

# **Duke University and Duke University Health System**

## **Licensing Principles and Income Sharing of Data from Human Sources Policy**

### **I. Preamble and Objectives**

The mission of Duke University (the “University”) includes the promotion of research and the expansion of knowledge. The mission of Duke University Health System (“DUHS”)<sup>1</sup> is the provision of high quality health care and innovation to build healthy communities. The purposes of the University and DUHS (collectively “Duke”) may be furthered by licensing certain data to third parties for use or study. Through such licensing arrangements, Duke believes data can be used to benefit society at large. This dissemination of data will be consistent with Duke’s efforts to promote open science.

Duke believes that it can best serve its aims and promote the relevance of its research endeavors by adopting this policy to set forth two sets of standards:

- A. The principles governing the nature of licensing transactions of data derived from human sources that Duke will pursue with third parties (Section II, below); and
- B. The principles for sharing a portion of the income realized from these data licensing transactions with those persons who have made significant intellectual contributions to the creation of the licensed data derived from human sources (Section III, below).<sup>2</sup>

### **II. Principles for Data Sharing and Licensing Transactions**

In deciding whether to share or to out-license data derived from human sources, Duke will adhere to the following principles:

- A. Promote Duke’s academic policy of encouraging scientific research and scholarship and improving medical care;
- B. Serve the public interest by ensuring the likelihood that data, or innovations that may be developed from them, will be made readily available to the public for research and development, including for commercial uses, through a selected commercial or non-commercial partner;
- C. Make available, through public posting or private distribution, information to individuals whose data are collected so that those persons can become reasonably aware of how their data may be used for research and development purposes;

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<sup>1</sup> For the purposes of this Policy, “DUHS” includes DUHS’ affiliates—Duke PRMO, LLC, Duke Integrated Network, Inc., and Duke University Affiliated Physicians.

<sup>2</sup> At institutions of higher education, sharing revenue long has been regarded as a means to incentivize the creation by faculty of intellectual property, ownership of which rests in the institution itself. Prior to the adoption of this policy, however, Duke had not provided for any similar mechanism for sharing income with persons who contributed significantly to the creation of valuable data. Duke is adopting this policy, in part, to codify Duke’s approaches to opportunities to share data derived from human sources through licensing transactions and other collaborations, whether income-producing or not, as well as to incentivize persons to create data of significance and importance.

- D. Presume generally and preferably, subject to exceptions in the discretion of the Responsible Officials, that data should be de-identified or configured as a limited data set, in accordance with the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”) Privacy Rule; that data should be non-exclusively licensed; and that licensees should be required to obtain Duke’s prior approval to sublicense to or share data with other parties; and that data cannot be shared in a way that would transfer ownership; and
- E. Receive fair market value for data shared through licensing transactions, thus providing tangible reward to members of the Duke community who create or enhance data to support Duke’s mission.

The Responsible Officials shall seek input from the President of the University in considering whether entering into a data licensing transaction is in the best interests of the University and DUHS if the transaction involves data that, in the judgment of either Responsible Official, could, (i) be opposed to the fundamental values of Duke, (ii) involve a particularly large data set that may implicate privacy and/or unusually important ethical considerations, or (iii) stigmatize discrete and insular protected class groups or populations.

### III. Principles for Income Sharing

#### A. Data Enhancers

Duke holds many forms of data, not all of which will give rise to income sharing under this policy when licensed for use by, or shared with, third parties. To be eligible for income sharing under this policy, a Covered Person as defined in Implementation Procedures, must have contributed individually identifiable creativity, ingenuity and intellectual effort to the data collection or curation that gave the data their licensable value; a Covered Person who meets this standard shall be considered a “**Data Enhancer**.” Duke will not rely solely upon the representation of a Covered Person who asserts that he or she is a Data Enhancer or is a sole Data Enhancer. Duke instead will conduct its own diligence as to whether the person meets this policy’s standard to be considered a Data Enhancer and, if so, whether other Duke community members also meet the standard.

Duke anticipates that there will be certain frequently occurring scenarios in which there will be no Covered Person who meets the definition of a Data Enhancer, such that Net Revenue (as defined below) will not be shared under this policy. Some of these include:

- i. Data created, collected and/or stored in the standard operations of Duke, including, for example, the routine delivery of clinical care.
- ii. Data to which ingenuity and creativity have been applied, but the Duke role or job position specifically requires the application of such qualities to the daily work of the Duke faculty and staff member.

Additionally, if Data are included or contemplated as part of a broader intellectual property license, income sharing will run through the *Policy on Inventions, Patents and Technology Transfer* and no additional income share will be given under this policy.

## B. Net Revenue

For all data licensing transactions, Duke seeks to obtain fair market value for its data.

The “**Net Revenue**” from any data licensing transaction will be calculated by subtracting, from the total monetary revenue received, (i) the direct costs of providing the data to the licensee, if not reimbursed by the licensee and (ii) 10% of the total revenue received, the latter of which is intended to recapture Duke’s costs in the original collection and storage of the data.

In the sole discretion of the Responsible Officials, as defined in Implementation Procedures, Duke instead may elect to calculate Net Revenue by deducting, from total monetary revenue received, any ascertainable actual costs from gathering, configuring, storing or otherwise creating the licensable value of the data.<sup>3</sup>

## C. Apportionment of Net Revenue

When no Data Enhancer is identified, the Responsible Officials will apportion the Net Revenue from a data licensing transaction, whether the data is created solely by the University, solely by DUHS or jointly, among the involved Duke entities on an equitable basis, which most often will be an equal basis.

If a Data Enhancer is identified, Duke intends to share Net Revenue as set forth below:

30% - Data Enhancer(s)  
35% - DU  
35% - DUHS

## Implementation Procedure

### I. Scope

This policy establishes Duke’s position with respect to sharing income generated through data licensing transactions. However, this policy does not alter or amend the ownership interests that Duke or other persons have in data under other Duke policies, including the *Duke University Policy on Intellectual Policy Rights* and the *Policy on Research Records: Sharing, Retention and Ownership*. This policy does not alter or amend Duke’s policy for income sharing for inventions covered under the *Policy on Inventions, Patents, and Technology Transfer*. Accordingly, as provided in Section V, Duke data that are licensed in connection with certain out-licensed IP, such as patents or algorithms, will not give rise to any additional revenue sharing under this policy.

### II. Applicability

This policy shall apply to the Duke University and its Schools of Medicine and Nursing and to all of DUHS.

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<sup>3</sup> Such costs may include, for example, any Duke cost sharing under outside grant funding or Duke special dispensations or dedicated funds made available for the collection or analysis of the data.

This policy applies to employees who are defined for purposes of this policy as all faculty, staff, and other persons receiving compensation from the University or DUHS for services rendered, as well as all research personnel, students and graduate assistants, whether compensated or not, who work on any research project under Duke control, and medical staff, whether compensated or not, who deliver clinical care in the context of DUHS (collectively “**Covered Persons**”).

This policy applies solely to data from human sources, including but not limited to DUHS patient records and data whose creation and use fall under the jurisdiction of research ethics committees (for example, the DUHS IRB and campus IRB). Human biospecimens, insofar as they retain any associated phenotypic data, are covered by this policy. This policy’s principles for determining data licensing transactions and for sharing income from such transactions do not apply to data that are not derived from human sources.

This policy is not intended to apply to the sharing of data derived from human sources if (i) those data are exchanged among Duke faculty and students solely for academic purposes, (ii) those data shared through agreements negotiated by the Office of Research Contracts, (iii) those data shared through Health Information Exchanges (NCHIE, NCHA, Federal eHealth Exchange, etc.); and (iv) Data licensed through procurement arrangements in which a vendor providing a good or service to Duke requires a license to the data as a condition of providing this good or service (e.g., IT operational contracts).<sup>4</sup>

### **III. Administrative Responsibility**

This policy will be jointly administered by (i) the Chancellor for Health Affairs at Duke University, President and Chief Executive Office of DUHS and (ii) the University Vice President for Research (the “**Responsible Officials**”). The Responsible Officials shall have all authority for making decisions under this policy, both with respect to entering into data licensing transactions and for sharing income when a Data Enhancer (as defined below) is identified.

In their sole discretion, the Responsible Officials may delegate administrative responsibilities to other offices, officers, committees or other bodies.

### **IV. Agreements**

The policy as amended from time to time shall be deemed to be a condition of initial or continuing employment of every Duke employee and a condition of enrollment and attendance of every student who works on any research project under Duke control and a condition of participating in the medical staff, whether compensated or not, delivering clinical care in the context of DUHS. All data licensing activities occurring after the effective date of this policy shall be subject to this policy.

### **V. Appeals**

Any party may appeal a decision under this policy to the President of the University or the President’s designee(s). Within ten business days after the President’s decision, any person

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<sup>4</sup> Data sharing and/or data use rights granted beyond the specific good or service being provided on behalf of Duke are not excluded from this policy.

aggrieved by the application of this policy may proceed as of right to binding arbitration before a single arbitrator pursuant to the commercial arbitration rules of the American Arbitration Association. Each party shall bear its own costs in connection with the proceedings; but in the event an Arbitrator finds that a party has proceeded in bad faith, the Arbitrator may award costs and expenses (including attorneys' fees) to the other party.

**V. Termination or Revision of Policy**

This policy may be changed or discontinued at any time by action of the Board of Trustees. Such changes or discontinuance shall not affect rights accrued prior to the date of such action.