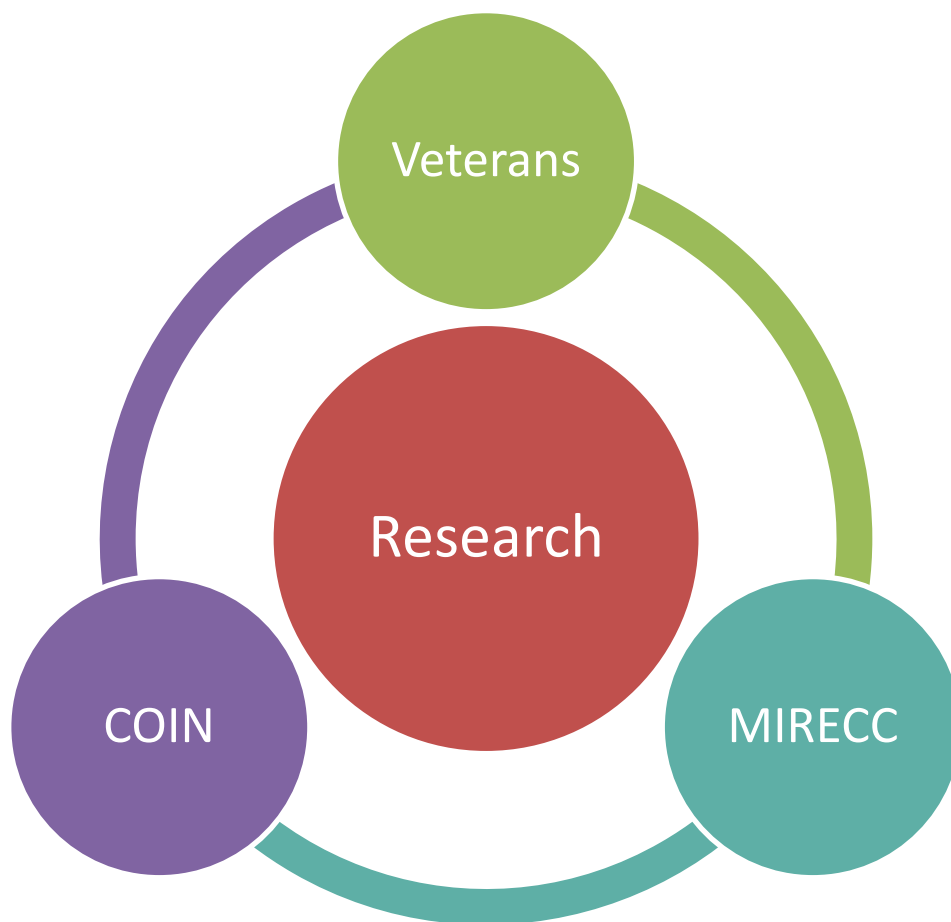


Veteran Research Advisory Board Member Binder



Research Veteran Advisory Board – Orientation Day 1 Agenda

Wednesday February 11, 2015 8:45-10:45am

- I. 8:45 – 9:30 Introductions (Paige Backlund)
- II. 9:30 – 10:15 Research 101 (Sarrah Nazem)
- III. 10:15 – 10:40 Community Engagement Discussion (Paige Backlund)
- IV. 10:40 – 10:45 Decide monthly meeting times

Action Items for Home: Review Day 1 Materials

VA



U.S. Department
of Veterans Affairs



Research 101

Sarra Nazem, PhD^{1,2}

Rocky Mountain Mental Illness, Research, Education and Clinical Center (MIRECC)¹;
University of Colorado, School of Medicine, Department of Psychiatry²



Overview

Scientific Method Research Process

Hypotheses

Variables

Measures

Designs

Experiential Exercise

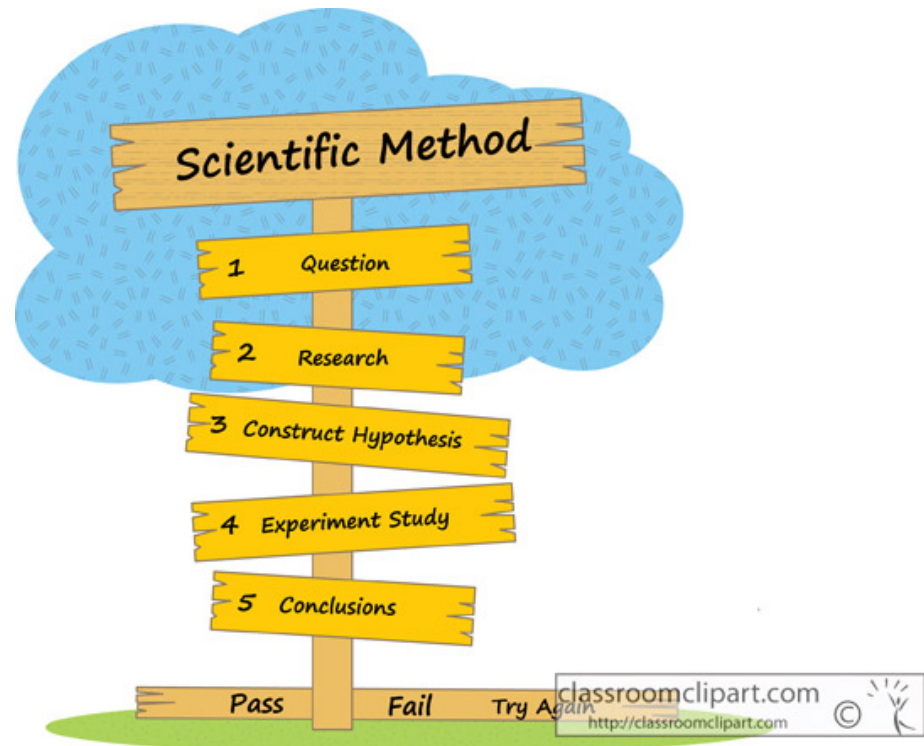
The Scientific Method

Set of procedures used to gain knowledge about the world

Based on reliable observation (empirical)

Systematic

Critical thinking





Why Do Research?





Unscramble these words...

WREAT

ETRYN

GRABE



Why Do Research?

Word Search Answers

WREAT – WATER

ETRYN – ENTRY

GRABE – BARGE

How did you do?

Prediction of social behavior (Vallone, 1990)

- Students who felt that they could predict their behavior with 84% confidence were correct only 71% of the time



General Research Process

Find a topic of interest

Review past research

Allows generation of better hypotheses

Make sure no one has done what you're interested in

Develop your question and procedures

Formulate hypotheses

Design the study

Undergo ethical review

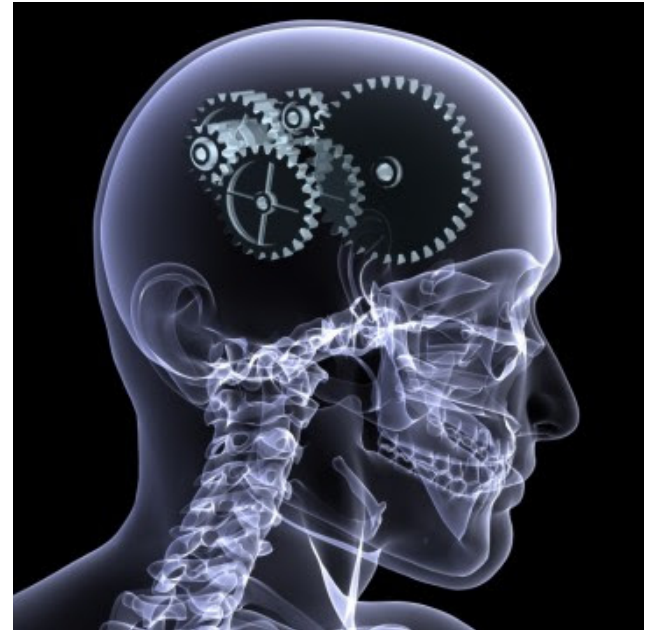
Human – Institutional Review Board (IRB)

Collect and analyze data

Write research manuscript, submit, & publish



Does chocolate improve memory?





Hypotheses

Testable statement of what we predict will happen in the study

Participants who receive treatment A will show $\geq 25\%$ decrease in depressive symptoms as reported on the BDI-II

Qualities of a good hypothesis

Clearly and precisely written

Testable/Falsifiable



Research Methods/Research Data

Quantitative

Numerical, counts, measurement

'Objective hard data'

Qualitative

In-depth understanding of human behavior

- Observation of what people do and say
- Meaning, concepts, symbols, descriptions

Smaller, focused samples

Helpful for hypothesis formation

- Exploratory, open-ended

Bonus!

Mixed Methods

- Combining elements of both!



Variables

Independent variable

The variable that is believed to effect the DV

- Treatment A (vs TAU/Placebo)

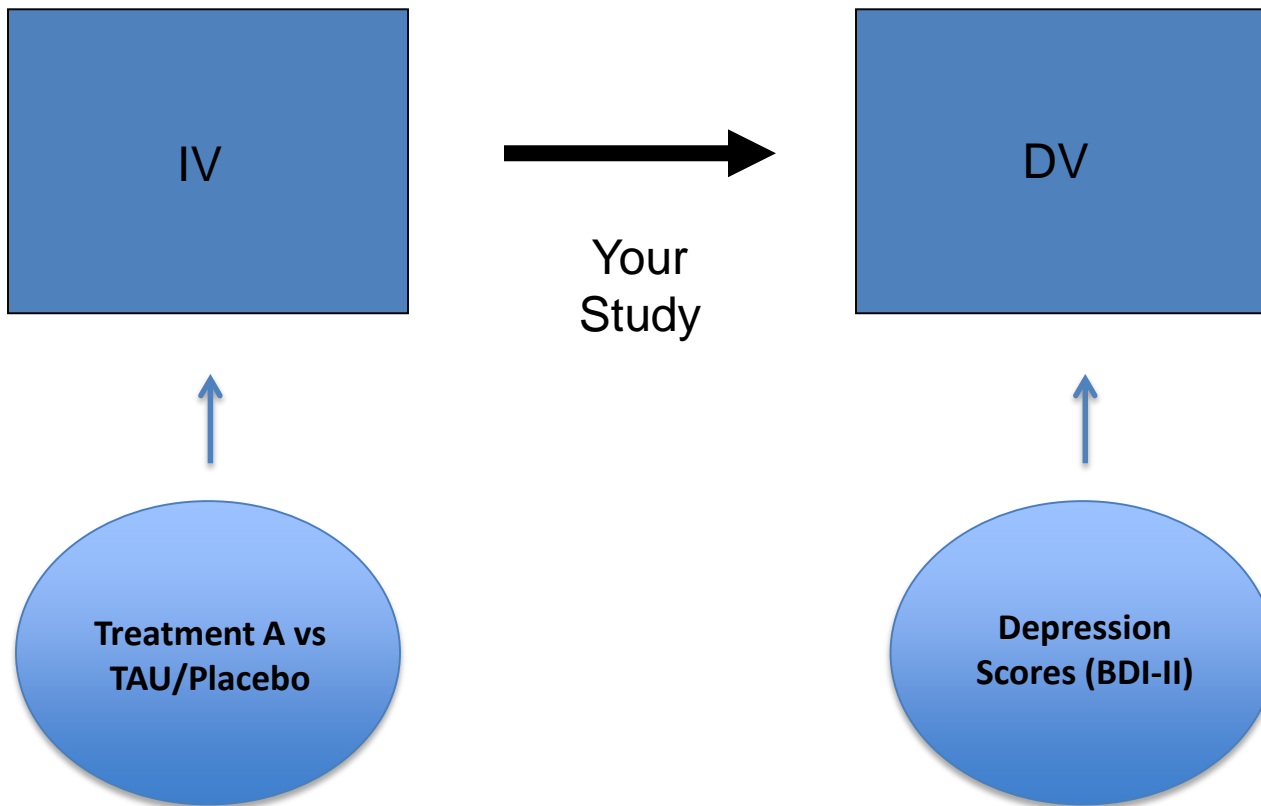
Dependent variable

The variable that is being measured; the outcome of interest, factor being predicted

- BDI-II Scores

Operationalization

Defining our variables



Measures

Direct Observation

Natural environment

Self-report

Surveys, questionnaires

Interviews

Diagnostic

Psychological Assessments

Cognitive abilities

Physiological data

Heart rate, skin response, blood pressure

Structured experimental tasks

Computer-based assessments





Designs

Case studies

Correlational studies

Epidemiological studies

Experimental studies

Randomized Controlled Trial (RCT)

Secondary data analysis/database studies

Case Studies

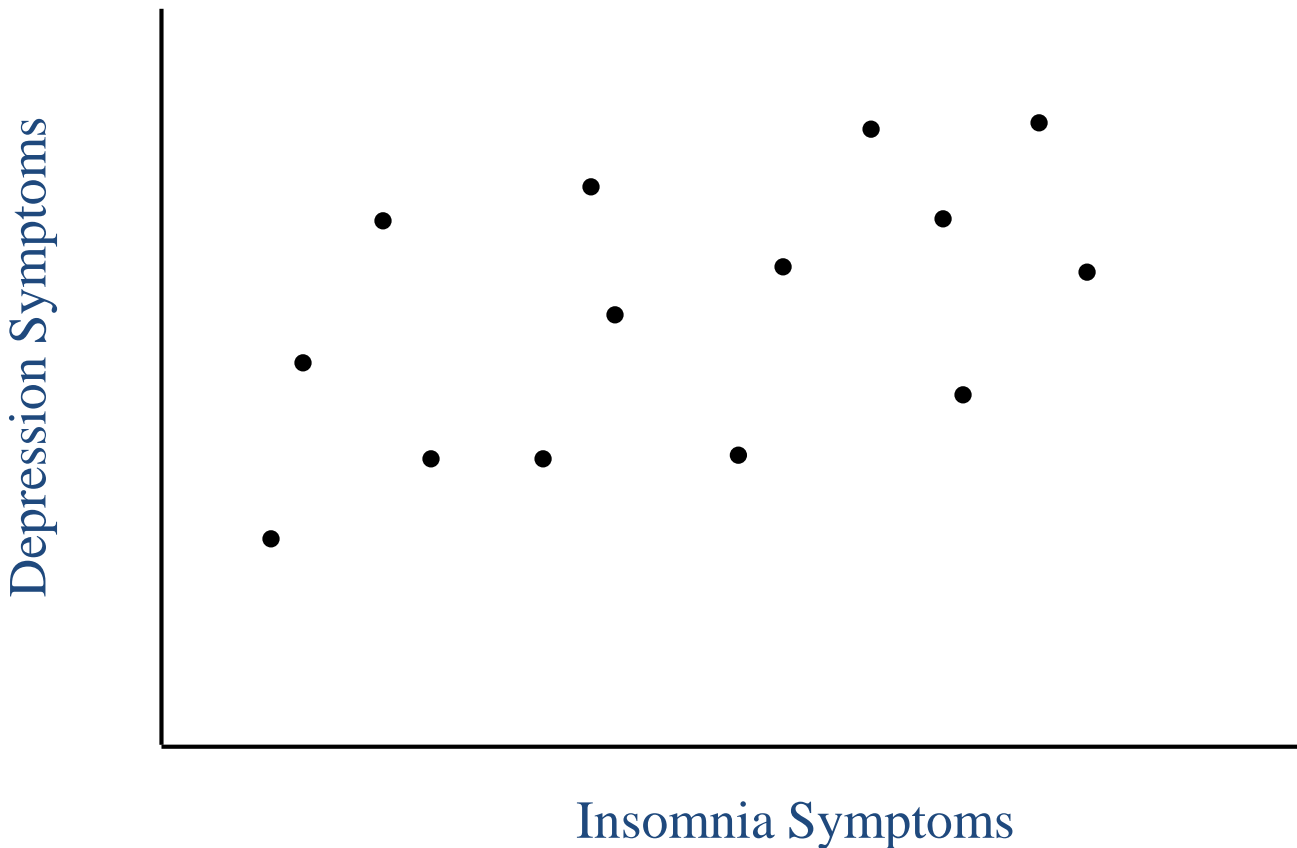
In-depth histories of the experience of individuals





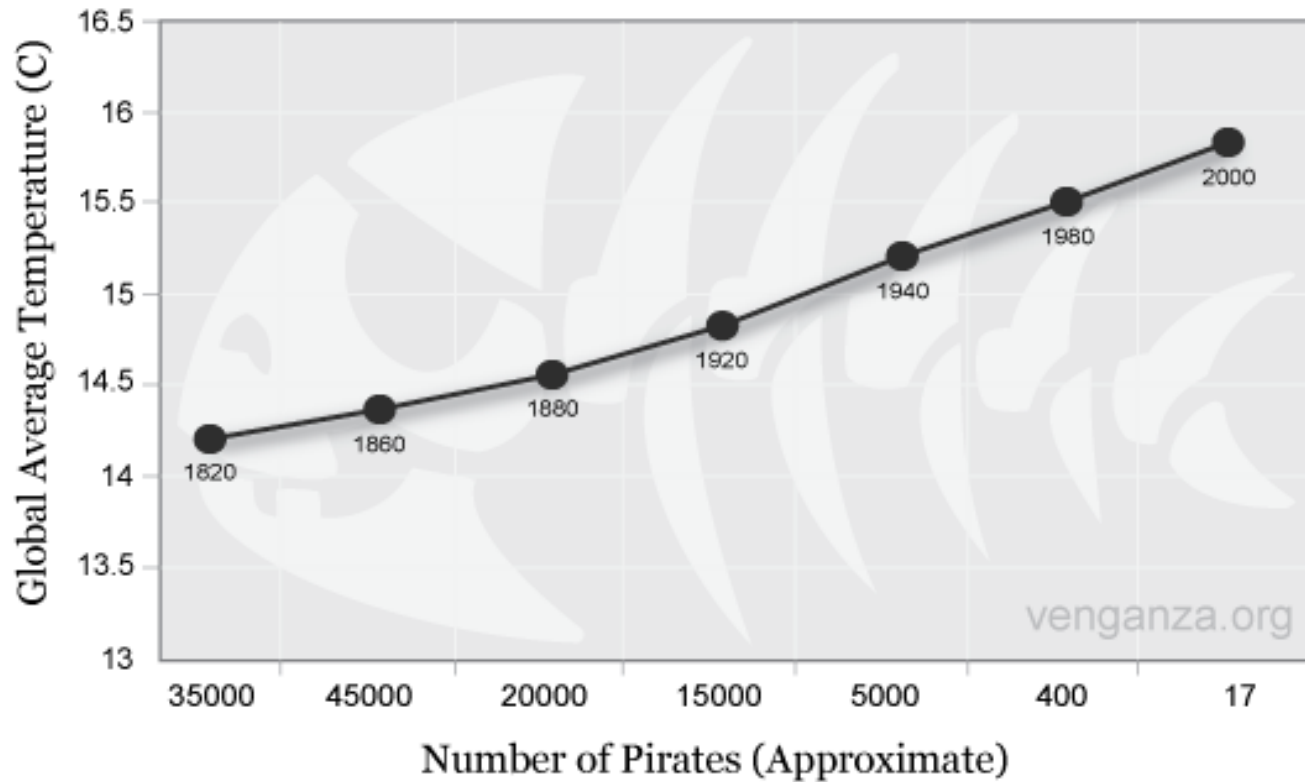
Correlational Studies

Examines the relation between an IV and a DV *without manipulating* either variable



Correlation \neq Causation

Global Average Temperature Vs. Number of Pirates



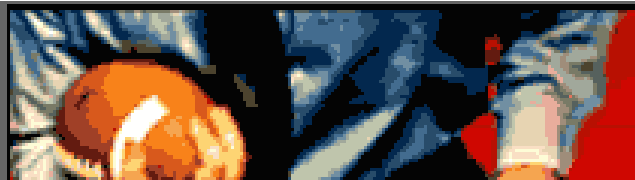
Violent behavior and TV viewing

Researchers at Columbia University and the New York State Psychiatric Institute tracked more than 700 boys and girls over 17 years. The following shows daily number of television viewing at mean age 14 and the percentage of aggressive acts then committed at mean age 16 or 22.

Study Group	Less than 1 hour	1 to 3 hours	3-plus hours
ASSAULT OR PHYSICAL FIGHTS RESULTING IN INJURY			
Males	8.9 %	27.5 %	41.7 %
Females	2.3 %	8.6 %	9.3 %
Total	5.7 %	18.4 %	25.3 %
ROBBERY, THREATS TO INJURE ANOTHER OR WEAPON USED TO COMMIT CRIME			
Males	6.7 %	14.0 %	20.9 %
Females	0 %	4.8 %	8.5 %
Total	3.4 %	9.6 %	14.6 %
ANY AGGRESSIVE ACT AGAINST OTHERS			
Males	8.9 %	32.5 %	45.2 %
Females	2.3 %	11.8 %	12.7 %
Total	5.7 %	22.5 %	28.8 %

Source: Science Magazine

presented by:



FULL BLITZ FANTASY FOOTBALL from CNNSI.c
WHERE OFFICE LEGENDS ARE MAI

CNN (from
 Science)
 march 2002

What was that study?

Table 4
Correlations between media habits and parental limits and outcomes ($n = 399-586$)

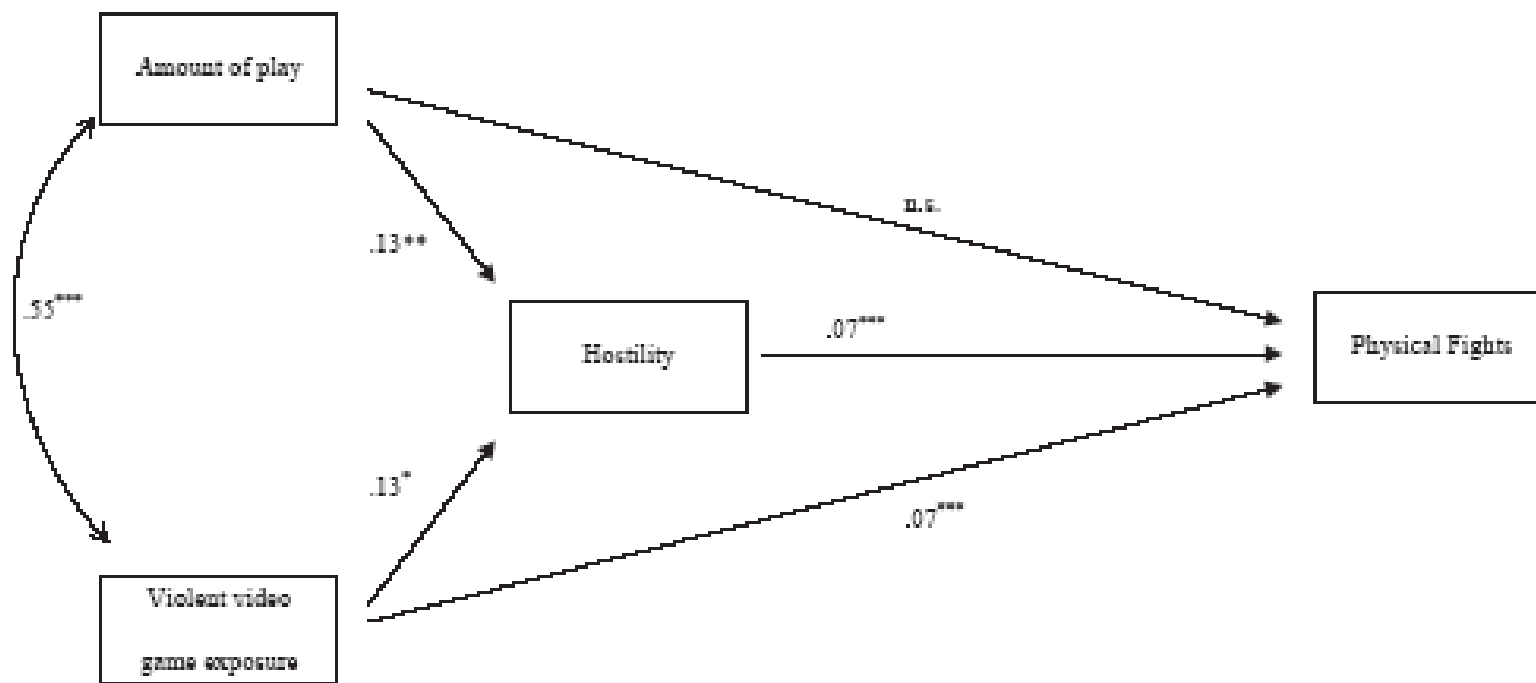
	Trait hostility	Arguments with teachers	Physical fights	Grades
Amount variables				
Amount of video game play	0.20 ^{***}	0.12 [*]	0.21 ^{***}	-0.25 ^{***}
Amount of time watching TV	0.20 ^{***}	0.10 [*]	0.12 ^{***}	-0.20 ^{***}
Amount of reading for pleasure	-0.08 [†]	-0.17 ^{***}	-0.07	0.07 [†]
Violent content variables				
Violent video game exposure	0.21 ^{***}	0.20 ^{***}	0.32 ^{***}	-0.23 ^{***}
Preferred violence in video games	0.31 ^{***}	0.25 ^{***}	0.36 ^{***}	-0.34 ^{***}
Preferred violence compared to 2 or 3 years ago	0.23 ^{***}	0.16 ^{**}	0.19 ^{***}	-0.14 ^{**}
Parental involvement scale	-0.14 ^{**}	-0.27 ^{***}	-0.18 ^{***}	0.27 ^{***}

[†] $p < 0.09$; ^{*} $p < 0.05$; ^{**} $p < 0.01$; ^{***} $p < 0.001$.

But yet...

D.A. Gentile et al. / Journal of Adolescence 27 (2004) 5–22

17



* $p < .05$. ** $p < .01$. *** $p < .001$.



Epidemiological Studies

Epidemiology – The study of the frequency and distribution of a disorder, or a group of disorders in a population

3 types of data:

- Prevalence
- Incidence
- Risk factors

Example: Medical conditions/diagnoses and risk for suicide attempt



Experimental Studies

Distinguishing Factor

Manipulate independent variable (IV) to determine effect on dependent variable (DV)

Example

Randomized Controlled Trial (RCT)

- Random assignment
 - Placebo/Control Group vs Experimental Group
- Blinding

Better control

Secondary Data Analysis/Database Studies

Data collected by someone/something else

Examples: census, medical databases, other large national studies



Our Study!

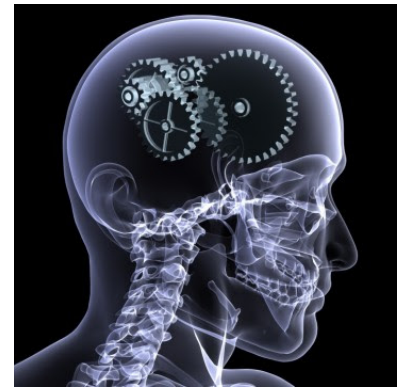
Review Past Research

Hypothesis/Design

Case Study?

Secondary Data/Database?

Experiment versus correlational?



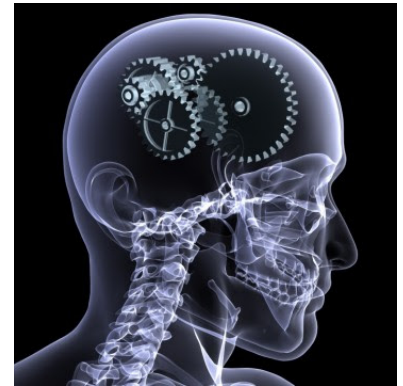


Correlational

What would this involve?

Survey about chocolate use?

Self-report on memory abilities?





Experiment

Who? Where? When?

Randomly assign groups

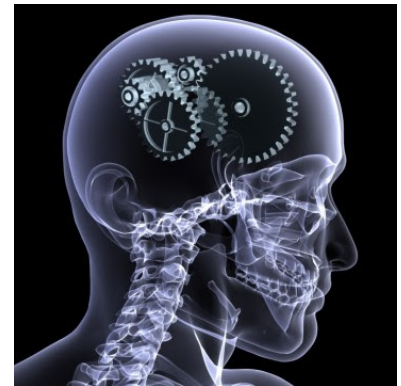
Group A: No chocolate

Group B: 24 ounces of chocolate

What's our procedure?

Consumption of chocolate versus ???

Memory test?



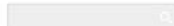
Resources

Scientific Method YouTube Video:

<https://www.youtube.com/watch?v=SMGRe824kak>

General Information:

<http://www.simplypsychology.org/research-methods.html>



Home | Social | Cognitive | Perspectives | Psychologists | Developmental | A-Z index

Home > Research Methods

Psychology Research Methods

by Saul McLeod published 2007



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Lab Experiment

- This type of experiment is conducted in a well-controlled environment – not necessarily a laboratory – and therefore accurate and objective measurements are possible.

Field Experiment

- These are conducted in the everyday (i.e. natural) environment of the participants but the situations are still artificially set up.

Related Articles

Aims and Hypotheses
Sampling Methods
Scientific Approach
Experiments
Variables
Experimental Design
Case Study
Correlation
Interviews
Ethics
Validity
Reliability
Research Report



Community

- Veterans
- Schools
- Healthcare providers
- Forums
- Neighbors
- Small Businesses
- Homeless
- Mental Health Providers
- Church –Mosques-Synagogues
- Stores
- Armed Forces-Servicemembers
- Children
- Community Centers

Engagement

- Fundraisers
- Boards
- Activities
- Discussions
- Charrettes (Interactive Public Forum)
- Communication
- Participation
- Arbitration
- Mediations
- Town Hall Meetings

Community Engagement



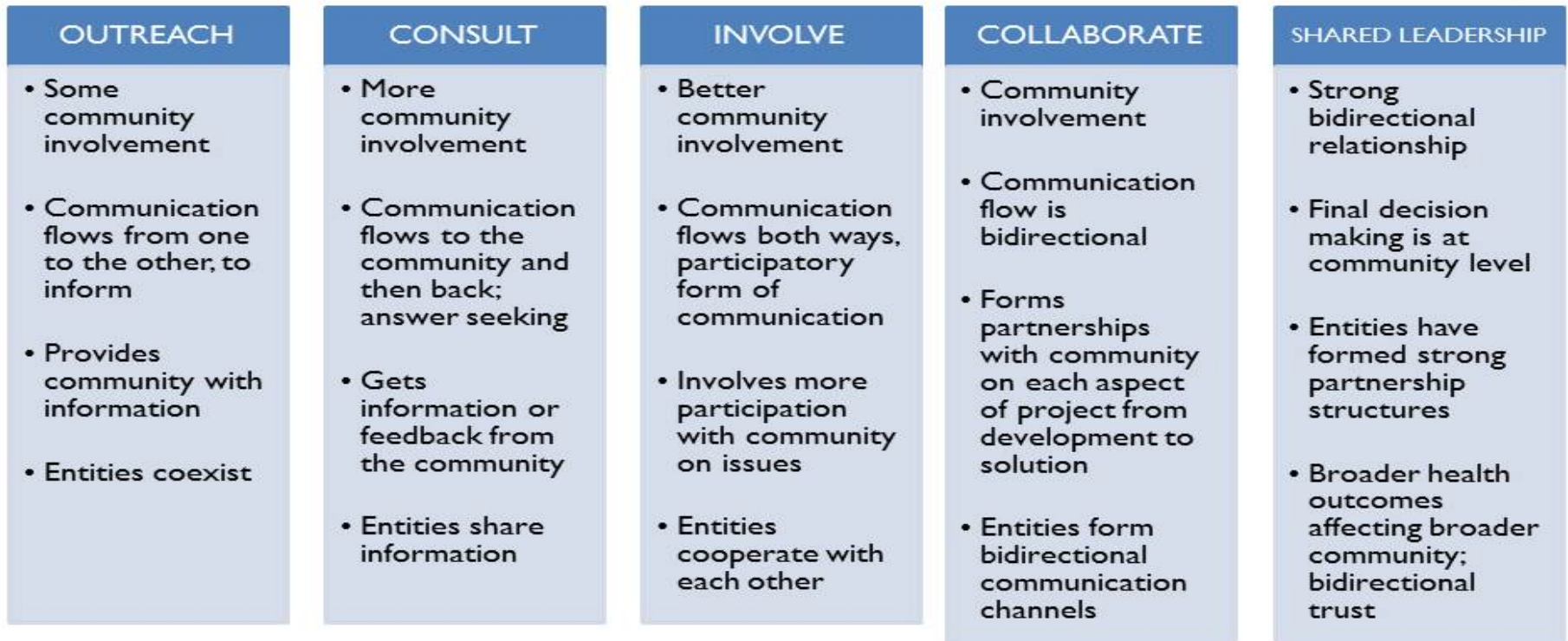
Together
Join Team
Include Assemble
Trust Partner
Friend With
Cooperate

Individual

Distrust
Exclude Apart
Counteract
Without Take
Individual Enemy
Opponent
Separate

Community Engagement Continuum

Increasing Level of Community Involvement, Impact, Trust, and Communication Flow



Reference: Modified by the authors from the international Association for Public Participation

The following are relevant examples for each stage of the Community Engagement Continuum to be used to guide decision-making in determining where on the continuum an investigator falls before meeting with the board and after.

OUTREACH:

- Investigator presents a project to the Board. Investigator does not ask the Board meaningful questions or try to obtain feedback from the Board. Information flows from the investigator to the Board and not vice versa.

CONSULT

- Investigator presents a project to the Board. Investigator asks questions and seeks feedback from the Board. Information flows both ways.

INVOLVE

- Investigator presents a project to the Board. Asks questions and seeks feedback. Incorporates feedback into the project and makes changes to the project based on interactions with the Board.

COLLABORATE

- Investigator presents a project to the Board. Asks questions and seeks feedback. Incorporates feedback into the project and makes changes to the project based on interactions with the Board.
- Investigator asks for and RECEIVES further help from 1 or more interested Board members outside of the Board meeting. During these interactions the investigator collaborates with the Veterans through mutual idea generation, decision making, and project planning and implementation. Investigator and Veterans work together meaningfully for the duration of the project.

SHARED LEADERSHIP

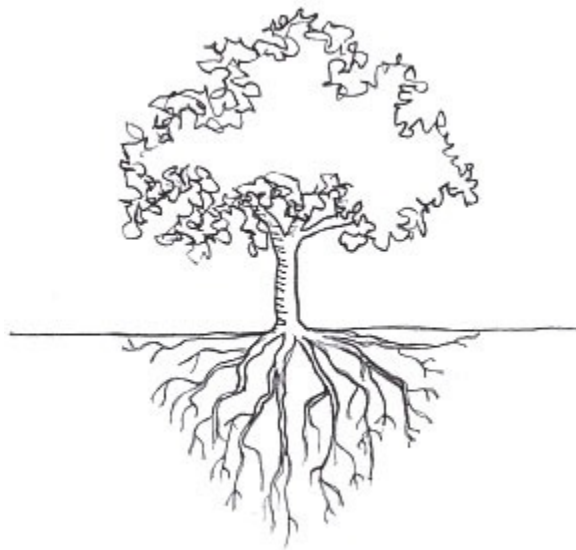
- Veteran Board member(s) partner with an investigator on a research idea of mutual interest and work together as co-investigators for the duration of the project.

Orientation Day 2 Agenda

Wednesday February 18, 2015 8:45-10:45am

- I. 8:45 – 9:30 Day 1 Review and Check-In, Community Engagement Discussion (Paige Backlund)
- II. 9:30 – 9:35 COIN/MIRECC Overview (Kelty Fehling, Leah Wendleton)
- III. 9:35 – 9:40 Break
- IV. 9:55 – 10:10 Research Review Process, March Review Hand Outs (Leah Wendleton, Kelty Fehling, Ashley O'Connor, Paige Backlund)
- V. 10:10 – 10:20 Discuss payment, grant, VA Research Days
- VI. 10:20 – 10:45 VA Confidentiality, Intellectual Property, Media Interactions (Daniel Warvi)

Action Items: Review March study documents thoroughly. Email liaisons and Board members with any questions.





Health services research examines the organization, delivery, and financing of health care, from the perspectives of patients caregivers, providers, and managers to improve the quality and economy of care.

<http://www.hsrd.research.va.gov/funding/what-is-hsr.cfm>



<http://www.seattledenvercoin.research.va.gov/>

Mission: Conduct high quality health services research that promotes Veteran-centered and value-driven care, generate and disseminate knowledge that contributes to the well-being of Veterans, work collaboratively with VA policy and operational leaders to implement research findings into clinical care, and train the next generation of health services researchers and leaders.

Focuses on healthcare needs of Veterans with complex chronic conditions such as:



- **Cardiovascular Disease**
- **Tobacco Dependence and PTSD**
- **COPD**
- **Chronic Pain**
- **Arthritis**
- **Hepatitis C**
- **Dementia**
- **Homelessness**

Primary Goals - conduct health services research that:

Advances Veteran-centered care

1. How to make care plans achievable for patients
2. How to use palliative care to improve the patient's health status and decision making
3. How to change the healthcare system to improve the patient's medical care experience

Veteran-centered research goal:
How to change to the healthcare system to improve the patient's medical care experience

Advances the science of value-driven care

1. Identifying the structure and processes used at high-value VA
2. Testing the comparative effectiveness of different ways to deliver high-value care
3. Developing new methods to measure and analyze value

Value-driven research goal:
Identifying the processes and structures used at high-value VA facilities

Sample of Current COIN Projects



- **Medical Foster Home: A Safe, Cost-Effective Substitute for Nursing Homes?**
- **Effectiveness of Medical Therapy, Endovascular Therapy and Surgery for Peripheral Arterial Disease**
- **Telehealth Care Management and Tobacco Cessation for Veterans with PTSD**
- **Improving transitions of care for rural Veterans referred to tertiary medical centers**
- **Palliative Care for Homeless Veteran's Facing End of Life Issues**
- **CASA**
- **Patient-Reported Health Status Survey**

COIN Investigators



Michael Ho, MD, PhD (Director) - cardiologist

Cari Levy, MD, PhD (Associate Director) – internist, geriatrician

Catherine Battaglia, PhD, MSHA, RN – health services researcher

Steven Bradley, MD, MPH – cardiologist

Meg Plomondon, PhD - biostatistician

Liron Caplan, MD, PhD - rheumatologist

Evelyn Hutt, MD – palliative care specialist

Thomas Maddox MD, MSc - cardiologist

Allan Prochazka MD, MSc - internist

Anne Lambert-Kerzner, PhD – health services researcher

David Bekelman, MD, PhD – internist, psychiatrist, palliative care specialist

Robert Burke, MD - hospitalist

Joseph Frank, MD - internist

Mental Illness Research, Education, and Clinical Center

The mission of the Rocky Mountain MIRECC is to study suicide with the goal of reducing suicidal ideation and behaviors in the Veteran population.

Towards this end, the work of the Rocky Mountain MIRECC is focused on promising clinical interventions, as well as the cognitive and neurobiological underpinnings of suicidal thoughts and behaviors that may lead to innovative prevention strategies.



Please visit us on our website:
www.mirecc.va.gov/visn19/

This means we research suicide prevention by studying it along a spectrum from its basic biological properties to translating it into communities.

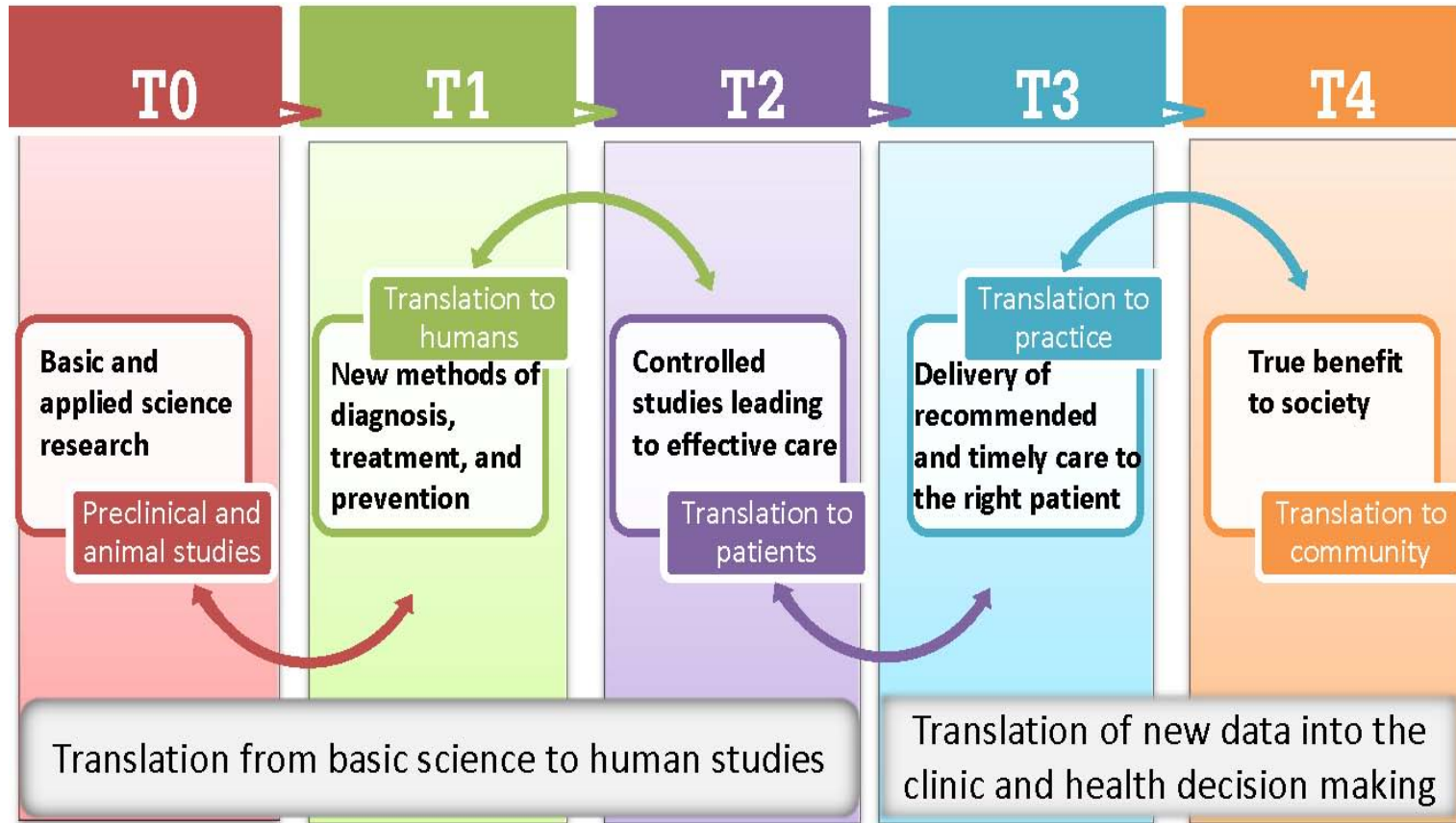


Figure . NIH Conceptual Framework – Operational Phases of Translational Research



Samples of Projects:

- **Creatine Augmentation in Veterans with SSRI Resistant Depression**
- **Neurobiology of Suicide Risk in Traumatic Brain Injury and Substance Abuse**
- **Brain Chemistry and Altitude in Bipolar Disorder**
- **Behaviorally Assessing Suicide Risk**
- **Differentiating Between Mild Traumatic Brain Injury and Behavioral Health Conditions**
- **Influence of PTSD on Perceptions of Injury**
- **Assessment of Cognitive Functioning as it Relates to Risk for Suicide in Veterans with HIV/AIDS**
- **Risk and Protective Factors for Suicidality among Female and OEF/OIF Veterans**
- **Burden, Belonging and Response to Pain in Veterans**
- **Evaluating a Psychological Treatment for Hopelessness among Veterans with Traumatic Brain Injury and Problem Solving Therapy for Suicide Prevention Among Veterans with TBI**
- **Blister Packaging Medication to Enhance Treatment Adherence and Clinical Response**
- **Acupressure and Stress Resilience**
- **Mindfulness-Based Intervention for Veterans Seeking Mental Health Services**
- **Home-Based Mental Health Evaluation: A Model for Assisting Suicidal Veterans with the Transition from Inpatient to home**
- **Rural Veteran Suicide Prevention Program: A Community Based Approach**



Denver Researchers:

Lisa Brenner, PhD, ABPP (Director)

Nazanin Bahraini, PhD

Jeri Forster, PhD

Hal Wortzel, MD

Sean Barnes, PhD

Peter Gutierrez, PhD

Theresa Hernández, PhD

Bridget Matarazzo, PsyD

Lindsey Monteith, PhD

Jennifer Olson-Madden, PhD

Nathaniel Mohatt, PhD

Gina Signoracci, PhD

Teo Postolache, MD

Joseph Simonetti, MD

Sarra Nazem, PhD

The Rocky Mountain MIRECC is co-located in Denver and Salt Lake City and is made up of Psychiatrists, Psychologists, Social Workers, a Nurse and a Biostatistician.



Beyond the Research:

Education Core

We endeavor to disseminate useful information about suicide prevention in ways that are accessible to Veterans and the community at large, and evaluate strategies to translate research-informed practices into everyday care.

We create educational products such as brochures, videos, and presentations in hopes to reach Veterans, their families and providers with accessible and relevant suicide prevention information.

Clinical Care

A of our Investigators are clinical providers in the VA, we also house a fellowship program that prepares entry-level clinicians into the VHA healthcare system.

Outside of direct care, our center houses a local and national consultation service for providers who have questions on how to assess and treat Veterans with suicidal ideation and suicide-related behavior.

Introduction to the ethics and regulation of human subjects research

Warren Capell, MD

Director, COMIRB

University of Colorado Denver

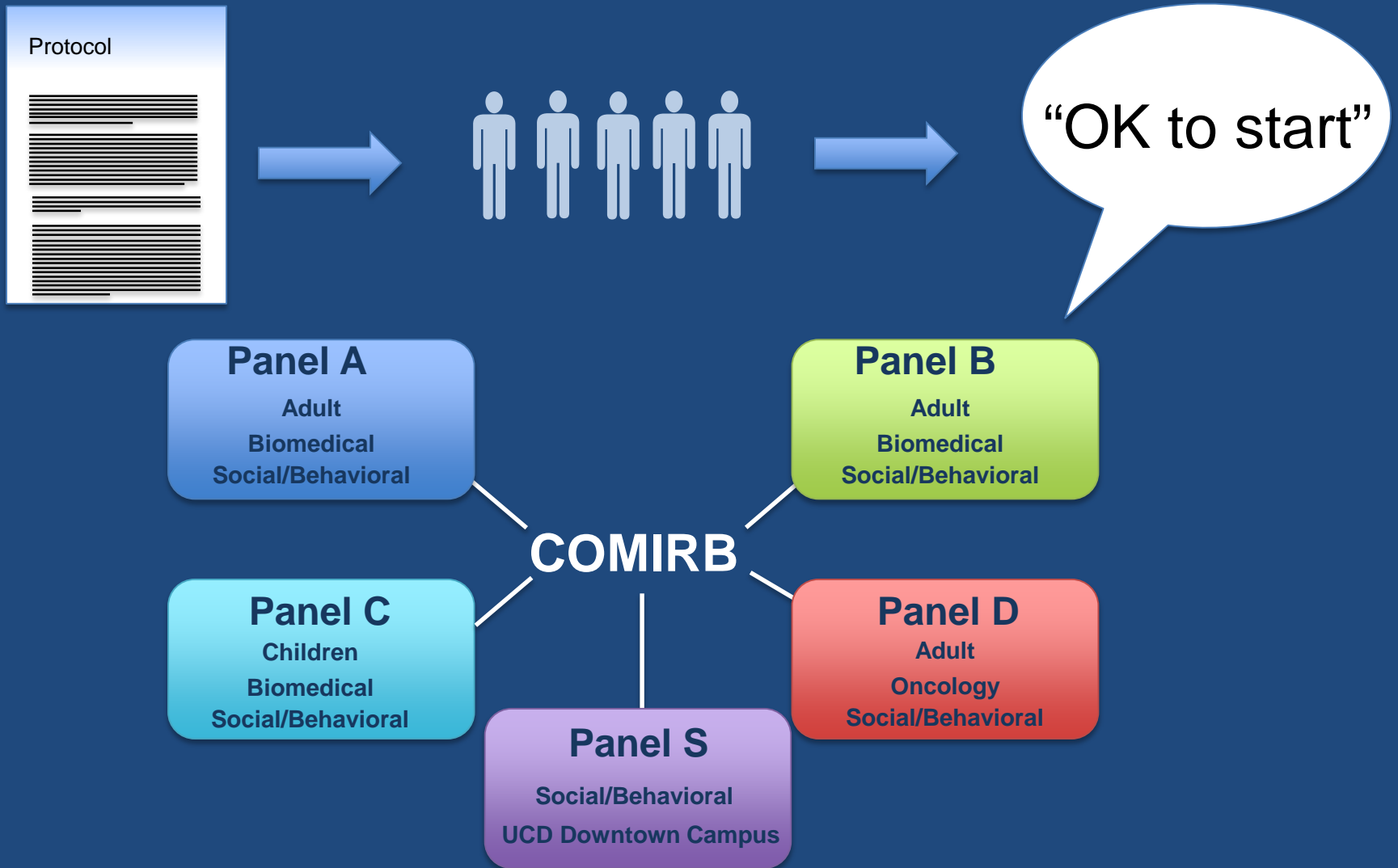
warren.capell@ucdenver.edu



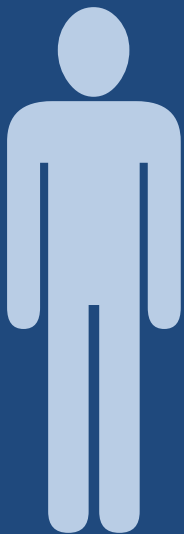
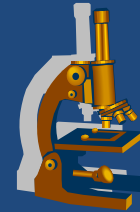
*Modified by:

Ashley O'Connor, MSW

What is an IRB?



IRB (panel) structure



IRB Function



Protocol Review

IRBs play a vital role in the ethical conduct of research

- Objective
- Protect
- Safety
- Fairness
- Approved \neq ethically conducted
- Investigator commitment



Criteria for IRB approval of research (45 CFR 46.111)

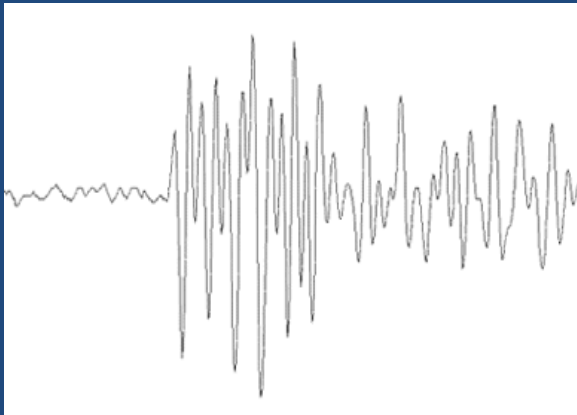
- 1) Risks are minimized
- 2) Benefits > Risks
- 3) Subject selection is equitable
- 4) Informed consent is sought
- 5) Informed consent documented

...and when appropriate:

- 6) Study is monitored to ensure subject safety
- 7) Privacy and confidentiality of subjects is protected
- 8) Additional safeguards for vulnerable subjects

Risk

Magnitude + Probability



Informed consent and research



Risks & Benefits

Alternatives

Rights

Resources

COMIRB

www.ucdenver.edu/comirb

(303) 724-1055

Clinical Research Support Center

(303) 724-1111

Board/Investigator Interface

Contact with
project and
timeline

- Kelty.Fehling@va.gov
- 720-857-5126
- Ashley.Oconnor@va.gov;
720-857-5114
- Leah.Wendleton@va.gov
303-399-8020 x4637

Submit research
materials to be
reviewed

- Abstract in plain English
- Grant proposal/IRB protocol
- 5-7 slide presentation
- 2-3 specific questions

After submission
review
investigator
attends meeting

- Presents study verbally including 2-3 questions for Board
- Chair opens discussion
- Receives notes and summary with action items/recommendations
- Based on engagement with Board, letter of support issued detailing meeting interaction and impact

Communication Checklist

*This should be utilized for each investigator presentation to track necessary tasks

___ **2 months prior to the Investigator's meeting:** reach out to investigator to make sure they are getting their documents together. Help them identify appropriate questions and ensure that the abstract is presented in layman's terms. Documents should be finalized and ready for distribution 1 month prior to the investigator's meeting.

___ **1 month prior to the investigator's meeting:** send investigator materials to the Veterans for their review. Also include questions to determine where the investigator falls on the CE continuum at that point. This response should be delivered to the liaisons with any other feedback the Vet has **2 weeks prior to the scheduled meeting.**

___ Schedule Investigator Monthly meeting survey and Follow-up in RedCap to come out the day after the meeting.

___ **Scheduled investigator meeting:** at end of meeting have initial discussion of engagement continuum and distribute survey to Vets.

___ **1 day following meeting:** liaison sends investigator and Veterans meeting minutes as well as action items and recommendations for the meeting. At this time the investigator will also be sent the meeting follow up survey to fill out in RedCap automatically and have back to the liaisons **8 days following the meeting.** The investigator will receive reminders from RedCap.

___ **8 days following the meeting:** investigator gets the meeting follow-up survey back to the liaisons who immediately downloads it and sends it out to the Vets and include question asking where they felt the interaction fell on the CE continuum. Veterans will consider the new position on the CE and bring decision to the beginning of the next meeting.

___ **1 month following meeting (at the beginning of the following month's meeting)** Majority rules where the interaction fell on the CE continuum

___ **1 month and 1 week following the meeting:** Representative of Veteran Advisory Board signs the LOS and email the investigator a letter of support detailing the experience and guided by the CE continuum.

___ **6 months following the meeting:** RedCap will email the investigator with a survey similar to the initial meeting follow up survey to gage impact of Vets on the study at 6 months

___ **12 months following the meeting:** RedCap will email the investigator with a survey similar to the initial meeting follow up survey to gage impact of Vets on the study at 12 months