VINCI Services

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Overview

1. VINCI
2. Data in VINCI
3. VINCI Services
    3.1. Feasibilities
    3.2. Data Needs Assessment (DNA)
    3.3. Support for the prospective study recruitment (Patients List)
4. Research Project Life Cycle

Objective

- Type of data assistance the VINCI Services team provides for the VA researchers
- Requirements for the each service
- How to request services from VINCI

Question #1

What is your primary role in research?

1. Investigator
2. Study coordinator
3. Programmer
4. Statistician
5. Other

Question #2

How often have you used VINCI Services?

1. Never used
2. One time
3. Multiple times

Question #3

What types of services from VINCI have you used?

1. Never used
2. Feasibility
3. Patient List
4. Data needs assessment
5. Multiple services

VINCI

- ✓ The VA Informatics and Computing Infrastructure **(VINCI)** is a major informatics initiative of the Department of Veterans Affairs (VA) that provides a secure, central analytic platform for performing research and supporting clinical operations activities.

- ✓ It is a partnership between the VA Office of Information Technology (OI&T) and the Veterans Health Administration Office of Research and Development (VHA ORD).

- ✓ VINCI includes a cluster of servers for securely hosting suites of databases integrated from select national VA data sources.

DATA in VINCI

- ✓ VINCI has data on more than 22 million patients receiving care at over 1,400 medical centers (inpatient), outpatient clinics, nursing homes, and non-VA medical centers

- ✓ Most data originates from the extensively used Veterans Health Information Systems and Technology Architecture (VistA), the VA electronic medical record system and from other data sources

VINCI Services

- Feasibility
- Data Needs Assessment (DNA)
- Support for the prospective study recruitment (Patients List)

VINCI Services

Feasibility

- Feasibilities provide aggregate counts for researchers during **the preparatory-to-research phase**. The deliverables result in summarized counts to assist in grant and IRB applications.
- Feasibilities help to understand **cohort size and structure**
- Feasibilities help to understand **impact of each criteria to cohort size and structure**
- Feasibilities result **cannot** be used for any publication
- **No regulatory documents** are required

Feasibility

Inclusion/exclusion criteria

- Location (nationwide or some specific location
- Time frame
- Age/gender/other limitation
- Diagnosis (ICD9*/10 codes (*VA uses ICD10 codes since October 2015. If time frame more than 3 years, please, provide both))
- Procedures (CPT codes or/and ICD-PC)
- Lab test. (topography, units, range)
- Medications (list of all generic and brand names, strength and route of administration)

Break downs

- Locations
- Time periods
- Age groups
- BMI groups
- Race
- Etc.

Feasibility

Attrition table

This is a funnel analysis. Numbers presented in column D are based on the number in the row above. For example, Row 8 will be less than or equal to the number in Row7

Criteria Definition	Query Definition	Number of distinct patients remaining	
Inclusion criteria			
Number of patients seen outpatient or inpatient with diabetes type 2 (ICD10 code) at Salt Lake City (station 660) from 1/1/2018-present			
Number of patients had prescribed insulin/type 2 diabetes medication (list of medication) at 1/1/2018-present			
Exclusion Criteria			**# Excluded**
Number of patients with serious health conditions (ICD10 codes) at 1/1/2018-present			

Feasibility

Attrition table _ Result

This is a funnel analysis. Numbers presented in column D are based on the number in the row above. For example, Row 8 will be less than or equal to the number in Row7

Criteria Definition	Query Definition	Number of distinct patients remaining
Inclusion criteria		
Number of patients seen outpatient or inpatient with diabetes type 2 (ICD10 code) at Salt Lake City (station 660) from 1/1/2018-present	Distinct patients seen inpatient or outpatient for diabetes type 2 at SLC from 1/1/2018 to present	14,320
Number of patients had prescribed insulin/type 2 diabetes medication (list of medication) at 1/1/2018-present	Distinct patients from D7 with inpatient or outpatient insulin and/or type 2 diabetes medications from any location from 1/1/2018 to present	10,717
Exclusion Criteria		
Number of patients with serious health conditions (ICD10 codes) at 1/1/2018-present	Distinct patients from D8 without serious health conditions diagnosed inpatient or outpatient at any location from 1/1/2018 to present	5,827

 # Excluded

4890

Feasibility Flowchart

	Request to VINCI@va.gov	Researcher
VINCI Services	Attrition table (time, location, criteria, codes, medications, labs range/units)	Researcher
VINCI Services	Create, run, review code Fill out attrition table Review result	
VINCI Services	Deliver Result Review result/Questions	Researcher

Data Needs Assessment (DNA)

VINCI Services supports VA research by assisting customers with Data Needs questions (DNA) relating to the VA Corporate Data Warehouse (CDW) and other VA data sources.

These questions range from

- ✓ data availability
- ✓ data location
- ✓ data definitions
- ✓ assistance with completing the DART application
- ✓ assistance with completing DART forms including CDW-domain checklist,
- ✓ assistance with IRB protocol preparation,
- ✓ etc.

Patients List

Electronic Medical Record (EMR)-driven recruitment support supplements traditional **patient recruiting** methods by leveraging patient data stored in the VA EMR

IRB approved prospective projects:

- Clinical trials (intervention: drugs, devises, tests, contact, etc.)
- Cohort studies
  - observational study
  - survey study

DART application for the research project is required

Patients List

Required Documents

- Research Request Memo*
- Research Study Institutional Review Board (IRB) Approval Letter
- Sample Informed Consent
- Research and Development (RD) Committee Approval Letter
- IRB Approval Waiver of HIPAA-Compliant Authorization*
- Research Protocol
- CDW-Domain Checklist*
- Request to Real SSN Access (if needed)*

Patients List - DART

Blank Documents (*)

- Research Request Memo*
- **IRB Approval** Waiver of HIPAA-Compliant Authorization*
- CDW-Domain Checklist*
- Request to Real SSN Access **IRB approval** (if needed)*

http://vaww.vhadataportal.med.va.gov/DataAccess/DARTRequestProcess.aspx#DocumentsAndForms

Patients List - DART

The Data Access Request Tracker (DART)

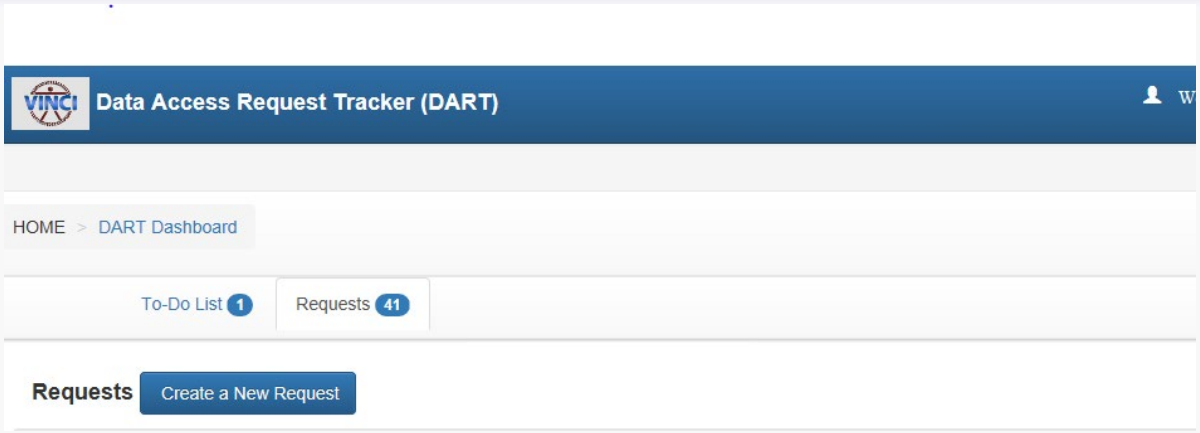
http://vaww.vhadataportal.med.va.gov/DataAccess/DARTRequestProcess.aspx#SubmitRequest

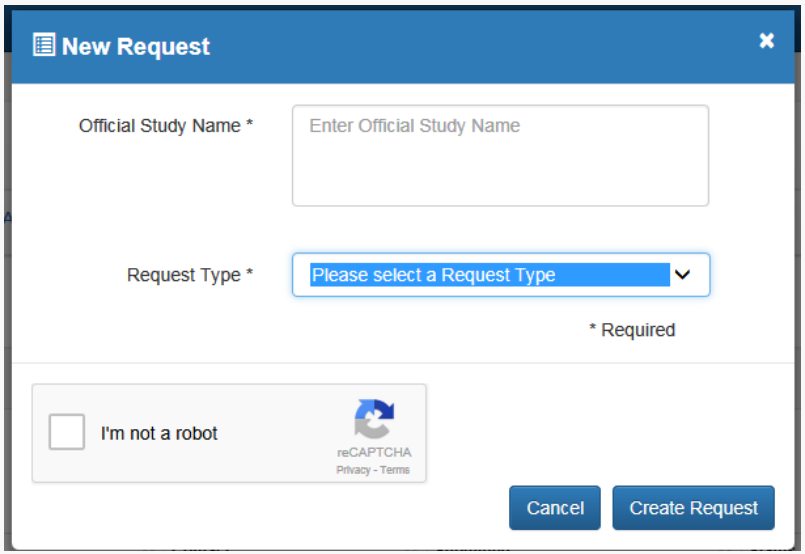
Patients List - IRB

Environment and security VINCI descriptions for use with IRB packages.

https://vaww.vinci.med.va.gov/VinciCentral/NewToVinci/IRBChecklist

Patients List - DART





Select

“Research Data Access”!

Patients List - DART

Activity Information

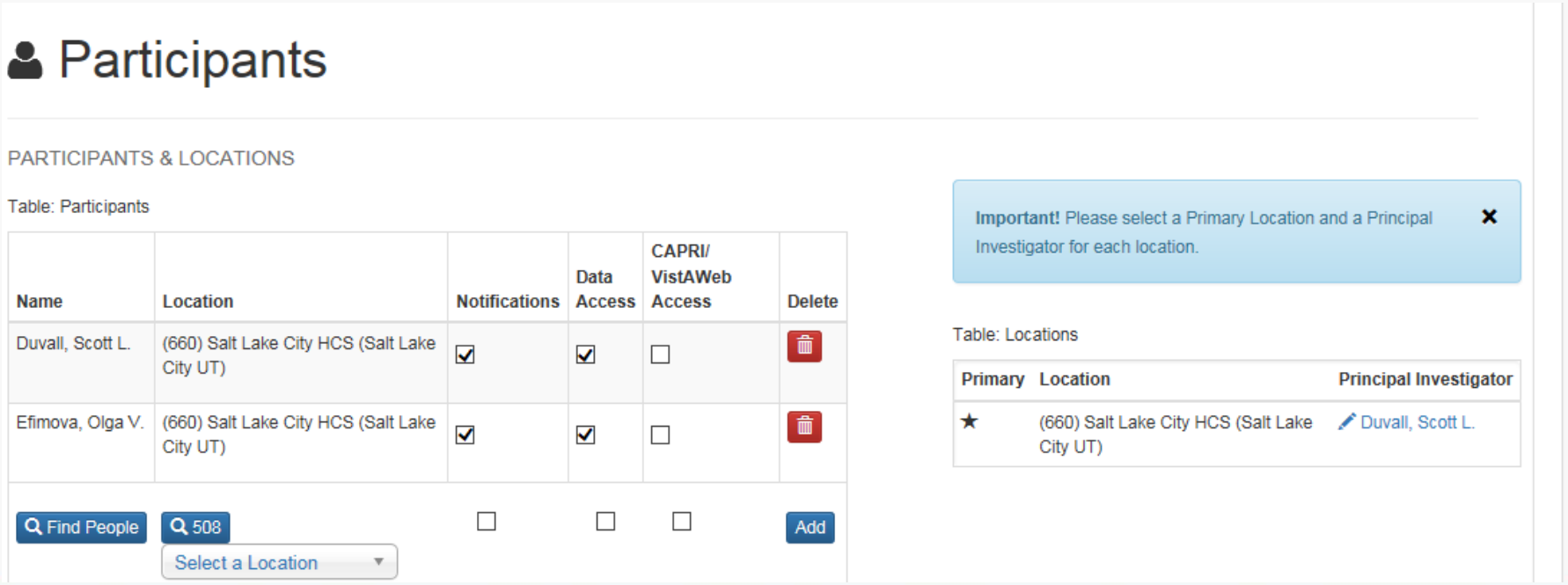
REQUEST INFORMATION

Short Name *	test
Does your project have an IRB or other Project Number?	(•) Yes ( ) No
IRB or Project Number *	12345
Does your project have an approval expiration date?	(•) Yes ( ) No
Approval Expiration Date *	09/01/2020
Study Start Date *	09/01/2019
Anticipated Study Close Date *	09/30/2023
Exemptions & Informed Consent *	
1. Has your study been determined to be an exempt human subjects study?	( ) Yes (•) No
1a. Does your study require subjects to give informed consent orally or in writing - or a HIPAA authorization in writing?	(•) Yes ( ) No
1b. Does your study have IRB approval for a full Waiver of Informed Consent?	( ) Yes (•) No
HIPAA Authorization *	
2. Does your study have IRB or Privacy Board approval for a Waiver of HIPAA authorization?	(•) Yes ( ) No
2a. Is the Waiver of HIPAA authorization only for recruiting or determining subject's eligibility?	( ) Yes (•) No
2b. Is the Waiver of HIPAA authorization for the entire study?	(•) Yes ( ) No

Patients List - DART

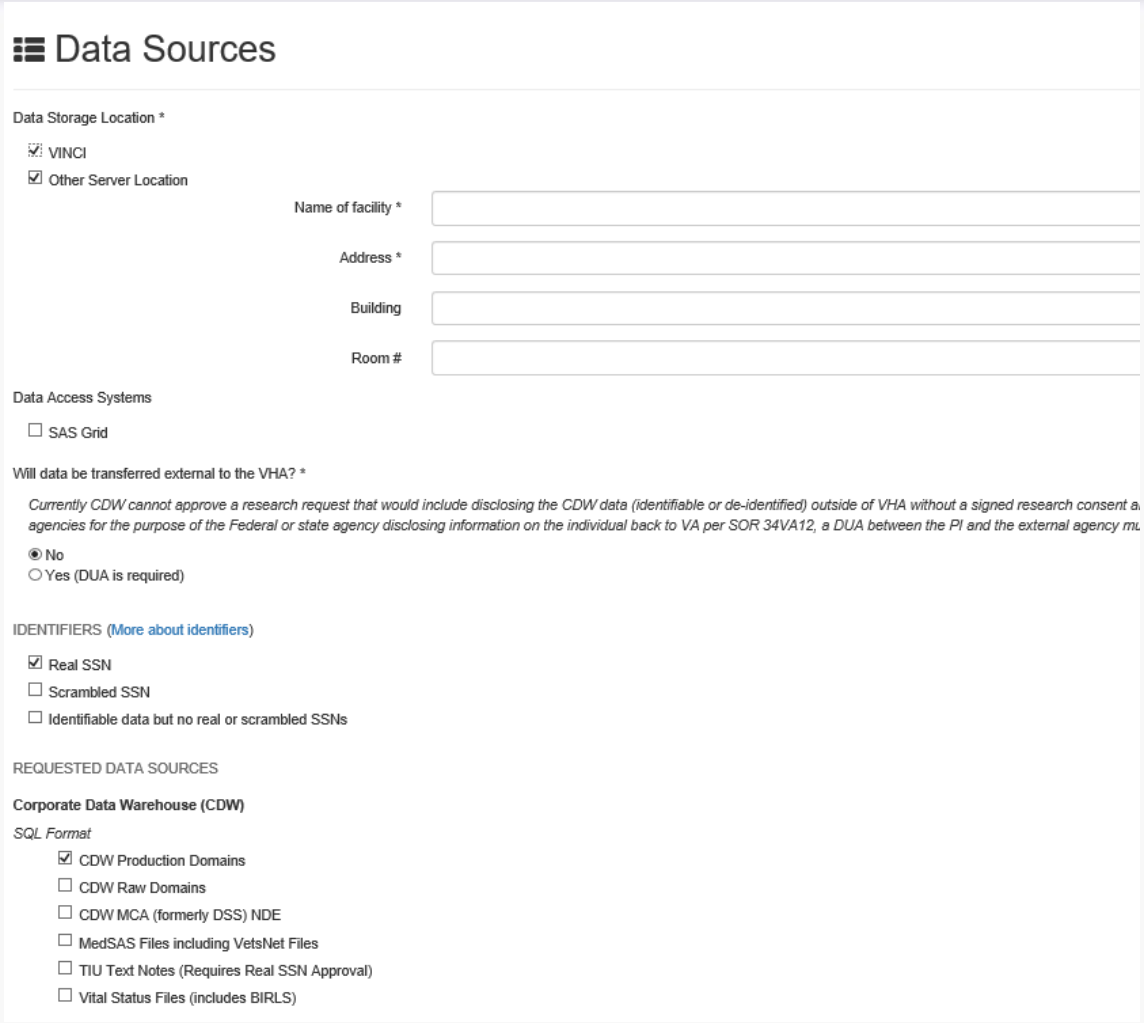
Participants

- Select “Notification” and “Data access”
- Select “CAPRI/VistAWeb Access” only for manual chart review on national level



Patients List - DART

Data Sources



Data Sources

Data Storage Location *

- [x] VINCI
- [x] Other Server Location

Name of facility *

Address *

Building

Room #

Data Access Systems

- [ ] SAS Grid

Will data be transferred external to the VHA? *

Currently CDW cannot approve a research request that would include disclosing the CDW data (identifiable or de-identified) outside of VHA without a signed research consent a agencies for the purpose of the Federal or state agency disclosing information on the individual back to VA per SOR 34VA12, a DUA between the PI and the external agency mu

- (•) No
- ( ) Yes (DUA is required)

IDENTIFIERS (More about identifiers)

- [x] Real SSN
- [ ] Scrambled SSN
- [ ] Identifiable data but no real or scrambled SSNs

REQUESTED DATA SOURCES

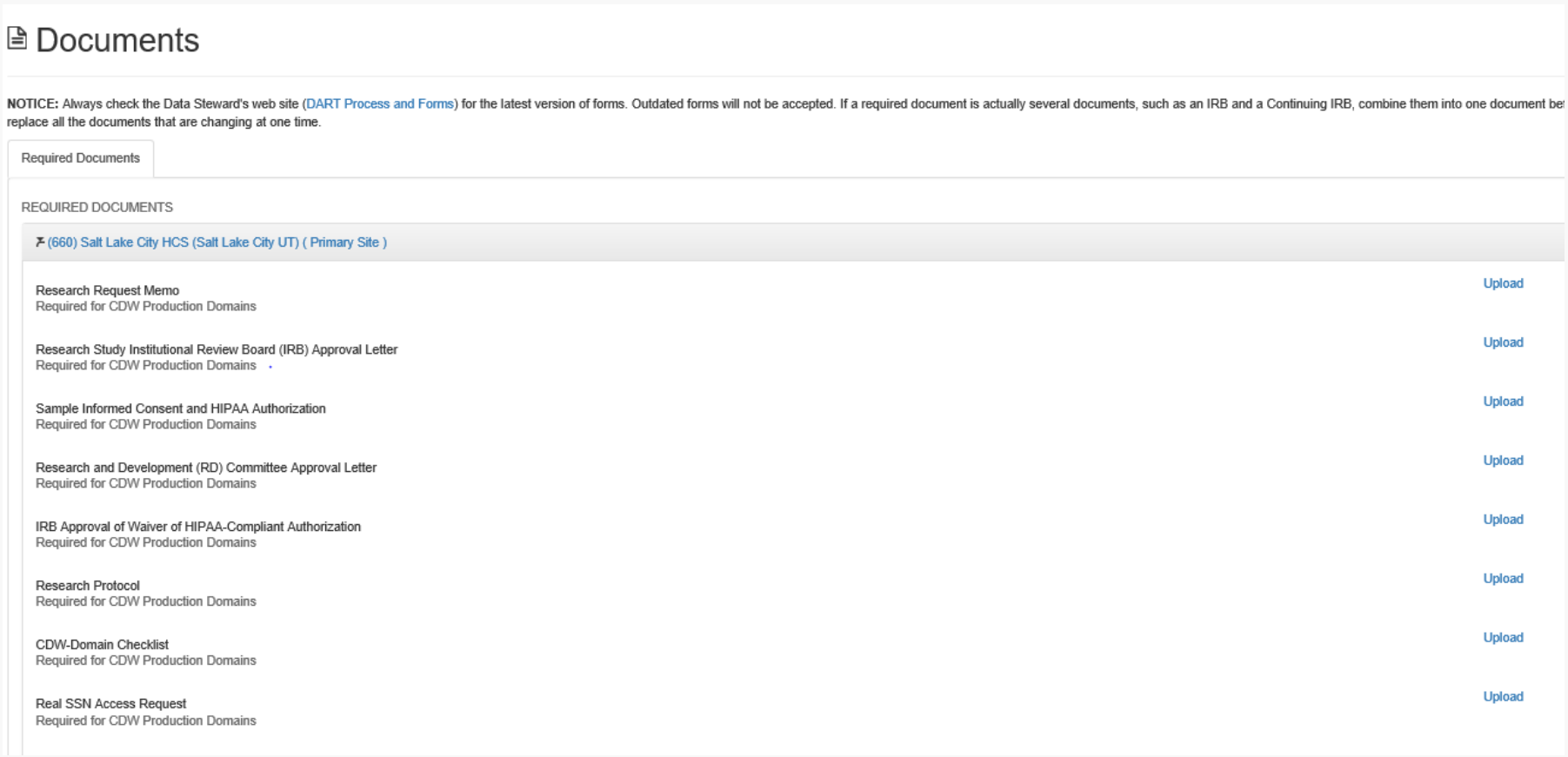
Corporate Data Warehouse (CDW)

SQL Format

- [x] CDW Production Domains
- [ ] CDW Raw Domains
- [ ] CDW MCA (formerly DSS) NDE
- [ ] MedSAS Files including VetsNet Files
- [ ] TIU Text Notes (Requires Real SSN Approval)
- [ ] Vital Status Files (includes BIRLS)

Patients List - DART

Documents



Patients List - DART

Research Request Memo

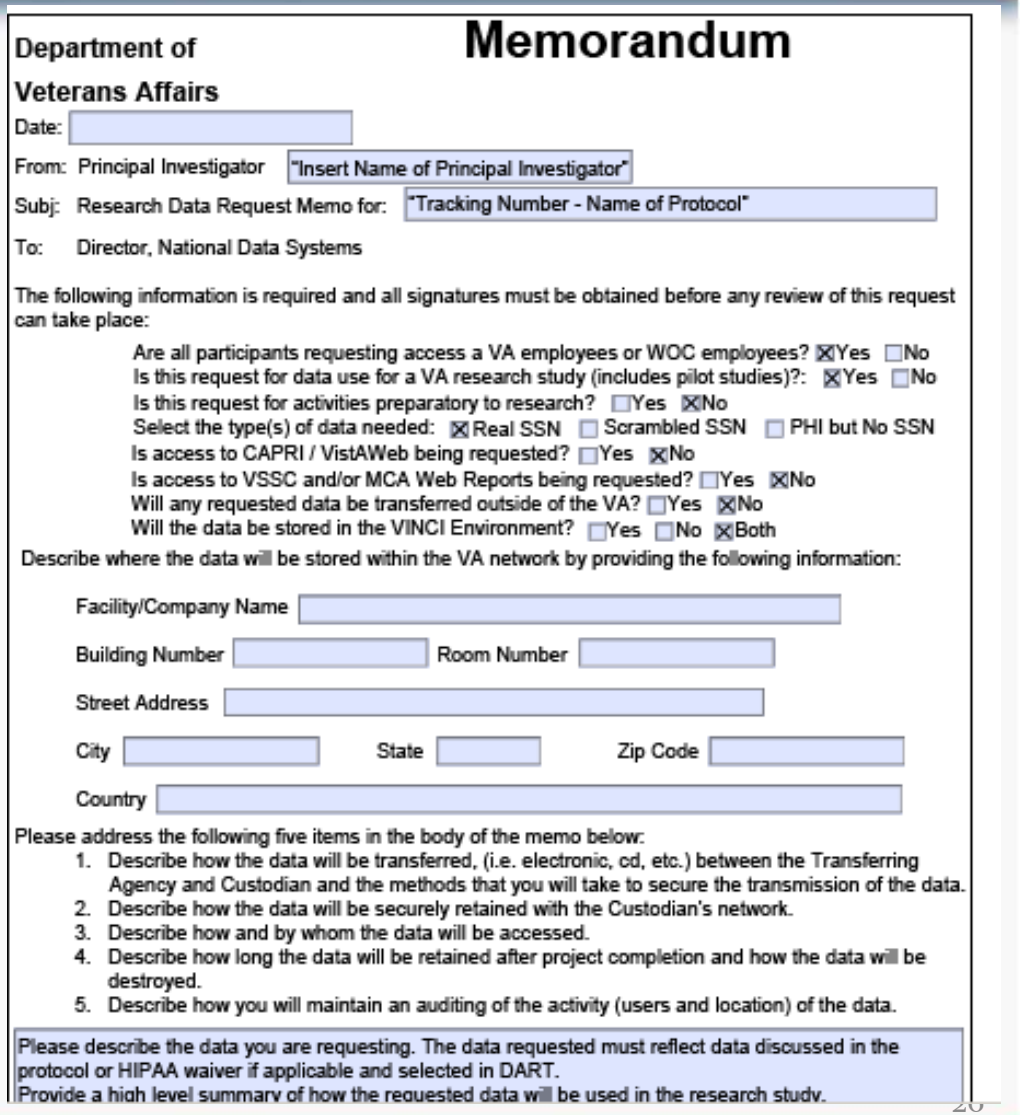
This is a clinical trial
The aim of the study is …
We are requesting list of patients meet Inclusion/Exclusion criteria:

1.
2.
Etc.

<u>With the following patient information</u>:

- Patient name
- DOB
- SSN
- Address
- Etc.

Patient list will be downloaded to the local server by using VINCI secure download tool and destroyed after project completion



Department of Veterans Affairs

Memorandum

Date:

From: Principal Investigator "Insert Name of Principal Investigator"

Subj: Research Data Request Memo for: "Tracking Number - Name of Protocol"

To: Director, National Data Systems

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

Are all participants requesting access a VA employees or WOC employees? ☒Yes ☐No
Is this request for data use for a VA research study (includes pilot studies)?: ☒Yes ☐No
Is this request for activities preparatory to research? ☐Yes ☒No
Select the type(s) of data needed: ☒Real SSN ☐Scrambled SSN ☐PHI but No SSN
Is access to CAPRI / VistAWeb being requested? ☐Yes ☒No
Is access to VSSC and/or MCA Web Reports being requested? ☐Yes ☒No
Will any requested data be transferred outside of the VA? ☐Yes ☒No
Will the data be stored in the VINCI Environment? ☐Yes ☐No ☒Both

Describe where the data will be stored within the VA network by providing the following information:

Facility/Company Name
Building Number Room Number
Street Address
City State Zip Code
Country

Please address the following five items in the body of the memo below:

1. Describe how the data will be transferred, (i.e. electronic, cd, etc.) between the Transferring Agency and Custodian and the methods that you will take to secure the transmission of the data.
2. Describe how the data will be securely retained with the Custodian's network.
3. Describe how and by whom the data will be accessed.
4. Describe how long the data will be retained after project completion and how the data will be destroyed.
5. Describe how you will maintain an auditing of the activity (users and location) of the data.

Please describe the data you are requesting. The data requested must reflect data discussed in the protocol or HIPAA waiver if applicable and selected in DART.
Provide a high level summary of how the requested data will be used in the research study.

Patients List - DART

Health Factors
Inpatient
Lab Chem
Master Veteran Index (MVI)
Outpatient
Patient
Pharmacy BCMA (Bar Code Medication Administration)
Pharmacy Outpatient
Pharmacy Patient
Program Integrity Tool (PIT)
Purchased Care
SPatient
Vital Signs
OMOP

CDW DOMAIN CHECKLIST

CDW Production

- ☐ Allergy
- ☐ Appointment
- ☐ Beneficiary Travel
- ☐ Consult
- ☐ CPRS Orders
- ☐ Dental
- ☐ Emergency Dept. Int. Software (EDIS)
- ☐ Enrollment (ADR)
- ☐ Health Benefits Request
- ☒ Health Factors
- ☐ Immunization
- ☒ Inpatient
- ☐ Integrated Billing
- ☒ Lab Chem
- ☐ Lab Microbiology
- ☒ Master Veteran Index (MVI)
- ☐ Mental Health Assessment
- ☐ Non-VA Meds
- ☒ Outpatient
- ☐ PAID Data **(Please see note on next page)
- ☒ Patient
- ☐ Patient Associated
- ☐ Patient Enrollment
- ☐ Patient Insurance
- ☐ Patient Record Flag
- ☐ PCMM (Primary Care Management Module)
- ☒ Pharmacy BCMA (Bar Code Medication Administration)
- ☒ Pharmacy Outpatient
- ☒ Pharmacy Patient
- ☒ Program Integrity Tool (PIT)
- ☒ Purchased Care
- ☐ Radiology
- ☐ Recall Reminders
- ☐ Reengineered Primary Care Management Module (RPCMM)
- ☒ SPatient
- ☐ Staff
- ☐ SStaff
- ☐ Surgery PRE, INTRA, and POST
- ☐ VistA Compensation & Pension
- ☐ VistA Waitlist
- ☒ Vital Signs
- ☐ Women's Health

CDW RAW*

- ☐ CAPRI Audit Trail table
- ☐ CliniComp
- ☐ Echocardiogram
- ☐ Equipment Inventory
- ☐ FBCS (Fee Basis Claim System)
- ☐ IFCAP (Integrated Funds Control, Accounting, and Procurement)
- ☐ Intravenous meds (IV)
- ☐ Oncology
- ☐ Prosthetics
- ☐ Pulmonary Function Test (PFT)
- ☐ Talent Management System (TMS)
- ☐ Unit Dose (Pharmacy)

CDW Raw data is data that has been pulled directly from the VistA sites and the data has not been verified or had business rules applied. It may not be current and there is limited documentation for users. Requests for CDW Raw data require additional time for creating data extracts and it is more difficult for studies to use.

Other Data

- ☐ CART CV Data
- ☐ Department of Defense and Department of Veterans Affairs Infrastructure for Clinical Intelligence (DAVINCI)
- ☐ Lung Cancer Screening Demonstration Cohort
- ☒ OMOP Common Data Model (CDW Production/Raw Source)
- ☐ PSSG Geocoded Files
- ☐ SAS Fee
- ☐ VINCI NLP Output

For additional information about the domains, please refer to the link below:
http://vaww.virec.research.va.gov/CDW/Documentation.htm

CDW Checklist V 6.5 October 31, 2019. This document revision supersedes any previous versions.

Patients List

Inclusion/Exclusion criteria

- Location (nationwide or some specific location
- Time frame
- Age/gender limitation
- **Distance from current address to VAMC**
- Diagnosis. ICD9*/10 codes (*VA uses ICD10 codes since October 2015. If time frame more than 3 years, please, provide both)
- Procedures. CPT codes or/and ICD-PC
- Lab test. Units, range
- Medications (list of all generic and brand names, strength and route of administration)

Note! Use variables from structured data only

Patients List

List of deliverable variables:

- ✓ Patient name
- ✓ DOB
- ✓ SSN/Last 4
- ✓ Address
- ✓ Phone
- ✓ Date/location of upcoming appointment
- ✓ Etc.

Limitation (will not be delivered)

- ✓ Problem list
- ✓ Current medications list

Patients List - Results

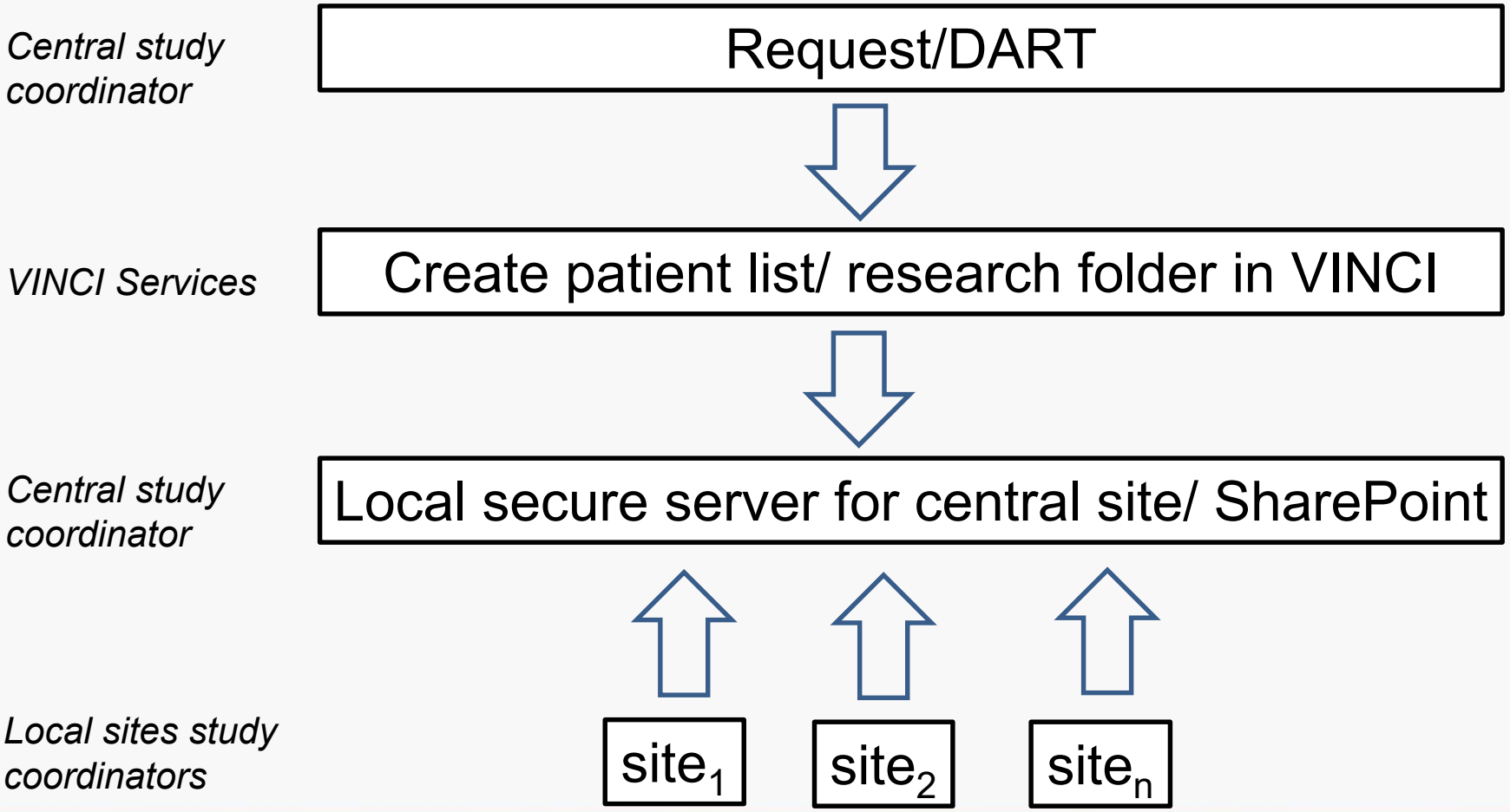
- Excel file saved in project research folder in VINCI
- Instructions to access VINCI
- Instructions to download file to local secure server

Occurrence:

- One time
- On regular base (monthly, quarterly, etc.)
- By Demand

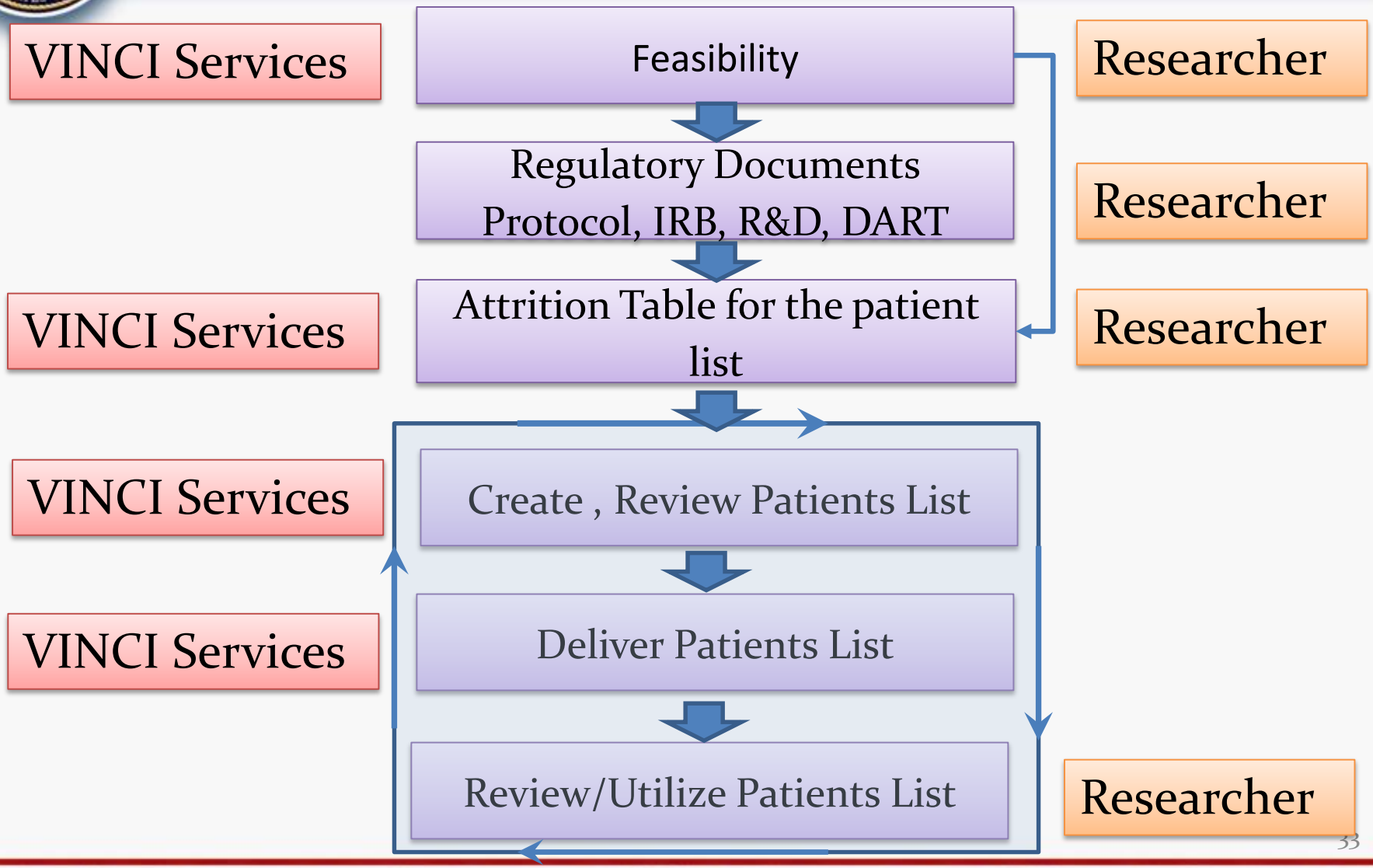
Patient List - Results

Multicentral project with CIRB

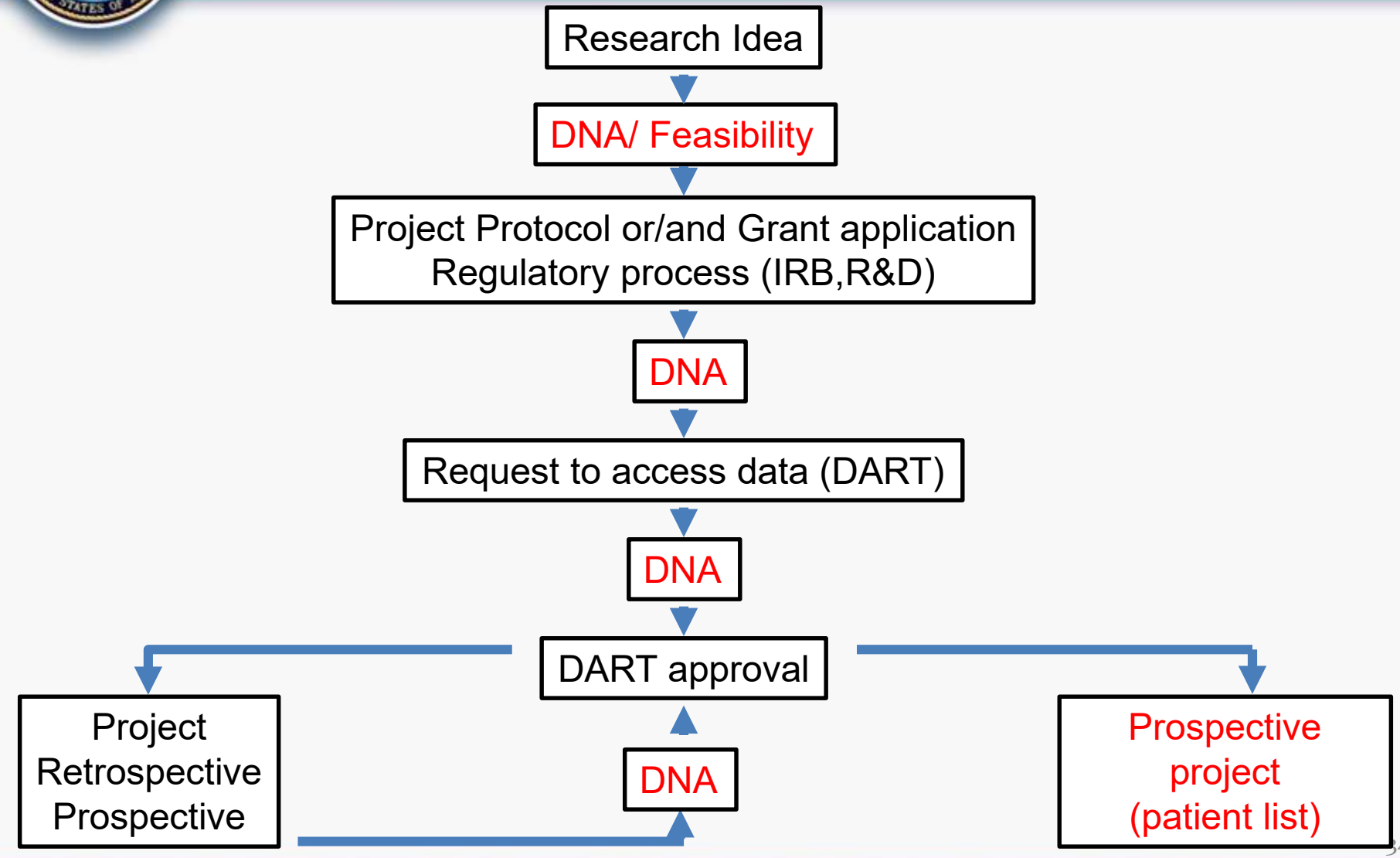


Patient List

Patient List Flowchart



Research Project Life Cycle



VINCI Services

- Feasibility (cohort size and structure/ no regulatory documents/ cannot be used for publications
- Data Needs Assessment (data and applications questions, assistance)
- Patient List (IRB-approved prospective studies, DART application, can be created on regular base)

Requests

VINCI@va.gov

Subject:

- Feasibility
- Data Needs Assessment
- Patient list

Feedback

We appreciate your opinions and feedback.

Please, take a moment to complete
our customer satisfaction survey.

Click **here** to access

QUESTIONS?

THANK YOU!