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Third Party Health Data Agreements – Mandated Contract Terms

This document identifies terms that must be included in any contract with a third party involving the use by that third party of Health Data acquired and maintained by UCLA Health. A third party is defined as any for-profit or not-for-profit entity.

Health Data is defined as 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; and/or (3) is used for operations, financial management, population health activities or quality metrics.

Prospectively-collected clinical research data and related research results will not be considered Health Data if these data are collected/created exclusively for a sponsored research (“Sponsored Research Data”); however, Sponsored Research Data that appears in the patient’s medical record is Health Data. (The use of Sponsored Research Data may be subject to contractual and regulatory obligations; release of Sponsored Research Data to any entity other than the sponsor of the study must be reviewed in advance by the Clinical Trials Administration Office.) Non-health data is all other data collected at UCLA Health.

UCLA Health requires that any third party use of its Health Data results in a tangible outcome that directly or indirectly benefits UCLA Health’s own patients and society, in general.

The interested third party must be agreeable to the following terms:

Health Data Use: The Interim Operating Guidelines Based on the Report to the President of the Ad Hoc Task Force on Health Data Governance (the “Interim Guidelines”) outline required agreement terms, which should be consulted. They are summarized as follows:

1. **Purpose must advance public benefit:** Access to and exchanges of Health Data must advance an articulable public benefit that is defined in advance of the transaction. Exchanges of any Health Data must not be solely for financial gain. The purpose of the exchange of Health Data must be set forth in the contract, and such purpose must further the University’s mission. Health Data cannot be “sold” as described in the cost recovery section below.
2. **Sharing of data must be non-exclusive:** The contract may not prohibit or otherwise limit the use of the Health Data by the University of California (UC) for any research, patient care or educational purpose for any time period, nor restrict the right of UC to enter into transactions, contracts and collaborations with other third parties. UC must continue to own any Health Data provided to a third party.
3. **Health Data must be de-identified and not include Protected Health Information:** Only de-identified Health Data (de-identified under the HIPAA standards per UCLA Health policy) may be shared. Exceptions to this mandate must be reviewed by the University of California Office of the President (UCOP), per the Interim Guidelines.
4. **Re-identification of individuals is prohibited:** The Health Data, either alone or in combination with other data that is or may become in the possession of third party, cannot be used to (i) identify any individual; or (ii) build or contribute to a consumer or other profile database. The third party shall not knowingly attempt to contact any individual whose de-identified data has been provided to the third party.
5. **Special approval is required for high-risk datasets:** high risk Health Data may be not be shared, including HIV, hepatitis, psychiatric illness, substance abuse treatment, laboratory testing for

drugs of abuse, sexual orientation and gender identity, and genetic tests. Exceptions to this mandate must be reviewed by UCLA counsel. If sharing of high risk Health Data would trigger potential for heightened public concern, harm to UC trustworthiness, or confusion among patients or the public, exceptions to this mandate also must be approved by the UCOP, per the Interim Guidelines.

6. **Approval is required for multi-campus datasets:** Only UCLA Health Data may be shared. Exceptions to this mandate in which Health Data from more than one UC health campus are requested must be reviewed by UCOP, per the Interim Guidelines.
7. **Data destruction required:** Within 30 days of the termination, cancellation, expiration or other conclusion of the agreement, the third party must permanently delete and destroy the Health Data provided unless UCLA determines, in its sole discretion, that deletion or destruction is technically impossible or impractical, and thus the third party shall continue to protect the Health Data in accordance with the terms of the final agreement. The third party must maintain strict access logs and provide UCLA Health the ability to audit these logs.
8. **No subsequent data use or disclosure is permitted:** Health Data cannot be resold, transferred, or reused for any other purpose other than what is outlined in the agreement with the third party. This includes affiliates of the third party.
9. **Publications:** When UCLA faculty and/or UCLA employees are involved, publications derived from the use of the Health Data must include UCLA authors and contribute in a meaningful way to improving the health of our patients and society. UC must also retain the unrestricted right to publish the Health Data provided to the recipient.
10. **Data to remain at UC to the extent feasible:** To the extent feasible, projects using Health Data are encouraged to be conducted within UC's HIPAA-secure environments, rather than through external transfers of large data sets outside UC. This practice of "bringing code to the data" enhances logical control over UC health data and may mitigate concerns over downstream use of data by third parties.
11. **Projects involve machine learning/artificial intelligence and/or the transformation for Health Data require special terms:** These projects require special definitions and attention to UCLA's rights to and control over data has been extracted and transformed by a third party for ingestion in their systems, and intellectual property in any data transformed from Health Data. See Interim Guidelines for guidance.
12. **Compliance with law and policy:** The contract should anticipate the creation of future UC guidance and policy, as well as any laws or guidance of government agencies, regarding the exchange of Health Data and allow for renegotiation of terms. The parties should either agree to negotiate in good faith to amend the terms of the agreement in the event of such new or amended UC policies, laws or regulatory guidance, or the term of the agreement should be relatively short (e.g., one to two years) to reduce the risk to UCLA.

Cost Recovery:

1. **Faculty and/or UCLA Employees Direct Costs:** Direct costs related to faculty and/or staff time (percent of their FTE) spent on the project must be covered by the third party.
2. **Indirect Cost Recovery:** Full indirect costs must be covered by the third party along with the direct costs of the project. Full indirect cost recovery means applying the federally-negotiated on-site research rate (currently 56% of the modified total direct costs (MTDC)) in effect at the time of the project. Any exceptions to full indirect cost recovery must be approved by the Vice Chancellor for Research.
3. **Data Preparation and Processing Costs:** Costs related to identifying and preparing the health data must be covered by the third party.

4. **No “Sale” of Health Data:** Other than the cost recovery outlined in this section, and the Data Infrastructure Cost outlined in this next section, UCLA may not receive direct or indirect remuneration for Health Data.

#### Value to UCLA Health and Society

TDG will be charged with securing appropriate consideration for the contemplated commercial use of the Health Data that will be licensed in the agreed upon partnership with UCLA faculty and/or UCLA employees. Determination of the appropriate commercial terms will be informed by input from the Health Data Oversight Committee (HDOC) taking into account the significant investment by UCLA Health in the technologies and infrastructure required to capture, aggregate, store, and secure health data (“Data Infrastructure Cost”), as well as the type of Health Data to be licensed and the use of that Health Data by the third party. Such consideration may take the form of one or more of the following:

1. **Access** by UCLA Health without cost to any products developed using the Health Data.
2. **Ownership** by the Regents of the University of California of any intellectual property derived from the Health Data.
3. **License** by UC to use “transformed” data for UC research, patient care or educational purpose.
4. **Payments** to the Regents of the University of California for the use of the Health Data or on the sale of products derived therefrom, as consistent with these mandated contract terms.
5. Other financial consideration as reasonably negotiated.

#### Liability

1. **Indemnification/Insurance:** The third party must agree to UCLA standard indemnification language and insurance requirements.
2. **License and Data Use Agreement:** The third party must agree to sign an appropriate license negotiated and executed by the Technology Development Group incorporating UCLA Health’s data use terms and conditions. Violations by the third party would be subjected to penalties.

If required, institutional review board (IRB) and conflict of interest (COI) reviews must be completed prior to the execution of any third party agreement.

#### Approvals:

Vice Chancellor, UCLA Health Sciences  
Chief Information Officer, UCLA Health Sciences  
Chief Health Sciences Counsel, UCLA Health  
Deputy General Counsel - Health Affairs & Technology Law, UCOP  
Chief Strategy Officer, UC Health  
Assistant Vice Chancellor for Research, UCLA