Report to the President:

President's Ad Hoc Task Force on Health Data Governance

January 26, 2018 | University of California

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I EXECUTIVE SUMMARY

As a public research university, the University of California ("UC") has a duty to be as innovative and strategic in safeguarding patient data as it is in using it to advance science and clinical care. In 2017, we began formally considering new ways to govern health data, bringing together scientists, clinicians, ethicists focused on the patient perspective, privacy and regulatory experts, and IT specialists to brainstorm a path forward. This is the first report on our work, which was initially presented to the President in September 2017 and finalized in January 2018.

The entire University of California Health system will increasingly run on data—to more precisely tailor the right interventions to keep people well. In many cases, the technical capacity and infrastructure needed to reap the benefits of data use resides outside of universities and medical centers, including in private companies in which the public's trust is wearing thin. Like many of our peer institutions, academic medical centers at UC regularly consider opportunities to collaborate with external partners to help analyze the data produced during patient care. Of course this data is private and sensitive and must be protected. But it must also be carefully shared if we are to unlock its potential for the ultimate benefit of our patients, and the people of California and beyond.

Collaboration among all sectors—government, non-profit, and commercial institutions—holds the greatest promise for data-intensive research to yield tools for patients and health care providers to better predict, prevent and treat illness. This will require us to navigate a new level of ethical, legal and social complexity. We will need to chart carefully where, and how, we go from here. Otherwise, important research efforts will only provoke more mistrust from a public that is increasingly suspicious of the misuse of data.

The existing regulatory and legal framework is an inadequate guide through this new terrain. Current law allows health care providers to share health data in very controlled ways (for example, by anonymizing it) without patient consent, a practice that may still undermine patient trust. These same laws also limit larger-scale data efforts that could benefit patients and the broader public.

We believe that trustworthy data-intensive collaborations in health care turn on more than just privacy. They require an ethic of *justice.* A justice-based model demands community input to shape scientific and health goals. It also means that we will need to create novel strategies for genuine patient engagement. These issues are of particular concern to those underserved communities with the most pressing medical needs and burden of disease.

We must be active stewards of the patient data under our control to ensure that it serves the highest and best uses for the citizens of California and beyond. Building on the efforts of many

others, UC will seek to marshal its experts to develop a model that evaluates data sharing activities and partnerships in light of the benefits they deliver to patients and the public. Data analysis holds a key to advancing science, improving patient care, and promoting public health – and these goals cannot become the casualty of the current crisis in trust. We don't know the full scope of what advanced analytics can do with health data, but we will never find out if we fail to build productive relationships between those who generate patient data and those who know how to make use of it. Rather than shrink from the complexity and danger of this new terrain, we need to face these challenges head on.

Principles & Recommendations

With the preceding considerations in mind, the Task Force presents the following core principles and recommendations:

1. 6 core principles for strong data governance:
    1. Attention to the University's Unique Responsibility and Mission
    2. Justice
    3. Active Stewardship
    4. Trustworthiness and Patient Engagement
    5. Sharing Data Outside UC for Public Benefit
    6. Promoting Alignment and Collaboration

2. 3 foundational recommendations:
    1. Pioneer a patient-informed, justice-based model of Health Data use, and demonstrate the need for and benefits of more active data use.
    2. Establish a System-level Health Data Office to identify and accelerate projects and partnerships to realize the public benefits of collaborations to analyze Health Data.
    3. Develop criteria and a process for evaluating projects and transactions involving access to UC Health Data by outside parties.

3. 1 interim process to address immediate next steps for current efforts at the University.

The membership of the Task Force is set forth in Appendix A to this report. The process for accomplishing the Task Force Goals is provided in Appendix B. Other Appendices provide: use cases (C) and a glossary of terms and abbreviations (D).

A special thank you should be given to Deanna Geddie and Maria Vitulli for their project management support and our colleagues at other academic medical centers who shared their knowledge and suggestions. Thanks also to Patricia Deacon for her efforts on the graphics in the figures.

II OVERVIEW

Purpose

The Task Force's efforts were derived directly from the President's charge of April 25, 2017.

The Task Force was asked to produce recommendations addressing the following issues:

- ✓ Define the scope of health data.
- ✓ Develop a mechanism for determining how UC Health should balance the competing interests in access to its health data.
- ✓ Determine how the University should identify and monitor such potential competing interests among its various system-wide initiatives and across campuses, particularly multiple transactions involving the same industry partner and, potentially, the same health data.
- ✓ Determine how the University should address the ethical, regulatory, compliance, and reputational implications of sharing health data for use by or in partnership with third parties.
- ✓ Identify whether there are specific activities concerning the use and disclosure of health data in which UC clearly should not engage.
- ✓ Determine whether and under what circumstances the University and/or its medical centers may enter into collaborations with third parties where certain activities are not deemed sponsored activities that incur indirect costs.

As further described below, existing laws and UC policies do not address the kind of active data management we will need in this era. When weighing the benefits before embarking on data-driven efforts, the University needs a consistent, replicable framework that protects patient privacy and data security, enhances responsible partnerships with third parties, and successfully balances competing interests in health data resources.

The Task Force has developed guidelines to address these issues. Since the Task Force was given only a short, 90-day timeframe to accomplish this task, additional work must follow the efforts of the Task Force to allow experts to weigh in on specific aspects of the proposed recommendations and to develop policies and guidance pertaining to third-party agreements involving UC health data. Recognizing that this will take some additional time, the Task Force has proposed an interim plan to track and oversee proposed third-party UC health data agreements.

Scope

Why is Scope Important?

To understand how the principles and recommendations outlined in this report may apply, we must first define the "Health Data" that will fall within scope. Scope is also critical because the Task Force unanimously agreed that a governance framework must drive outcomes that are timely, effective, and consistent. Often, data can have multiple legal definitions, and those requesting access to data may report through various infrastructures across the University, including researchers who do not sit within UC Health. Clear definitions will limit ambiguity in decision-making about proposals relevant to Health Data and lead to efficient and timely governance processes. For all of these reasons, it is important to establish a simple and operational definition for Health Data.

What is Health Data?

The Task Force's recommendations will apply to projects and activities involving Health Data as further described below. Health Data includes two categories: Source Health Data, which is the primary and original data set, and Derived Health Data, which represents some transformation of the original source data.

Source Health Data is any information pertaining to the health, care, and treatment of UC Health patients and plan members which:

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

Derived Health Data is any derivation of source Health Data irrespective of how trivial or complex the derivations may be.

We also seek to clarify one possible area of ambiguity – clinical trials. For purposes of this report, research data created exclusively for a sponsored clinical research study pursuant to Institutional Review Board (IRB) approval and collected pursuant to a patient authorization or consent that is approved by the IRB is *not* Health Data. Disclosure of such research data to the sponsor would be governed by law and existing UC policy, ***not*** this proposed data governance framework. However, instances of such data that are contained in the medical record (in whatever form) ***are*** Health Data within the scope of this governance framework. In addition, clinical trial data that is considered excluded from the Health Data definition and out of scope, is limited only to the data acquired as part of the IRB-specified clinical trial. Any other Health Data associated with the subjects participating in that clinical trial will be considered Health

Data as defined above. Research data that is generated pursuant to a protocol that is exempt or excluded from full IRB review, or involves a waiver of authorization, will be considered Health Data and within scope of this governance framework.

What is Non-Health Data?

Broadly, all data not defined as Health Data falls outside of the scope of the Task Force's recommendations and is "Non-Health Data." We do note, however, that the boundary between Health Data and Non-Health Data is evolving, as the lines between research and clinical care continue to soften in the context of translational research. Use cases, with examples, to help illustrate different types of data sets and whether they would be considered Health Data or Non-Health Data are provided in Appendix D.

III OBSERVATIONS AND ASSUMPTIONS

It seems axiomatic by now that critical advances in healthcare and medicine will increasingly depend on data-driven insights. If the randomized clinical trial was the workhorse of twentieth century medicine, data might be the workhorse of twenty-*first* century medicine. Much data is generated in the course of clinical care and research activity and is now legible in a way it never was. It can be analyzed with machine learning and other advanced data analytics tools to generate new insights about disease, treatments, and quality of care. In this century, every healthcare organization, including UC, will consider data among its most significant resources.

But using Health Data at scale is fraught with paradox and potential controversy. This data is private and sensitive; yet, it must be analyzed at scale in order to unlock its breakthrough value. And analyzing health data at scale may involve sharing sensitive data with outside parties, including those that patients do not know or trust. This raises the potential risk that the third party may use the data in ways that are unpredictable or even offensive to those whose data is involved. These circumstances, as we have seen, can have a devastating impact on community trust.

Existing ethical and regulatory frameworks reflect this tension but do not resolve it. Our laws encourage nonconsensual sharing of Health Data in ways that may still undermine patient trust, and they also limit large-scale data-intensive efforts that may benefit patients and the public good and that patients might therefore support.

Broader shifts in the health care delivery system are intensifying this paradox. Today, we are shifting to a learning healthcare system, in which providers have a financial incentive to keep you well, rather than react to instances of sickness and disease. This new system depends on using data to continuously predict, prevent, and tailor interventions to keep people well.

While health care systems will run on data and advanced technical systems to continuously make meaning of it, we have no unifying approach to the difficult choices and tensions that we face. Consider a few:

Data-driven health research is said to benefit the public good, but whose public and whose good are being accounted for? What is the responsibility of a public institution in discerning the public good of data-driven health research?

- Data-intensive research and the learning healthcare system require marshaling data from a large, fragmented group of people. Some patients see little value in proposed uses of their Health Data, or object to sharing their data with certain partners or for certain projects. Yet, such data may be essential to the project. How do we build cohesion when there are differing values and standpoints among researchers, clinicians, and patients?
- When is it appropriate for a *public* institution to collaborate with a *for-profit* commercial partner to analyze Health Data collected in the course of publicly-funded clinical care?
- What about de-identified data? Even in scenarios where Health Data is lawfully used or shared to produce a broad public benefit (including when data is de-identified), sharing such data may still damage our reputation or undermine the trust of our patients and the public. Are such disclosures always wise?
- Inevitably, some promises of data-driven health research - the breakthroughs, the new treatments, disease prevention - may not pan out. How do we unlock the concrete benefits of data-intensive healthcare activities while filtering out the hype?

Current Ethical and Legal Frameworks Have Limited Value

We have tried to approach these issues with the necessary humility. We are not the first to consider the Gordian Knot of issues arising in the data-driven era of health care. Numerous clinicians, health systems, ethicists, regulators, and advisory groups have worked to address the dilemmas we have described here. However, these existing efforts, while trenchant, leave significant gaps and opportunities.

To begin, existing regulatory and ethical mechanisms do not resolve the fundamental tension between our duty to safeguard Health Data about our patients, and the emerging imperative to collect, analyze, and share Health Data on a large scale.

The current paradigm – informed by HIPAA privacy regulations and the Common Rule – simply does not contemplate the research and analysis currently made possible by large-scale data storage capacity combined with machine learning and other advanced analytics. For example, HIPAA permits de-identified Health Data to be disclosed or used without authorization from individual patients. But de-identified data is less useful for some research purposes, limiting the fruitfulness of some research. Moreover, providing a third party with access even to de-identified Health Data (including for-profit commercial entities) may damage the trustworthiness of a health system.

Many disclosures of patient-identifiable information, by contrast, require individual authorization. But seeking individual authorization for thousands or even millions of patients represented in a given record set is highly impractical, particularly long after the data was collected, and HIPAA rules limit individual authorizations for unspecified future research. An IRB may lift the individual authorization requirement for use of identifiable Health Data, but this practice concerns many patients and privacy advocates who may hold a principled objection to *any* use of Health Data without individual authorization. Moreover, the current system was not developed based on detailed patient and/or public input, so we really have little evidence of its acceptability to UC Health Patients.

The current paradigm truly satisfies no one: the existing mechanisms for data sharing may restrict data-driven initiatives that could yield significant public benefits, and these mechanisms are nevertheless insufficiently trustworthy from a patient privacy standpoint. Current regulations also fail to distinguish between privacy as an intrinsic value in itself – where its violation is a dignitary harm – and the importance of privacy and security as a means to prevent downstream actual harms, such as discrimination in employment or insurance coverage.

There have been numerous proposals to address the flaws we have noted above in the existing regulatory environment. Some suggest that Health Data should be expressly treated as patients' property. Proponents argue that individual patients should have granular, real-time control over Health Data and the right to individually authorize all, or nearly all, uses or disclosures of Health Data, including driving patient-initiated Health Data efforts. Some assert that technology will soon enable the quick and easy individual consent (e.g., via smart phone), boosting sharing and patient autonomy at the same time.

There is merit in this property-rights approach, especially the recognition that patients have a right to the Health Data about them and should be able to directly contribute those data to various research and other data projects. Indeed, patients' rights to their medical records are already enshrined in law. Our concern is that this approach may do little to forge the solidarity needed to realize benefits that only materialize at a group or societal level. As bioethicist Barbara Evans has explained, there are some benefits we may *enjoy* as autonomous individuals (such as a new cure or lower-cost care resulting from insights in large-scale Health Data

analysis) that we can only *realize* through sustained cooperation with others. For some collective benefits, we need to develop a governance model that fosters and catalyzes collective action among a large, fragmented group of patients who may not share a sense of what constitutes sufficient benefit to make sharing their data worthwhile.

We have considered several governance frameworks for Health Data developed at well-regarded health systems. Some require, even for de-identified data disclosures, that there must be foreseeable benefits from the proposed initiative and minimal risk to patients represented in the data set. This is a strong step in the right direction.

But the governance efforts we examined do not appear to directly engage patients in data governance at an enterprise level. It is quite possible that the definition of the public good, crafted in closed governance bodies may be a narrow one – and one that is not shared by the patients whose data are disclosed.

Build New Approach to UC Health Data Governance

We seek to borrow and build upon current efforts and debate to begin a new approach to Health Data governance at UC. We believe that the elusiveness of a meaningfully shared conception of the "public good" is a central problem in Health Data governance. As one scholar wrote, "whose good is being served" by a particular disclosure of Health Data, and who decides?

In this respect, we have found a critical missing element to existing law and data governance frameworks – there is no express concern with *justice*. We believe this holds the key to forging a mechanism for a shared vision of the public good, which can foster broader data sharing.

Data sharing does not occur in a social vacuum; it occurs within and is conditioned by an American health care system that is profoundly fragmented and unequal. Under-served and disenfranchised communities may not be represented in a large data set used to develop a breakthrough cure. Or, they may be highly represented, but do not participate in determining what kinds of public benefits ought to be pursued with such data, nor are they engaged and informed about whether the hoped-for benefits actually materialize. We observe that broad disclosures of Health Data can be perhaps too easily justified by invoking the "common good" and the "public benefits" of data sharing. Underscoring this point, in the approaches we surveyed, we did not identify a mechanism for dynamically engaging patients in an ongoing effort to define the kinds of public benefits that would support the creation or disclosure of large data sets. It is true that IRBs include a public representative. But our point is that there is no unitary "patient perspective" in a divided and unequal health care system.

To build solidarity about the benefits of data sharing and drive collective participation by data subjects, we must have a deep and dynamic commitment to meaningfully engaging

communities that have been traditionally marginal to the research and health policy agenda. We advocate for a justice-informed process for discerning the public good on an ongoing basis.

The primary hallmarks of a justice-informed approach to data governance should embrace direct and sustained patient engagement and ongoing attentiveness to social inequalities. Thus, the "public benefits" of data sharing should be defined by a process to elicit authentic input from the public, including medically underserved and disenfranchised communities, as to the types of use cases and outcomes that merit the broad sharing of Health Data. Transparency to patients and the public is also critical – both about the proposed and actual outcomes of data sharing efforts. A justice-informed approach will build public trust in the kinds of data sharing arrangements that will be necessary to unlock the breakthrough potential of large-scale Health Data research.
We note the special concerns that arise from collaborations with commercial partners. In recent high-profile cases, health systems have shared Health Data sets with for-profit companies, where the purposes and benefits of the agreement appeared unclear. Cross-sector sharing can be particularly problematic because protections are less clear in the consumer sphere, or when various data sets are merged and circulated.

We do not suggest that collaborations with commercial partners are necessarily improper. To the contrary, we see great promise in the responsible use of data to yield significant public benefits in health and wellness for society. We reject the idea that merely safeguarding data is responsible data stewardship. We advocate for a principle of "active stewardship," which *requires* engaging with all sectors to advance healthcare and medicine. We reject reflexive objections to partnerships on the sole basis that they involve private corporations. These partnerships may yield real public benefits, especially when private organizations offer advanced computing power or specialized expertise to assist with Health Data research.

At the same time, we also acknowledge the reasonableness of public concern about consolidating data into large institutions with undiscerned motivations for later uses of these data. Public concern is heightened when organizations seek to use data for profit or when it becomes apparent that a particular commercial entity is not a trustworthy steward of the data. We must combat the narrow, opaque process used to create private data sharing arrangements, where the goals of the partnership are balanced in private without reference to the complex interests and priorities of the data subjects.

To avoid the erosion of trust that can result from such arrangements, we advocate that any University Health Data sharing arrangement, including those using de-identified Health Data, requires an express articulation of the public benefits of the transaction ***before*** we share the data. Financial benefit alone does not constitute such a public benefit. Put even more simply, the University will not sell Health Data. We further underscore that direct and sustained patient engagement will help reduce the opacity that has undercut the trustworthiness of these arrangements.

We recognize that there is no off-the-shelf model for this kind of justice-informed data governance model, though there are relevant practices that have already developed in certain precision medicine and patient-centered research projects across the country. We recommend that the University spearhead, resource, and support a diligent effort to study and design a dynamic, sustained patient engagement strategy for data governance that is expressly focused on justice. Given our public mission; the rich, complex diversity of our State and the patients we serve; an inundation of technology companies around our campuses; and our own world-class expertise in data science, clinical care, research, and ethics, UC should be a pioneer in advancing the existing paradigm toward a justice-based model of Health Data use for the public good.

With the foregoing in mind, the Task Force has developed the following principles, which we believe should serve as a foundation for the University's approach to Health Data use going forward.

IV PRINCIPLES

All decisions governing access to and use of UC Health Data should be governed by the following principles.

1. 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.

2. 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.

3. 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 collaborate 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.

4. 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.

5. Sharing 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.

6. 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.

V RECOMMENDATIONS

RECOMMENDATION 1: Pioneer a patient-informed, justice-based model of Health Data use, and demonstrate the need for and benefits of more active data use.

Consistent with our proposed principles, we expressly acknowledge the justice imperative as a condition to drive needed collective action. We also believe in the wisdom of patients and the corresponding need to create new mechanisms to improve patient access to their clinical data, though we acknowledge there is much work to do in ensuring patient access to data and broader collective data sharing efforts. It is the responsibility of the University to develop innovative mechanisms to try to accomplish these goals – through development of novel methods and rigorous evaluation of their usefulness.

We, therefore, recommend that UC convene and invest in a team of our own experts to advance the development of a justice-based model of Health Data use at UC. This team will seek broad input from all constituencies, conduct research, and serve as thought leaders – to lead the conversation within UC and with outside stakeholders to seek answers about how best to use Health Data to benefit the public good, including:

- How do we inspire broad, collective action to share data for research?
- What are the most-promising areas of data-driven clinical research – how do we separate the real promise from the hype?
- What is the unique role and responsibility of a public institution in using and sharing Health Data?
- How do we determine whether data-driven health research benefits the public good – *whose* public and *whose* good are being served?
- How should the current regulations, including HIPAA and the Common Rule, change to account for current technological and scientific capabilities, as well as constantly evolving technology?
- What do patients want? In a fragmented health care system, with significant inequality, how do we effectively discern patient voices and standpoints? What do they deem to be beneficial and how can we share information with them in a way that is both meaningful and accessible? What are the best ways to find out?
- How should UC policies and practices change? How do we continue to evaluate and update them as we learn more?

As a first step, we recommend that this team convene a global conference of stakeholders from a variety of perspectives (including ethicists, scientists, other providers, health plans,

population health experts, other governments, and patient representatives) to discuss the ethics of data use and sharing and issues regarding meaningful patient engagement and consent. Notably, the discussion must engage patients from a variety of perspectives and communities – not only professional advocates, but also patients from various regions and backgrounds. This convening should also undertake the task of designing and carrying out an actual patient engagement event or series of events around the State.

A key goal of the conference would be for UC to help drive the global conversation. While this conference wouldn't necessarily provide all the answers, diverse input will identify the myriad issues requiring further debate. UC would publish a report from this focused on our own efforts and, ideally, the broader debate going forward.

RECOMMENDATION 2: Establish a System-level Health Data Office to identify and accelerate projects and partnerships to realize the public benefits of sharing Health Data.

In order to fully realize the public benefits of Health Data sharing, we believe strongly that UC should build and invest in infrastructure and dedicated personnel to launch promising data initiatives more quickly and efficiently. We recommend the establishment of a system-level Health Data Office led by a Chief Health Data Officer. The Health Data Office team would drive and oversee high-risk and multi-campus projects involving sharing our health data. Convening and working with a Health Data Governance Committee (see below), the Office would facilitate and accelerate the process of balancing interests, weighing benefits versus burdens and resolving legal, ethical and reputational issues raised. The Office would also actively find, evaluate, and help advance opportunities for innovative partnerships and projects involving the use and analysis of UC Health Data.

As part of developing a justice-based model of data governance, UC will need to monitor and oversee whether (a) the governance decisions it made fulfilled the intentions of this report and (b) these decisions were made consistently. To drive this, the Health Data Office would conduct periodic evaluations to assess the positive and negative outcomes of the projects UC has undertaken. Based on this analysis, the Office would share learnings to identify best practices and refine our policies and procedures accordingly. As technology continues to evolve, along with the policy and regulatory landscape, establishing a proactive, nimble, and dynamic process for data governance will be crucial to the success of UC's endeavors.

In addition, we suggest that each campus establish a similar approach to provide oversight of projects that involve sharing local Health Data. Campuses should be expected to designate someone to take on the responsibility of a local Chief Health Data Officer with appropriate support to drive and oversee such projects, and to periodically evaluate the effectiveness of the operation. These individuals can be appointed from existing personnel (e.g., Health System Chief Information Officer) but they will need sufficient time to devote to these tasks to be able to respond to requests in a business timeframe.

RECOMMENDATION 3: Develop criteria and a process for evaluating projects and transactions involving access to UC Health Data by outside parties.

Overview

As discussed above, we believe we have an obligation to be active stewards of UC Health Data, to ensure that such data is used to its fullest potential to create advances in health care that will benefit the public. But such access also introduces complexities that the University must deal with. For example, if a for-profit entity accesses UC Health Data and improves its ability to offer analytic or diagnostic services to medical providers, should the University share in the financial benefits, and if so, how? Similarly, how do we balance patient privacy with an opportunity to improve health care? Might there be circumstances in which a commercial endeavor is at odds with an academic endeavor of the University? And are there specific third-party uses of UC Health Data that UC simply should not support?

We were charged with determining how to identify and monitor outside access to UC Health Data and how to balance these potentially competing interests while complying with legal and ethical requirements and being mindful of potential risks to the University's reputation. Ultimately, we have concluded that achieving this will require the following:

1. A Presidential policy clearly articulating the University's high-level principles governing the management and active stewardship of UC Health Data.
2. A governance body and process to review and assess external requests, and make decisions regarding appropriate access.
3. A data set access tracking system that will capture the existence of relevant data sets, as well as all transactions (current and proposed) allowing access to them.
4. A process for sustained and meaningful public engagement in the development of Health Data governance policy at UC, including a mechanism to allow for ongoing engagement in the longer term as policies necessarily evolve.

While we offer some observations and recommendations regarding what such a governance body might look like and how it might operate, as well as important elements of a data set access tracking system, doing so in a thoughtful manner requires more expertise and more time. But UC Health and others are already fielding a number of requests for access to UC Health Data, so there is an immediate need for a means of dealing with such requests.

An Interim Process in the Near Term

To address current and near-term projects involving disclosure of Health Data to a third party, we propose the following Interim process:

1. Establish standard contracting guidance for agreements in which third parties are provided access to UC Health Data:

- Sharing of data must be non-exclusive;
- If the other party will be able to view Health Data, it must be de-identified according to HIPAA privacy regulations;
- The third party must be prohibited from re-identifying the data (e.g., combining it with consumer data);
- The third party may not further disclose the data (including to an affiliate, unless specifically agreed);
- The third party may only use the data for a discrete purpose specified in the agreement and must return or certify destruction of the data after such use; and
- As applicable, UC should receive an appropriate license to the "transformed"/structured data.

To the extent feasible, projects using UC 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.

In addition to meeting the above criteria, disclosure of Health Data to a third party must have a clearly articulated public benefit, consistent with the governing principles, and not be solely for financial gain or commercial advantage. An individual campus's project that meets the foregoing criteria would not require review beyond existing campus processes, unless one of the criteria in 3, below, is met.

2. Establish a small "Tiger Team" at the UCOP/system level that will be tasked with reviewing projects referred to them in accordance with the escalation procedure described below. This Tiger Team will include the necessary expertise to evaluate all facets of a proposed agreement (e.g., legal/regulatory, privacy, ethical, reputational) and will consider projects based on the principles. Recommendations by the Tiger Team must be made on a business timeframe.

3. Establish an escalation procedure. If a proposed campus-level project involving external access to Health Data does not meet the criteria stated above, then it needs to be escalated for review by the Chancellor or his/her designee (e.g., Vice Chancellor for Research or Vice Chancellor for Health Sciences). A process for campus evaluation of third-party health data access requests is set forth in Appendix C1.

In addition, projects meeting the following criteria would also need to be submitted to the Tiger Team for review:

- Projects involving Health Data from multiple campuses; OR
- Projects that are "High-Risk" because they involve:
    - Sharing patient-identifiable Health Data; or

- Have the potential to cause public concern, undermine our trustworthiness, or generate confusion among patients or the public.

The Tiger Team will make a recommendation about whether and on what terms to proceed, but importantly, the ultimate decision will always rest with the relevant Chancellor(s) or his/her designee(s). In scenarios in which the data-sharing interests of two campuses conflict or a campus's interests conflict with those of the University as a system (e.g., a third party seeks access to a multi-campus data set and an individual campus seeks to opt out or enter into its own agreement for its subset of that data), the Tiger Team would review the situation and propose a resolution. However, authority to resolve the conflict would rest with a decision-making body that would include the Chancellors (or their designees) of the affected campuses, and the EVP of UC Health. A process for escalation to the Tiger Team of Third Party Health Data Access Requests is set forth in Appendix C2.

4. Develop a simple dashboard that allows for consideration and comparison of ongoing and proposed projects involving external access to Health Data. For agreements that require escalation to the Tiger Team for review, the UC project lead will submit a form with basic information about the project, including the nature of the data set, parameters of proposed use, and adherence to standard contracting criteria.

5. Issue interim guidelines. In the near term, UC Health, in collaboration with Research Policy Analysis and Coordination (RPAC) and Office of General Counsel (OGC), should issue operating guidance based on the process described in this section to be followed throughout the University.

A Solution to UC Health Data Governance in the Longer Term

1. Create a system-wide policy governing access to Health Data.
It is important that UC has a clear policy setting forth its approach to allowing access to UC Health Data. This policy should be based on the principles discussed in Section VI and should apply to all UC Health Data. Importantly, this policy should be developed – and evolve – informed by the efforts undertaken under Recommendation 1 to develop and evaluate a justice-based model of data use.

In drafting this policy and associated guidance, the interim process outlined above should serve as a starting point. A key goal is to develop a clear, streamlined approach to decision-making to allow projects to move forward quickly and efficiently.

As an overarching principle to articulate in the policy, if it is determined that UC's objectives are best achieved by access to a combination of data sets, there should be a presumption that the steward of any individual component of such a data set cannot "opt out." That being said, if a steward strongly objects to inclusion in the larger data set, consistent with the escalation procedure discussed above, there should be an appeal process in which those concerns are fairly considered.

2. Establish a system-level Health Data Governance Committee (HDGC). In order to ensure that the overarching objectives of the University are met, it is important that access to UC's Health Data be as streamlined as possible, while still ensuring that certain principles and standards are maintained. The accomplishment of these objectives will be best achieved with executive-level oversight. To this end, we recommend the establishment of a UC Health Data Governance Committee (HDGC). This could be a reconstitution of the existing UC Health Data Executive Committee and/or Governing Board recently established by the UC Chief Information Officer.

We envision that this Health Data Governance Committee would serve as a high-level group to provide oversight, review potential projects and to resolve conflicts that arise, in consultation with relevant campus leadership as appropriate. This Committee would review projects in accordance with UC policy governing access to Health Data. It's critical that the Committee have clear decision-making authority and a process for escalation.

Each campus should be expected to create a similar oversight mechanism for coordinating access to its single-campus Health Data sets.

Importantly, the Health Data Governance Committee should have a means to seek advice from the public, as novel questions arise with the evolution of technology, science, and policy. This may include having a representative of the patient perspective on the Committee. In addition, the Health Data Governance Committee should have representatives from relevant UC offices, including OGC, UC Health, Compliance, Research, and others.

3. Implement a Health Data Set Access Repository (HDAR). In order to balance conflicting interests and manage multiple requests for access to a given Health Data set, it is critical that the Health Data Office have insight into access arrangements for all such data sets. For this, we recommend the establishment of a fairly simple system-level Health Data Set Access Repository (HDAR) for information on system-wide data sets that fall under the purview of the Health Data Office, as well as associated access agreements. The key goal is to establish a minimally burdensome means of collecting information about projects and transactions involving access to Health Data. To accomplish this, a team of UC experts (and, as needed, external advisors) should be convened to identify best practices and assess workable solutions for UC; existing models and practices within UC and other large complex organizations should be considered.

University staff who are responsible for access agreements (both in the Health Data Office and their counterparts on campuses) would use the HDAR to be aware of other entities requesting access to a given data set and any terms that have already been put in place. In addition, they would be able to see what other data sets a given entity has accessed and under what terms. Such information is critical in the evaluation of potential conflicts and risk assessment, including determining whether there may be any reputational risks presented by a specific transaction.

We also envision that UC faculty and staff would be able to access the repository to learn what Health Data sets are available for additional analysis and research. This could be an important part of the University's active stewardship of its Health Data. One question for consideration is whether to allow similar access to the public more generally, to maximize the opportunity for discovery and research.

In designing the HDAR, there will be tradeoffs to consider, most commonly between a desire to capture abundant information and the need to minimize administrative burden and delay. Issues for consideration include:

- Which data set agreements to include? Every single agreement pertaining to every single data set, or just those that pose increased risks of some sort?
- At what point should information about a data set be added to the HDAR? On this point, we recommend adding only when access by a third party is contemplated.
- Who will be responsible for capturing agreement information? A central office at OP/campuses, or the existing offices that will be handling these transactions?

Campuses should be expected to create similar systems to be aware of and manage access to local Health Data sets. An open question is whether campuses should be required to roll their data up into the system-wide HDAR. Again, this will be a cost (burden) versus benefit decision.

Determine Sponsored Activities and Indirect Cost Assessment

Occasionally, third party agreements may be associated with requests to reduce or waive standard indirect cost recovery (ICR) rates. The rationale for such requests (either from the third party or the internal UC investigator) may include: the third party providing in-kind benefits (e.g., otherwise unavailable technology, software, cloud storage, specimens, etc.), the third party being a "start-up" operation with limited capital, non-UC based sites of collaboration, to name a few. UC campuses have existing mechanisms for making such decisions, typically under authority delegated from the Chancellor to a Vice Chancellor (e.g., Research or Health Sciences). These approaches need not be changed as they work effectively. There is a need, in the long term, to establish a process to manage such decisions for multi-campus, third party requests for reduced ICR if inter-campus decisions are in conflict.

VI NEXT STEPS

Based on the initial draft of this report, the President has established a small Tiger Team to review projects referred to them in accordance with the escalation procedure set forth in this report, and to implement the near-term actions prescribed above, including development of an interim process and operating guidelines for review of requests for access to UC Health Data while a more permanent set of policies and procedures is developed, and the proposed structure and functions of a UC Health Data Office.

In addition, to carry out the recommendations discussed above, we recommend the President appoint an Implementation Task Force charged with the goals outlined below:

1. Each UC campus should establish a local process for the governance of its own Health Data, and to facilitate the system-level process.

2. Determine specifics for implementation of Recommendation 1 (establishing a justice-based model for Health Data use), including establishment of a team of UC experts.

3. Recommend members to be appointed to the Health Data Governance Committee by the President and draft the Committee's charge for approval by the President, including jurisdiction, establishment of clear decision-making authority.

4. Research policies, practices, and processes of other key institutions to inform the Committee's activities.

5. Review (i) UC's existing privacy policies and Notices of Privacy Practices and (ii) UC medical centers' terms and conditions of service and informed consent documents; consider whether they should be updated to be consistent with the recommendations in this report.

6. Draft a Presidential UC Health Data Access Policy, building on the Principles endorsed by the UC Regents Health Services Committee.

7. Review the interim process described under Recommendation 3 above, including lessons learned, and recommend a long-term process for reviewing and tracking access requests, resolving conflicting interests, and considering requests to reduce indirect costs.

8. Determine how best to establish an adaptive mechanism for incorporating the public perspective into the development of UC policy on Health Data Governance, and to seek further input as the technological and regulatory landscapes evolve.

9. Oversee the creation of a Health Data Access Repository.

10. Determine the needed infrastructure and associated costs for carrying out the recommendations in this report – including the development of a justice-based model of data use and a tracking system in Recommendation 1.

VII APPENDICES

A. Task Force Steering Committee and Working Group Members

B. Process

C. Flow Diagrams (Campus and System)

D. Use Cases

E. Glossary

Appendix A. Task Force and Working Group Members

Acknowledgements

The Task Force Steering Committee and Working Groups contain members from across the UC system and included faculty, Regents, and staff. A special thank you and recognition should be given for the input and work of each member for his or her time, energy, and passion in helping to bring these recommendations to fruition. The members took these recommendations, and created implementation plans and detail to support an informed, efficient, and sustainable model for UC.

The Task Force would also like to thank the UC Health Chief Executive Officers for their support of these efforts and also for supporting those recognized below who took on this challenge in addition to their ongoing responsibilities.

Steering Committee Members		
Christine Gulbranson (Chair)	Senior Vice President, Innovation & Entrepreneurship	UC Office of the President
John Stobo	Executive Vice President, UC Health	UC Office of the President
Richard Sherman	Vice Chair, UC Regent's Health Services Committee	UC Office of the Regents
Lars F. Berglund	Director, Clinical & Translational Science Center	UC Davis Health
Pradeep Khosla	Chancellor	UC San Diego
Ex officio members		
Rachel Nosowsky	Deputy General Counsel, Education and Health Affairs	UC Office of the President
John C. Mazziotta	Vice Chancellor, UCLA Health Sciences and CEO, UCLA Health	UC Los Angeles Health
Elizabeth Engel	Chief Strategy Officer, UC Health	UC Office of the President

Working Group Members		
John C. Mazziotta (Chair)	Vice Chancellor, UCLA Health Sciences and CEO, UCLA Health	UC Los Angeles Health
Michael Blum (Vice Chair)	Associate Vice Chancellor for Informatics	UC San Francisco School of Medicine
Elizabeth Engel (Subgroup Chair)	Chief Strategy Officer, UC Health	UC Office of the President
Wendy Streitz (Subgroup Chair)	Executive Director, Research Policy Analysis and Coordination	UC Office of the President
Howard Federoff (Subgroup Chair)	Vice Chancellor, Health Affairs and CEO, UCI Health	UC Irvine Health
James Chalfant	UC Academic Senate Chair, FY 16-17	UC Office of the President
Robert Currie	Chief Technology Officer, Genomics Institute	UC Santa Cruz
Barbara Koenig	Director, Bioethics	UC San Francisco
Chris Longhurst	Chief Information Officer	UC San Diego Health
Roslyn Martorano	UC Systemwide Privacy Manager	UC Office of the President
Lucila Ohno-Machado	Chair, Department of Biomedical Informatics and Associate Dean for Informatics and Technology	UC San Diego School of Medicine
Michael Troncoso	Managing Counsel, Health Law and Medical Center Services	UC Office of the President
Jeffrey Wajda	Chief Medical Information Officer	UC Davis Health

Appendix B. Process

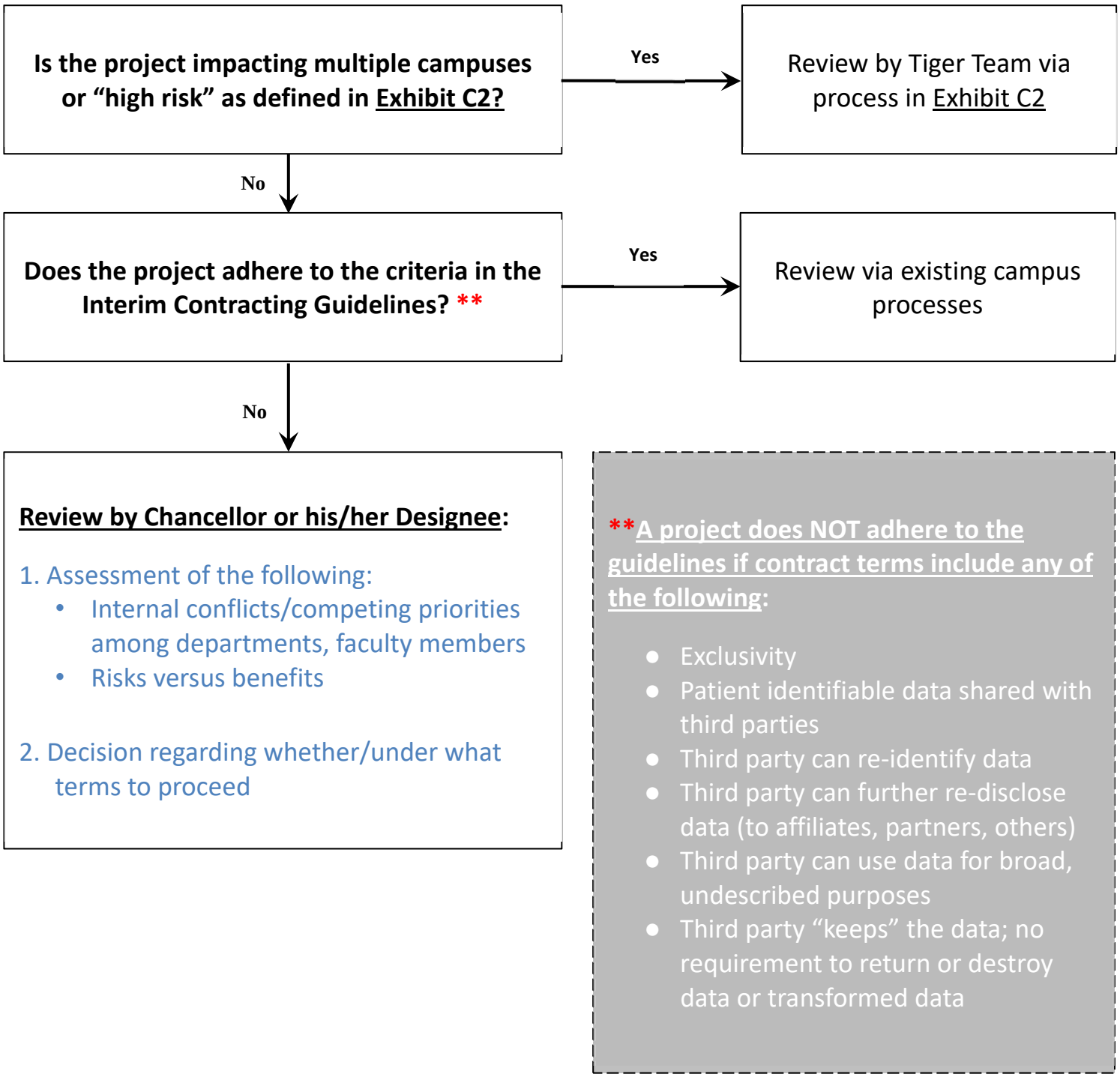
To complete the goals outlined in the charge, the Task Force took the following steps:

1. Formation of Subgroups:

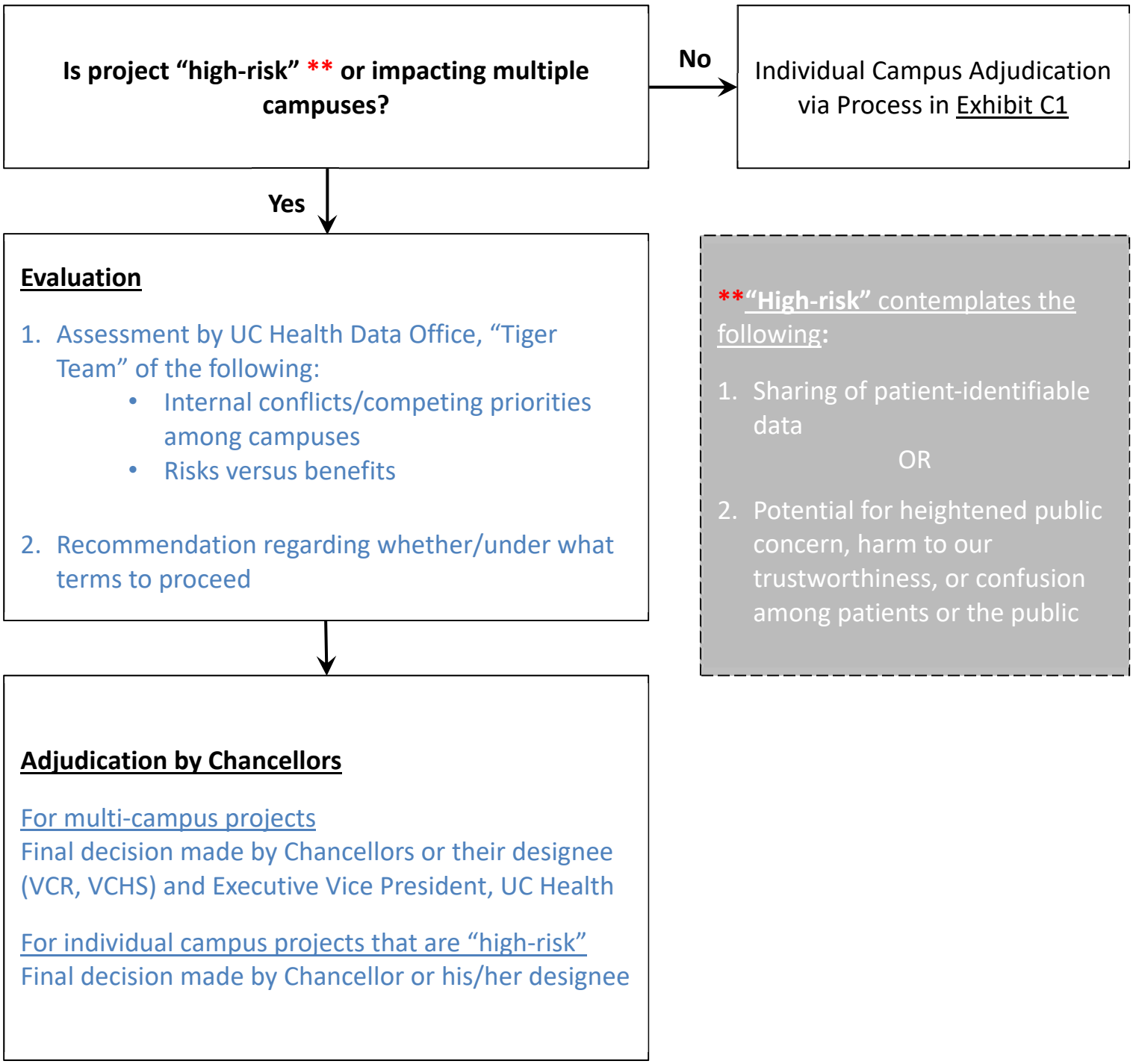
   The Working Group was divided into three subgroups focusing on balancing, overseeing and monitoring data access by outside parties (Subgroup A), assessment of ethical, regulatory, compliance, reputational, and business implications of sharing data (Subgroup B) and determining when collaborations with third parties are deemed sponsored activities and incur indirect costs (Subgroup C). The subgroups were overseen by the Working Group, which was, in turn, overseen by the Steering Committee.
2. Review of current/past UC policies and guidance
3. Review of UC Health Data Governance Plan
4. Review of Academic Senate white paper on data use
5. Input from outside academic medical centers:
   a. Johns Hopkins University
   b. Mayo Clinic
   c. Partners Health Care (Harvard)
6. Define governing principles
7. Draft recommendations and next steps

Appendix C. Flow Diagrams (Campus and System)

C.1 PROCESS FOR CAMPUS EVALUATION OF THIRD-PARTY HEALTH DATA ACCESS REQUESTS



C.2 PROCESS FOR ESCALATION TO TIGER TEAM OF THIRD-PARTY HEALTH DATA ACCESS REQUESTS



Appendix D. Scope Use Cases

Health Data

a. Any Electronic Health Record (EHR) data or data derived from the EHR – A faculty member is working on a QI project involving drug dosing. She receives a data set extracted from the EHR that includes data on drugs administered in the hospital and drug levels. After analyzing, cleaning, and annotating the data, she creates a predictive algorithm and tool that predicts patients' drug level when specific patient characteristics and dose are entered into the tool. The prediction requires access to the annotated data set derived from the original data set to function. She wishes to collaborate with an external third party to expand the functionality to additional drugs and offer the tool for use by other health center.
While she is not including the original EHR data, the data are derived from the EHR data and are considered Health Data.

b. Manipulated imaging data – A faculty member receives a data set of MRI cases from the PACS system. He converts them to another format to de-identify them and then removes remaining ePHI. He annotates the images with specific findings. He plans to share the derived, annotated images with an external collaborator to develop an algorithm to automate detection of these findings.
Despite the fact that the data set has been manipulated and additional data added, it is still considered Health Data.

c. Clinical trial data – As part of a clinical trial, a faculty member collected thousands of images of skin lesions that were biopsied. The images were stored in the EHR and the pathology reports were included in the EHR. The faculty member wants to work with another faculty member at an outside institution to develop an algorithm that predicts whether a skin lesion is malignant based on a picture using the data set for training. He transforms the images and de-identifies them.
Even though the data set was collected during a clinical trial, has been manipulated from its original format, and is being shared for research, since it was included in the EHR and generated a clinical report, it is still considered Health Data.

d. An external collaborator requests de-identified claims data for a set of patients to develop an algorithm which predicts future costs of care and readmissions.
While there may be limited clinical data in this request, all billing, coding, charge, and claims data are considered Health Data.

Non-Health Data

a. Research study – A faculty member is conducting an IRB-approved study with patient authorization to collect blood pressure and other clinical health measurements on individuals and follow them for development of disease. The measurements are done externally and neither the data nor any analysis is integrated into the EHR. The investigator wishes to share these data with an academic collaborator for further analysis.
These data are not Health Data as they were collected as part of an IRB-approved clinical trial with patient consent, were not used for direct patient care, did not generate a clinical care report, and were not included in the EHR or other care delivery systems.

Appendix E. Glossary

EHR: Electronic Health Record

HDAR: Health Data Set Access Repository - A simple, system-wide means of keeping track of access agreements that fall under the purview of the Health Data Office.

ICR: Indirect Cost Recovery

IRB: Institutional Review Board

Tiger Team: (new, just formed) A small, UC-level group that will be tasked with reviewing proposed projects involving sharing of health data on an interim basis in accordance with the escalation procedure described in Recommendation 3. Members will have the relevant expertise to evaluate the various facets of a proposed project (e.g., Legal/regulatory, privacy, security, ethical, and reputational).

UC-HDGC: UC Health Data Governance Committee (new, to be appointed in the longer term) A proposed governance body to review and assess external request for Health Data and make decisions regarding appropriate access.