Health Data Oversight Committee (HDOC) Charter and Membership

This document serves as the charter for the Health Data Oversight Committee (the “HDOC”). The HDOC reports to the Vice Chancellor, Health Sciences, and is chaired by the Chief Information Officer, Health Sciences. The Chancellor has designated the Vice Chancellor, Health Sciences, as the Chancellor’s designee for purposes of making decisions consistent with the Interim Operating Guidelines Based on the Report to the President of the Ad Hoc Task Force on Health Data Governance (the “Interim Guidelines”).

Committee Responsibilities:

- Make recommendations to the Vice Chancellor, Health Sciences on contracts involving health data with third parties (any for-profit or not-for-profit entities) by determining if a proposed relationship provides significant value to UCLA Health and society, determining that the contract meets mandated contract terms, and exercising oversight over the process for agreement negotiation and approval.

- Determine significant value to UCLA Health and society:
  - Attention to the University’s Unique Responsibility and Mission: The University’s mission is to create and share knowledge and to serve the public. Our mission requires us to use and share data responsibly and strategically. UC must have a strategy that safeguards data, uses data to broadly benefit the public, and ensures just distribution of benefits and burdens of data sharing.
  - Justice: The University recognizes that there are significant inequalities in our society and in the American health care system. In an unequal society, developing a legitimate conception of the public good requires authentic, sustained, dynamic engagement with the public, including building adaptive mechanisms to ensure that under-served and disenfranchised communities participate in setting the health research, clinical and policymaking agendas.
  - Active Stewardship: We must carefully and responsibly manage data collected in the course of caring for our patients. We will apply professional skepticism and rigor in assessing the promised benefits of any use of Health Data. We recognize, however, that key advances in medicine and health care increasingly depend upon the creation and analysis of large Health Data sets. Consistent with our mission, we have a duty to proactively use and share such data to promote improvements in human health and wellness, breakthroughs in medicine and public health, and improvements in the quality, cost, and access to health care for all. We must also seek to share data, both within UC and beyond, with those who will apply the most advanced and rigorous scientific approaches and who will share those outcomes (both successes and failures) to the benefit of UC patients and society at large.
  - Trustworthiness and Patient Engagement: In fulfilling the University’s mission, our data practices and procedures must be worthy of the public’s trust. The University should empower patients by promoting their access to and understanding of Health Data about them, and give them the opportunity to share their data for research of their choosing. Data subjects should participate in the development of governance of clinical data, including how it is used, collected, and disclosed by the University. The University should be transparent about its activities involving data, including what we’ve learned; the benefits our data use has or has not produced; and how our learnings or outcomes can impact patients and the public. We recognize that our governance must be adaptive over time to reflect evolving technology, science and public policy.
Sharing Clinical Data outside UC for Public Benefit: The University must collaborate with others to create new knowledge and benefit the public. This means partnering with all sectors, including non-profit, for-profit and government entities. The University must articulate a clear public benefit in any arrangement in which clinical data is shared outside of the University, especially for commercial transactions. Financial gain and commercial development, by themselves, are not a clear public benefit.

Promoting Alignment and Collaboration: UC is a single University. The University should ensure that a particular data sharing arrangement with an outside party does not unreasonably foreclose other arrangements or projects involving the same clinical data or outside party. The University must also ensure that its agreements do not prevent the use of data to advance its broader mission, including aggregation and/or sharing of University data.

- Ensure that the agreement meets the terms identified in the Third Party Health Data Agreements – Mandated Contract Terms document. All contracts with a third party involving the use by that third party of health data acquired and maintained by UCLA Health must meet these terms (unless an exception is granted under the terms set forth below).

- Exercise oversight over process for agreement negotiation and approval:
  - Potential relationships are first received (via the Data Release Request) and vetted by the Data Release Subcommittee (DRS) of the Data Strategy and Governance Committee, which reports to the UCLA Health IT Steering Committee. This committee will specifically evaluate the relationship for the following:
    - Conflict of Interest
    - Dataset De-identification
    - High-RiskDatasets
    - IRB Needed/Approved
    - Multi-Campus Datasets
    - Data Management
  - The Data Release Subcommittee will refer the following to the University of California Office of the President (UCOP), per the Interim Guidelines: (i) arrangements that propose sharing patient-identifiable data (protected health information under the HIPAA standards); or (ii) arrangements where there is potential for heightened public concern, harm to UC trustworthiness, or confusion among patients or the public, including the use of extremely sensitive data.
  - Once vetted and approved by the Data Release Subcommittee (and UCOP, where applicable), a contract will be drafted and negotiated by the UCLA Technology Development Group (TDG), with specific attention to the following:
    - Direct Costs
    - Indirect Costs
    - Data Preparation and Processing Costs
    - Value to UCLA Health and Society
    - Indemnification
    - License & Data Use Agreement
  - The negotiated contract is then reviewed by the HDOC with a proposed turnaround time for a recommendation of two business days.
    - If the HDOC determines that the relationship will provide significant value to UCLA Health and society, and if the agreement meets the terms required in the Third Party Health Data Agreements – Mandated Contract Terms document, the
HDOC will make a recommendation to the Vice Chancellor, Health Sciences to execute the agreement (subject to UCOP approval noted below).

- If the HDOC determines that the relationship will NOT provide significant value to UCLA Health and society, the draft contract does not move forward and further negotiations with the third party are terminated.
- If the HDOC determines that the relationship will provide significant value to UCLA Health and society if the project is modified, or if the agreement does not meet the terms required in the Third Party Health Data Agreements – Mandated Contract Terms document but may still be renegotiated, the HDOC will communicate required modifications to TDG to allow renegotiation of the contract terms with the third party. A revised contract is then returned to the HDOC for review, which then may make a recommendation to the Vice Chancellor, Health Sciences to execute the agreement (subject to UCOP approval noted below).

  - Exception process: In the event the relationship will provide significant value to UCLA Health and society, but the third party will not agree to the Third Party Health Data Agreements – Mandated Contract Terms, the HDOC or its designee may seek an exception from the Vice Chancellor, Health Sciences to execute the agreement.
  - Required approval by UCOP: For multi-campus projects, final decisions will be made by the Chancellors (or their designees) of the campuses involved, and the Executive Vice President of UC Health.

HDOC will review any arrangement that involves the following:

  - The provision of “Health Data” to a third party. 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.

HDOC will not be required to review the following arrangements:

  - 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 study (“Sponsored Research Data”), with the exception that 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, but are not subject to HDOC review).
  - Revisions to proposed or existing arrangements that have previously been approved by the HDOC, unless revisions would affect the evaluation of significant value to UCLA Health and society, as set forth above.

The HDOC will always act in the best interest of our patients and society when evaluating relationships involving Health Data with third parties, and thus has the option to seek patient input on data use if deemed necessary.

Committee Logistics:

The HDOC will begin with an in-person kickoff meeting. Subsequently, the HDOC will meet on an ad hoc basis when a draft contract requires review. As such, a phone meeting will be scheduled immediately in order to allow for the two business day turnaround. The draft contract will be provided to the

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committee members prior to the call. No later than 1 business day after the phone meeting, each committee member will complete a short electronic form outlining their recommendation. The committee chair will then compile the forms to determine the committee’s overall recommendation. The HDOC will meet in-person yearly to review/revise this charter, determine the successes/failures of various third party relationships, and review/revise any of the mandated contract terms.

Committee Members:

Chief Information Officer, UCLA Health Sciences (Chair)
Chief Counsel, UCLA Health Sciences
Chief Compliance Officer, UCLA Health Sciences
Ethicist
Chief of Communications, UCLA Health Sciences
Director, UCLA Clinical and Translational Science Institute
Chief Data Officer, UCLA Health Sciences
Chief Operating Officer, UCLA Hospital System
Senior Director, UCLA Health Research and Innovation
Vice Dean for Research, David Geffen School of Medicine
Professor, UCLA Anderson School of Management
Assistant Vice Chancellor for Research, UCLA

Referenced Documents:
1. Third Party Health Data Agreements – Mandated Contract Terms
2. Process Flow Diagram for Third Party Health Data Agreements Involving UCLA Faculty
3. Third Party Health Data Agreements – Data Release Request

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