Using a Secure Research Environment

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Learning Objectives

- List the types of data which have regulatory requirements for confidentiality, protection and/or privacy.
- Recognize your legal and contractual role in these protections and the penalties for non-compliance.
- Differentiate between identified, deidentified and limited datasets and their storage and give examples.
- Identify the requirements for your access to Carilion's systems and patient data.
- Describe Carilion's secure research environment and list several available software programs.
- Outline the process for new software consideration.

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Why/When Do We Need Them?

- Some types of data have requirements for confidentiality
  - Personally Identifiable Information (PII)
  - Protected Health Information (PHI) (patients)
  - Family Educational Rights and Privacy Act (FERPA) (students)
  - Department of Defense (DOD)
  - Company Confidential
  - Intellectual Property (IP)

- YOU DON'T OWN THE DATA

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Why/When Do We Need Them?

- You have contractual obligations
  - Data Use Agreements
  - Material Transfer Agreements
  - Non Disclosure Agreements
  - Access Confidentiality Agreements
- Environment must be appropriate for the project
  - Sponsor requirements
  - Risk classification with Carilion
  - Risk classification with VT

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Why/When Do We Need Them?

- Academic and Healthcare organizations have different regulatory requirements.
- Be understanding of each institutions requirements and policies.
- Collaborative projects require compliance with all parties' requirements.
- Effectively, this means the most stringent of all requirements must be followed, not the least stringent.

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HIPAA (Health Insurance Portability and Accountability Act of 1996)

- “The Privacy Rule standards address the use and disclosure of individuals' health information—called "protected health information" by organizations subject to the Privacy Rule — called "covered entities," as well as standards for individuals' privacy rights to understand and control how their health information is used. ” (hhs.org)
- Carilion is a “covered entity.” Virginia Tech is not.
- Non-compliance can lead to substantial civil money penalties.
- A person who knowingly obtains or discloses individually identifiable health information in violation of the Privacy Rule may face a criminal penalty of up to $50,000 and up to one-year imprisonment.

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HIPAA and Research

Research. "Research" is any systematic investigation designed to develop or contribute to generalizable knowledge. The Privacy Rule permits a covered entity to use and disclose protected health information for research purposes, without an individual's authorization, provided the covered entity obtains either: (1) documentation that an alteration or waiver of individuals' authorization for the use or disclosure of protected health information about them for research purposes has been approved by an Institutional Review Board or Privacy Board; (2) representations from the researcher that the use or disclosure of the protected health information is solely to prepare a research protocol or for similar purpose preparatory to research, that the researcher will not remove any protected health information from the covered entity, and that protected health information for which access is sought is necessary for the research; or (3) representations from the researcher that the use or disclosure sought is solely for research on the protected health information of decedents, that the protected health information sought is necessary for the research, and, at the request of the covered entity, documentation of the death of the individuals about whom information is sought. A covered entity also may use or disclose, without an individuals' authorization, a limited data set of protected health information for research purposes (hhs.org)

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Additional Requirements (hhs.org)

- Minimum Necessary. A central aspect of the Privacy Rule is the principle of "minimum necessary" use and disclosure. A covered entity must make reasonable efforts to use, disclose, and request only the minimum amount of protected health information needed to accomplish the intended purpose of the use, disclosure, or request.
- Data Safeguards. A covered entity must maintain reasonable and appropriate administrative, technical, and physical safeguards to prevent intentional or unintentional use or disclosure of protected health information in violation of the Privacy Rule and to limit its incidental use and disclosure pursuant to otherwise permitted or required use or disclosure.

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Deidentification of Data Sets

“De-identified health information neither identifies nor provides a reasonable basis to identify an individual. There are two ways to de-identify information; either: (1) a formal determination by a qualified statistician; or (2) the removal of specified identifiers of the individual and of the individual's relatives, household members, and employers is required, and is adequate only if the covered entity has no actual knowledge that the remaining information could be used to identify the individual.” (hhs.org)

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HIPAA 18 Identifiers

1. Names
2. All geographical subdivisions smaller than a state
3. **Dates** (except year)
4. Phone numbers
5. Fax numbers
6. Email addresses
7. Social Security numbers
8. Medical record numbers
9. Health plan beneficiary numbers
10. Account numbers
11. Certificate/license numbers
12. Vehicle identifiers and serial numbers
13. Device identifiers and serial numbers
14. Web URLs
15. IP addresses
16. Biometric identifiers
17. Full face photos
18. Any other unique identifying number, characteristic, or code.

(may include rare conditions)

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Access Requirements and Timing

	Background Check	ACA	OIG exclusion screen	Vaccines/ Screens	Govt ID and TSG info
Carilion employee	At hire	At hire/annual in-services	At hire and monthly	At hire	At hire
VT Employee	Presumed through VT hire	At First project onboarding and annually through HART	At First project onboarding and monthly	Presumed through VT hire	At First project onboarding
VT student*	At VSA# onboarding	At VSA# onboarding and annually through HART	At VSA# onboarding and monthly	At VSA# onboarding	At VSA# onboarding
VTCSOM	Presumed through VTCSOM enrollment	At First project onboarding and annually through HART	At First project onboarding and monthly	Special VSA process	At First project onboarding

* Project is related to VT student program. If a VT student is working with a Carilion investigator unrelated to their program at VT, they would be hired as a paid intern and fall under the Carilion employee requirements.

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Access to Systems for Research

	TriNetX System for Feasibility Exploration	TriNetX Download Datasets ^	Epic Login for Research ~	REDCap Projects ~	Sparc secure research environment $ ~	PRISM IRB Application Software
Carilion employee	Chair/Dept approval	Carilion IRB approved protocol				Leverages Carilion login
VT Employee	R&D Sr Dir approval #					IRB approval for Carilion login $
VTCSOM	VTCSOM Dean approval					Leverages Carilion login
VT student* (HSIS, TBMH, undergrad, etc.)	R&D approval #					n/a

* Project is related to VT student program.
$ Additional costs to Carilion associated with access.
^ Publication for TriNetX Analytics requires Carilion IRB protocol. Requirement based on Carilion's Data Use Agreement with TriNetX, which is project-specific, with an approved IRB protocol, specified data, and particular use only.
# Requirement based on Carilion's Member Agreement with TriNetX to allow academic partners access to TriNetX through our partnership on projects.
~ Role based access – access granted to authorized users who have defined IRB approved research protocol. Only minimum amount of access is granted to accomplish the purpose of the protocol/project. The PI is responsible to ensure the minimum necessary standard is maintained.

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Requirements by Data Set Type*

Type	Additional Information	Storage Requirements (minimum)	Storage Preferences (securest possible)
Aggregated	(no cell size <11)	None	None
Row level deidentified	No HIPAA identifiers. No other information that could be used to re-identify like rare conditions. Expert determination of de-identification.	Sparc for TriNetX. Otherwise, none, unless Leadership provides additional stipulations	Sparc, as the ability to truly de-identify a dataset becomes more difficult with AI and accessibility to other datasets that could be leveraged to cross reference for linkages.
Row level, Limited dataset, Non-sensitive	May include dates and/or zips. If re-identified, potential of harm to patient minimal.	Sparc, Carilion REDCap, or similar secure research environment under a HIPAA covered entity.	Sparc, Carilion REDCap, or similar secure research environment under a HIPAA covered entity.
Row level, Limited dataset, Sensitive	May include dates and/or zips. If re-identified, potential harm to patient more than minimal.	Sparc, Carilion REDCap, or similar secure research environment under a HIPAA covered entity.	Sparc and/or Carilion REDCap
Row level, Identified, Non-sensitive	Includes fields that may be used for reidentification, either directly or if combined with other source data. Potential harm to patient is minimal risk.	Sparc and/or Carilion REDCap	Sparc and/or Carilion REDCap
			Carilion REDCap

Assumptions:

Patients are not consented for the use of their data.

Carilion Leadership decided through appropriate mechanisms to share such data.

Notes (text) are always considered identified and sensitive.

Determination of images is based on whether there is embedded PHI in the image.

Sparc Secure Research Environment

- Cloud-based, secure research environment
- Accessible storage of research project files in addition to advanced analytics programs to apply to those files for analysis.
- Folders are set up specifically for each approved project, with access limited to the research team, as specified on the protocol. This mitigates most of the minimal risk of privacy breach.

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Sparc Secure Research Environment

- Once access is authorized, the clients utilize their institution's credentials to sign in.
- Data are prevented from download from the environment, without appropriate permissions and managed by the Health Analytics Research Team (HART).
- Sparc is also used for long term cold storage of protocol data for the duration of the protocol data retention requirements post-closure.

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Researchers Perspective: Navigating the Environment

- Secure research environments empower external collaborations with centralized management for projects
- Massive data storage available with powerful programs and compute
- Together with other informatics solutions, like REDCap and TriNetX, provides data management through the life cycle
- Makes it easy to do the right thing

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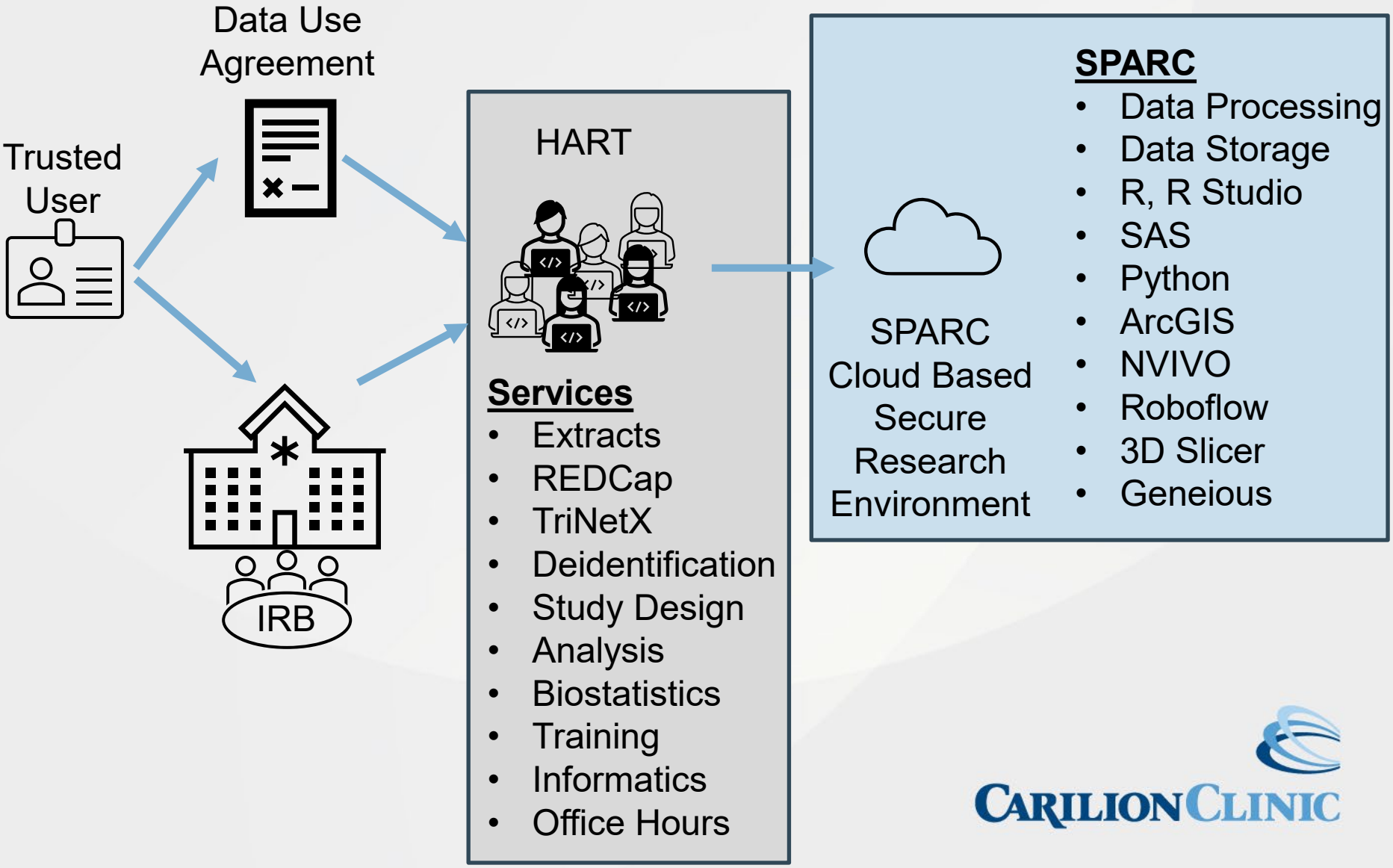
Sparc: Current Environment



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Sparc Software

- SAS Viya and Statistics
- R and R-Studio
- Python
- NVIVO
- Geneious
- Roboflow
- 3D Slicer
- ArcGIS
- Microsoft Excel, Powerpoint, Word.

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Sparc Assessing New Software

- Novel functionality beyond current offerings
- Number of projects/users impacted
- Cost of licensing / Funding to acquire licensing
- Licensing structure to maximize positive client impact (shareable licenses)
- Vendor Risk Assessments to ensure safety of software in environment
- Comparison to other similar software
- Ability / ease to administer
- Note: Carilion cannot install VT software licenses on Sparc without being in violation of the license as we are separate legal entities.

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Sparc Workspace Options

- Regular: 4vCPU/16GB Memory (Power)
- PowerPro: 8vCPU/32GB Memory
- Super: 32vCPU/128GB Memory
- Dedicated server with GPU: Up to 32vCPU/128GB Memory with NVIDIA L4 Tensor Core
  - Average dedicated server is 8vCPU/64GB Memory. Swap NVME drives for up to 1TB of swap memory

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Sparc: Where We're Headed…

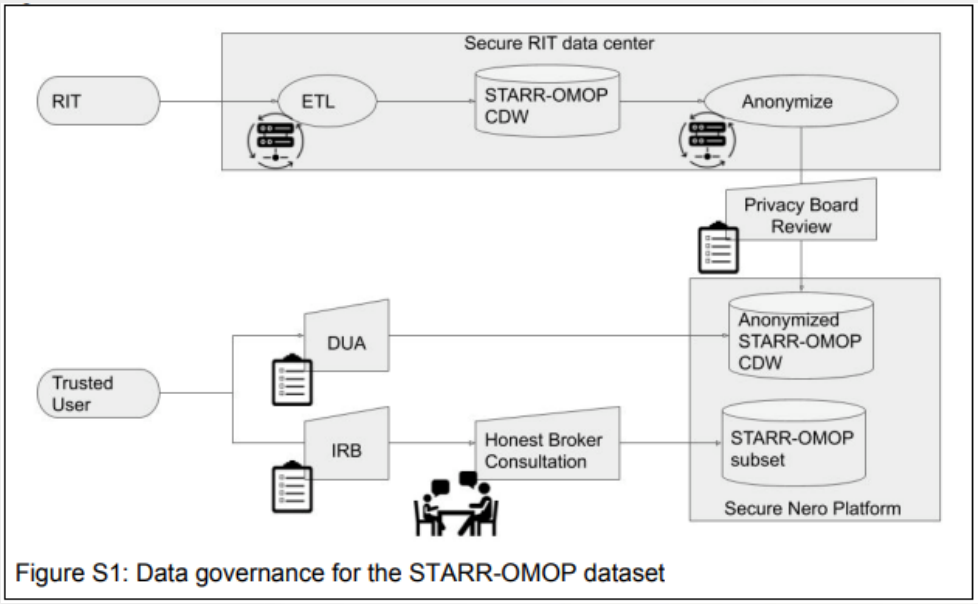
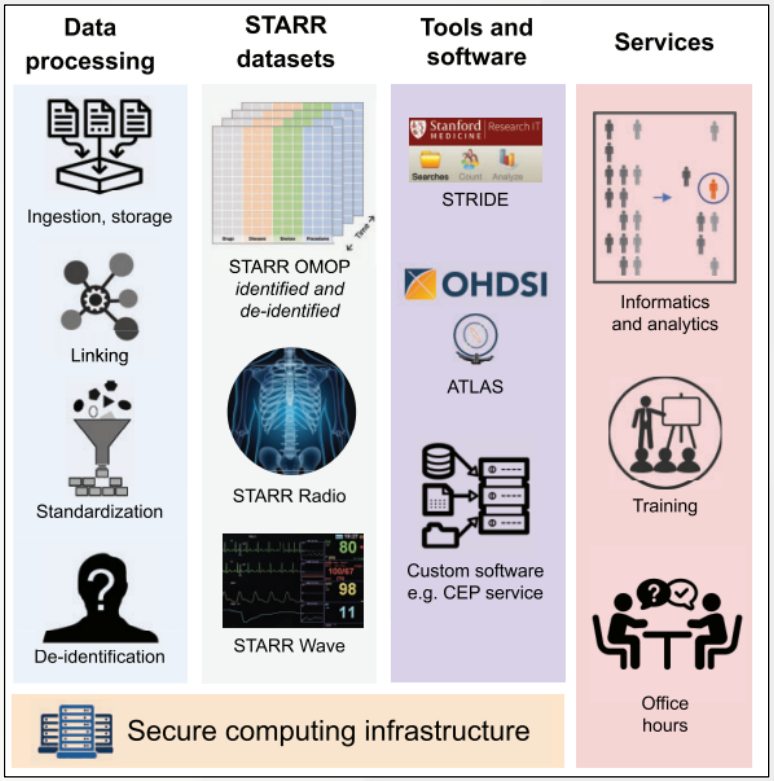


Figure S1: Data governance for the STARR-OMOP dataset

Datta S et al. arxiv 2023



Callahan A et al. JAMIA 2023

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Summary

- Carilion values external collaborations with partners like VT.
- Carilion is governed by regulations surrounding sharing of Protected Health Information.
- Carilion has implemented processes, policies and a secure research environment (Sparc) to enable safe and appropriate data sharing to empower our researchers while protecting our patients. We all share this responsibility.

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Summary

- Sparc provides powerful analytics tools and compute with massive storage in a secure research environment and continues to evolve its offerings.
- Sparc continues to evolve and expand to meet the needs of our researchers.

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