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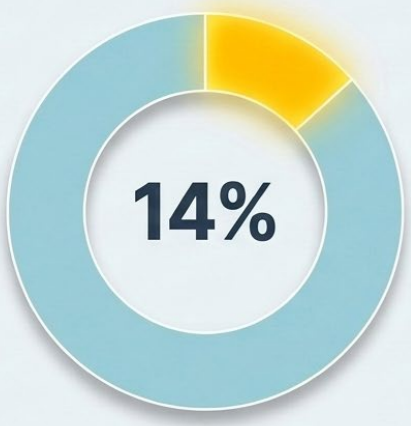
UCLA Technology Development Group RIA Monthly Training Seminar Series: Health Data Governance and HDOC Data Use Agreements

What is a DUA?

A Data Use Agreement (DUA) is a contractual agreement, between the “provider” of the data and the “recipient” of the data, used for the transfer of non-public data, or data that is subject to some restrictions on its use (i.e. HIPAA and/or Security Requirements).

Complete DUA execution matrix and historical footprint

Fiscal Year	HDOC-Related	Standard	Grand Total
2025	34	191	225
2026	42	278	320
Grand Total	**76**	469	**545**



Over the two-year tracking period, HDOC requests represented a stable 14% (76 of 545) of total executed agreements.

Why are DUAs Needed?

- Ensures that both parties agree and understand the conditions under which the data is being provided, such as:
  - Purpose for which the data may be used
  - Use of Results
  - Publication Rights
  - Destruction and Security Requirements
  - Specific Terms/Protections for certain data types (e.g. UCLA Health Data)
- Protects the investigator and the Institution from any liability arising from the way a recipient uses the data

TDG Intake Process for DUAs

https://tdg.ucla.edu/ucla-researchers-innovators/receipttransfer-materials-data

Submit Request for the Receipt or Transfer of Materials for Research Purposes

SUBMIT AN MTA

Does your request contemplate making available or otherwise transferring “UCLA Health Data” (defined below) to a “Third Party” (defined below) outside of UCLA Health? *

If YES, upload your approval from UCLA’s Data Release Subcommittee or Health Data Oversight Committee, as the case may be, at the end of this request form. If you DO NOT have written approval from UCLA Health Data Oversight Committee, please submit your request to UCLA HDOC in parallel to this submission. UCLA Health Data Oversight Committee can be found at https://www.ctsi.ucla.edu/researcher-resources/pages/third_party.

"UCLA HEALTH DATA" is any information pertaining to the health, care, and treatment of UCLA Health patients or health plan members which:

(1) results in a report used in treatment or monitoring of a patient; (2) generates a claim or a bill for services that are provided; or (3) is used for operations, financial management, population health activities or quality metrics.

Honest Broker

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- Data Steward whose role is to facilitate the exchange and sharing of data in research and healthcare
- Primary responsibilities are to ensure privacy, security and ethical use of data
- Data honest brokers are important in contexts where sensitive or personally identifiable information is involved, such as healthcare, genetics and social sciences research
- Data honest brokers help balance the need for data driven insights and research with the essential goals to protect individual privacy and maintain data integrity

UCLA Definition of Health Data

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Any information pertaining to the health, care and treatment of UCLA health patients or health plan members which:

1. Results in a report used in treatment or monitoring of a patient
2. Generates a claim or bill for services that are provided
3. Is used for operations, financial management, population health activities or quality metrics

* De identified data is still health data if it meets the above definition.

Clinical Data Releases

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- UCLA Faculty may establish Third Party Health Data Agreements with any for profit or not for profit entity outside UCLA Health.
- Agreements allow Faculty members to partner with Third Parties and Share UCLA Health Data for projects that have the potential to improve human health and benefit society
- Collaborators and Study Teams should be able to explain the amount of data, type of data, the source of data needed and how it will be used.
- Collaborators must adhere to the Third Party Mandated Contract Terms
- A material transfer agreement (MTA) or Data Use Agreement (DUA) is a written contract entered into by the Faculty member and a recipient of research material that governs the transfer of tangible research materials and data between two organizations.
- Agreements can only be signed by TDG, OCGA or Vice Dean of Research

HDOC Review

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- **Recipient/PI**: Conflicts of interest, competes against internal research efforts
- **Purpose**: Why is the data being shared? How is the data being obtained?
- **Type of Data**: Health vs Research, Identified, Limited or De-identified
- **Consented**: Yes/No; does the consent specifically name the recipient?
- **Source**: Retrospective, Prospective, EHR, Images, Specimens
- **Data**: Cohort and specific data elements to be shared
- **Amount**: Number of unique subject records
- **Funding**: Cost recovery
- **Benefit**: Clear statement of the benefit to UCLA and the benefit to the recipient
- **Exemptions**: Provide requests to mandated terms early to prevent delays in agreement negotiations.

UCOP Mandated Terms for Data Sharing

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Key Terms

- Only de-identified data should be provided to the recipient
- Re-identification of individuals is prohibited
- If a multi-campus dataset, only UCLA data can be provided to the recipient
- High Risk Datasets, includes HIV, Hepatitis, Psychiatric Illnesses, Substance Abuse Treatment, Lab Results for Drugs of Abuse, Sexual Orientation/Gender Identity, Genetic Testing Results shall not be provided to recipient
- University shall retain ownership of any rights it may have in the Data and Recipient does not obtain any rights in the Data other that the right to use the Data for purposes contemplated under the Agreement.
- Data to remain at the University to the extent feasible.
- No Monitoring or Auditing of Data

Third Party Mandated Contract Terms

UCOP Mandated Terms for Data Sharing

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Key Terms

- Publication required
- Machine Learning or Artificial Intelligence will not be used to re identify subjects or used to train a classification algorithm.
- No subsequent use or disclosure
- Data destruction required
- Compliance with law and policy.
- Indemnification*
- Insurance*

* *Exemptions for these terms can only be provided by risk/legal team*

Third Party Mandated Contract Terms

Documents Needed

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- Please ensure you have the following documents ready for your HDOC submission:

1. IRB approval or exemption notice
2. Protocol that describes the projects objectives
3. Informed Consent Form (if applicable)
4. Case Report Forms or Data Dictionary
5. CIRC letter (if applicable)

Release Workflow

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Task 1: Study team submits a Data Release Ticket Data Releases | Clinical and Translational Science Institute and in parallel submits a Material Transfer Agreement (MTA) to TDG.

Task 2: Consultant sends study team a Qualtrics survey, study team completes the survey, requests any exemptions to the mandated terms and provides requested documents

Task 3: Consultant reviews Qualtrics, and Associated Documents and may meet with study team for clarifications

Task 4: Consultant facilitates submission to all necessary committees, AI/ML sub-committee, HDOC, IT oversight groups (Risk, OHIA etc)

Task 5: Consultant creates an internal data use agreement (DUA) that aligns with committee's recommendations and circulates for signatures

Task 6: Consultant issues HDOC approval letter with signed internal DUA to study team and contracting office (TDG/OCGA). This letter notes that TDG will work with study team to put in place an External DUA. Both an Internal and an External DUA is required for the data transfer.

Task 7: Ticket Closed

Best Practices

- Review the Mandatory Terms with Sponsor and ensure that you have submitted any required requests for exemptions to HDOC prior to HDOC's review
  - Be aware of common terms in DUAs which require exemptions:
    - Data Destruction Timelines for Registry Agreements
    - Sensitive Data
    - Use of AI
- Submit the HDOC and TDG requests in Parallel
- Both an External and an Internal DUA is required. The External MTA may be an SRA.
- UCLA Health Data transfers to other UC Campuses require a DUA and HDOC review.
- Submissions of UCLA Health Data to certain NIH designated data repositories (e.g. NCI, NCBI/dbGap) do NOT required HDOC review and approval, provided the data submission application includes the following additional terms:
    - Publication Required: Requestor agrees to make results of studies using the data available to the larger scientific community.
    - Collaboration Required: Requestor must provide a letter of collaboration with the primary study investigator(s).
    - Not-for-profit Use Only: Use of the data is limited to not-for-profit organizations.