Pursuing Research with an External Collaborator

June 6, 2018

CARILION CLINIC

Course Objectives

- How to foster/ initiate collaborations with an external partner
- The necessary contracts to initiate working with an external partner
- How to share data and reagents with an external partner
- How to define a research collaboration from an independent contractor arrangement

Why Collaborate with an External Partner

- Collaboration Drives Innovation
  - Watson and Crick
  - Brown and Goldstein
  - Procter and Gamble
- Translational Research Opportunities
  - Bench to Bedside
- Professional Development
  - Increased publication and funding opportunities

Mechanisms to Foster Collaboration

- Personal communication
- Poster sessions at conferences
- Literature reviews
- Professional Associations
- LinkedIn
- Networking through Colleagues
- Think Global, Act Locally

Steps to Pursuing Research with an External Collaborator

- Initiate conversation with external collaborator
- Complete Research and Development application completing section below:

V. Non-Carilion Collaborator Contribution, including Students (see details below)			
Name	**Role &Responsibility**	**Institution**	**In-Kind Contribution**
If your project has any non-Carilion collaborator or team member, including students and faculty from other institutions such as VT (including VTCRI & VA-MD Vet Med), VTCSOM, VCOM, LTC/Nursing facilities, etc. Please include a Letter of Intent and a Statement of Work, which can be downloaded at here. NOTE: Additional agreements may be required.			

Steps to Pursuing Research with an External Collaborator

- Carilion Clinic Research and Development Office will determine what agreement is appropriate for your research
  - Contract/ Agreement negotiation is performed by the respective research offices, not the investigators
    - These offices at other institutions may include Technology Transfer Office, Grants and Contracts, Clinical Trials Office or IRB
  - Contract/ Agreements are signed by Institutional signatory authority
    - Dr. Daniel Harrington is the signatory authority for Carilion Clinic

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Contracts and Agreements

- Receiving, sharing, acquiring or generating data requires an agreement or contract
  - Agreements where **confidential information** is exchanged include the following
    - Non-disclosure agreement (NDA)
    - Confidentiality Agreement (CA)
    - Material Transfer Agreement (MTA)
    - Clinical Trial Agreement (CTA)
    - Research Collaboration Agreement (RCA)
    - Independent Contractor Agreement (ICA)
    - Master Research Agreement
    - Certificates of Confidentiality

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Contracts and Agreements

- Agreements that may permit or prevent unspecified future uses of data or unspecified secondary uses of data
  - Data Sharing Agreement
  - Data Use Agreement (DUA)
  - Business Associate Agreement (BAA)

Contracts and Agreements

- Agreement often associated with a third party include the following
  - Service Provider or Data Storage Agreement (Cloud Storage)
  - Memorandum of Understanding (MOU)
  - Cooperative Research and Development Agreement (CRADA)
  - Consortium Agreement

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Contracts and Agreements

- Research Collaboration Agreement (RCA)
  - Contract between Carilion Clinic and external party stating the PI and sub-I (external party) wish to perform research per the terms of the agreement

Terms of the Research Collaboration Agreement (RCA)

- Performance
- Compliance
- In-kind contractor
- Period of performance
- Termination
- IRB Approval
- Data and reporting
- Study monitoring
- **Publications**
- **Confidentiality**
- **Intellectual property**
- **Liability and Insurance Debarment**
- Use of parties name
- Modification
- Assignment
- Governing Law
- Notices
- **Signatures by Carilion Clinic and external parties with signature authority**

Statement of Work (SOW) Exhibit A

- Effective dates
- Name of all investigators and contact information
- Trial parameters
- Compensation (Generally zero)
- **Summary of Design (Roles and Responsibilities)**
- **Study milestones**

Health Insurance Portability and Accountability Act

- HIPAA applies to HIPAA “covered entities” and HIPAA “business associates”. In rare circumstances, a researcher may be acting as a HIPAA covered entity if he or she is providing health care and conducting certain electronic transactions for which the Department of Health and Humans Services has developed a standard such as payment claims (i.e. billing Medicare). A researcher may also be subject to HIPAA standards if he or she is using or disclosing protected health information (PHI) on behalf of a covered entity. The terms under which such uses or disclosure on behalf of a covered entity are customarily set forth in a business associate agreement.

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Business Associate Agreement: Exhibit B

- Under the U.S. Health Insurance Portability and Accountability Act of 1996, a HIPAA **business associate agreement** (BAA) is a contract between a HIPAA-covered entity and a HIPAA **business associate** (BA). The contract protects personal health information (PHI) in accordance with HIPAA guidelines.
- Signed by officials of Carilion Clinic and external party

For more information:

https://www.hhs.gov/hipaa/for-professionals/covered-entities/sample-business-associate-agreement-provisions/index.html

Request for Access to Protected Health Information

- General Study information
- Type of Information requested
- **You will need to sign this document**
- If you do not have prior EPIC access you will need to complete the Access and Confidentiality Agreement
- **Once your protocol has been IRB approved, (Health Analytics Research) will submit request to TSG to grant you EPIC access.**

PHI contacts: Kristina Cooper

Institutional Review Board (IRB)

- Determine the IRB of record
- Is a reliance agreement in place
  - A reliance **agreement** (also called an **IRB** Authorization **Agreement**) is a document signed by two or more institutions engaged in human subjects research that permit one or more institutions to cede review to another **IRB**.
- Will a third party IRB be used (WIRB)
- If human subjects research, the institution that is the source of study participants is usually the IRB of record

Data Management

- Access and Collaboration
  - Minimal Necessary Principal (least privileges)
    - Be clear on personnel who will collect or work on the data (IRB Application and Statement of Work)
    - Whether data must be accessed remotely
    - DUA and data sharing agreement will state restrictions on data
    - How data will be used in the future; if so what measures, will be taken to meet assurances of privacy, security and confidentiality

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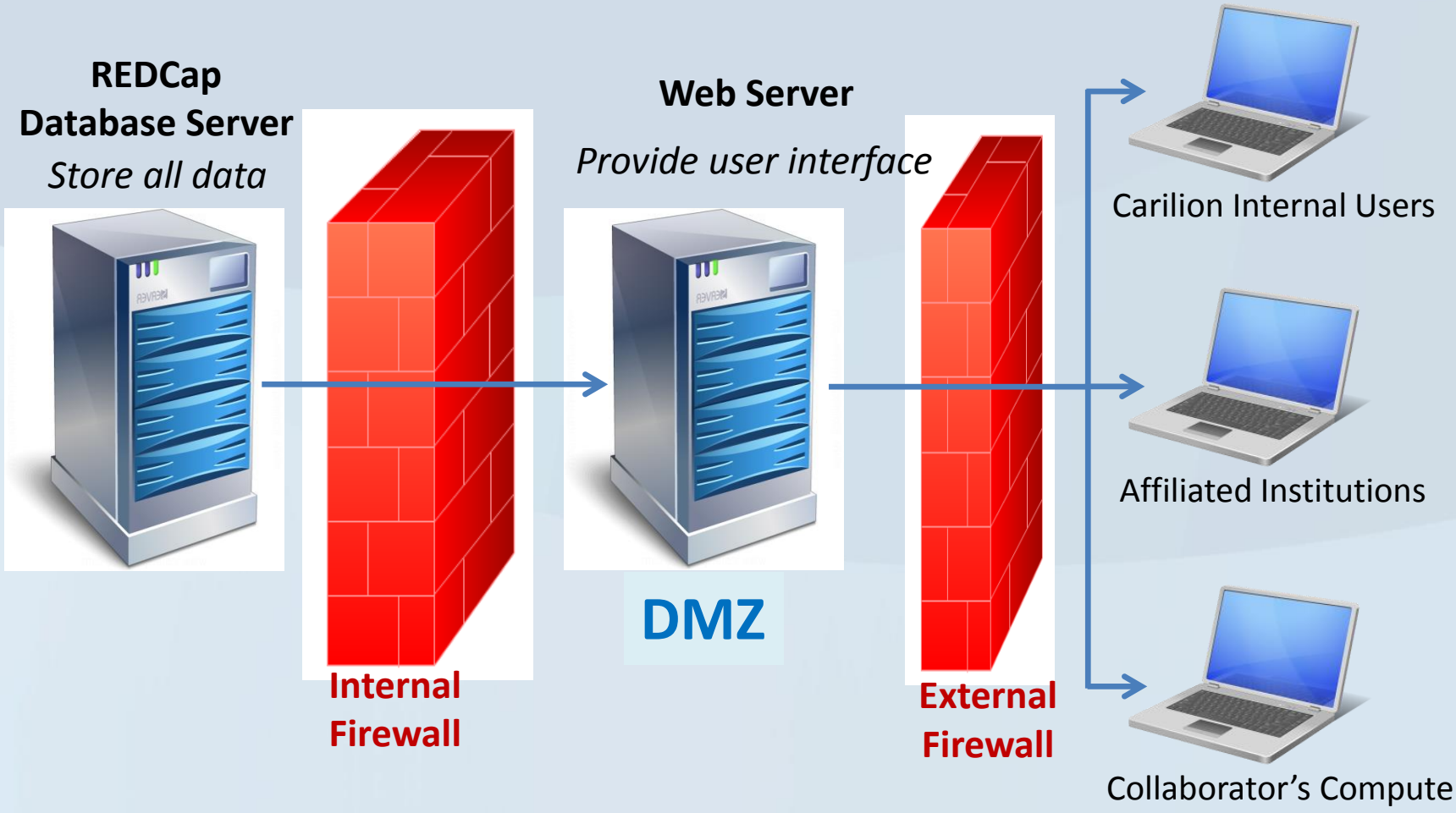
Data Management

- Storage and Backup
  - How is data sharing tracked and documented
  - Where is it stored
  - How is it protected
  - Can mobile devices be utilized
  - How is PHI stored by collaborator
  - Data backup plan
  - Estimated size of the database

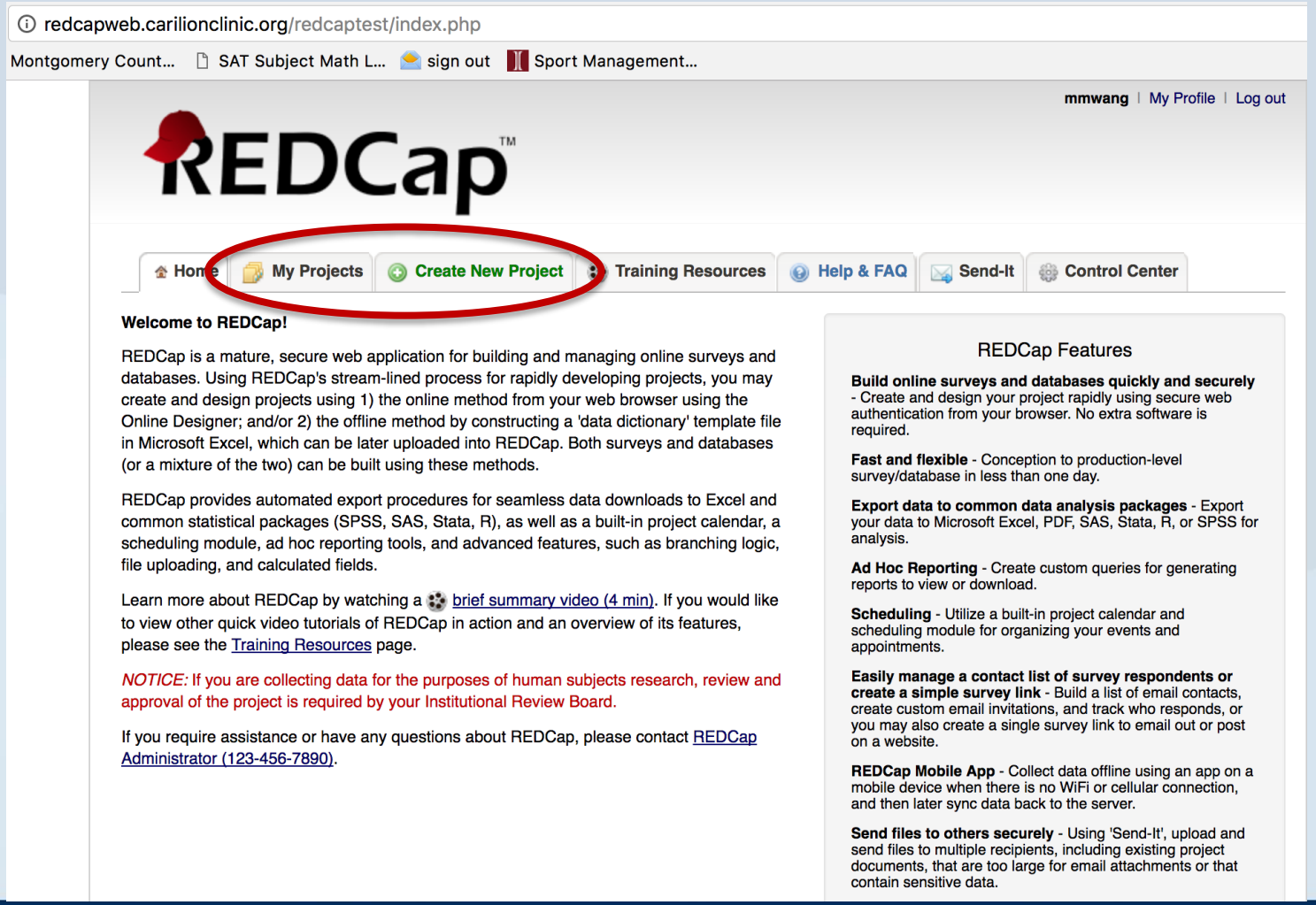
REDCap (Research Electronic Data Capture)
REDCap is a web-based tool for building and managing databases and online surveys. REDCap is used to collect virtually any type of data (including HIPAA-compliant environments) and can help you ensure data quality, efficiency, & study operations.

Some benefits of REDCap include:
quick, easy & flexible
online designer feature & forms library
can import excel csv data dictionaries
forms storage
secure on & offline data capture
multi-site access
Survey development and launch
full control to add new study users to projects
audit trails for tracking data entry & modification
project calendar for team operations

Carilion REDCap Infrastructure



Carilion Clinic REDCap



Carilion Clinic REDCap

- https://redcapweb.carilionclinic.org
- Min Wang, Health Analytics Research Manager will serve as site administer
  - mmwang@carilionclinic.org
- Mattie Tenzer, HART Director
  - mmtenzer@carilionclinic.org

Project Conclusion

- Retention
  - Identifiable data should be held for minimal amount of time necessary to conduct research
  - Corporate sponsored clinical trial will have a contractual obligations on data retention
- Disposal: Returning, Destroying and Archiving

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Reporting, Publication and Public Access

- Before submitting or publically disclosing you should ascertain if your data could be the subject of a patent filing
  - Invention Disclosure Form
- Check the information to authors section of the journal to insure you understand the requirements to publish in journal
- If data is placed on a public website, you may want to consider the impact if your data is combined with other publically available sources
- Publishing is expensive! Develop an agreement with your collaborator

Regulatory and Legal (Definitions)

- **Privacy Rule Requirements** - When the researcher is using PHI protected by HIPAA, then rules in addition to the Common Rule may apply.7 HIPAA governs uses and disclosures of PHI by a HIPAA "covered entity" which means a health plan, health care providers that electronically transmit data in a HIPAA transaction, and health care clearinghouses. (45 CFR § 160 and subparts A and E of § 164)
- b. **Permitted uses and disclosures** - Covered entities can use or disclose PHI for research purposes in the following circumstances (per 45 C.F.R. § 164.512(i)):
- o **Authorization**: The researcher obtained specific written authorization from the research participant. (45 CFR 164.508)
- o **Preparatory Research**: The researcher asserts that the use or disclosure of PHI is "solely to prepare a research protocol or for similar purposes preparatory to research, that the researcher will not remove any [PHI] from the [CE], and representation that [PHI] for which access is sought is necessary for the research purpose."8 (45 CFR 164.512(i) (1) (ii) of the Privacy Rule)
- o **Documented Approval**: An IRB or Privacy Board approves a waiver of research participants' authorization for use/disclosure of information about them for research. (45 CFR 164.512(i))
- o **Research of Decedents' PHI:** The research focuses solely on decedents' information. (45 CFR164.512(i)(1)(iii))
- o **Limited Data Set:** The CE and researcher enter into a data use agreement, pursuant to which the CE may disclose only a limited data set to the researcher for research, public health, or health care operations. A limited data set excludes certain direct identifiers of the individual, relatives, employers, and household members. The covered entity providing the data and research must sign a Data Use Agreement that "(1) describes the permitted uses and disclosures of the information and (2) prohibits any attempt to re-identify or contact the individuals." 9 (45 CFR 164.514(e))
- o **De-identified**: If PHI is de-identified the health information is no longer PHI or subject to the Privacy Rule. 45 CFR 164.514(a)-(c). A CE can always access, use and disclose for research purposes health information that has been de-identified in accordance with 45 CFR 164.502(d), and 164.514(a)-(c) of the Rule without needing to follow the Privacy Rule. Data can be identified either through (1) stripping certain specified elements from the data, or (2) having an expert determine through statistical analysis that there is a "very small" risk that an individual could be identified based on the data.
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- c. **HIPAA Waivers -** If your research involves PHI, it may be eligible for a waiver of the requirement of authorization but such waivers must be reviewed by an IRB or Privacy Board. Check with your IRB.
- d. **HIPAA Security Rule** - The HIPAA Security Rule (45 CFR Part 160 and 164, subparts A and C) establishes national standards to "protect individuals' electronic personal health information that is created, received, used or maintained by a covered entity."

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