Inside the VA/DoD Collaboration Guidebook for Healthcare Research
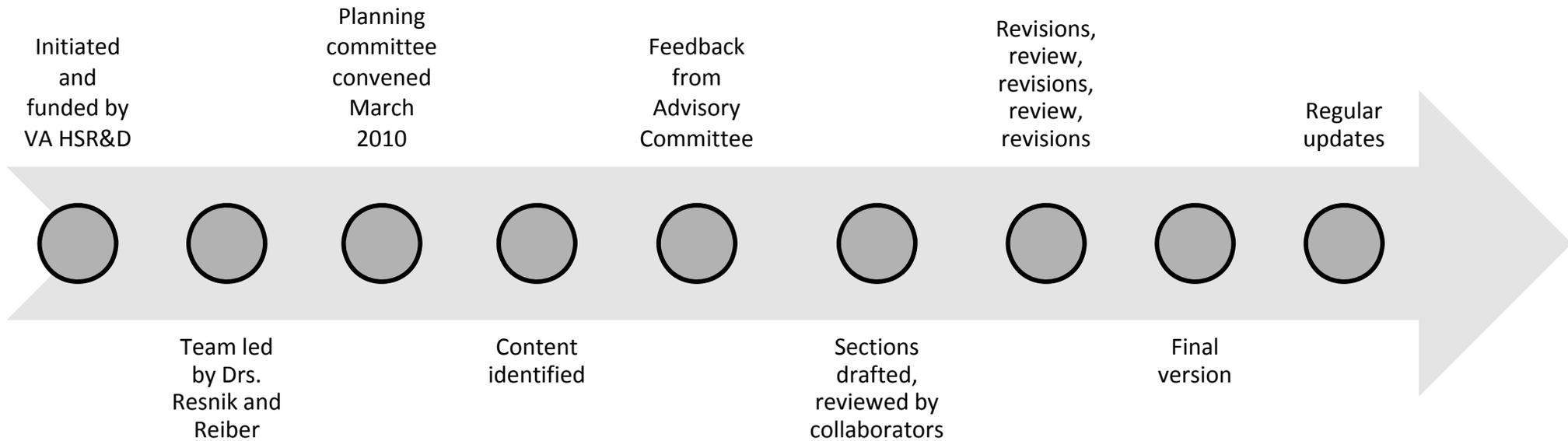
National Cyber Seminar
June 23, 2011

Purpose

The purpose of this Guidebook is to facilitate collaborative human subject healthcare research between the Department of Veterans Affairs (VA) and the Department of Defense (DoD)

VA/DoD Research Collaboration Guidebook | 2010

VA/DoD Collaboration Guidebook for Healthcare Research
December 30, 2010

History of Guidebook Project

Initiated and funded by VA HSR&D

Team led by Drs. Resnik and Reiber

Planning committee convened March 2010

Content identified

Feedback from Advisory Committee

Sections drafted, reviewed by collaborators

Revisions, review, revisions, review, revisions

Final version

Regular updates

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Acknowledgments

What's in the Guidebook?

Section I: Overview

Section II: Nuts and Bolts

Research infrastructure

Where to start

Seeking a collaborator

Planning a proposal

Administration of research funds

Formalizing an agreement

Human research protections

Data security and resources

Media relations/public affairs

Case examples

Recommendations

Section III: Appendices

Acronym list

DoD Clinical Investigation Programs
by Region

Templates, sample documents

Why Collaborate?

- To answer research questions
- Shared responsibility
- Pooling of financial and human resources
- VA-DoD COLLABORATION
- Share skills in navigating Department culture/ policies
- Sharing of expertise / perspective
- Gain greater credibility
- Increase efficiency and funding opportunities
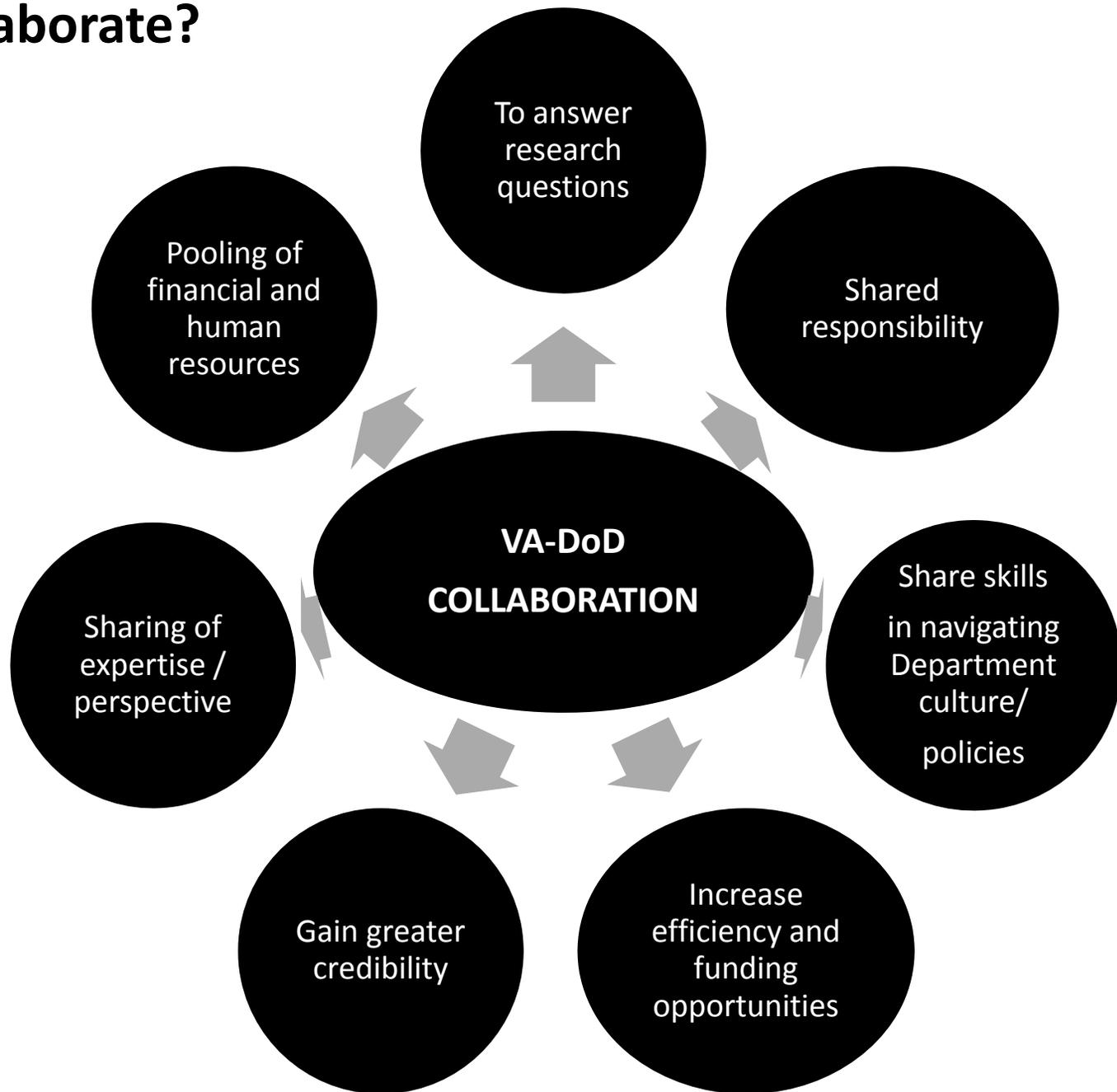
GUIDEBOOK TIP

Experienced investigators warn that it is inadvisable for an inexperienced assistant professor or junior investigator seeking an independent research career to be involved in collaborative projects as PI, due to the complexity and length of time involved.

Guide to Research Infrastructure

The Guidebook describes research infrastructure of:

VA	Army
Navy	Air Force

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                        │  Office of the │
                        │  Secretary of Defense │
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CONGRESS

Office of the Secretary of Defense

Air Force

- Research, Development, Test, and Evaluation
- Operational Maintenance

Department of Defense

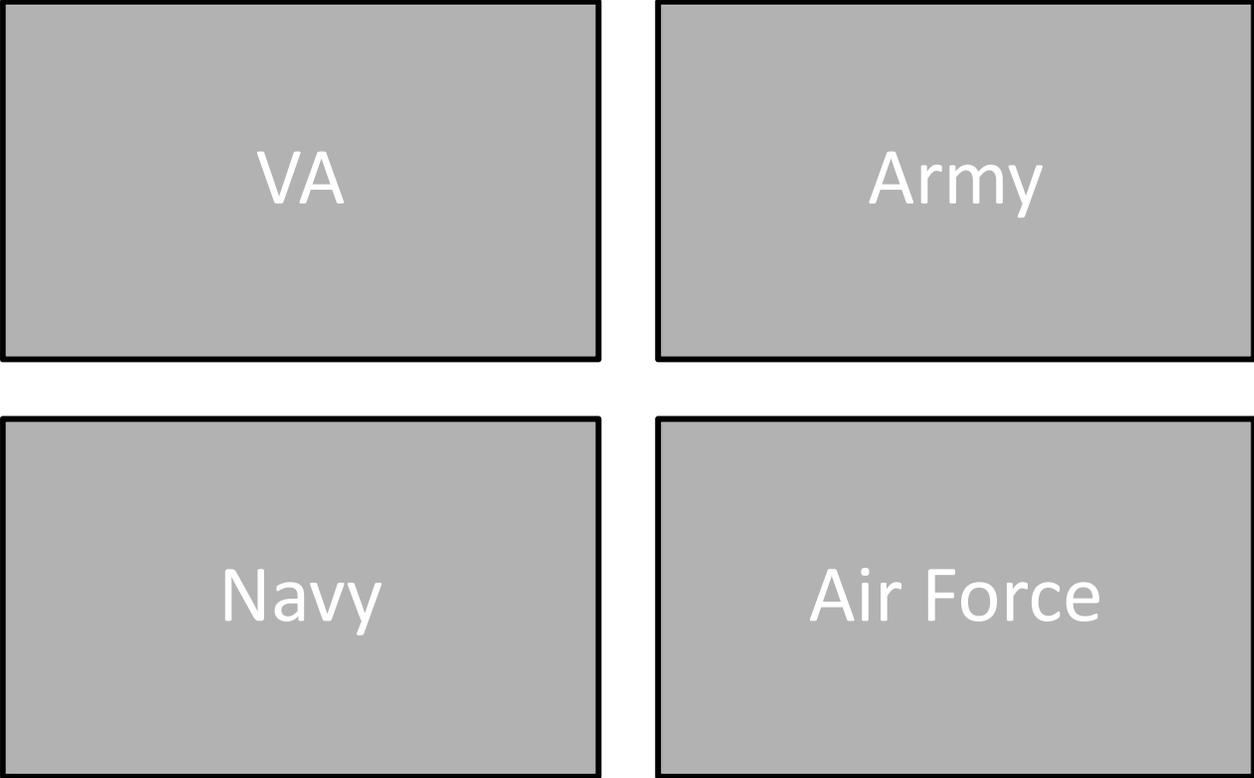- Defense Threat Reduction Agency
- Defense Advanced Projects Agency
- Advanced Concept Technology Demonstrations
- Family Assistance
- US Special Operations Command

Assistant Secretary of Defense for Health Affairs

- Research, Development, Test, and Evaluation
- Operational Maintenance
- Procurement

Air Force Medical Service

SGE-C Compliance

Air Force Medical Support Agency

Surgeon General (Modernization)

SG5 (Acquisitions)

Clinical Investigation Facilities

Air Force Research Locations

Planning Your Proposal

Consider:

Funding source

Human subjects concerns

Scientific methodology

Development of collaborative agreements

Data sharing

Staffing

Budget
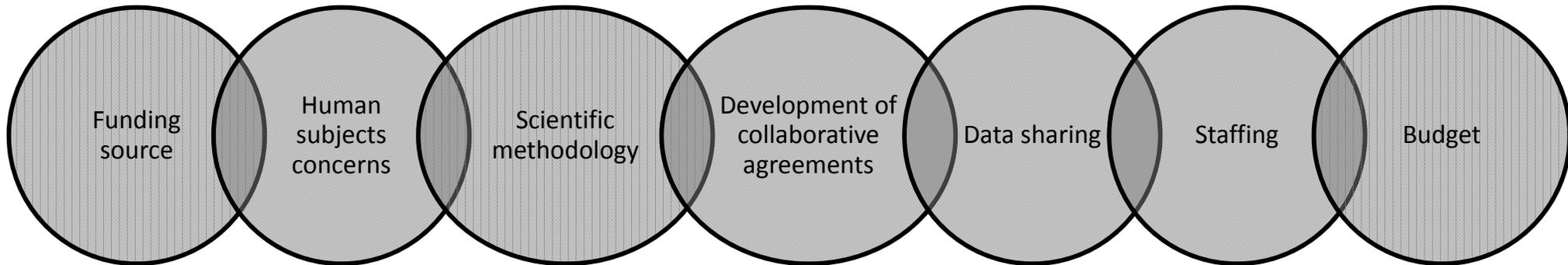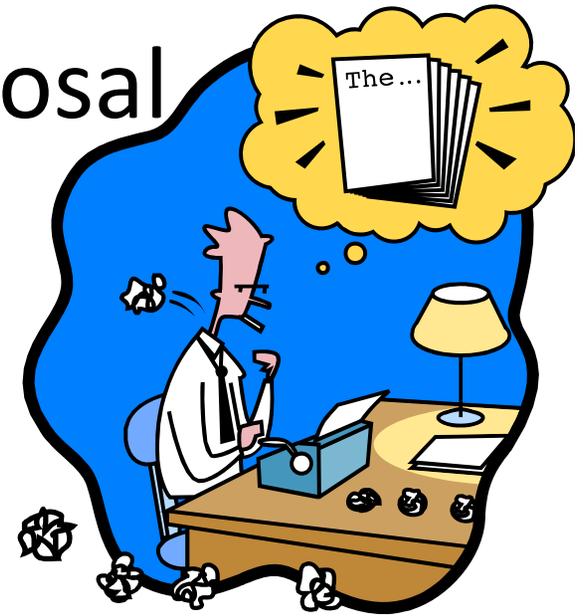
GUIDEBOOK TIP

When planning your research, develop a back-up plan for possibilities like collaborator reassignment or deployment.

Funding Sources

- Identifies sources of research funding
- Provides links to intramural and extramural funding announcements

DoD Research Funding Opportunities, Sources

SOURCE OF SUPPORT	TYPE OF AWARD	TYPE OF FUNDS (P6, P8)	WHO CAN SERVE AS PI?
US Army Clinical Investigation Program (CIP) http://fhp.osd.mil/cip.jsp	Intramural funding	P8	Military investigators
US Army Medical Research & Materiel Command https://mrmc.amedd.army.mil/index.cfm?pageid=medical_r_and_d.overview	Intramural funding to laboratories (i.e. ISR)	P6	Investigators assigned to military research laboratories
Telemedicine and Advanced Technologies Research Center http://www.tatrc.org/?p=funding_aamti	AAMTI funding	P8	Military or General Schedule (GS) investigators at MTF
Navy Commander's grants http://www.onr.navy.mil/Contracts-Grants/Funding-Opportunities.aspx	Local intramural funding	P8	Navy researchers at specific medical centers
Navy Clinical Investigations awards http://www.onr.navy.mil/Contracts-Grants/Funding-Opportunities.aspx	BuMed intramural funding	P8	Navy researchers at any Navy MTF (collaborations permitted)
Wounded, Ill and Injured Program (WII) http://www.onr.navy.mil/Contracts-Grants/Funding-Opportunities.aspx	BuMed intramural funding	P8	Military investigators (collaborators permitted)
Office of Naval Research (ONR) http://www.onr.navy.mil/	Intramural and extramural	P6	Military, industry, academia in defined program areas
Air Force Clinical Investigation Program http://fhp.osd.mil/cip.jsp	Intramural funding	P8	Military investigators
Air Force Intramural Research http://www.wpafb.af.mil/library/factsheets/factsheet.asp?id=8981	Research management working group	P6	Air Force researchers in DoD facilities working on established Air Force thrust areas

Get Leadership Involved!

Meet with your proposed collaborator, members of their leadership team and research infrastructure to cement the relationship and ensure that everyone is on board.

Administration of Funds

Highlights key aspects of administration of funds including:

Hiring personnel	Travel	Consultants

Supplies and Equipment	Stipends

Formalizing an Agreement

Cooperative Research and Development Agreement (CRADA)

- Legal, enforceable agreement
- Usually between a federal agency and one or more non-federal parties

Memorandum of Agreement (MOA)/ Memorandum of Understanding (MOU):

- Binding legal document that holds parties responsible to their commitment or outlines a partnership

Key Content Areas for Research Agreements

|		
Resource Sharing	Research Reporting	Roles & Responsibilities of Each Party
Negotiating and Protection of Intellectual Property	Data Use Issues	Human Subjects Issues

TIPS for Navigating VA and DoD IRBs

✓ Have experienced assistance for each party

✓ Identify which IRBs must approve

✓ Check with all IRBs as they may have differing requirements

✓ Leave plenty of extra time to prepare the application(s)

✓ Have a contact person at each IRB; contact that person to ensure you are using the most current forms & templates

✓ Have each IRB "pre-review" the application

✓ **The IRB approval process for a multi-site project is a serial process and can take between 12-18 months.**

✓ Develop an appropriate timeline prior to grant submission

✓ Get letters of support and/or signed impact statements from all departments and services

✓ Have a trained, qualified Principal Investigator at each study site

Data Sharing and Resources

- Access to medical records and protected health information is limited to research and/or clinical staff within each agency

- Working out a data collection, sharing and analysis plan is critical to the success of a collaborative project
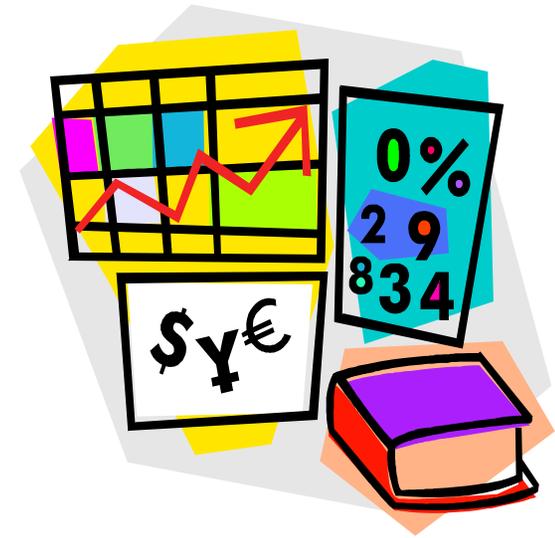
Data Sharing and Resources

| VA Data Sharing Agreements	DoD Data Sharing Agreements
• CRADA • Data Collection Agreement • Data Use Agreement (DUA) • Business Associates Agreement (BAA)	• TRICARE Management Activity DUA • BAA • Computer Matching Agreement (CMA)

GUIDEBOOK TIP

Both VA and DoD facilities require varying levels of security clearance, credentialing, appointments (i.e. VA WOC) and information security access requirements.

This process can be lengthy and can hold up study activities if not done in advance.
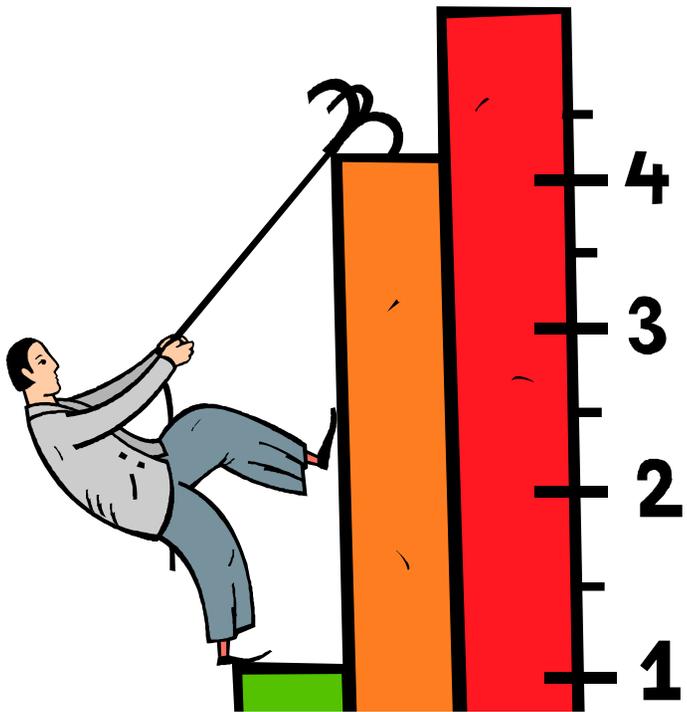
Case Examples

HEROES Project

Severe TBI studies

Community Reintegration Project

Mentored Research Training Initiative

Empirically-Based Cognitive Rehabilitation: the SCORE Study Collaboration

National Survey of Service Members and Veterans from Vietnam and OIF/OEF with Major Traumatic Limb Loss

Questions

1. How did you identify collaborators and build collaborative relationships for your research?

2. What has been the greatest challenge and the greatest reward you've encountered as a result of collaborative research?

3. How was your research funded?

4. Did you encounter start-up delays? If so, do you have any advice for other investigators as to how these types of delays could be avoided?

5. What type of agreement did you have between the VA and DoD? How long did it take to formalize your agreement?

6. Please share your top two recommendations to investigators contemplating collaborative research

7. Please talk about your experience in working IRBs from several Departments

8. What special considerations have you encountered for PR and Media?

Link to Guidebook Online:
http://www.research.va.gov/va-dod/

Feedback and updated information for this Guidebook can be sent to: vhaprovadodguidebook@va.gov