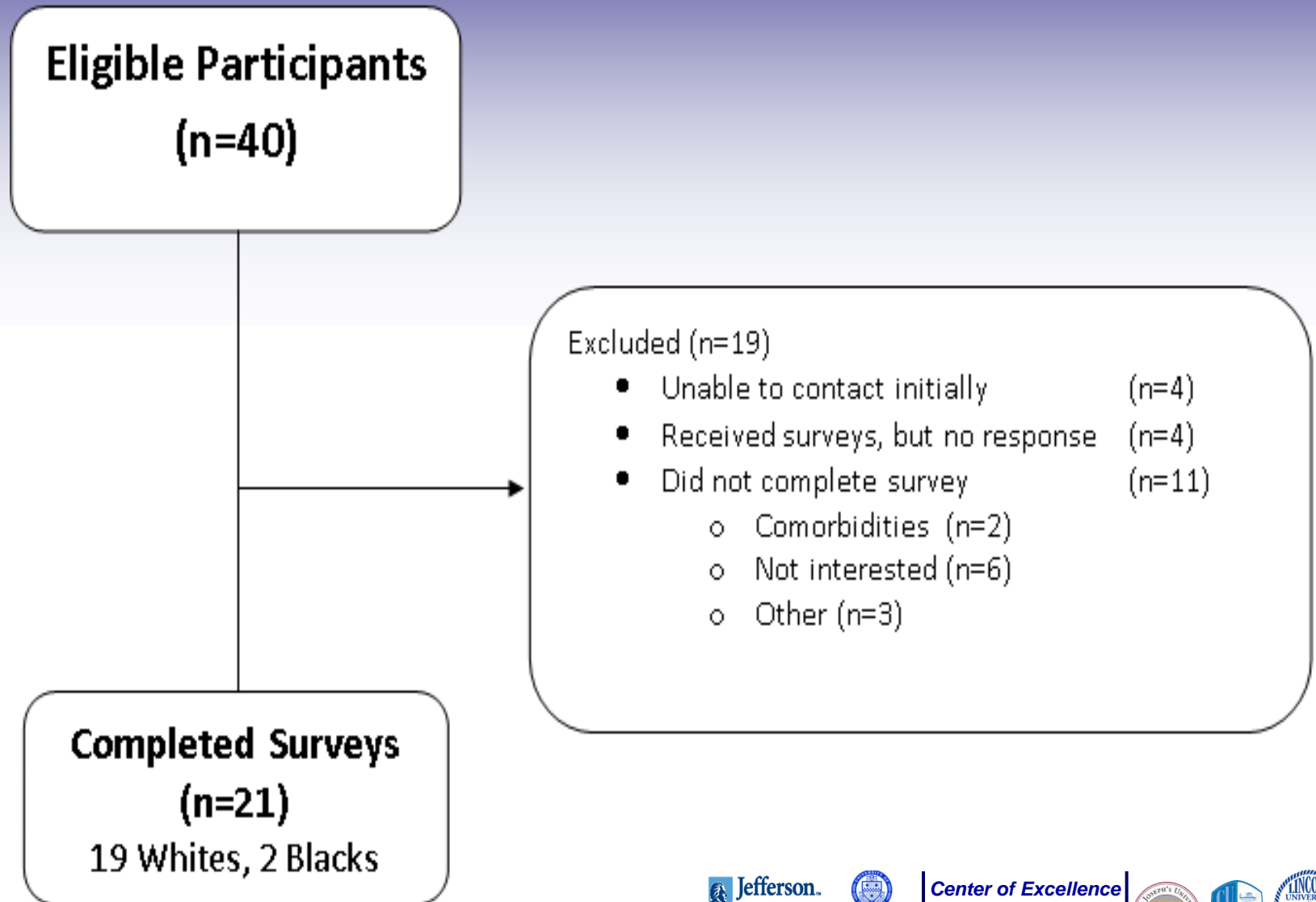


Figure 2: Participant Accrual for Phase II

Phase II: Participant Characteristics

Table 1: Summary of Participant Characteristics for Phase II, n=21 participants

Characteristic		N(%)
Study Site	Thomas Jefferson University	14 (67)
	University of Pittsburgh	7 (33)
	Fox Chase Cancer Center	-----
Age	≤ 65	11 (52)
	> 65	10 (48)
Gender	Male	9 (43)
	Female	12 (57)
Race	White	19 (90)
	Black	2 (10)
Marital Status	Married	11 (52)
	Not Married	10 (48)
Education	≤ High School	8 (38)
	> High School	13 (62)

Note: Recruitment is not complete for Phase II



Intention to Join CCV Study

If the vaccine were available today and you were asked to join the Colon Cancer Vaccine Study, what do you think you would do?

6

I would join

11

I am unsure what I would do

4

I would not join

Background Characteristics of Participants by Joining the CCV Study if the Vaccine Were Available Today

Table 2: Summary of Background Characteristics of Participants by Joining the CCV Study

<u>Characteristics</u>		Would Not Join/Unsure	Would Join	P-Value
		n (%)	n (%)	
Age	≤ 65	10 (90.91)	1 (9.09)	0.0635
	> 65	5 (50.00)	5 (50.00)	
Sex	Male	5 (55.56)	4 (44.44)	0.3310
	Female	10 (83.33)	2 (16.67)	
Race	White	14 (73.68)	5 (26.32)	0.5000
	Black	1 (50.00)	1 (50.00)	
Marital Status	Married	8 (72.73)	3 (27.27)	1.0000
	Not Married	7 (70.00)	3 (30.00)	
Education	≤ High School	5 (62.50)	3 (37.50)	0.6311
	> High School	10 (76.92)	3 (23.08)	

Fisher's Exact Test, n=21

Summary of Survey Responses: Joining the CCV Study if Vaccine Were Available Today by Thoughts about Joining the CCV Study

Table 3: Summary of Joining the CCV Study If Vaccine Were Available Today by Thoughts about Joining the CCV Study

Survey Items	Would Not Join/Unsure		Would Join		P-Value
		n (%)	n (%)	n (%)	
Important thing for me to do	Disagree	10 (66.67)	0 (0.00)		0.0124
	Agree	5 (33.33)	6 (100.00)		
Could help protect my health	Disagree	7 (46.67)	0 (0.00)		0.0609
	Agree	8 (53.33)	6 (100.00)		
Could help prevent a recurrence	Disagree	10 (66.67)	1 (16.67)		0.0635
	Agree	5 (33.33)	5 (83.33)		
Family thinks I should join	Disagree	13 (86.67)	2 (33.33)		0.0307
	Agree	2 (13.33)	4 (66.67)		
My doctor thinks I should join	Disagree	13 (86.67)	2 (33.33)		0.0307
	Agree	2 (13.33)	4 (66.67)		

Fisher's Exact Test, n=21

Phase II: Implications

- **Representations of Theoretical Model**

- **Saliency and Coherence**

- Those patients who agreed that joining is important and want to join, may be more likely to follow through with the requirements of participation
 - Time and effort of research staff is not wasted

- **Response Efficacy**

- Protect my health (67%)
 - Prevent a recurrence (48%)
 - False hope or false reassurance (therapeutic fallacy)

- **Social Influences (i.e. doctor and/or family)**

- 13 participants (61%) disagreed with believing their family thinks they should join and 13 participants (61%) disagreed with believing their doctor thinks they should join
 - Provide more information to the providers and/or encourage participants to talk with family members about the vaccine and invite them to read the informational booklet and/or in the future attend the in-person decision counseling session

MY
FOCUS

Identify factors that may influence trial participation

- **Age has a tendency to be associated with intention to join the CCV study**
- **Attitudinal Factors**
 - Important thing for me to do
 - Could help protect my health (marginally significant)
 - Could help prevent a recurrence (marginally significant)
 - Family thinks I should join
 - Doctor thinks I should join
- **Preliminary analyses, all these factors may change!**

Future of Health Services Research

- **Phase III**

- Identify patients interested in trial participation
- Determine preference for trial participation
 - Combine informational booklet and web-based decision counseling
 - Refer interested patients to study coordinator for vaccine trial enrollment

Table 4: Summary of participants that would like to be notified when the vaccine trial is ready to enroll by participants who would join if vaccine were available today

Survey Item		Would Not Join n (%)	Unsure n (%)	Would Join n (%)
Would you like to be notified when the vaccine trial is ready to enroll?	No	2 (9.52)	0 (0.00)	0 (0.00)
	Yes	2 (9.52)	11 (52.38)	6 (28.57)

Lessons Learned

- **Important to participate in clinical research**
 - The Immortal Cells of Henrietta Lacks” by Rebecca Skloot
 - Understand the trial
 - Make an informed decision
- **Importance of a statistician**
- **The value of reading literature**

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Thank You!

Are There Any Questions?



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