THE UCLA CLINICAL AND TRANSLATIONAL SCIENCE INSTITUTE

HONEST BROKER SERVICES AND DATA ACCESS

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www.ctsi.ucla.edu ▪ bringing CTSI innovations to the greatest health needs in Los Angeles
Data Access History: Clinical Data Request Tools

Before CareConnect and CTSI circa 2010

- CareConnect / xDR (OHIA)
  - 2013-14

2015
- i2b2
- UC-ReX

2016
- LADR (UCLA, Cedars)

2017
- LADR (added City of Hope, USC, CHLA)

2018
- ACT
- ATLAS (UCLA IPH) Genome sequencing

2019
- DDR (OHIA)

2020
- UC Health Data Warehouse (UCOP)
- UC CORDS
- ULEAD (OHIA)
- N3C (NIH)
- SlicerDicer (OHIA)

2021+
- UC CORDS
Managing UCLA Health Data

Best Data Management Solution

- ULEAD
- REDCap
- HIPAA-Safe Server/Box
Data Workflow Re-engineering: Compliance Fast Track Approval
• **Compliance does not need to review** since not considered a data release if access is just by UCLA investigators [Data can not leave ULEAD]

• **IRB does not need to review if De-identified or Limited Dataset** since it would not be considered human subjects unless it is a rare disease.

Phase 1 will allow the following activities:

**CTSI**
1. Ability to provide data to researchers in ULEAD (flat files)

**Researchers**
1. Ability to copy data provided by CTSI into a User Folder within ULEAD
2. Ability to bring other data into ULEAD
3. Ability to connect to approved data sources
4. Ability to blend data from CTSI with other data sources. E.g. Cancer Registry, images, etc.
5. Ability to load data into a database (Microsoft Access)
6. Ability to analyze and visualize data
7. Limited ability to develop, train and test ML models
8. Ability to summarize results and prepare reports/graphs
9. Ability to share summarized data with the UCLA Health research community, within ULEAD

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**ULEAD Specifications**

Phase one of the ULEAD platform will offer each user the features listed below, and will support 250 concurrent users.

- Virtual Desktop: Compute: 4 CPUs (10~ GHz), RAM: 32 GB. Can be increased on a case-to-case basis
- Database: MS Access
- Software: Python, R, SQL Server, SAS
  - For licensed software such as SAS and MATLAB, users must bring their own license
- Personal Storage: User Folder within ULEAD. 50GB+ storage
- Collaboration: Team Folders within ULEAD
- Data Transfer In & Out: Data Transfer Folders within ULEAD
- Internet access: Websites approved by OHIA
- Interfaces: Allowed with approved databases and applications
Compliance Fast Track Pilot

Low Risk
1. Consent Given (any type of data)
2. De-identified data <100,000
3. Limited Data <100,000
4. Identified (Locked Down)
5. Identified <500

High Risk
1. High Volume >100,000
2. PHI >500 (not locked down)
3. Sensitive Data

Risk-Based Decision Tree
- Low Risk → Pre-Approved
- High Risk → Data Provisioning

Review of Protocol/Consent
- Yes
- No

Data Use Agreement+
- Data Handling

Consent
- Yes
- No

Scientific Review
- Value

Request Form Submission

Low Risk
1. Consent Given (any type of data)
2. De-identified data <100,000
3. Limited Data <100,000
4. Identified (Locked Down)
5. Identified <500
1. Mental Health Disorder
2. Eating Disorder
3. Substance Abuse Disorder
4. Sexually Transmitted Disease (including HIV)
5. Child Abuse
6. Domestic Abuse
7. Sexual Abuse
8. Abortion
9. Transplant Donor-Recipient
10. Adoption
11. Financial Billing Data

Less Sensitive:
- De-identified/Limited Dataset
- Recreational use in Social History Fields
- Global Problem List, Past Medical History, or Diagnosis Fields
Decision Tree

- Research
  - Identified
    - Non-Consented
    - Consented
      - Internal
        - Sensitive
        - PHI Locked or <500
          - Not Sensitive
          - Sensitive
  - De-Identified or Limited
    - Non-Consented
    - Consented
      - >100,000 or Sensitive Data
      - Internal Data Sharing
      - Internal
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### Risk Assessment

1. Identified
   - Locked or <500
2. Unconsented
3. Sensitive
4. Large #
5. External sharing

Risk Assessment
Chair Attestation:

The above Principal Requestor:

☒ is in good standing to perform the proposed project associated with this data request; and
☒ has the resources and capability to manage the data being requested.

By signing this attestation, the Department/Division will be responsible to ensure the above Principal Requestor adheres to this Data Use Agreement and will share in the financial responsibility associated with a data breach that stems from a violation of this agreement.
Fastest – preset data (top 100-150 data elements)
Faster – preset data + additional pre-programmed data element
Fast – All pre-programmed data elements

Slow – Custom request of well defined data
Slower – Custom request of ill defined data
Slowest – Custom request of ever changing and non-defined data