

Good Data Practices Cyberseminar Advisors

- Matthew L. Maciejewski, PhD
- Peter Groeneveld, MD, MS
- Jennifer Garvin, PhD
- James F. Burgess, PhD

GDP 2015 Schedule

Sep 15

Planning for Data: Early, Often and Ongoing

- *Sarah L. Krein*

Sep 17

Mind the gap: Using administrative & claims data to answer your research question - *Todd Wagner*

Sep 22

Decisions, decisions, decisions: Selecting methods and tools for data analysis - *Denise Hynes*

Sep 24

Using REDCap: Data management in studies linking primary and secondary data - *Stephen Deppen*



Planning for Data: Early, Often and Ongoing

Sarah L. Krein, PhD, RN

September 15, 2015

Ann Arbor VA

Center for Clinical Management Research
& The University of Michigan



Poll #1: About you

- What is your role in research and level of experience?
 - Research investigator
 - New? Experienced?
 - Data manager/analyst
 - New? Experienced?
 - Project coordinator
 - New? Experienced?
 - Other – please describe via the Q&A function

Heidi: Poll Question

Session Outline

- Identify factors that influence data needs
- Discuss data-related questions that need to be answered early in protocol development
- Data privacy and security
- Data for Research vs. Operations (QI)

Why is **advance planning** related to data **important**?

Project
feasibility

Necessary for
developing
study protocol

Identify
potential issues
before you start

Study team
composition

Budgeting

Timeline

. . . if you don't know where you're going,
you might not get there.

-- Yogi Berra



Session Outline



Identify factors that influence data needs

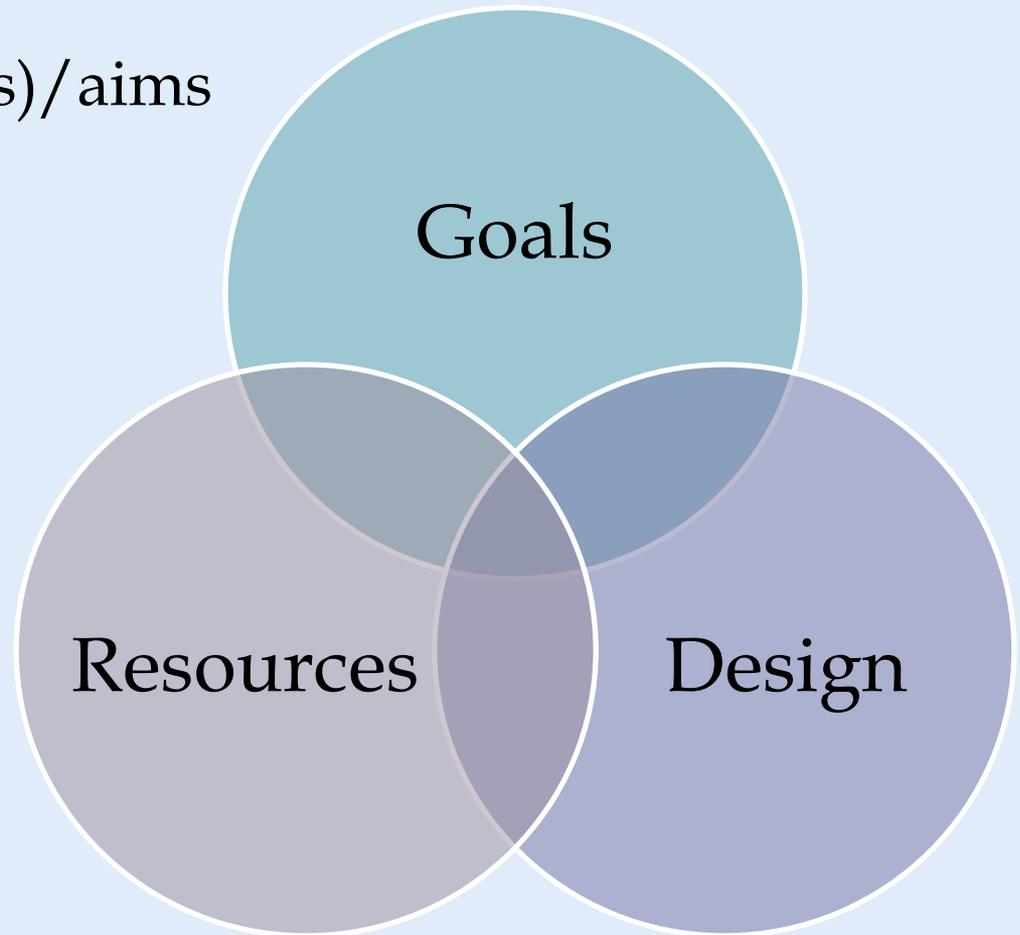
Discuss data-related questions that need to be answered early in protocol development

Data privacy and security

Data for Research vs. Operations (QI)

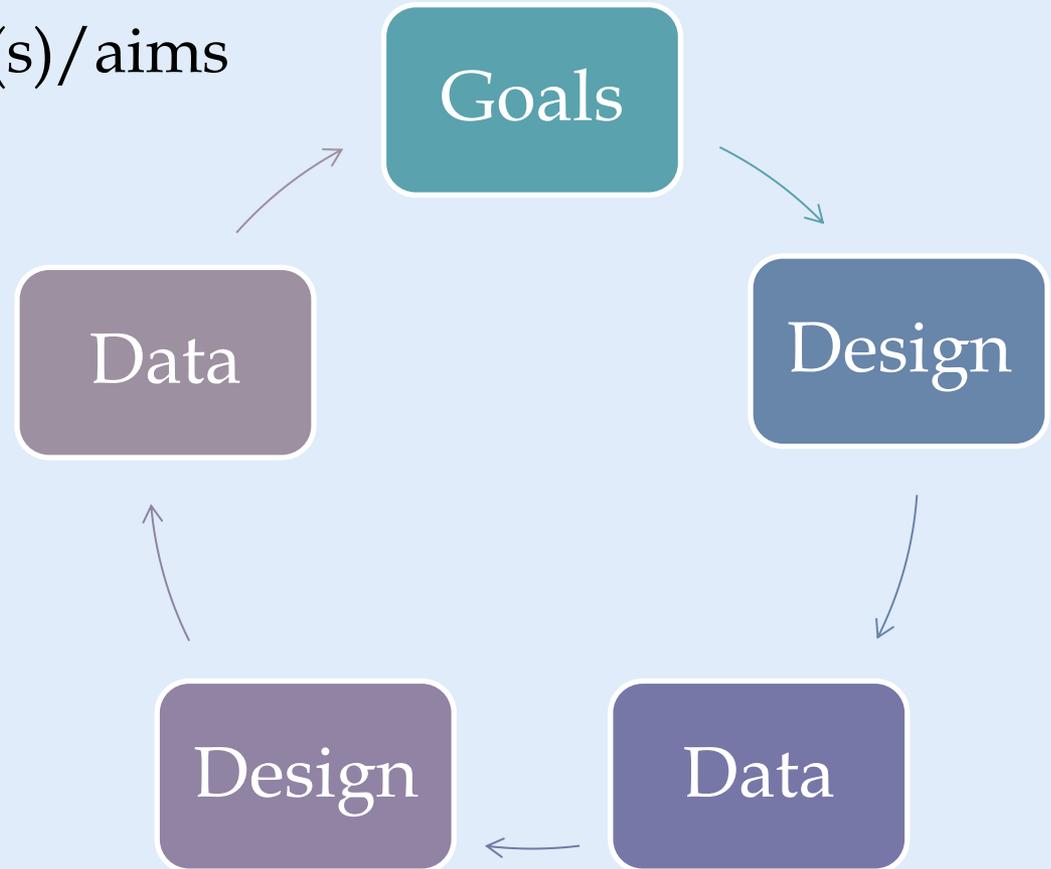
Factors that influence data needs

- Goals of the study
 - research question(s)/ aims
- Study design
- Resources



Process of identifying data needs

- Goals of the study
 - research question(s)/ aims
- Study design
- Resources



Session Outline

Identify factors that influence data needs

? Discuss **data-related questions** that need to be answered early in protocol development

Data privacy and security

Data for Research vs. Operations (QI)

Can I use existing data sources?

VA or
non-VA

National,
regional,
local

Level/unit
of analysis

Timeframe

Do I need to collect data directly?



Surveys



Qualitative



Direct
Measurement



Data
Frequency

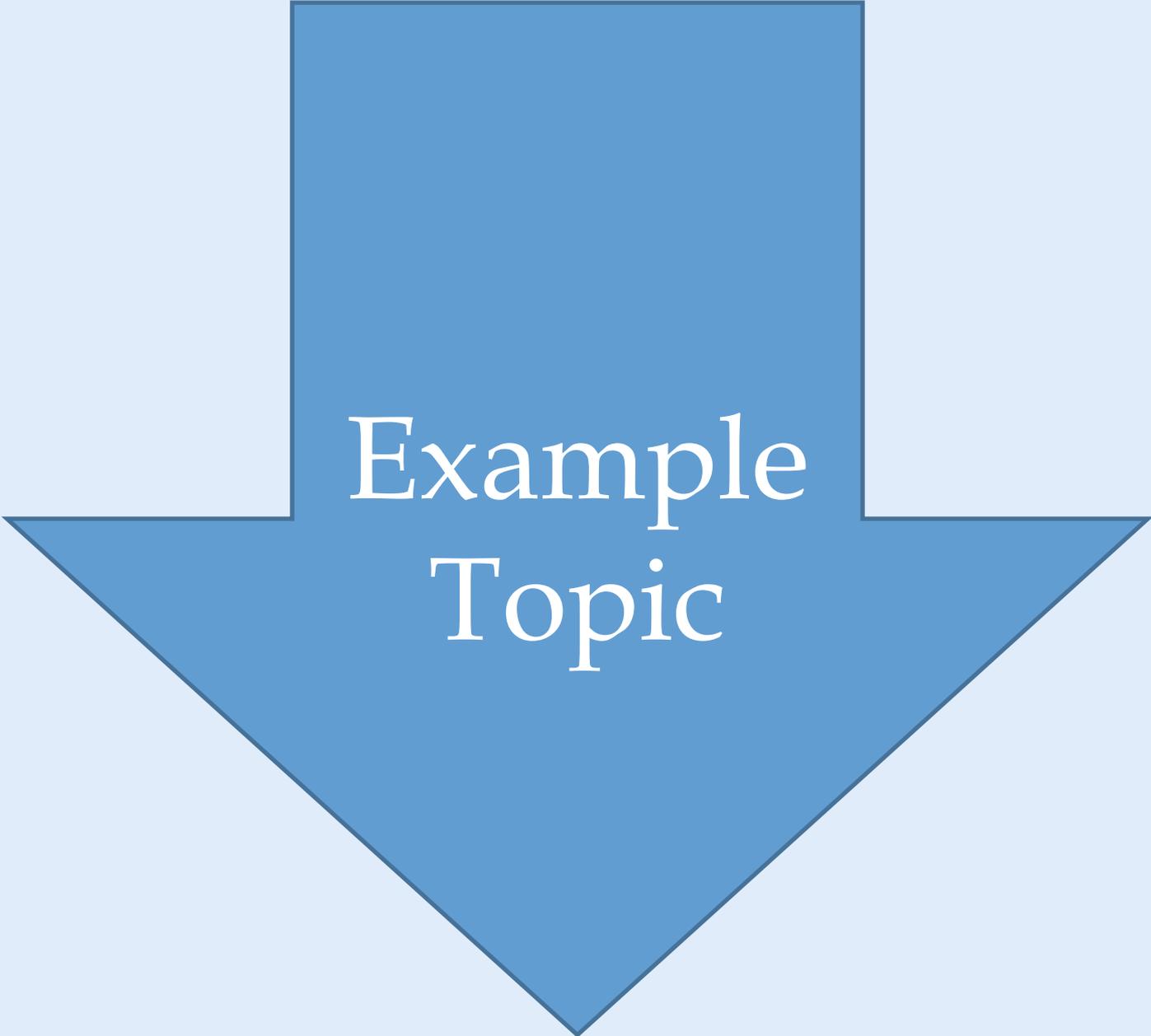
How will I obtain my data?

Secondary data

- Already extracted (existing data sources)
- Needs manual extraction (chart abstraction)
- Non-VA dataset

Primary data

- Sample identification
- Method(s) (software/personnel)
- Equipment/tools



Example
Topic

Peripherally Inserted Central Catheter (PICC)

Increasing utilization

Use is highly variable

Not always appropriate

Associated with complications



Little is known about PICC use, practices or appropriateness in VHA

Example Research Questions

1. What is the volume of PICC use at VAMCs?

2. What factors influence PICC use, care and management at VAMCs?

3. What are staff perceptions and practices related to PICC use in VHA?

4. What is the Veteran experience related to PICC use in VHA?



1. What is the volume of PICC use at VAMCs?



What would be your choice of data to answer RQ1?

1. What is the volume of PICC use at VAMCs?

- a) Existing VA data
- b) Survey of VAMCs
- c) Create new data repository
- d) Other

Heidi: Poll Question



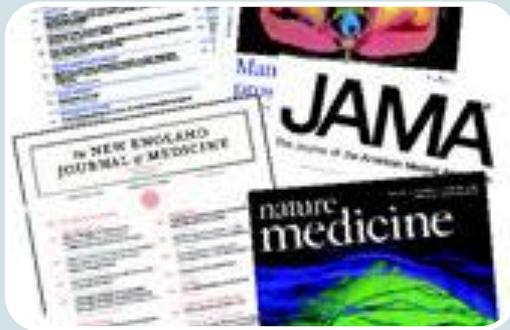
Likely answer- RQ1

1. What is the volume of PICC use at VAMCs?

a) Existing VHA data sources

- Procedures
- Products
- Association with infectious complications

How will I identify data sources to answer my question?



Search
the
literature

Talk
with
colleagues

Post
inquiry on
HSRDATA
listserv

Where can I find information about VA data sources?



VA Information Resource Center

HERC

Health Economics Resource Center



VHA Data Portal



VA Support Services Center (VSSC)



VHA Program Offices

VA INFORMATION RESOURCE CENTER (VIREC)

VIREC Home
VA/CMS Home
About Us
New Users of VA Data
FAQs
Acronyms
HelpDesk



Quick tips on popular topics related to using VA data for research. [Learn more...](#)

[Data Issues Brief, June/July 2015](#)

[Upcoming Cyberseminars](#)

[Real SSN Data Request Process](#)

[VA REDCap Project](#)

[Data Tip of the Month](#)

CONVERSATIONS ABOUT VA DATA
HSRData Listserv



CURRENT VA DATA NEWS
Data Issues Brief



GATEWAY TO DATA RESOURCES
VHA Data Portal



Data News

[NPCD Retirement Data Extended](#): NDS had extended the retirement date to October 1, 2016.

[More info...](#)

[New CDW Domain Released](#): Vista Compensation and Pensions (C&P) 1.0 domain

[More info...](#)

[Change in DART Request Process](#): As of March 26, 2015, VA Form 9957 is no longer required for DART requests. The Research Request Memo has been updated accordingly. The new memo is required for all DART requests and should be signed by the facility ISO.

[More info...](#)

[New CMS Data for Researchers](#): 2011 USRDS Medicare Claims data; 2012 Patient Assessment data; and 2013 USRDS Core CD, Transplant CD, and Hospital CD data.

[More info...](#)

[DSS Name Changed to MCA](#):

New from VIREC

[VIREC at HSR&D/QUERI Conference](#)

Get the scoop on VIREC projects and learn about how we can support your work with VA data.

[Open Positions at VIREC](#)

VIREC is recruiting for two positions in our Data Knowledge area

- [Associate Director for Research](#)
- [Social Science Analyst](#)

[New & Updated Documentation](#)

- [CDW](#): discrete frequencies, record and null counts, data contents, domain layout
- [ADUSH Enrollment Files](#): historical variable attributes, proc contents

[Medical SAS Research User Guides](#)

FY14 guides describing variables in Inpatient, Outpatient, and Inpatient Encounters datasets.

[CDW Factbooks](#)

VIREC Resources

[Working with VA Data](#): Guide to VA data sources, topics, tools, and access.

[VA/CMS Data for Research Project](#): Data custodian for CMS and USRDS data for VA research.

[Research User Guides](#): Detailed information on select data sources, including variable descriptions.

[The Researcher's Notebook](#): Practical information on using data from researchers in the field.

[Data Reports](#): Technical reports, data investigations, and data quality updates.

[Summary Information](#): Current and historical information about dataset variables, counts, and frequencies.

[Publications](#): A complete list of peer reviewed articles and journal supplements published by VIREC.

Health Economics Resource Center

HERC Home

▼ Data

Overview

▶ Types

▼ Sources

HERC Average Cost

Managerial Cost Accounting (MCA)

Non-VA

Financial Management System (FMS)

▶ Methods

▶ Courses and Seminars

▶ Publications

▶ Resources

▶ About Us

▶ More Health Care

Data

Overview

Researchers undertaking economic analysis have a variety of datasets to choose from. This document describes databases located at the VA Austin Information Technology Center (AITC). These include the VA General Ledger (FMS), utilization files, fee basis files, and data from the VA fixed asset package, the Managerial Cost Accounting System (MCA; formerly the Decision Support System (DSS)), and the HERC average cost datasets. In FY13, many datasets migrated to VA's Corporate Data Warehouse (CDW). Researchers will need access to the VA Informatics and Computing Infrastructure (VINCI) workspace to analyze these data.

Researchers should also be aware that the CDW include additional data sources not on the Austin system, including data in the VA computerized medical records system (VISTA) and vital status files.

Types and Sources of VA Cost and Utilization Data

	VA									
	HERC AVERAGE COST	HERC PERSON-LEVELCOST	MCA NDE	MCA IPD	MCA ALBCC	FMS	PAID	NPCD PTF/MED SAS	PBM	VISTA
Inpatient	X	X	X	X				X		
Outpatient	X	X	X	X				X		
Pharmacy			X	X					X	X
Labor					X	X	X			
Other										

Types and Sources of Non-VA Cost and Utilization Data



- Data Sources Overview
- ADUSH Enrollment File
- AITC Mainframe
- BIRLS Death File
- CDW
- HERC Average Cost Data
- MCA (formerly DSS) NDEs
- MCA (formerly DSS) Web Reports
- Medical SAS Inpatient & Outpatient Data Sets
- NPCD
- OEF/OIF/OND Roster
- PTF
- VA/CMS Data
- VETSNET
- Vital Status File
- VSSC Web Reports



Welcome to the VHA Data Portal!

The one-stop-shop for data users' needs.

The VHA Data Portal is a collaborative effort among the following to provide a central gateway to information about VHA data:

- **VHA National Data Systems (NDS)**
- **VA Information Resource Center (VIREC)**
- **VA Informatics and Computing Infrastructure**
- **VHA Data Quality Program**

Our mission is to promote a knowledge-sharing culture that support VHA data users. The portal integrates information from multiple common format and single location to promote a comprehensive knowledge and to facilitate a positive end-user experience.

News

CDW Review

On June 30, 2015, National Data Systems released an email with an embedded questionnaire to individuals identified who have access to VHA's Corporate Data Warehouse (CDW). The questionnaire requested feedback from users regarding his/her use of CDW, most importantly inquiring if access is still needed in the performance of a user's official duties.

...responded to [Sources/DataSourcesOverview.aspx](#) and here:

Cyberseminars

- Sept 15: [Identifying and Extracting Functional Status Data in the CDW Health Factors Domain](#)
- Sept 15: [Planning for data: Early, often and ongoing](#)
- Sept 17: [Mind the gap: Using administrative and claims data to answer your research question](#)
- Sept 22: [Decisions, decisions, decisions: Selecting methods and tools for data analysis](#)
- Sept 24: [Using REDCap: Data management in](#)

Popular Links

Data Access Request Tracker (DART)

- [DART Overview and Forms](#)
- [Launch DART Application](#)

NDS Operational Access Requests

- [NDS Healthcare Operations Request Process](#)
- [CAPRI and VistAWeb Request Process](#)

Resources

- [Corporate Databases Monograph](#)
- [DAR](#)



A-Z Index: 1 | 2 | A | B | C | D | E | F | G | H | I | J | K | L | M | N | O | P | Q | R | S | T | U | V | W

Business Operations

- [CBI Metrics](#)
- [HIMS](#)
- [Improvement Opportunities](#)
- [Physician Productivity](#)
- [Trip Pack](#)
- [OPES Portal](#)

Capital and Planning

- [Capital Reports](#)
- [Planning Reports](#)
- [Clinical Inventory Reports](#)
- [VAST - VHA Site Tracking Reports](#)
- [Capital Portal](#)
- [Operational & Planning Tools Portal](#)

Clinical Care

- [Clinical Programs](#)
- [Mental Health](#)
- [Nursing Outcomes \(VANOD\)](#)
- [Primary Care](#)
- [Rehabilitation Services](#)
- [Virtual Care and Telehealth](#)

Patient Centered Care

- [Patient Centered Care](#)
- [Patient Complaint Tracking & Patient Satisfaction](#)
- [National Veterans Service and Advocacy Program Portal](#)

Quality & Performance

- [Measures & Monitors](#)
- [Quality Management](#)
- [Utilization Management](#)

Resource Management

- [Employee Safety](#)
- [Finance](#)
- [Human Resources](#)
- [DSS Portal](#)
- [Employee Survey Portal](#)
- [Organizational Health Portal](#)

Special Focus

- [Care Mgmt & Social Work Services](#)
- [Homeless](#)
- [OEF/OIF/OND](#)
- [Rural Health](#)
- [Women Veterans Health](#)
- [VA - DOD Sharing](#)
- [OEF/OIF/OND Portal](#)

Access & Clinic Administration

- [Wait Times and Wait Lists](#)
- [Clinical Operations Data](#)
- [Consults](#)
- [Accelerating Care Initiative](#)
- [Systems Redesign Portal](#)

Workload

- [Bed Control](#)
- [Workload](#)



Search for VHA Data
Search RAMP

Check Your Access Levels

VHA Data Users Call
1-855-767-1051 #65157955
[Join Online Meeting](#)
3rd Thursday of the month.
3:00 - 4:00 EST



Announcements

- ▶ 8/12/2015 Pyramid Analytics Questions/Concerns [more»](#)
- ▶ 5/28/2015 IE 11 Fix [more»](#)
- [All Announcements >>>](#)

VSSC Top Links

- [Pyramid Cube Library](#)
- [Cube Library](#)

Executive Summaries

Help Desk Request

Suggestion Box



VHA Office of Informatics and Analytics Home

[About OIA](#)

[OIA Resources](#)

[OIA Communications Resources](#)

[OIA Divisions](#)

[My VeHU Campus](#)

[OIA Connections Blog](#)

[eHealth](#)

[OIA Feedback Form](#)

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[About OIA](#)



[OIA Resources](#)



[OIA Communication Resources](#)



[OIA Divisions](#)



Analytics and Business Intelligence (10P2B)

Analytics and Business Intelligence (ABI) provides timely, reliable analytic and business intelligence data and products to support and improve clinical and operational programs at all levels of the VA health care delivery system. ABI was established as part of the VHA realignment to address organizational needs related to data acquisition, storage, analytics, and reporting. ABI supports the goal that VA be a data driven organization.

Our Goal: The Right Information to the Right Person at the Right Time

ABI's products and services are managed by programs within three main areas:

- [Clinical Analytics & Reporting \(CAR\)](#)
- [Director's Office](#)
- [Operational Analysis & Reporting \(OAR\)](#)

Analytics and Business Intelligence Websites

- [VHA Support Service Center](#)
- [Operational Metrics Home Page](#)
- [Inpatient Evaluation Center](#)
- [Performance Measurement](#)
- [Patient Experience](#)
- [Field Analytics](#)
- [Clinical Assessment, Reporting, and Tracking \(CART\)](#)

OIA Divisions

[Analytics and Business Intelligence \(10P2B\)](#)

[Connected Health \(10P2D\)](#)

[Health Informatics \(10P2A\)](#)

[Health Information Governance \(10P2C\)](#)

[Program Support Operations \(10P2F\)](#)

[Strategic Investment Management \(10P2E\)](#)

I Am Looking for...

Sources for answering RQ1

1. What is the volume of PICC use at VAMCs?

- a) Existing national VHA data sources
 - VIREC website & VHA Data Portal
 - Corporate Data Warehouse (CDW)
 - SAS medical data sets
 - VHA Program Offices
 - Inpatient Evaluation Center (IPEC)

Data access request process



Did You Know?

Researchers can now request access to CAPRI, VistAWeb, and the Homeless Registry through DART.

DART

[Overview](#)
[Operations](#)
[Research](#)
[Resources](#)

Tips for DART Users

VA Form 9957 is no longer required in DART. All information is now captured in the new Research Request Memo dated March 2015. The new memo will be required for all requests moving forward and should be signed by the facility ISO.

Data Access Request Tracker (DART) Request Process

[Launch DART Application](#)

Overview

The Data Access Request Tracker (DART) application is a workflow application that guides data users through the process of requesting access to data and guides reviewers through the review process. It gathers and retains required information and documents submitted by the requester and makes them available to the appropriate reviewers. Reviewers receive notifications with links to the request to be reviewed and can approve them or request additional information or actions from projects. E-mail notices from reviewers are sent automatically to the requester at each stage of the review process.

Requesting Access

Instructions

1. [Launch DART](#) and follow the prompts for a Research Request.
2. Select the data source(s) and data tool(s) to be requested.
3. Complete and upload the required documents as listed in DART for the data source(s) or data tool(s) selected. Some of the following documents will be required:

Research Project Documents and Approvals

- Research study protocol
- Research and Development Committee Approval Letter(s)
- Institutional Review Board (IRB) Approval Letter(s)
- IRB Approved HIPAA Authorization or [Waiver of HIPAA Authorization](#)
- IRB Approved Sample Informed Consent or Waiver of Informed Consent

Data Request Forms

- [Research Request Memo](#) – **NEW** – This replaces the 9957 for **ALL** Research requests submitted through DART after March 25, 2015
- [Real SSN Access Request](#) – **NEW** – required for access to real SSNs
- [OEF/OIF/OND DUA Instructions](#) – OEF/OIF/OND Roster File only
- [OEF/OIF/OND DUA](#) – OEF/OIF/OND Roster File only

“Preparatory to research” data access

- A provision of the
 - HIPAA Privacy Rule
 - VHA Handbook 1200.05
- Allows VHA to provide personal health information for development of a VHA research protocol without:
 - the patient’s authorization or
 - a waiver or an alteration of authorization by an Institutional Review Board (IRB).

Identifying prep to research data access request process via VHA Data Portal

Department of Veterans Affairs
VHA Data Portal

Home Data Sources Data Access Tools Resources Training About Us Support

Data Access > Preparatory to Research Access

Preparatory to Research Access

Did You Know?
VA/CMS data cannot be accessed preparatory to research. VHA provides cohort size estimates through its Pre-Request Consultation Service for researchers intending to use VA/CMS data.

Preparatory to Research
Overview
Request Access
Data Sources
Tools

Tip for Researchers
Scan each required document and submit as individual files to ensure requests are processed in a timely manner.

Overview

The term "preparatory to research" refers to a provision of the HIPAA Privacy Rule. This provision and VHA policy allow a covered entity (e.g., VHA) to provide personal health information (PHI) to a VHA researcher for the purpose of developing a VHA research protocol without:

- the patient's authorization or
- a waiver or an alteration of authorization by an Institutional Review Board (IRB).

Under the HIPAA Privacy Rule and VHA policy, VHA must obtain from the researcher representations that:

- the use is requested solely to prepare a research protocol or for similar purposes preparatory to VHA research,
- the PHI will not be removed from the covered entity, and
- the PHI for which use or access is requested is necessary for the research purpose.

Note: Pilot studies are not considered preparatory to research activity and require IRB approval. Visit the [Research Request Process](#) page for more information on requesting data for IRB approved projects.

VHA prohibits using preparatory to research data to contact or recruit subjects. Authorization to use data preparatory to research ceases once the protocol has been submitted to the IRB and the Research and Development (R&D) Committee for review. VHA Handbook 1200.05, page 27 provides more information.

Requesting Access

Access to data sources and data access tools is available through several request processes, including:

- Local Customer User Provisioning System (CUPS) POC Request Process
- National Data Systems (NDS) Preparatory to Research Request Process
- Patient Care Services (PCS) Request Process
- Pharmacy Benefits Management (PBM) Request Process
- VA/CMS Pre-Request Consultations

Determining which process to use for requesting access depends on the data source or data access tool:

- Expand a source or tool in the list below for an outline of its access request process.
- View Terms and Definitions used in these outlines.

Data Source Request Processes

Expand a data source in the list below to view an outline of its data request process.

ADUSH Enrollment Files

Level of Access	Identifier	Functional Task Code	Data Source Location	Data Format	Type of Access	Request Process
National	Scrambled SSN	110NND1	AITC Mainframe	SAS	Direct	Local CUPS POC Request Process
MSN	Scrambled SSN	110NND1	AITC Mainframe	SAS	Direct	Local CUPS POC Request Process
Local	Scrambled SSN	110NND1	AITC Mainframe	SAS	Direct	Local CUPS POC Request Process

[AITC Mainframe](#)

BIRLS Death File

CDW Data

Data Source	Level of Access	Identifier	Data Format	Type of Access	Request Process
CDW Data	National	Real, scrambled SSN or no SSN	SQL	Extract	NDS Preparatory to Research Request Process
BIRLS Death File	National	Combined Real and Scrambled SSN	SAS*	Extract	NDS Preparatory to Research Request Process
MCA (formerly OSS) NDSs	National	Real or Scrambled SSN or Patient SID	SQL*	Extract	NDS Preparatory to Research Request Process
MCA (formerly OSS) NDSs	National	Real or Scrambled SSN	SAS†	Extract	NDS Preparatory to Research Request Process

Data preparatory to research – Data Portal (2)



[-] CDW Data

Data Source	Level of Access	Identifier	Data Format	Type of Access	Request Process
CDW Data	National	Real, scrambled SSN or no SSN	SQL	Extract	NDS Preparatory to Research Request Process
BIRLS Death File	National	Combined Real and Scrambled SSN	SAS*	Extract	NDS Preparatory to Research Request Process
MCA (formerly DSS) NDEs	National	Real or Scrambled SSN or Patient SID	SQL†	Extract	NDS Preparatory to Research Request Process
MCA (formerly DSS) NDEs	National	Real or Scrambled SSN	SAS†‡	Extract	NDS Preparatory to Research Request Process
Medical SAS	National	Real SSN or Scrambled SSN	SAS*	Extract	NDS Preparatory to Research Request Process
VETSNET	National	Real or Scrambled SSN	SAS*	Extract	NDS Preparatory to Research Request Process
Vital Status File	National	Scrambled SSN	SQL	Extract	NDS Preparatory to Research Request Process
Vital Status File	National	Real SSN Crosswalk	SQL	Extract	NDS Preparatory to Research Request Process

* Copies of Mainframe SAS Data Sets.

† Although DSS is now known as MCA, the SQL tables for the MCA NDEs within CDW are under a DSS Schema and still use the DSS name (Example: Dss.ALBCC).

‡ MCA NDE legacy SAS Data Sets.

The [Corporate Data Warehouse \(CDW\)](#) page provides more information about this data source.

Memo to request Prep to Research Data

**Department of
Veterans Affairs**

Memorandum

Date:

From: Principal Investigator

Subj: Data Access for Preparatory to Research

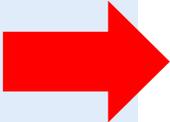
To: VHA Health Information Access, National Data Systems

The following information is required and all signatures must be obtained before any review of this request can take place:

Is this Principal Investigator a VA employee? Yes No

Check the type(s) of data needed: Real SSN Scrambled SSN Identifiable but No SSN

Will the data be stored in the VINCI Environment? Yes No



Please provide a brief description of how you will use the data to prepare the proposal. Be sure and include the following in your description:

- The name of the facility of the IRB or other Committee where the Protocol will be submitted.
- Date when the Protocol will be submitted to the IRM
- Provide a justification if Real SSN is requested.
- List the participants' names and whether they are VA Employee, Contractor, or Without Compensation (WOC)

Estimated time the data will be needed for (should not exceed six months):



Approvals

Memo to request Prep to Research Data

Approvals

As the Principal Investigator, I certify that the data will be transferred, retained, utilized, and destroyed in accordance with VA and VHA policy including the following: VA Handbook 5011.5, Chapter 4 (Alternative Workplace Arrangements); VA Directive and Handbook 6500, Information Security Program; VA Directive and Handbook 6502, Privacy Program; and VHA Directive 1605, VHA Handbook 1200.05, 1605.1, and 1605.2.

I affirm that:

- Representations necessary for preparatory access as required by the HIPAA Privacy Rule have been made and are documented in my research files;
- I understand that access and use of data preparatory to research is limited to that which is necessary to prepare a research proposal;
- The data reviewed will not be used for contacting or recruiting subjects;
- The data will not be reused for any other purpose;
- Only aggregate data will be recorded and used only for background information;
- Individually identifiable information will be deleted when my proposal is approved;
- and National Data Systems data access requirements will be complied with.

I acknowledge and affirm that I am the responsible party should there be any data incidents/ breaches involving downloaded data from this request.

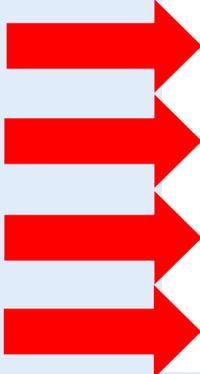
NAME OF PRINCIPAL INVESTIGATOR	DATE SIGNED	<input style="width: 95%; height: 20px;" type="text"/>
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NAME AND TITLE OF SUPERVISOR	DATE SIGNED	<input style="width: 95%; height: 20px;" type="text"/>
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ISO Verification of Training and Account Status

NAME OF INFORMATION SECURITY OFFICER	DATE SIGNED	<input style="width: 95%; height: 20px;" type="text"/>
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NAME OF OFFICE OF RESEARCH AND DEVELOPMENT REPRESENTATIVE (FOR NDS USE ONLY)	DATE SIGNED	<input style="width: 95%; height: 20px;" type="text"/>
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Available data for RQ1

1. What is the volume of PICC use at VAMCs?

- CPT codes (PICC specific): 0 to > 900
- ICD-9 procedure codes (all CVCs): 0 to > 3000
- Event Capture: 0 to > 800

Preparatory to research conclusion- RQ1



Example Research Questions

1. What is the volume of PICC use at VAMCs?

2. What factors influence PICC use, care and management at VAMCs?

3. What are staff perceptions and practices related to PICC use in VHA?

4. What is the Veteran experience related to PICC use in VHA?



3. What are staff perceptions and practices related to PICC use in VHA?



How would you obtain/collect data to answer RQ3?



- a) Use existing VA data?
- b) Conduct a survey?
- c) Use qualitative methods (interviews, focus groups)?
- d) Other?

Heidi: Poll Question



Likely answer- RQ3

3. What are staff perceptions and practices related to PICC use in VHA?

b) Conduct a survey,

c) Use qualitative methods

Conduct a VA staff survey

- Who ?
 - E.g., PICC inserters
- How ?
 - E.g., Electronic, REDCAP
- Regulatory considerations
 - E.g., Union approvals

Organizational Assessment Sub-Committee (OASC) Review and National Union Notification

The OASC of the VHA National Leadership Council is responsible for reviewing and approving all research and operations surveys that involve **employees** beyond one VISN.

To obtain OASC review, the following information should be sent to Martin Charns (Martin.Charns@va.gov)

- Purpose of survey
- Intended audience and number invited to participate
- Modality of survey administration
- Proposed administration dates
- Copy of survey
- Plan to disseminate survey to your target respondent group
- Anticipated use of results
- Have you piloted the survey with the potential respondent group? (Y/N)
- Would you like assistance developing your survey? (Y/N)
- Contact person
- Project director

Please Note:

OASC review is not required for surveys that are being sent to employees entirely within one VISN.

OASC has no jurisdiction over surveys to Veterans.

OASC only has authority to review surveys (paper and pencil or web based) and not interviews.

Blackout dates for 2015: Investigators may not distribute surveys to VA employees July through September.

National Union Notification

If surveys are to be conducted at more than 5 sites, investigators should request for Labor Management Relations to notify the national unions. When fewer than 5 sites are involved, investigators should coordinate with the local HR and union representatives to notify the unions. Unions must be notified before surveying can begin.

If national union notification is needed, please submit your survey documents, including the survey instrument and list of all the sites involved, to ORD Central Office through the JIT system. ORD staff will submit the request to Labor Management Relations (LMR) to notify the national unions. This process may take several weeks. The assigned LMR Specialist will often work with the PI and staff directly to answer any additional questions and will notify you upon notification.



(<http://www.research.va.gov/resources/oasc.cfm>)

How will I store & manage my data?

Local server

VINCI

Level of security

Physical storage

Accessibility to collaborators, co-Is

Considerations- how will I analyze my data?

	Qualitative	Quantitative
Software	√	√
Personnel	√	√

Session Outline

Identify factors that influence data needs

Discuss data-related questions that need to be answered early in protocol development

🔒 Data privacy and security

Data for Research vs. Operations (QI)

Privacy and Security Considerations

- Who are the study subjects?



Privacy and Security Considerations

What steps will be needed to ensure subject protection with respect to privacy confidentiality, etc.?

Privacy and Security Resources

VHA Handbook 1200.05 -- *Requirements for the Protection of Human Subjects in Research*

Program for Research Integrity
Development & Education (PRIDE)

Local IRB/human studies coordinator,
chair, committee member

Editorials

The BMJ requires data sharing on request for all trials

BMJ 2015 ; 350 doi: <http://dx.doi.org/10.1136/bmj.h2373> (Published 07 May 2015)

Cite this as: *BMJ* 2015;350:h2373

Data Sharing?

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Heeding calls from the Institute of Medicine, WHO, and the Nordic Trial Alliance, we are extending our policy

The movement to make data from clinical trials widely accessible has achieved enormous success, and it is now time for medical journals to play their part. From 1 July *The BMJ* will extend its requirements for data sharing to apply to all submitted clinical trials, not just those that test drugs or devices.¹ The data transparency revolution is gathering pace.² Last month, the World Health Organization (WHO) and the Nordic Trial Alliance released important declarations about clinical trial transparency.^{3 4}

These announcements come on the heels of the US Institute of Medicine's (IOM) report on sharing clinical trial

Session Outline

Identify factors that influence data needs

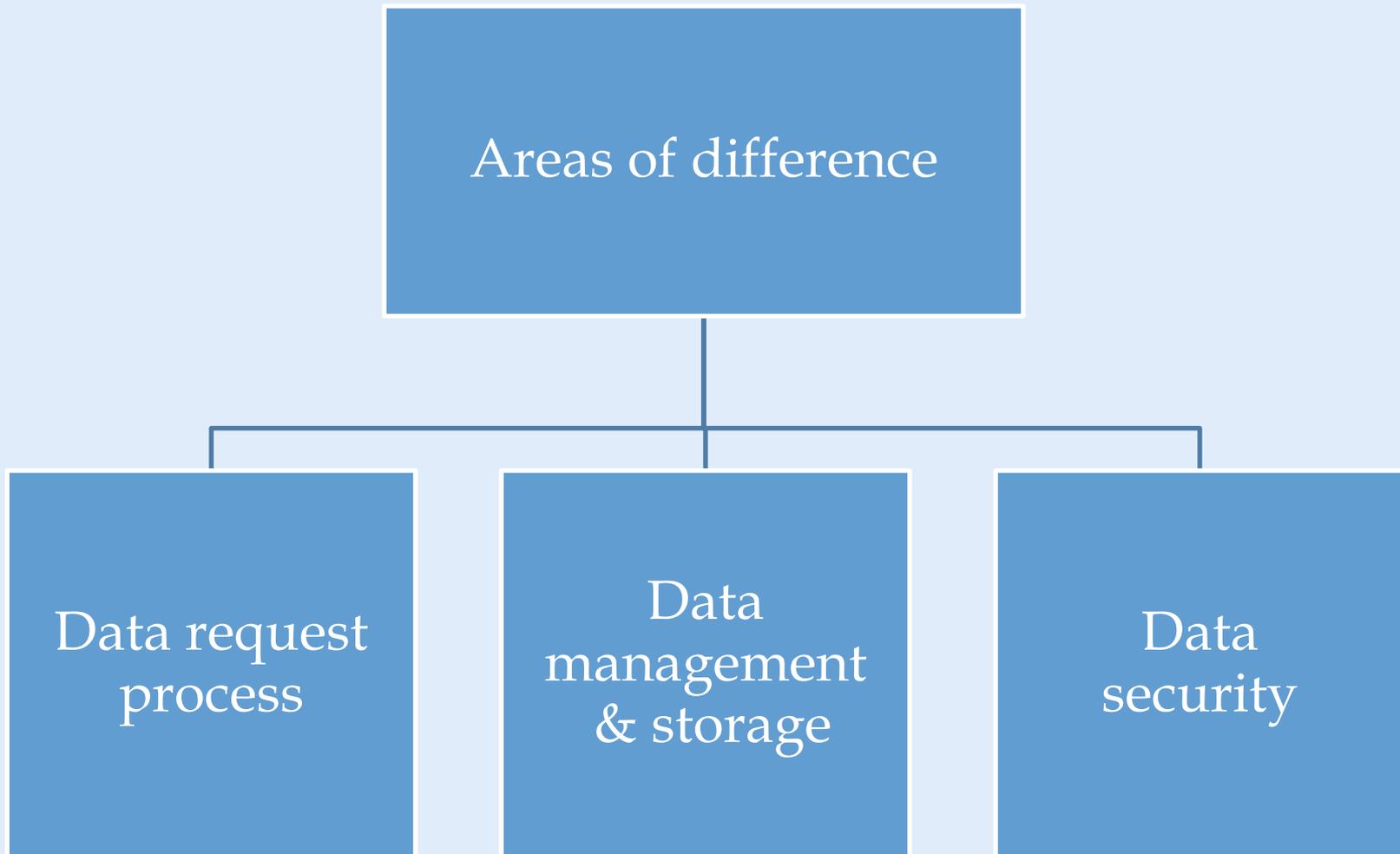
Discuss data-related questions that need to be answered early in protocol development

Data privacy and security



Data for Research vs. Operations (QI)

Research vs. operations (QI)



Advance planning questions

- ❑ What are my study goals and proposed design?
 - Is it research or operations?
- ❑ Can I use existing data sources?
 - What are potential (VA and/or non-VA) data sources?
 - Are the data feasible for addressing my study aims?
- ❑ Do I need to collect data directly?
 - What type of data? From whom?
- ❑ How will I obtain the data (secondary and/or primary)?
- ❑ How will I store & manage my data?
- ❑ How will I analyze my data?
- ❑ Who do I need on my study team?
- ❑ What is the required study budget & timeline? (i.e., is it affordable?)

Describe your data needs in your research protocol

- Primary data collection elements
- Secondary data sources needed
- EHR data
- Identifiers needed and how they will be used
- Other protected health information
- Level of data: national, VISN, local
- Secondary research sites with access to data (which?)

Include your data needs in your other research documents

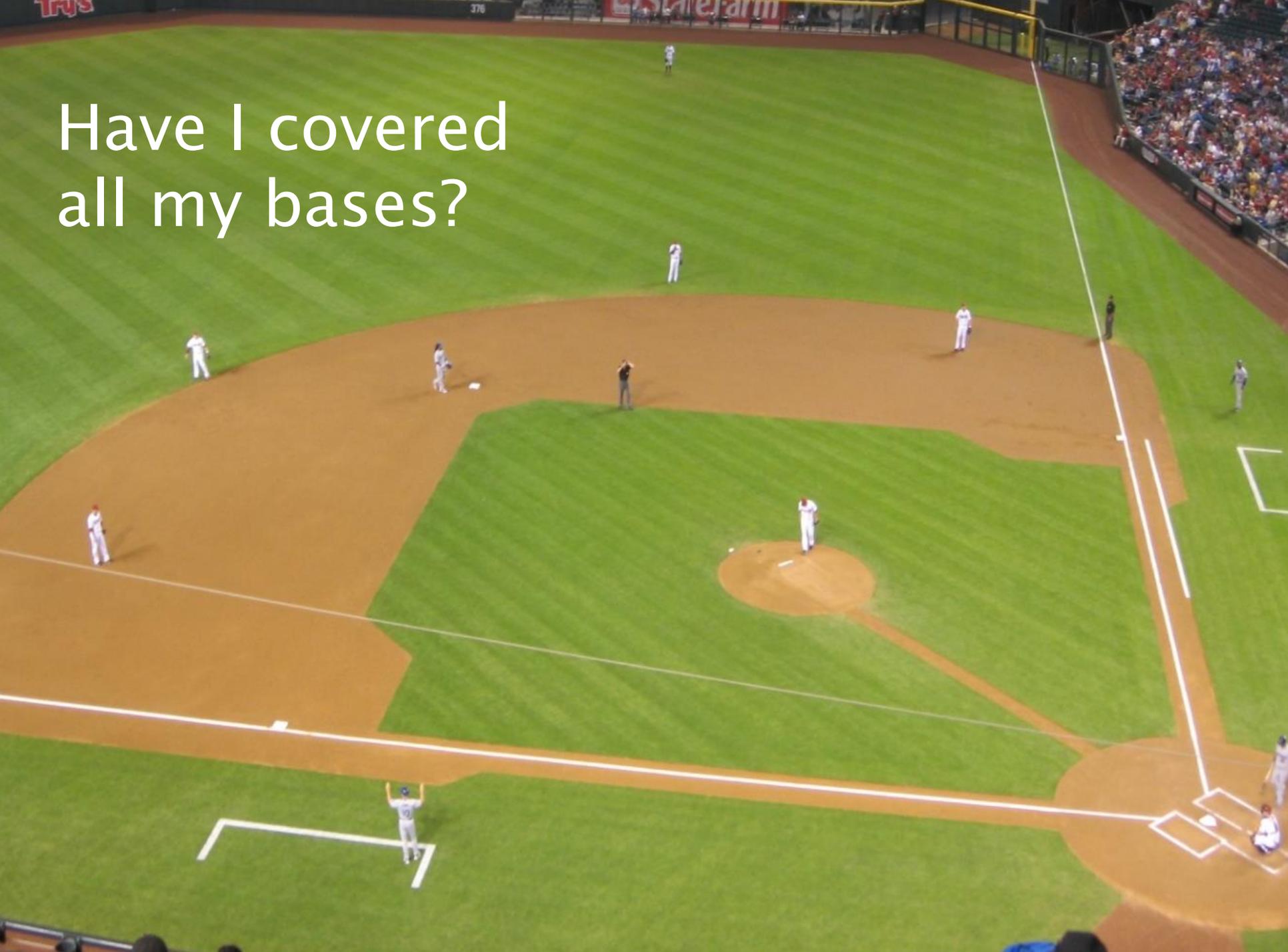
❑ HIPAA Waiver

- Protected Health Information
- Data sources
- National, VISN, local

❑ Be as specific as possible, especially if national EHR data is needed

- CAPRI
- VistAWeb

Have I covered
all my bases?





Thank you!
Sarah.Krein@va.gov

Useful links

Data Information Resources

- VIREC website
<http://vaww.virec.research.va.gov/>
- HERC website
<http://www.herc.research.va.gov/>
- VHA Data Portal
<http://vaww.vhadataportal.med.va.gov/>
- VSSC website
<http://vssc.med.va.gov/>
- VHA Program Offices websites
<http://vaww.va.gov/health/programs.asp>

Regulatory Resources

VHA Handbook 1200.05 Requirements for the Protection of Human Subjects in Research

<http://www.research.va.gov/resources/policies/default.cfm>

Program for Research Integrity Development & Education (PRIDE)

<http://www.research.va.gov/pride/default.cfm>