

**DOCUMENT 3:
THE INDIANA NETWORK FOR PATIENT CARE: A CASE STUDY OF
A SUCCESSFUL HEALTHCARE SHARING AGREEMENT**

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1 Introduction

Healthcare costs have risen dramatically in the past few years and these increases are hurting employers, patients, payers, and healthcare providers alike. One important way to reduce such costs is to enable and facilitate healthcare data sharing with appropriate privacy and security protections.¹ The most significant benefit to healthcare data sharing is the improvement of the quality and efficiency of clinical care by having access to the complete mosaic of a patient's records at the point-of-care. Such access will reduce medical errors and duplication of tests.² Further, healthcare data sharing can also enhance public health through advanced biosurveillance methods and streamlined collection of data for quality measurement and research.³

The virtues of healthcare data sharing have been recognized at the national level. For the past few years, various government agencies have been funding efforts to establish data sharing communities. In April 2004, those efforts were further bolstered by President Bush's directive for widespread adoption of interoperable electronic health records within 10 years. By Executive Order, he established the new Office of the National Coordinator of Health Information Technology ("ONCHIT") under the U.S. Department of Health and Human Services. This new office is designed to facilitate the development and adoption of a national health information network.⁴ It is envisioned that this will be accomplished through the linkage and interoperability between local community health information exchanges across the nation.⁵

Developing and drafting healthcare data sharing agreements, and enabling the infrastructure to support them, will continue to be a growing area of law due to the substantial support from the healthcare industry and government, and the prospect of improved clinical care that will benefit us all. The purpose of this paper is to describe one successful healthcare data sharing effort and provide an analysis of the underlying contract that makes it possible.

2 Role of Legal Counsel

As a result of this national focus and the benefits to quality of care, public health and scientific research, many communities now have initiated the development of local area health information exchanges to facilitate data sharing and need legal guidance. For example, a community may seek counsel on whether to set up a separate legal entity to oversee the effort or utilize some other form of governance structure. There are also questions about the use of public and private funds to start the project. Of course, healthcare data sharing requires close compliance with federal laws, such as the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”). Similarly, state laws may also apply to healthcare records. For example, state law may dictate special handling required for communicable disease or mental health records beyond what is specified in HIPAA. These laws must be considered carefully in drafting any agreement between the various parties for sharing healthcare data.

3 Evolution of Indianapolis’ Network

Regenstrief Institute, Inc. (“Regenstrief”) is a non-profit institution, affiliated with Indiana University, whose mission is to facilitate medical research, medical education, and clinical care. Regenstrief has been developing and implementing clinical data repositories and software tools to serve healthcare providers for more than three decades, and is a national leader in healthcare data sharing and data standardization.⁶ In 1972, Wishard Memorial Hospital, Indianapolis' safety net hospital, began using the Regenstrief Medical Record System (“RMRS[®]”), which serves as the hospital’s electronic medical record. In 1989, Indiana University Hospital also adopted RMRS as its electronic medical record system. In 1997, Indiana University Hospital, Methodist Hospital, and Riley Hospital for Children merged to become Clarian Health Partners (“Clarian”). Soon thereafter, all Clarian hospitals began using the RMRS system.⁷

A grant to Regenstrief from the National Library of Medicine in 1994 enabled the creation of the first healthcare data sharing across multiple, non-affiliated hospitals in Indianapolis. In that project, Wishard Memorial Hospital provided access to its electronic medical record data to emergency department physicians caring for patients in the Community Hospital East and Methodist Hospital emergency rooms in Indianapolis.

The benefits of having this data available at point-of-care soon became evident, and all five of the major Indianapolis hospital systems and one large primary care group then agreed to transmit their data to Regenstrief for use by other participating hospitals to render emergency care. A written agreement detailing the conditions surrounding participation and use of the data in the Indianapolis Network for Patient Care (“INPC[™]”) was executed in 1998 by Regenstrief and all participants. The founding participants included: Clarian Health Partners, Inc., Community Hospitals of Indiana, Inc., Indiana University Medical Group – Primary Care, St. Francis Hospital and Health Centers, St. Vincent Hospital and Health Care Center, Inc., and Wishard Memorial Hospital (an operating division of The Health and Hospital Corporation of Marion County).

In 2004, the INPC agreement was revised to address HIPAA requirements, expand the potential use of the INPC network, and allow for participation by other healthcare entities. A copy of that agreement is attached as Attachment A.

4 Analysis of Agreement

The INPC is not a separate legal entity. Instead, it is a contractual collaboration between Regenstrief and the participating hospitals and physician groups. In short, the participating hospitals agree to submit a variety of electronic health data to a large system maintained by Regenstrief. Each participant's data is stored in separate files and is not co-mingled with other participants' data. The agreement allows for the submission of the data to Regenstrief and the use and disclosure of the data for a variety of purposes.

Obviously, the submission of data to Regenstrief for storage, standardization, and use by care providers at other institutions requires clear agreements about the use of data and strong technical controls. The INPC agreement serves as the cornerstone for the interrelationship among the otherwise highly competitive participating institutions. It provides a mechanism to promote cooperation and trust by defining the data that will be submitted to the INPC network, describing the authorized uses and disclosures of the data, providing for a participatory management structure, ensuring compliance with applicable laws, and, providing protection from liability for the participants should unforeseen events occur. This section will discuss the key provisions of the INPC agreement.

4.1 Storage of Information and Administration of the Network

The INPC network must have a large store of data to be of value to treat patients. The agreement defines the data that the participants must submit by defining a minimum subset of data that must be submitted and encouraging the submission of any other data that the participants wish to submit. At a minimum, the participants must submit emergency room encounter information for each emergency department visit and encounter information for other hospital visits. Encounter information includes patient demographic information, reason for the visit, treating health care providers, date and place of visit, diagnosis, and procedures. In addition, each participant must submit vital signs, pathology reports, radiology studies, laboratory test results, cardiology studies, and other diagnostic tests to the extent that each participant has the ability to submit the data electronically.

Participants provide the data to Regenstrief in Health Level 7 ("HL7[®]") format through a secure electronic transmission.⁸ Even though the messages are sent in HL7 format, there can be wide variation in the reporting of the data. For example, codes used to identify individual clinical observations like a simple pathology test might be named or coded differently by different sending organizations. Thus, a critical contribution of Regenstrief's developers is the standardization of reporting patient data. Before going live with a new health care data provider, Regenstrief maps the data and standardizes results so that when a patient record is later accessed and aggregated, data from many sources can be presented in a consistent manner for clinicians. This standardization is an ongoing process as new data is constantly submitted. Regenstrief uses a number of standardized code sets to translate and report results such as the LOINC[®] system

developed and maintained by Regenstrief.⁹ The participants agree to cooperate in this coding process.

4.2 Uses of Information

The wealth of information on the INPC network serves many useful purposes. Through the agreement, the participants authorize the use and disclosure of their data to treat patients, to promote research, and to fulfill governmental reporting responsibilities.

4.2.1 For Clinical Care

Clearly, the most fundamental and important use of the INPC network is to treat patients. The participants authorize Regenstrief to disclose their data to other participants when a patient presents to another participant for treatment. Both state and federal law allow broad sharing of health data between health care providers for purposes of treating a patient. Neither Indiana state law, nor the Privacy Rule under the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") requires patient consent to disclose health data for treatment purposes.¹⁰

Each participant must identify those individuals under its supervision that may access data on the INPC network. These individuals may include hospital employees (*e.g.*, hospital-based physicians, physicians with admitting privileges, nurses, etc.), but may also include individuals who work for physician groups affiliated with a hospital. Participants regularly submit a list to Regenstrief of the individuals who are authorized to access INPC data. It is up to each individual participant to: (1) train their designated personnel about the confidentiality of patient data; (2) ensure that the personnel will only access the INPC for treatment purposes; (3) require that the personnel hold passwords to the INPC confidentially; (4) require such personnel to participate in surveys and studies about the efficacy of the INPC; and (5) ensure that personnel understand that breaches of confidentiality may result in exclusion from the INPC and other discipline.

Personnel designated by the participants do not have unfettered access to INPC data. When a patient presents for treatment at one of the participant's treatment locations, an electronic HL7 admission message is sent from the participant to Regenstrief indicating that a patient has presented to the health care provider for treatment (*e.g.*, presented to an emergency room, arrived for an office appointment or outpatient procedure, or been admitted as an inpatient to a hospital). A patient is under the "treatment" of a participant when a health care provider is providing, coordinating, or managing the health care of a patient. The admission message verifies that a patient has actually presented for treatment, and the participant has a right to receive information about the patient from the INPC network. At that point, the INPC system goes to work and searches each participants' files for information about the patient. The information is aggregated and can be viewed as a single virtual medical record over a secure internet connection between Regenstrief and the requesting participant. The designated personnel may access that patient's data on the INPC network for only a limited time period to reduce any potential for misuse. For example, if a patient presents to an emergency room, the patient's data is available to the participant's designated personnel for a twenty-four hour period after the admission message is received by Regenstrief. The record can be printed in hard copy for inclusion in the participant's medical record.

4.2.2 For Research

INPC data may also be used for scientific research purposes. The agreement provides for the use of INPC data for research by delegating a substantial amount of responsibility to Regenstrief (a long-standing medical research institution with considerable experience in reviewing and evaluating research proposals), while maintaining appropriate levels of control by the participants over their data on the INPC network. All of this is accomplished while still maintaining compliance with HIPAA's complicated rules relating to the use of patients' data for research purposes.

The agreement defines a hierarchy of approvals that are required before INPC data may be used for research purposes. The participants recognize that, as a research institution and a long-term custodian of a plethora of health data, Regenstrief has considerable experience working with researchers for requests to access the data. As a result, the agreement delegates to Regenstrief the authority to review research requests on behalf of the participants and, when a desirable project is identified, present the project to the participants. Subject to some exceptions, Regenstrief must obtain approvals from the participants prior to using or disclosing their data for research. Importantly, the agreement generally prevents the use of participants' data when the purpose of the study is to directly compare the participants or providers themselves. For example, without specific approval from the affected participants, data cannot be used to compare individual patient outcomes, financial information, or charges to patients on a participant-by-participant basis. This assures the participants that their data will not be used to their detriment for purposes of pitting one against the other.

First, the agreement's research provisions provide for the use of data for research projects that were specifically identifiable at the time the agreement was signed. These projects relate to the operation of the INPC itself, as well as a cancer research project known as the Shared Pathology Informatics Network. These research projects already have been subjected to review and approval by the participants and Institutional Review Boards ("IRBs").¹¹ Data may be used for these projects without further approval from the participants.

Second, research projects that involve independent agreements between one or more participants and Regenstrief are not subject to the terms of the agreement. Thus, if one participant consents to allow the use of its data that is stored on the INPC system, a separate agreement (independent of the INPC agreement) may be executed between Regenstrief and that participant.

Third, HIPAA's Privacy Rule allows for the use and disclosure of health information without a patient's consent or approvals from an Institutional Review Board if: (1) the data is used only for uses that are preparatory to a research project; or (2) the data relates to a deceased individual. As long as the data is used consistently with HIPAA's limitations on this data, Regenstrief has the ability to use participants' data for these purposes without any further approval from the participants.

Fourth, HIPAA allows for the use of deidentified data and "limited data sets" without a patient's consent or approvals from an Institutional Review Board.¹² The agreement delegates to Regenstrief the ability to use and disclose deidentified information and limited data sets on behalf of the participants without further approval from the participants. In other words, the

participants do not have to approve the specific research project(s) for which the data will be used or disclosed. However, Regenstrief may not use or disclose such data unless the entity requesting the data has obtained an approval from an Institutional Review Board acceptable to Regenstrief for the use of deidentified data or limited data sets (even though HIPAA's Privacy Rule would not otherwise require IRB approval).

Finally, if a research use or disclosure does not fall into one of the foregoing five categories, Regenstrief must propose it to the INPC's Management Committee (see [Section 4.5](#) below for a discussion of the Management Committee). Any such research project must be approved by: (1) an IRB approved by Regenstrief; (2) the participants whose data is proposed to be used; and (3) Regenstrief. Any participant may decline to allow its data to be used for the research project, but that does not preclude the other participants from allowing the use of their data. Because Regenstrief maintains each participant's data in segregated files, this separation is possible.

4.2.3 For Public Health

Indiana, like many states, requires health care providers and other entities to report certain information that impacts public health. Reporting communicable diseases, positive lead levels, or Shigella isolates are examples. The electronic HL7 feeds that participants provide to Regenstrief to populate the INPC provide an efficient way to screen for reportable events. Regenstrief filters the incoming messages for reportable conditions and reports them to Indiana and Marion County Health Departments on behalf of the participants. This public health function is enhanced through a grant funded by the Centers for Disease Control through the Indiana State Department of Health that allows Regenstrief to construct a network to capture chief complaint information and other data in real time from all 140 Indiana hospital emergency rooms for biosurveillance and outbreak detection.

4.3 Confidentiality

The INPC system contains and discloses highly confidential information that is protected by both federal and state law. As a result, the agreement contains stringent confidentiality provisions. All information stored on, and received through, the INPC network must be kept confidential pursuant to all applicable laws, as well as each participant's own internal rules and regulations relating to the confidentiality of patient health information. Serious breaches of confidentiality must be reported to the INPC Management Committee (*see* [Section 4.5](#) below). Participants further agree to educate their workforces about their confidentiality obligations and to appropriately discipline workforce members who violate those obligations. As an added protection to the participants' business and proprietary interests, Regenstrief agrees that no data (including aggregate data on a participant-level basis) concerning a participant will be provided to other participants or published in an identifiable form without the written permission of the affected participant. Such data would include patient volume, charges to patients or payers, and participants' practice patterns.

4.4 HIPAA Business Associate Provisions

In the age of HIPAA, the privacy and security of the data on the INPC are important factors in the structure of the INPC agreement. The Privacy Rule and Security Rule¹³ promulgated

pursuant to HIPAA apply to "covered entities" and define how individually identifiable health information may be used and disclosed and how it must be protected.¹⁴ In general, covered entities are required to take reasonable administrative, physical, and technical steps to ensure the privacy and security of individually identifiable health information. The INPC, itself, is not a covered entity; however, most of the participants that submit data to the INPC network are covered entities and must comply with the Privacy and Security Rules.

The Privacy Rule clearly allows the use and disclosure of health information for the purposes outlined in the agreement – treatment,¹⁵ research,¹⁶ and public health reporting.¹⁷ Without the INPC system, the participants could independently exchange health information for these purposes. However, covered entities may *also* engage third parties to receive and disclose health information on their behalf. The Privacy and Security Rules refer to these individuals as "business associates" and require covered entities to obtain satisfactory assurances from business associates that the business associate will appropriately safeguard the health information that it creates, receives, or discloses on behalf of the covered entity.¹⁸

The agreement recognizes that Regenstrief acts as the participants' business associate for purposes of storing their health information, disclosing it on their behalf for treatment, evaluating research projects and ensuring that they meet HIPAA requirements prior to disclosure, and reporting health information for public health purposes. As a result, an Article in the agreement is devoted to meeting HIPAA's mandates and requires Regenstrief to implement reasonable safeguards to protect both the privacy and security of the health information and to assist the participants with their responsibilities to provide their patients' with access, accounting, and amendment rights to the health information. Note that, due to the manner in which data is submitted electronically to the INPC system, HIPAA's amendment procedures have been tailored to provide for the electronic submission of amendments by the participants to the INPC network with little or no manual work on the part of Regenstrief to amend patient records.

4.5 Management Committee

Data sharing arrangements require heightened levels of cooperation among entities that are otherwise competitors in health care delivery. Moreover, in an age of increased sensitivity about the privacy of health information, entities are concerned with sharing health information beyond their own borders. As a result, governance mechanisms for data sharing arrangements that allow participants to provide meaningful input in, and oversight of, the operations of the arrangement foster the creation, development, and success of the arrangement.

The governance provisions of the agreement strive to meet these goals through the INPC's Management Committee. The Management Committee is comprised of two representatives from each of the founding participants, as well as representatives from Regenstrief. As the INPC network continues to grow, it has been acknowledged that the addition of new participants could create a large and unwieldy Management Committee. As a result, membership on the Management Committee may be limited in the future to Regenstrief, founding participants, and other members added at the discretion of the current Management Committee.

If the agreement serves as the constitutional document for the INPC, the Management Committee is its legislative body and has the power to fashion the development of the INPC

within the confines of the agreement. The Management Committee meets as necessary to resolve various issues surrounding the INPC network, such as the confidentiality of health information, compliance with new laws and regulations, the addition of new participants and the expansion of the INPC, modifications to the required information that is submitted to the INPC, technical issues relating to submission and access to the information, and research uses of the health information. Each participant exercises one vote on the Management Committee. Management Committee decisions are binding upon all participants; however, founding participants may abstain from complying with a Management Committee decisions if their objections are not met with reasonable accommodations.

4.6 Indemnification

While no one wants or expects liability issues to arise with the INPC network, the participants and Regenstrief enjoy a measure of protection through the agreement's indemnification provisions. The participants agree to indemnify one another and Regenstrief if damages or expenses are incurred as a result of a participant's breach of the confidentiality of the health information it receives from the INPC system, or as a result of a participant's submission of inaccurate, incomplete, or defamatory data to the INPC network. Regenstrief similarly agrees to indemnify the participants for its own breach of the confidentiality of the health information on the INPC system (whether through disclosure or through acts or omissions in the design and/or maintenance of the INPC system).

4.7 Term and Withdrawal

The INPC network originally began in 1998 and, through a recent amendment to the agreement, the founding participants have agreed to continued participation through at least April 13, 2009. The agreement provides for annual automatic renewals thereafter unless notice is provided one-hundred and eighty-days before renewal. Notwithstanding, participants may withdraw from the INPC network upon the agreement of Regenstrief or for cause. "For cause" terminations are allowed in the following circumstances: (1) a significant breach of confidentiality by another participant or Regenstrief (but only after the Management Committee has rendered a non-binding advisory opinion on whether the breach was significant); (2) excessive and unexpected costs related to the participant's membership in the INPC; or (3) a prolonged period during which the participant cannot access its own information on the INPC.

Upon withdrawal, a participant is no longer required to submit data to the INPC network; however, its data may still be subject to some uses by the INPC system. Remaining participants will no longer have access to the data for treatment purposes, but Regenstrief may still continue to use the data for research purposes for an additional two years after withdrawal (unless the withdrawal is a result of *Regenstrief's* breach of confidentiality). In cases where the withdrawing participant had agreed to allow its data to be used for research projects prior to withdrawal, the data may still be used for such projects for the duration of the project (even if the project lasts for more than two years after the withdrawal). After the two-year period (or the duration of pre-existing research projects), the withdrawing participant's data will remain on the INPC system, but may not be used for any purpose other than risk management and legal defense purposes. Regenstrief's confidentiality obligations survive for as long as it holds the health information.

5 What Does The Future Hold?

Today, the five INPC participating hospital systems operate a total of 15 hospitals and more than 100 clinics and day surgery facilities, distributed over Indianapolis and surrounding counties (approximately 400 square miles). Together, they generate 165,878 in-patient admissions, and 450,000 emergency room and 2.7 million out-patient visits per year.

The Marion County Health Department and the Indiana State Department of Health also contribute data to INPC for clinical use, such as childhood immunization information and public health laboratory results. Indiana Medicaid has agreed to include much of their administrative data (including prescription records), and RxHub (a joint venture of pharmacy benefit management entities) is now delivering medication usage history for INPC patients seeking care in Indianapolis emergency rooms.¹⁹

Counting the data from all participants (some who have joined more recently than others), the INPC repository now carries 660 million clinical observations, such as lab reports; 14.5 million text reports, such as discharge summaries and radiology reports; 45 million radiology images; and 450,000 EKG tracings. These are now growing at the respective rates of 88 million, 2 million, 25 million and 80,000 per year.

Currently, Regenstrief receives a number of requests from other healthcare providers in the region to become participating members of the INPC network, and work is underway to enable adding these new participants. In addition, Regenstrief continues to seek other healthcare data sources to contribute data to the INPC network to further enhance the patient data available for treatment, as well as for providing a richer base of information for research and public health purposes. The current INPC agreement discussed in this paper is continually being reviewed and will be modified when necessary to accommodate changes in events, strategic direction and/or changes in state or federal law.

ENDNOTES

¹ J. Walker, et. al., “The Value of Health Care Information Exchange and Interoperability,” *Health Affairs Web Exclusive* (January 19, 2005).

² P.C. Smith, et. al., “Missing Clinical Information During Primary Care Visits,” *Journal of the American Medical Association* 293, no. 5 (2005); J.M. Overhage, et. al., “A Randomized Controlled Trial of Clinical Information Shared from Another Institution,” *Annals of Emergency Medicine* 29, no. 1 (2002); and A. Stiell, et. al., “Prevalence of Information Gaps in the Emergency Department and the Effect on Patient Outcomes,” *Canadian Medical Association Journal* 169 (2003).

³ D. Brailer, “Interoperability: The Key to the Future Health Care System,” *Health Affairs Web Exclusive* (January 19, 2005).

⁴ *Federal Register*, November 15, 2004 (Volume 69, Number 219), pp. 65599-65600.

⁵ Recent legislation introduced by Senators Hilary Rodham Clinton (D-NY) and William H. Frist (R-TN) known as the Health Technology to Enhance Quality Act ("Health TEQ Act") would codify the creation of ONCHIT. Under the legislation, the National Coordinator would be directed to develop a nationwide interoperable health information technology infrastructure that reduces health care costs, improves quality, facilitates health care research and the reporting of public health information, and ensures that patient health information is secure and protected. The legislation would also call for the adoption of standards for the electronic exchange of health information. ONCHIT would also be required to conduct a study of both national and state privacy laws and practices to determine how the variation among such laws and practices may impact the electronic exchange of health information among states, between states and the federal government, and among private entities. ONCHIT will be required to make recommendations to harmonize these laws and to award grants to states to facilitate electronic exchange of information. Limited exceptions to physician referral, antikickback, and antitrust laws would be created to allow hospitals and other entities to provide hardware to physicians to encourage electronic exchange of information and to allow competitors to avoid antitrust violations if they collectively purchase standard compliant hardware, software, and support services for electronic exchange of health information. See S. 1262, 109th Cong., 1st Sess. (2005).

⁶ President George W. Bush, "Transforming Health Care for Americans with Health Information Technology," May 27, 2004, said "the reason why Indianapolis is farther down the road, if you notice, hospitals can talk to hospitals, which hasn't happened in many communities." <http://www.whitehouse.gov/news/releases/2004/05/20040527-5.html>.

⁷ C.J. McDonald, et. al., "The Regenstrief Medical Record System: A Quarter Century Experience," *International Journal of Medical Informatics* 54, No. 3 (1999), pp. 225-253.

⁸ According to its website, "Health Level Seven is one of several American National Standards Institute (ANSI) - accredited Standards Developing Organizations (SDOs) operating in the healthcare arena. Most SDOs produce standards (sometimes called specifications or protocols) for a particular healthcare domain such as pharmacy, medical devices, imaging or insurance (claims processing) transactions. Health Level Seven's domain is clinical and administrative data. Our mission is to: "To provide standards for the exchange, management and integration of data that support clinical patient care and the management, delivery and evaluation of healthcare services. Specifically, to create flexible, cost effective approaches, standards, guidelines, methodologies, and related services for interoperability between healthcare information systems." See <http://www.hl7.org>.

⁹ LOINC[®] stands for the Logical Observation Identifiers Names and Codes. Its purpose is to facilitate the exchange and pooling of results, such as blood hemoglobin, serum potassium, or vital signs, for clinical care, outcomes management, and research. Currently, most laboratories and other diagnostic services use HL7 to send their results electronically from their reporting systems to their care systems. However, most laboratories and other diagnostic care services identify tests in these messages by means of their internal and idiosyncratic code values. Thus, the care system cannot fully "understand" and properly file the results they receive unless they either adopt the producer's laboratory codes (which is impossible if they receive results from multiple sources), or invest in the work to map each result producer's code system to their internal code system. LOINC codes are universal identifiers for laboratory and other clinical observations that solve this problem. See <http://www.regenstrief.org/loinc/>.

¹⁰ As data sharing arrangements grow and cross state borders, legal counsel will have to engage in significant analysis of competing state laws and policies regarding data sharing for treatment and other purposes. Indeed, a central component of the Health TEQ Act will require ONCHIT to engage in a study of various state laws that could impede the exchange of electronic health information and to recommend harmonization of these laws. Currently, only Indiana institutions participate in the INPC for purposes of exchanging data for treatment purposes and Indiana has traditionally allowed liberal sharing of health data for treatment purposes. See Ind. Code § 16-39-5-1. However, the INPC Agreement addresses this issue by requiring each participant to warrant that it is authorized to allow access to its data under all laws that are applicable to the participant. Violation of this representation can result in breach of the Agreement and, potentially, the enforcement of the Agreement's indemnification provisions.

HIPAA's Privacy Rule recognizes the importance of sharing health data among providers for treatment purposes without a patient's consent. *See* 45 CFR § 164.506(c)(3).

¹¹ An Institutional Review Board is a properly constituted committee that is charged with reviewing and monitoring biomedical research involving human subjects. They are designed to protect the rights and welfare of human subjects participating in such research. *See generally* 21 CFR Part 56.

¹² "Deidentified" data and "limited data sets" are both defined by HIPAA's Privacy Rule. *See* 45 CFR §§ 164.514(a) and 164.514(e). In general, deidentified data and limited data sets are health information from which all, or most, individual identifiers have been removed and which cannot reasonably be traced back to any specific individual.

¹³ 45 CFR Parts 160 and 164.

¹⁴ HIPAA's Privacy Rule and Security Rule apply to "covered entities" which are health plans, health care clearinghouses, and health care providers that transmit any health information in electronic form in connection with certain defined electronic transactions. 45 CFR § 160.103.

¹⁵ *See* 45 CFR § 164.506(c)(2).

¹⁶ *See* 45 CFR § 164.512(i). The Privacy Rule sets forth a complicated structure of approvals (subject to some exceptions) before health information may be used for research. That structure is reflected in the INPC Agreement through the hierarchy of research uses discussed in Section 4.2.2 above.

¹⁷ *See* 45 CFR § 164.512(b).

¹⁸ *See* 45 CFR §§ 164.502(e)(1) and 164.504(e).

¹⁹ "New Service Will Enable Physicians to Make Safer, Better Informed Care Decisions Resulting in Reduced Medication Errors and Adverse Drug Events," RxHub press release, <http://www.RxHub.net> (November 9, 2004).

ATTACHMENT A

INDIANAPOLIS REGIONAL NETWORK FOR PRIMARY AND EMERGENCY CARE SECOND PARTICIPANTS' AGREEMENT

CONCEIVED, DRAFTED AND NEGOTIATED BY

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**INDIANAPOLIS REGIONAL NETWORK
FOR PRIMARY AND EMERGENCY CARE
SECOND PARTICIPANTS' AGREEMENT**

**ARTICLE I
Definitions**

Section 1.01 Agreement. The term "Agreement" shall mean this document, namely the Indianapolis Regional Network for Primary and Emergency Care Second Participants' Agreement.

Section 1.02 Business Associate. The term "Business Associate" shall mean Regenstrief when it, pursuant to this Agreement:

(a) On behalf of a Covered Entity, but other than in the capacity of a member of the workforce of such Covered Entity, performs, or assists in the performance of:

(1) A function or activity involving the use or disclosure of PHI, including claims processing or administration, data analysis, processing or administration, utilization review, quality assurance, billing, benefit management, practice management, and repricing; or

(2) Any other function or activity regulated by the Privacy Rule; or

(b) Provides, other than in the capacity of a member of the workforce of a Covered Entity, legal, actuarial, accounting, consulting, data aggregation (as defined in 45 CFR § 164.501), management, administrative, accreditation, or financial services to or for a Covered Entity, where the provision of the service involves the disclosure of PHI from such covered entity, or from another business associate of the Covered Entity to the Business Associate.

Section 1.03 Covered Entity. The term Covered Entity shall mean a Participant that is a health care provider who transmits any health information in electronic form in connection with a transaction covered 45 CFR Parts 160, 162, or 164.

Section 1.04 Designated Record Set. The term "Designated Record Set" shall mean a group of records maintained by or for a Covered Entity that is: (a) the medical records and billing records about Individuals maintained by or for a covered health care provider; (b) the enrollment, payment, claims adjudication, and case or medical management record systems maintained by or for a health plan; or (c) used in whole or in part, by or for a Covered Entity to make decisions about Individuals. For these purposes, the term "record" means any item, collection, or grouping of information that includes PHI and is maintained, collected, used, or disseminated by or for a Covered Entity.

Section 1.05 First Agreement. The term "First Agreement" shall mean the Indianapolis Regional Network for Primary and Emergency Care Participants' Agreement which was executed by the parties in 1998.

Section 1.06 Full Participants. The term "Full Participants" shall mean those participating entities that will both submit and store Information on the Network and have access to the Network Information under the terms of this Agreement. The current Full Participants shall be: Clarian Health Partners, Inc., Community Hospital of Indiana, Inc. (and its affiliates and subsidiaries), I.U. Medical Group — Primary Care, St. Francis Hospital and Health Centers, St. Vincent Hospital and Health Care Center, Inc., and Wishard Memorial Hospital (an operating division of The Health and Hospital Corporation of Marion County). Additional Full Participants may be added under the procedures in [Section 11.02](#).

Section 1.07 HHS. The term "HHS" shall mean the United States Department of Health and Human Services.

Section 1.08 Individual. The term "Individual" shall mean a person who is the subject of PHI, and shall have the same meaning as the term "individual" as defined in 45 CFR § 160.103 and shall include a person who qualifies as a personal representative in accordance with 45 CFR § 164.502(g).

Section 1.09 Information. The term "Information" shall mean written or electronic patient information relating to a patient's diagnosis, treatment, tests, or prognosis stored by the Participants on the Network. Such Information may include, but not be limited to, admission, discharge, transfer, medical, prescription, billing, and/or other data for patients seen at, or provided laboratory services or prescription medication, at the Participants' facilities or offices.

Section 1.10 Limited Data Set. The term "Limited Data Set" shall mean PHI that excludes all direct identifiers of an Individual or of all relatives, employers, or household members of the Individual that are required to be removed pursuant to 45 CFR § 164.514(e).

Section 1.11 Network. The term "Network" shall mean the Indianapolis Regional Network for Primary and Emergency Care as described in this Agreement.

Section 1.12 Participants. The term "Participants" shall mean both Storing Participants and Full Participants. Additional Participants may be added under the procedures in [Section 11.02](#).

Section 1.13 Parties. The term "Parties" shall mean Regenstrief, Full Participants, and Storing Participants.

Section 1.14 Privacy Rule. The term "Privacy Rule" shall mean the Standards for Privacy of Individually Identifiable Health Information at 45 CFR Parts 160 and 164.

Section 1.15 Protected Health Information ("PHI"). The term "Protected Health Information" and the abbreviation "PHI" shall have the same meaning as the term "protected health information" in 45 CFR § 160.103, limited to the individually identifiable health information created or received by Business Associate from or on behalf of a Covered Entity.

Section 1.16 Regenstrief. The term "Regenstrief" shall mean the Regenstrief Institute, Inc. and its employees and research scientists.

Section 1.17 Required By Law. The term "Required By Law" shall have the same meaning as the term "required by law" in 45 CFR § 164.103.

Section 1.18 Secretary. The term "Secretary" shall mean the Secretary of the United States Department of Health and Human Services or his or her designee.

Section 1.19 Storing Participants. The term "Storing Participants" shall mean those participating entities that will only submit and store Information on the Network. A Storing Participant shall not have access to the Information stored on the Network except for the Information actually submitted by that Storing Participant. Additional Storing Participants may be added under the procedures in [Section 11.02](#).

Section 1.20 Treatment. The term "Treatment" shall have the definition assigned to it by the Privacy Rule at 45 CFR § 164.501, namely, the provision, coordination, or management of health care and related services by one or more health care providers, including the coordination or management of health care by a health care provider with a third party, consultation between health care providers relating to a patient, or the referral of a patient for health care from one health care provider to another.

ARTICLE II **Recitals**

Section 2.01 Replacement of First Agreement. The Parties previously entered into the First Agreement, and now wish to update and restate the First Agreement through this Agreement. The Parties desire this Agreement to supercede and replace the First Agreement. The First Agreement was created in the context of a specific contract with the National Library of Medicine to study the effects of city-wide sharing of health information used in emergency rooms and in primary care on the cost of health care and the efficacy of treatment for patients. Its scope of usage was limited to emergency room encounters and primary care encounters and to clinical information held by the Participants that would be useful for the care of patients during those encounters. Since that time, the Participants have agreed to allow their Information to be used for additional research purposes, most notably the Shared Pathology Informatics Network which seeks to create a Web-based system capable of searching existing electronic databases, such as the Network, to locate human specimens and associated clinical and pathologic data needed for cancer research. At Management Committee meetings, Participants have expressed

an interest in broadening the Network to care providers in settings such as the hospital or the group practices for treatment purposes.

Section 2.02 Purposes of Second Agreement.

(a) The Participants desire to continue and expand their participation in the Network by storing Information on the Network, allowing Full Participants access to such Information, and/or retrieving patient data from the Network in order to provide informed health care to their patients consistent with letters of intent and other commitments the Participants have made since the execution of the First Agreement to submit additional Information to the Network and participate in research projects related to the Information.

(b) The Parties recognize the benefits in increased quality of patient care to be gained from the sharing of patients' medical information. Through the sharing of health information of patients who are seen by more than one of the Participants, the Network seeks to reduce the costs of care inefficiencies such as unnecessary repeat testing and increase the accuracy of medical diagnoses through common and rapid access to patient information through electronic means to lead to improved outcomes for patients.

(c) The Parties further recognize the enormous opportunities to utilize the broad-based and ever-growing collection of Information on the Network for research purposes related to, among other things, studying the efficacy and cost-reducing effects of broad-based access to patient information and reviewing the Information to learn about specific diseases and their treatment.

(d) Since the execution of the First Agreement, the Privacy Rule issued under the Health Insurance Portability and Accountability Act of 1996 has clarified the responsibilities and agreements that must exist to protect the privacy of PHI and simplified the requirements for sharing such information for Treatment purposes. In addition, new grants and contracts have been awarded in which some or all of the Participants are involved that allow for an expansion of the information that the Participants wish to share among one another and for research purposes. The Privacy Rule gave organizations with existing data sharing contracts (such as the First Agreement) until April 14, 2004 to create a new agreement that follows the HIPAA requirements for business associate agreements. Because the First Agreement contemplates the use and disclosure of Information for both treatment and research purposes, it is necessary to revise the First Agreement through this Agreement to ensure that the Network's use and disclosure of Information operates within the framework created by the Privacy Rule.

ARTICLE III
Storage of Information

Section 3.01 Storage of Information on the Network. The Participants shall store Information in electronic data files dedicated to each respective Participant on the Network. The Participants agree that they each shall make good faith efforts to store, at a minimum, the following information:

(a) For Participants with emergency departments, encounter information for each emergency department visit, and for Participants with primary care or hospital visits, encounter information for such visits. Encounter information shall include: patient demographic information, reason for visit, treating health care provider(s), date of visit, place of visit, diagnoses, and procedures.

(b) Vital signs, pathology reports, radiology studies and images, discharge summaries, operative notes, inpatient medications, laboratory test results, cardiology studies, and other diagnostic tests to the extent that Participants have the capability to submit such information electronically.

Participants may store Information in addition to the minimum set of Information required by this Paragraph and are encouraged to submit any and all information that may be relevant to the clinical care of a patient. The Management Committee may not vote to reduce the Information to be submitted to the Network defined in this Agreement. Notwithstanding any of the foregoing, Participants shall not be required to submit any information that is protected from disclosure by 42 C.F.R. Part 2 (alcohol and drug abuse patient records that are maintained in connection with the performance of any federally assisted alcohol and drug abuse program), and shall not submit psychotherapy notes as that term is defined by 45 C.F.R. § 164.501.

Section 3.02 Participants' Representation Regarding Legality of Storage. To the best of each Participant's knowledge, storing the Information on the Network does not violate any rights, including copyrights, of third parties.

ARTICLE IV
Access to Information

Section 4.01 Participant Access for Treatment.

(a) Subject to the conditions set forth below, when a patient is under the Treatment of a Full Participant, all other Full Participants shall grant the treating Participant (and the individuals the treating Participant designates pursuant to [Section 4.04](#)) full access to the Information stored on the Network for purposes of treating the patient.

(b) Recognizing the value of allowing broad access to health information to treat patients, a Full Participant may also propose to the other Participants (through the Management Committee) to allow physician practices whose physicians are on staff at a Full Participant to have access to the Information for Treatment encounters that occur outside of the boundaries of the Full Participant (*e.g.*, for affiliated physician office visits). Each Participant, through its Management Committee representative, may decide whether to allow such access and shall inform the Management Committee of such a decision. The Full Participant requesting such access shall be responsible for ensuring that the members of the physician practice group agree to and comply with the conditions set forth in [Section 4.04](#).

(c) As approved by the individual Participants and pursuant to any separate agreement between such Participants and Regenstrief (either directly or as a subcontractor with another non-profit community organization), Regenstrief may transmit or deliver reports (including, but not limited to, face sheets, laboratory results, radiology reports, and dictated notes) to health care providers with whom the Participants have an agreement or obligation to provide such reports. The financial terms and other details of such transmissions or deliveries shall be governed by the respective separate agreements.

Section 4.02 Participant Access for Other Purposes. Subject to a reasonable retrieval fee to be determined by Regenstrief, each Participant will have access to the Information it stores on the Network in accordance with its own internal regulations governing access to its own internal records (provided said regulations are reasonable and adequately protect the confidentiality of the Information). The reasonable retrieval fee noted in this Section does not apply when a Full Participant seeks Information for the Treatment of a patient.

Section 4.03 Participants' Representation Regarding Legality of Access. Each Participant represents and warrants that it is authorized to allow the Full Participants, Regenstrief, and Regenstrief's subcontractors to access the Information as set forth in this Agreement pursuant to the Privacy Rule and Indiana Code §§ 16-39-5-1 and 16-39-5-3, and/or pursuant to a duly executed authorization from any Individual to whom the Information applies.

Section 4.04 Access to Information By Participants' Personnel. Each Participant shall determine the personnel under its control (including any personnel of physician practice groups allowed to access Information pursuant to [Section 4.01\(b\)](#)) who may access the Network to retrieve Information for the Treatment of patients. For Participants who are technically able to do so, each Participant shall provide daily electronic files to Regenstrief of the individuals it designates under this Section. If such electronic notice is not feasible, each Participant shall provide lists of such individuals through e-mail, hard copy, or facsimile to Regenstrief no less frequently than biweekly. Each Participant shall certify:

(a) That such designated personnel have received training regarding the confidentiality of PHI under the Privacy Rule and all other applicable State and local laws and agree to protect the Information in compliance with the Privacy Rule, such laws and this Agreement;

(b) That such designated personnel shall only access the Network for purposes of Treatment of a patient;

(c) That such designated personnel have agreed to hold any passwords, or other means for accessing the Network, in a confidential manner and to release them to no other individual;

(d) That such designated personnel have agreed to participate in various studies that may be conducted from time to time related to various issues surrounding the Network, including, but not limited to, the efficacy and usefulness of the Network; and

(e) That such designated personnel agree and understand that their failure to comply with the terms of this Agreement may result in their exclusion from the Network and may constitute cause for disciplinary action by the Participant.

Section 4.05 Access Reporting to Participants. Upon request, Regenstrief shall provide to each Participant statistical summaries indicating the number of accesses to the requesting Participant's own Information by accessing site and including a list of all queries to the Network by patient names and date of birth. The foregoing summaries shall be provided at no cost. Additional detail about a Participant's own Information may be obtained by a Participant at a reasonable fee in compliance with the provisions of this Agreement.

ARTICLE V **Confidentiality**

Section 5.01 Confidentiality. The Participants agree that any Information obtained from the Network will be kept confidential pursuant to the Privacy Rule and all other applicable federal, state, and local laws, statutes and regulations, as well as each Participant's own rules and regulations governing the confidentiality of patient records and information. Participants agree to report promptly to the Management Committee any serious breach of the confidentiality of the Information of which it becomes aware. Any hard copy of patient Information acquired from the Network for Treatment purposes will be placed in the correspondence section of the patient's medical record which is maintained by each Participant.

Section 5.02 Enforcement of Confidentiality by Participants. Each Participant agrees to enforce the confidentiality provisions of this Agreement by appropriately disciplining individuals within each Participant's organization who violate the confidentiality of the Information pursuant to each Participant's respective confidentiality and disciplinary policies. Such discipline may

include, but not be limited to: warnings; suspensions; termination; or modification, suspension, or revocation of medical staff privileges.

Section 5.03 Access to Participants' Business and Proprietary Data. Regenstrief agrees that no data (including aggregate data on a Participant level basis) concerning a Participant will be provided to other Participants or published in an identifiable form without the written permission of the affected Participant. Such data includes, but is not limited to, patient volume, charges to patients or third-party payors and similar reimbursement data, and Participants' practice patterns.

Section 5.04 Otherwise Permitted Uses of Information. Notwithstanding any other Section of this Agreement, Business Associate may use or disclose for any lawful purpose Information that: (a) is in the possession of Business Associate prior to the time of the disclosure to Business Associate by the Participants and was not acquired, directly or indirectly, from the Participants or the Network; or (b) is made available to Business Associate by a third party who has the legal right to do so.

ARTICLE VI **Administration of the Network**

Section 6.01 Regenstrief Role. Regenstrief shall administer the Network and may delegate responsibilities related to Network administration to one or more subcontractors. Regenstrief shall obtain adequate assurances from its subcontractors that only specifically authorized representatives of the subcontractor shall be granted access to the Network in connection with the subcontractor's responsibilities. The Participants acknowledge and agree that access to data (including aggregate data) shall be granted to Regenstrief for all of its functions and obligations under this Agreement and shall be granted to Regenstrief's subcontractors for the sole purpose of assisting Regenstrief in maintaining the technical operations of the Network. The Participants acknowledge that Wishard Memorial Hospital is currently a subcontractor of Regenstrief for purposes of assisting Regenstrief in the maintenance of the Network by installing new operating systems, defining networks, performing data back-up functions, and assisting with hardware problems. While it is contemplated that Wishard Memorial Hospital will continue to perform these functions, should Regenstrief require a different or additional subcontractor, such a subcontractor shall be subject to the approval of the Management Committee pursuant to Section 10.02, unless Regenstrief performs such functions itself. Regenstrief shall employ security mechanisms that are consistent with the final Security Standards (45 CFR Parts 160, 162, and 164) issued pursuant to the Health Insurance Portability and Accountability Act of 1996 to provide for the security of the Information.

Section 6.02 Provision of Network Equipment and Software.

(a) Regenstrief will provide, at its own cost, the computer software necessary to allow Participants to store and access Information on the Network and will arrange for the installation of, and bear the cost of, the necessary communication lines and/or encryption devices (at Regenstrief's discretion) to allow the secure transfer of the Information to and from the Network by the Participants to the extent that the Participants do not already maintain such lines or devices. Regenstrief will also provide personnel to assist with the mapping of test results and physician codes into a standard form accessible by all Participants. Regenstrief will also provide support for initial training, troubleshooting, and maintenance of equipment it provides that is used for Network connectivity.

(b) Except as provided [Section 6.02\(a\)](#), to the extent that Participants do not have equipment (including, but not limited to computers and printers) that was supplied in conjunction with the First Agreement for use in accessing the Network, the Participants shall use their own existing equipment to access the Network (*e.g.*, video terminals, printers at Participants' sites) and all Participants shall provide other necessary supplies such as printer paper, ink cartridges, and toner, as is the current practice.

Section 6.03 Ownership of Network Equipment.

(a) Through the First Agreement, certain Participants received computer hardware associated with the Network such as computers, printers, and communication lines. Such equipment obtained through the First Agreement and the contract between Indiana University and the National Institutes of Health through the National Library of Medicine providing for the creation and maintenance of an Indianapolis Regional Network for Primary and Emergency Care shall be and remain the sole property of NLM even though used by the Participants in their respective facilities.

(b) From time to time, grants and contracts in which the Participants agree to participate that relate to the use and disclosure of the Information may provide for the purchase of additional equipment related to the Network. The ownership of any such equipment shall be governed by the relevant grant or contract.

(c) Any equipment or communication lines supplied by individual Participants shall remain the sole property of the supplying Participant. Equipment, software, intellectual property, or communication lines supplied by Regenstrief shall remain the sole property of Regenstrief, but shall be available for use by the Participants in conjunction with this Agreement.

Section 6.04 Disclaimer of Warranties. Although all equipment associated with the Network that is supplied by Regenstrief (or that was previously supplied by Indiana University or Regenstrief pursuant to the First Agreement) shall remain the property of NLM or Regenstrief (as applicable) and the Parties do not intend for the provision of the equipment to constitute a sale or lease under the Indiana Uniform Commercial Code, the Participants nevertheless acknowledge that any equipment associated with the Network provided to the Participants by Regenstrief (or that was previously supplied by Indiana University or Regenstrief pursuant to the First Agreement) is provided **AS IS WITH ALL FAULTS. REGENSTRIEF HEREBY DISCLAIMS ANY WARRANTIES, WHETHER EXPRESS OR IMPLIED, WHICH MAY BE CLAIMED REGARDING ANY OF THE EQUIPMENT SUPPLIED TO THE PARTICIPANTS. REGENSTRIEF SPECIFICALLY HEREBY EXPRESSLY DISCLAIMS ANY IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE.** The Participants agree to hold harmless Regenstrief for any failure of any hardware, commercial software, communication lines, or other equipment supplied by Regenstrief for use in connection with the Network or for the failure to supply or maintain said equipment. Regenstrief shall take all reasonable steps to assure that manufacturers' and sellers' warranties may be enforced by the Participants, and shall cooperate with the Participants in exercising warranty rights.

Section 6.05 Use of Network Equipment. The Participants agree that any equipment associated with the Network, whether supplied by Regenstrief or a Participant, shall not be used in any way that interferes with Network-based activity.

Section 6.06 Cooperation With Regenstrief.

(a) The Participants agree to provide assistance and cooperate with Regenstrief with regard to the installation and maintenance of the software or equipment necessary to store Information on and access the Network. The Participants agree to exercise reasonable care in the use of the equipment provided by Regenstrief (and any equipment previously provided through the First Agreement), and further agree to immediately notify Regenstrief or its designee upon the malfunction of any of said equipment.

(b) The Participants agree to cooperate in the process of standardized coding of physician orders and test results.

ARTICLE VII
Creating, Using, and Disclosing Information for Research

Section 7.01 Review of Research Requests.

(a) Regenstrief, from time to time, may act as Participants' Business Associate for purposes of reviewing requests for the use and disclosure of the Information for

research purposes that are submitted to Regenstrief and may use and disclose Information in accordance with this Article. When Regenstrief reviews a research proposal or project for the use of Information, Regenstrief will verify the identity of the person or entity requesting the Information and also verify the authority under which the request for Information is made.

(b) Any research proposal that Regenstrief reviews pursuant to [Section 7.01\(a\)](#) that proposes to use all or any subset of the Information must contain at least: (a) the name(s) of the sponsor(s) of the research and the name(s) of any institution(s) under whose auspices the sponsor(s) is working; (b) the specific question to be addressed by the research (no researcher shall be permitted to access the Information without identifying a targeted goal for the research); (c) the Information to which access is requested; (d) the proposed use of said Information; (e) whether the research will require the identification of specific patients; (f) whether the research will require the identification of specific Participants; (g) any proposed publication of the results of the research; and (h) the means for protecting the confidentiality of the Information.

(c) Regenstrief shall require third parties to warrant that research publications arising from the use of Information under this [ARTICLE VII](#) will contain only aggregate data and will not specifically identify any patient whose Information is received pursuant to this Agreement unless a specific authorization to do so is obtained from a patient.

(d) In no event will Regenstrief allow Information to be disclosed for research projects that have the effect of comparing the Participants (such as individual Participant outcomes, Participant financial information, or charges to patients or third-party payors and similar reimbursement data) without specific approval from each of the institutions involved or unless such comparisons are an implicit component of a research project that complies with the provisions of [Section 7.02](#) or [Section 7.03\(a\)](#).

[Section 7.02](#) Specific Pre-Approved Research Projects. The Parties acknowledge that certain research projects are ongoing at the time of the execution of this Agreement and the use and disclosure of Information for such projects have been approved by the Participants and appropriate Institutional Review Boards. Therefore, the Parties agree that Information may be used and disclosed, consistent with the appropriate Institutional Review Board approval, for the following projects:

(a) Regenstrief may use and disclose the Information for the purposes originally outlined and approved by the contract between Indiana University and the National Institutes of Health through the National Library of Medicine providing for the creation and maintenance of an Indianapolis Regional Network for Primary and Emergency Care.

(b) Regenstrief may use and disclose the Information for purposes related to the Shared Pathology Informatics Network ("SPIN") supported by the National Cancer Institute and with which each of the Participants have a subcontract.

Section 7.03 Other Research By Regenstrief or Third Parties.

(a) *General Rule – Approvals Required.* Except as otherwise provided below in this [Section 7.03](#), any use or disclosure of the Information (whether in identified or deidentified form) for research not allowed by [Section 7.02](#) (Pre-Approved Projects for Research Uses and Disclosures), shall be proposed to the Management Committee and approved by: (1) an Institutional Review Board designated or approved by Regenstrief; (2) the Management Committee Representatives of any Participant whose Information is used in the research; and (3) Regenstrief. Prior to allowing the use of its Information for research purposes, a Participant may require that the project be subjected to the review of an Institutional Reviewing Board of its own choice. A Participant may decline to allow its Information to be used for a particular research study, but that shall not preclude the use or disclosure of the remaining Participants' Information for such project.

(b) *No Further Approvals Required – Independent Agreements Between Participants and Regenstrief.* If Regenstrief has entered into, or enters into, any other agreement with one or more Participants that complies with the Privacy Rule with regard to the research uses and disclosures of the Participant's own Information stored on the Network, the provisions of such an agreement shall govern the use and disclosure of that Participant's Information and the approvals required by [Section 7.03\(a\)](#) shall not be required.

(c) *No Further Approvals Required – Preparatory to Research and Decedents' Research.* Regenstrief (as Participants' Business Associate) may, and the Participants (as Covered Entities) hereby delegate the authority to Regenstrief to, authorize the use or disclosure of Information (whether in identified or deidentified form) for research projects without further approval from Participants under [Section 7.03\(a\)](#), if the research projects meet the following criteria (provided that all Privacy Rule requirements regarding research have been met, including, but not limited to, the guidelines set forth in [Section 7.04](#)):

(1) Regenstrief may use or disclose identifiable PHI for reviews preparatory to research (consistent with 45 CFR § 164.512(i)(1)(ii)); and

(2) Regenstrief may use and disclose identifiable PHI for research on decedent's information (consistent with 45 CFR § 164.512 (i)(1)(iii)).

At the request of a Participant, Regenstrief shall provide reports of the research disclosures made pursuant to this Section.

(d) *No Further Approvals Required – Certain Disclosures of Deidentified Information and Limited Data Sets.* Regenstrief (as Participants' Business Associate) may, and the Participants (as Covered Entities) hereby delegate the authority to Regenstrief to, authorize the use or disclosure of deidentified Information or Limited Data Sets to any entity that has obtained an approval from an Institutional Review Board acceptable to Regenstrief for the use of deidentified Information or Limited Data Sets in connection with a research project. Further, Regenstrief may use or disclose deidentified Information or Limited Data Sets without further approval from a Participant if such deidentified Information or Limited Data Sets are included in classes or categories of queries that are approved by the Management Committee or an Institutional Review Board acceptable to Regenstrief. At the request of a Participant, Regenstrief shall provide reports of the research disclosures made pursuant to this Section.

Section 7.04 Guidelines for Using and Disclosing Information. When a research project has been approved pursuant to [Section 7.02](#) or [Section 7.03](#), Regenstrief shall act as the Participants' Business Associate for purposes of disclosing the Information to the researchers. Regenstrief shall use the following guidelines when using or disclosing PHI or deidentified data:

(a) *Initial Determination of Scope of Information To Be Disclosed.* For each research project, Regenstrief shall make a threshold determination of whether the minimum necessary use or disclosure of Information to comply with the request involves the use or disclosure of identifiable Information, a Limited Data Set, or deidentified Information. In making this threshold determination and when further disclosing Information in connection with the research project, Regenstrief may rely on and adopt the determination of an Institutional Review Board as to the scope of the minimum necessary disclosure for the research project. If a research disclosure is made pursuant to an Individual's authorization, the scope of the authorization shall constitute the minimum necessary disclosure. In the event Regenstrief determines it is necessary to disclose the entire subset of Information on the Network concerning an Individual to comply with the research request, Regenstrief will document the justification for releasing the entire subset of Information. An Institutional Review Board's determination that the entire subset of Information on the Network is necessary, or an Individual's authorization, shall constitute such documentation.

(b) *Conditions For Disclosing Individually Identifiable Health Information.* If PHI is requested for a research project, Regenstrief shall not use or disclose the PHI unless: (A) authorizations that comply with the Privacy Rule allowing the use or disclosure of the PHI for the specific research purpose are obtained or have obtained from all Individuals whose PHI will be used or disclosed; or (B) a waiver of the authorization

is obtained from an appropriate Institutional Review Board or Privacy Board in accordance with 45 CFR § 164.512(i). Notwithstanding the foregoing, Regenstrief may use or disclose identifiable PHI for reviews preparatory to research (consistent with 45 CFR § 164.512(i)(1)(ii)) and for research on decedent's information (consistent with 45 CFR § 164.512 (i)(1)(iii)) without an authorization or the waiver thereof; provided that the use or disclosure of the PHI is consistent with the minimum necessary standard of the Privacy Rule. This [Section 7.04\(b\)](#) shall not apply to information in a Limited Data Set or deidentified information.

(c) *Conditions For Disclosing Limited Data Sets.* If a Limited Data Set is requested for a research project, Regenstrief shall not use or disclose the Information unless Regenstrief, on behalf of the affected Covered Entity Participants, obtains a "Data Use Agreement" from the individual or entity using the Limited Data Set or to which the Limited Data Set will be disclosed. Such Data Use Agreement shall comply with the requirements of 45 CFR § 164.514(e). Regenstrief further agrees to maintain copies of all Data Use Agreements related to Covered Entity Participants' Information and to forward same to the Covered Entity upon request.

(d) *Conditions For Disclosing Deidentified Information.* If deidentified Information is used or disclosed, Regenstrief shall act as Covered Entities' Business Associate for purposes of deidentifying the Information and shall ensure that no health information that is used or disclosed identifies an Individual and that there is no reasonable basis to believe that the information can be used to identify an Individual. All deidentification of PHI shall be conducted in compliance with 45 CFR § 164.514(a) – (c).

Section 7.05 Involvement of Participant Investigator in Research. As a condition of approval of a research project not conducted by Regenstrief, any sponsor of research using all or any subset of the Information shall be required to invite an investigator from any Participant whose Information is used in the research and an investigator from Regenstrief to participate in the research project.

Section 7.06 Access to Network by Researchers. No researcher, other than Regenstrief, shall have direct access to identified Information on the Network (although access to deidentified Information and Limited Data Sets may be permitted if allowed under [Section 7.02](#) or [Section 7.03](#)). Information that is not deidentified and that is requested by researchers other than Regenstrief shall be retrieved by representatives of Regenstrief. Any use of the Information for research by Regenstrief shall be limited to the purpose of the research as approved or allowed by [Section 7.02](#) or [Section 7.03](#).

Section 7.07 Cooperation by Participants' in Network Evaluations. The Participants agree to cooperate in studies conducted from time to time by the Regenstrief related to various issues surrounding the Network, including, but not limited to, the efficacy and usefulness of the

Network. Such cooperation by the Participants may include, but not be limited to, participation in interviews, the completion of surveys, and the submission of other written or oral evaluations.

ARTICLE VIII
HIPAA Business Associate Provisions

Section 8.01 Limits on Use and Disclosure.

(a) Business Associate agrees to not use or further disclose PHI other than as permitted or required by this Agreement or as Required By Law. Business Associate may use and disclose PHI to perform those functions, activities, or services that Business Associate performs for, or on behalf of, each Covered Entity as specified in this Agreement, provided that such use or disclosure would not violate the Privacy Rule if done by a Covered Entity, including but not limited to storing Participant Information on the Network and maintaining the Network, making disclosures to Participants for Treatment purposes, using and disclosing Information for research purposes in compliance with [ARTICLE VII](#), and reporting Information to appropriate governmental agencies for public health purposes (including, including, but not limited to, screening laboratory data on behalf of Covered Entities and making legally required reports to the Indiana State Department of Health). Any such use or disclosure shall be limited to those reasons and those individuals as necessary to meet the Business Associate's obligations under this Agreement.

(b) Business Associate will not make the following disclosures that are otherwise allowed to be made by a Covered Entity under 45 C.F.R. § 164.512 unless compelled to do so by law or unless such a disclosure is specifically authorized or required by this Agreement (including, but not limited to, [ARTICLE VII](#)):

- (1) About victims of abuse, neglect, or domestic violence;
- (2) For health oversight activities;
- (3) For judicial and administrative proceedings;
- (4) For law enforcement purposes;
- (5) About decedents;
- (6) For cadaveric organ, eye, or tissue donation purposes;
- (7) To avert a serious threat to health or safety;
- (8) For specialized government functions;

- (9) For workers' compensation purposes;
- (10) For marketing purposes;
- (11) For fundraising purposes.

If Business Associate is requested to make a disclosure for one of the foregoing reasons, it shall forward such request to the Covered Entity so that the Covered Entity can coordinate and prepare a timely response. Business Associate shall make PHI available to the Covered Entity for the foregoing reasons if requested to do so in writing by the Covered Entity for the Covered Entity to coordinate and prepare a timely response.

(c) Notwithstanding [Section 8.01\(a\)](#), Business Associate may use PHI for the proper management and administration of the Business Associate or to carry out the legal responsibilities of the Business Associate. Furthermore, Business Associate may disclose PHI for the proper management and administration of the Business Associate, provided that disclosures are Required By Law, or the Business Associate obtains reasonable assurances from the person to whom the PHI is disclosed that it will remain confidential and used or further disclosed only as Required By Law or for the purpose for which it was disclosed to the person, and the person notifies the Business Associate of any instances of which it is aware in which the confidentiality of the PHI has been breached.

(d) If a Business Associate provides data aggregation services, the Business Associate may use PHI to provide data aggregation services to a Covered Entity as permitted by 42 CFR § 164.504(e)(2)(i)(B), except as otherwise provided by this Agreement.

Section 8.02 Safeguards. Business Associate agrees to use reasonable and appropriate administrative, physical and technological safeguards to prevent use or disclosure of the PHI other than as provided for by this Agreement. In addition, by April 21, 2005 (or such other later compliance date as established by the United States Secretary of Health and Human Services), Business Associate shall implement such safeguards and security measures as are necessary to comply with the HIPAA Security Standards as set forth in 45 CFR Parts 160, 162, and 164. Business Associate shall provide periodic reports to the Management Committee related to the security measures implemented by Business Associate for the Network, including any security issues that have arisen since any prior report. The provisions of this Section with regard to the security of records management shall survive the termination of this Agreement.

Section 8.03 Report of Improper Use or Disclosure. Business Associate agrees promptly to report to a Covered Entity any use or disclosure of the Covered Entity's PHI not provided for by this Agreement of which Business Associate becomes aware.

Section 8.04 Agents and Subcontractors. Business Associate agrees to ensure that any agent, including a subcontractor, to whom it provides PHI received from, or created or received by the Business Associate on behalf of, a Covered Entity, agrees to the same restrictions and conditions that apply through this Agreement to the Business Associate with respect to PHI.

Section 8.05 Access to Records. Business Associate shall provide reasonable access to PHI in a Designated Record Set in the Business Associate's possession to the Covered Entity to which the PHI belongs in order for the Covered Entity to meet the requirements under 45 CFR § 164.524 with regard to providing an Individual with a right to access the Individual's PHI. Prior to making a request to Business Associate under this Section, Participants shall make a good faith effort to gather the requested PHI from their own data sources that feed the Network. In any event, Business Associate shall not respond directly to requests from Individuals for access to their PHI in a Designated Record Set. Business Associate will refer such Individuals to the relevant Covered Entity so that the Covered Entity can coordinate and prepare a timely response to the Individual.

Section 8.06 Amendments to PHI.

(a) Business Associate shall provide reasonable access to PHI in a Designated Record Set in the Business Associate's possession to the Covered Entity to which the PHI belongs for Covered Entity to make any amendments that Covered Entity agrees to make pursuant to 45 CFR § 164.526 or to otherwise allow Covered Entity to comply with its obligations under 45 CFR § 164.526. Amendments to PHI in the Network shall be made by Covered Entity to the Network through routine submissions of Information via an electronic interface from a system operated by the Covered Entity. Business Associate shall have no obligation to independently make such amendments or to enter such amendments into the Network. No Covered Entity shall agree to any request for an amendment without consulting with Regenstrief to determine whether Regenstrief and the Network are physically, administratively, and technologically capable of complying with the amendment.

(b) Business Associate shall not respond directly to requests from Individual's for amendments to their PHI in a Designated Record Set. Business Associate will refer such Individuals to the relevant Covered Entity so that the Covered Entity can coordinate and prepare a timely response to the Individual.

Section 8.07 Documentation and Provision of Disclosures.

(a) Business Associate shall document such disclosures of PHI and information related to such disclosures as would be required for Covered Entity to respond to a request by an Individual for an accounting of disclosures of PHI in accordance with 45 CFR § 164.528. Such documentation shall be kept with regard to all

disclosures of PHI except for the disclosures that are excepted from the accounting requirement at 45 CFR § 164.528(a) (as it may be amended from time to time), which currently include the following:

(1) To carry out treatment, payment, and health care operations as provided in 45 CFR § 164.506;

(2) To Individuals of PHI about them as provided in 45 CFR § 164.502;

(3) Incident to a use or disclosure otherwise permitted or required by the Privacy Rule, as provided by 45 CFR § 164.502;

(4) Pursuant to an authorization by an Individual as provided in 45 CFR § 164.508;

(5) For Covered Entity's facility directory or to persons involved in an Individual's care or other notification purposes as provided in 45 CFR § 164.510;

(6) For national security or intelligence purposes as provided in 45 CFR § 164.512(k)(2);

(7) To correctional institutions or law enforcement officials as provided in 45 CFR § 164.512(k)(5);

(8) As part of a Limited Data Set in accordance with 45 CFR § 164.514(e); or

(9) That occurred prior to April 14, 2003.

(b) For each non-excepted disclosure, Business Associate shall document the following information: (i) the date of the disclosure; (ii) the name of the entity or person who received the PHI and, if known, the address of such entity or person; (iii) a brief description of the PHI disclosed; and (iv) a brief statement of the purpose of the disclosure that reasonably states the basis for the disclosure.

(c) Business Associate shall provide to a requesting Covered Entity, within a reasonable time period after Covered Entity's request, information collected in accordance with this Section, to permit Covered Entity to respond to a request by an Individual for an accounting of disclosures of PHI in accordance with 45 CFR § 164.528. However, Business Associate shall not respond directly to requests from Individual's for an accounting of disclosures. Business Associate will refer such Individuals to the

relevant Covered Entity so that the Covered Entity can coordinate and prepare a timely response to the Individual.

Section 8.08 Availability of Internal Practices, Books and Records. Business Associate shall make its internal practices, books, and records relating to the use and disclosure of PHI received from, or created or received by the Business Associate on behalf of, a Covered Entity available to the Secretary, in a reasonable time and manner designated by the Secretary, for purposes of determining a Covered Entity's compliance with the Privacy Rule.

Section 8.09 Change or Revocation of Permission. Each Covered Entity shall provide Business Associate with notice of any changes in, or revocation of, permission by an Individual to use or disclose PHI, or of any restriction to the use or disclosure of PHI that the Covered Entity has agreed to in accordance with 45 CFR § 164.522, if such changes or restrictions affect a Business Associate's permitted or required uses and disclosures. A Covered Entity shall not agree to any such changes or restrictions without consulting with Regenstrief to determine whether Regenstrief and the Network are physically, administratively, and technologically capable of complying with such changes or restrictions, and without obtaining Regenstrief's consent (which will not be unreasonably withheld). No Business Associate shall be responsible for any use or disclosure that fails to comply with any such change or revocation that occurs prior to being notified by the Covered Entity pursuant to this Section.

Section 8.10 No Request to Use or Disclose in Impermissible Manner. Except as necessary for the management and administrative activities of the a Business Associate as allowed in [Section 8.01\(c\)](#), a Covered Entity shall not request a Business Associate to use or disclose PHI in any manner that would not be permissible under the Privacy Rule if done by Covered Entity. No Business Associate shall be responsible for any compliance with, or failure to comply with, a request from Covered Entity to use or disclose PHI in a manner that would not be permissible under the Privacy Rule if done by Covered Entity.

Section 8.11 Notice of Privacy Practices. Each Covered Entity shall provide Business Associate with the Notice of Privacy Practices that Covered Entity produces in accordance with 45 CFR § 164.520, as well as any changes to such notice. Each Covered Entity shall ensure that its Notice of Privacy Practices includes provisions that adequately inform Individuals: (a) that their PHI may be used and disclosed and received from other health care providers for Treatment purposes; (b) of the research uses and disclosures of PHI set forth in this Agreement; and (c) that their PHI may be used and disclosed by Business Associate to perform functions like those allowed in this Agreement.

Section 8.12 Limited Data Set Provisions. With regard to Limited Data Sets used by Regenstrief, the following provisions of this Article shall apply to the use and disclosure of such Limited Data Sets: [Section 8.01](#), [Section 8.02](#), [Section 8.03](#), and [Section 8.04](#). Further, with

regard to Regenstrief's use of Limited Data Sets, Regenstrief agrees not to identify the information or contact the Individuals whose information comprises the Limited Data Sets.

Section 8.13 Mitigation. Business Associate agrees to mitigate, to the extent practicable, any harmful effect that is known to Business Associate of a use or disclosure in violation of the requirements of this Agreement.

ARTICLE IX **Indemnification**

Section 9.01 Indemnification by Participants. A Participant that breaches the confidentiality of the Information, or submits inaccurate, incomplete, or defamatory data to the Network ("Breaching Participant") agrees to indemnify and hold harmless any other Party against whom any claim or cause of action is brought ("Sued Party") by any individual arising out of or resulting from such breach of confidentiality or submission of inaccurate, incomplete, or defamatory data by the Breaching Participant or any individual for whom such Participant is responsible. Such indemnification shall include the payment of all costs associated with defending such claims or causes of action, whether such claims or causes of action are meritorious, including reasonable attorney fees and any settlement by or judgment against the Sued Party arising out of or resulting from any breach of confidentiality of the Information, or the submission of inaccurate, incomplete, or defamatory data to the Network by the Breaching Participant or any individual for whom such Participant is responsible. In the event a suit is brought against the Sued Party under circumstances where this Section applies, the Breaching Participant, at its sole cost and expense, shall defend the Sued Party in such suit if written notice thereof is promptly given to the Breaching Participant within a period wherein the Breaching Participant is not prejudiced by lack of such notice. If the Breaching Participant is required to indemnify and defend, it will thereafter have control of such litigation, but the Breaching Participant may not settle such litigation without the consent of the Sued Party, which consent shall not be unreasonably withheld. This Section is not, as to third parties, a waiver of any defense or immunity otherwise available to the Sued Party; and the Breaching Participant, in defending any action on behalf of the Sued Party, shall be entitled to assert in any action every defense or immunity that the Sued Party could assert in its own behalf.

Section 9.02 Indemnification by Regenstrief. Regenstrief agrees to indemnify and hold harmless any other Party against whom any claim or cause of action is brought ("Sued Party") by any individual arising out of or resulting from any breach of confidentiality of the Information (whether through disclosure or through acts or omissions in the design and/or maintenance of the Network) by Regenstrief or any individual for whom Regenstrief is responsible. Such indemnification shall include the payment of all costs associated with defending such claims or causes of action, whether such claims or causes of action are meritorious, including reasonable attorney fees and any settlement by or judgment against any Sued Party arising out of or resulting from a breach of confidentiality of the Information by Regenstrief or any individual for

whom Regenstrief is responsible. In the event a suit is brought against the Sued Party under circumstances where this Section applies, Regenstrief, at its sole cost and expense, shall defend the Sued Party in such suit if written notice thereof is promptly given to Regenstrief within a period wherein Regenstrief is not prejudiced by lack of such notice. If Regenstrief is required to indemnify and defend, it will thereafter have control of such litigation, but Regenstrief may not settle such litigation without the consent of the Sued Party, which consent shall not be unreasonably withheld. This Section is not, as to third parties, a waiver of any defense or immunity otherwise available to the Sued Party; and Regenstrief, in defending any action on behalf of the Sued Party, shall be entitled to assert in any action every defense or immunity that the Sued Party could assert in its own behalf.

ARTICLE X **Management Committee**

Section 10.01 Composition and Duties of Management Committee. Each Participant will be entitled to be represented by two individuals on a Management Committee to coordinate the operations of the Network and to have full authority to act on behalf of the Participant with regard to Network operations. Regenstrief shall also be represented by two individuals on the Committee, however Regenstrief may have any number of observers on the Committee to help accomplish the work of the Committee. Each Party shall specifically identify their Management Committee representatives in writing to Regenstrief. Communications and notices regarding the Network shall be provided to the named representatives and Regenstrief shall be able to fully rely on the actions and representations of a Participant's designated representatives or any proxy representative that the Participant chooses to send to a meeting or communicate with Regenstrief, and shall be fully protected in such reliance. This Committee will meet from time to time, but not without at least seven days' notice, to consider and resolve various issues surrounding the Network, including, but not limited to: technical issues, confidentiality, the scope of Information stored and accessed by Participants, the use of the Information, and any other issues related to the Network or the Participants' participation therein.

Section 10.02 Voting. Each Participant and Regenstrief shall be entitled to exercise one vote on decisions made by the Committee, regardless of the number of their respective Committee members. At any meeting of the Management Committee, the holders of a majority of the eligible votes that may be voted on the business to be transacted at such meeting shall constitute a quorum, and a vote of 80% of the votes held by the members of the Committee constituting the quorum shall be necessary for the transaction of any business at the meeting. No decision made by the Management Committee may contravene any provision of the Agreement or the spirit or intent thereof.

Section 10.03 Force of Management Committee Decisions. Any decisions made by the Management Committee in accordance with [Section 10.02](#) shall control the relationship between the Parties and their respective obligations hereunder, and shall be binding on all Parties

notwithstanding any other provision of this Agreement unless: (a) a specific Section of this Agreement affirmatively prevents its alteration by the Management Committee; or (b) a Party objects in writing (i) within ten (10) days after a Management Committee decision is made with which it objects, or (ii) in the case of a meeting at which the Party's representatives were not present, within ten (10) days after receipt of written notification of the Management Committee decision. Such an objecting Party shall be entitled to abstain from complying with such decision without penalty unless the Party's concerns regarding the decision are accommodated by the other Parties to this Agreement.

ARTICLE XI **Amendment and Addition of Subsequent Participants**

Section 11.01 Amendment. This Agreement contains the entire agreement of the Parties and supercedes all previous negotiations and agreements, whether written or oral, including, but not limited to the First Agreement. This Agreement may be amended only by an instrument in writing signed by the Party against whom the change, waiver, modification, extension, or discharge is sought, unless otherwise indicated in this Agreement.

Section 11.02 Addition of New Participants. The Participants acknowledge that additional Participants may be added to the Network. Such additional Participants may be added to the Network upon approval of the Management Committee in compliance with [Section 10.02](#). Subsequent Participants shall be required to execute an Agreement substantially similar to this Agreement.

ARTICLE XII **Term and Termination**

Section 12.01 Term of the Agreement. The term of this Agreement shall begin on April 14, 2004 and shall last through April 13, 2009. This Agreement shall thereafter automatically renew as of each subsequent April 14 as to each Party unless such Party has provided written notice of its intent to withdraw pursuant to [Section 12.03](#) at least one hundred eighty (180) days before the renewal date. The withdrawal of less than all of the Participants shall not be considered a termination of the Agreement and the remaining Participants shall continue to participate under the terms of the Agreement, as amended.

Section 12.02 Use and Disclosure of Information After Termination. Upon the complete termination of this Agreement, the Participants agree that the Information stored on the Network as of the date of the termination of the Agreement shall remain on the Network for use and disclosure, subject to Regenstrief's desire to continue maintaining the Network, under the following conditions:

- (a) For a period of two (2) years after the termination of the Agreement as to all Parties, Regenstrief may continue to use the Information for scientific and research

purposes, including, but not limited to, publication of research results in accordance with [ARTICLE VII](#) and [ARTICLE VIII](#). After the two-year period, Participants may request that their Information no longer be used or disclosed for any purpose. Until such a request is made, Regenstrief may continue to use the Information in compliance with this Section, provided Regenstrief gives prior written notice to the affected Participants of any such use. Notwithstanding the foregoing, Information must continue to be stored on the Network for a longer period of time to the extent that Participants have agreed to make their Information available for research project approved pursuant to [ARTICLE VII](#), in which case the Information shall continued to be stored, and may continue to be used and disclosed, for the duration of such research projects in compliance with the terms of the projects. After the applicable period discussed above, Regenstrief shall no longer use or disclose the Information for research purposes and the provisions of [ARTICLE V](#) (Confidentiality) and [ARTICLE VIII](#) (HIPAA Business Associate Provisions) shall continue to apply to the Information.

(b) Full Participants may continue to access all Network Information pursuant to [ARTICLE IV](#) and [ARTICLE V](#) of the Agreement until such time as an election is made by a submitting Participant to disallow such access to its own Information. If a Participant elects to disallow access to its own Information on the Network, such electing Participant's Information will no longer be available to other Full Participants and such an electing Participant, if a Full Participant, shall thereafter be precluded from accessing the Network. Notwithstanding, Information may continue to be used and disclosed for the reasons described in Section 12.05.

(c) Continued use and disclosure of the Information pursuant to [Section 12.02\(a\)](#) and [Section 12.02\(b\)](#) shall be subject to [ARTICLE V](#), [ARTICLE VII](#), [ARTICLE VIII](#), and [ARTICLE IX](#).

Section 12.03 Withdrawal of a Participant. A Participant may withdraw from this Agreement in connection with any renewal of this Agreement pursuant to [Section 12.01](#). Except as provided in the preceding sentence, a Participant may withdraw from this Agreement prior to any renewal of the Agreement only: (a) upon written agreement between the withdrawing Participant and Regenstrief; or (b) for cause. The following shall constitute adequate cause for the withdrawal from this Agreement:

(a) A significant breach of another Participant's duties of confidentiality under [ARTICLE V](#) of this Agreement with regard to Information stored on the Network by the withdrawing Participant, or a significant breach of Regenstrief's duties under [ARTICLE VII](#) or [ARTICLE VIII](#) with regard to Information stored on the Network by the withdrawing Participant (provided that the Participant has allowed a reasonable time for Regenstrief to cure any such significant breach). Any claim of a significant breach by a Party shall be submitted to the Management Committee which will determine, pursuant

to [Section 10.02](#) of this Agreement, whether a claimed breach is significant enough to constitute cause under this Agreement. This determination shall be an advisory opinion and shall not be binding on any party to this Agreement and shall not act as a waiver or determination of any Party's rights under federal, state or local laws. In a vote to determine whether a breach is significant, the complaining party(ies) and the alleged-breaching party(ies) shall not participate.

(b) Excessive and unexpected expenses incurred by the withdrawing Participant as a result of its participation in this Agreement that exceed \$10,000 for any given period of twelve (12) months during the term of this Agreement (including any renewal period) and that are documented through generally accepted accounting methods; or

(c) The inability of a withdrawing Participant to access its own Information submitted to the Network due to causes controlled by Regenstrief. Such inability shall not constitute cause until a Participant has provided notice to Regenstrief or its designee that such Information is inaccessible and after Regenstrief is unable to cure such inaccessibility after having been given sixty (60) days to do so after notice is provided.

Section 12.04 Use and Disclosure of Information After Withdrawal.

(a) A Participant that withdraws from this Agreement, regardless of whether such withdrawal complies with [Section 12.03](#) of this Agreement, need not continue submitting additional Information for storage on the Network. However, any Information stored on the Network at the time of the withdrawal must be left on the Network for a period of two (2) years after the termination of the Agreement, during which time Regenstrief may continue to use the Information for scientific and research purposes, including, but not limited to, publication of research results in accordance with [ARTICLE VII](#) and [ARTICLE VIII](#). After the two-year period, Participants may request that their Information no longer be used or disclosed for any purpose. Until such a request is made, Regenstrief may continue to use the Information in compliance with this Section, provided Regenstrief gives prior written notice to the affected Participants of any such use. Notwithstanding the foregoing, Information must continue to be stored on the Network for a longer period of time to the extent that Participants have agreed to make their Information available for research project approved pursuant to [ARTICLE VII](#), in which case the Information shall continued to be stored, and may continue to be used and disclosed, for the duration of such research projects in compliance with the terms of the projects. After the applicable period discussed above, Regenstrief shall no longer use or disclose the Information for research purposes and the provisions of [ARTICLE V](#) (Confidentiality) and [ARTICLE VIII](#) (HIPAA Business Associate Provisions) shall continue to apply to the Information.

(b) Notwithstanding the foregoing [Section 12.04\(a\)](#), if a Participant withdraws because of a significant breach of Regenstrief's duties under [ARTICLE VII](#) or [ARTICLE VIII](#) with regard to Information stored on the Network by the withdrawing Participant, the provisions of [Section 12.04\(a\)](#) shall not apply and Regenstrief may no longer use or disclose the Information for research purposes.

(c) Upon a Participant's withdrawal, the Information stored by such Participant on the Network shall no longer be accessible by the Full Participants and all confidentiality provisions contained in this Agreement shall remain in force. Notwithstanding, Information may continue to be used and disclosed for the reasons described in [Section 12.05](#).

[Section 12.05 Infeasibility of Return of Information](#). The Parties recognize that due to the interconnectivity of the Network and the fact that the Participants will be relying on the Information on the Network to make Treatment decisions for patients, it is necessary for the Information to remain on the Network for potential risk management and legal defense purposes. Therefore, it is infeasible for Information to be returned or destroyed at the termination of the Agreement or the withdrawal of a Participant. However, if elected in compliance with, or mandated by a term of, this Article, Information may no longer be available for Participants to access after the termination of this Agreement or the withdrawal of a Participant except for the purposes that make the return or destruction of the Information infeasible. Regenstrief shall continue to store the Information on the Network subject to the confidentiality obligations in this Agreement and shall not further use or disclose the Information except as allowed by this Agreement, including, but not limited to, the reasons set forth above that make the return or destruction infeasible.

ARTICLE XIII **Miscellaneous Provisions**

[Section 13.01 Governing Law](#). The scope, performance, validity, enforcement, and all other aspects of this Agreement shall be governed by the laws of the State of Indiana, unless otherwise preempted by the laws of the United States of America.

[Section 13.02 Multiple Counterparts](#). This Agreement may be executed in multiple counterparts, each of which will be deemed an original, but all of which together will constitute one and the same

[Section 13.03 Incorporation By Reference](#). All exhibits attached to this Agreement are incorporated by reference and made a part of this Agreement as if those exhibits were set forth at length in the text of this Agreement.

[Section 13.04 Gender](#). Any reference to gender will be deemed to include the masculine, the feminine, and the neuter genders unless the context otherwise requires.

Section 13.05 Headings. Any subject headings used this Agreement are included for purposes of convenience only, and shall not affect the construction or interpretation of any of its provisions.

Section 13.06 Succession and Assignment. This Agreement will be binding on, and will inure to the benefit of, the Parties and their respective successors and assigns. No party may assign or transfer any rights or obligations under this Agreement without the prior written consent of the other Parties, which consent shall not be unreasonably withheld.

Section 13.07 No Third Party Rights. This Agreement does not and will not create in any natural person, corporation, partnership, or other organization any benefits or rights, and this Agreement will be effective only as to the Parties and their successors and assigns.

Section 13.08 Compliance With Laws. The Parties to this Agreement intend and in good faith believe that this Agreement complies with all federal, state, and local laws. If any provision of this Agreement is declared void by a court or arbitrator, or rendered invalid by any law or regulation, that portion shall be severed from this Agreement, and the remaining provisions shall remain in effect, unless the effect of the severance would be to substantially alter the Agreement or obligations of the Parties, in which case, the Parties agree to attempt in good faith to renegotiate the Agreement to comply with such law(s) to the satisfaction of all Parties. In the event the Parties are not able to mutually agree to a new agreement within one hundred eighty (180) days, then this Agreement shall terminate and all data shall be returned to each Participant and the data shall be deleted from the Network.

Section 13.09 Notice. All notices, requests, demands, and other communications associated with this Agreement shall be in writing and will be deemed to have been duly given on the date of service if served personally on, or by facsimile transmission to, the party to whom notice is to be given, or on the third day after mailing if mailed to the party to whom notice is to be given by certified mail, return receipt requested, and properly addressed to the individuals executing this Agreement on behalf of the respective Parties as set forth on the signature portion of this Agreement, with a copy to other persons as such Parties may designate in writing to Regenstrief.

Section 13.10 Independent Contractors. It is mutually understood and agreed that in performing their respective duties and obligations hereunder, the Parties are at all times acting as independent contractors with respect to each other. Nothing in this Agreement shall constitute or be construed to create a partnership or joint venture between or among the Parties.

Section 13.11 Conditional Participation. Each Participant's participation in the Network is conditional on the continued control and development of the repository software by Regenstrief and the operation and management of the Network by Regenstrief or its subcontractor. This Agreement shall be voidable and the Participants shall be entitled to

withdraw pursuant to [Section 12.03](#) of this Agreement if another party acquires control of the Network.

Section 13.12 Notification of Claims. Each Party shall promptly notify all other Parties upon notification or receipt of any civil or criminal claims, demands, causes of action, lawsuits, or governmental enforcement actions arising out of or related to this Agreement, regardless of whether the other Parties are named as a party in such claims, demands, causes of action, lawsuits, or enforcement actions.

Section 13.13 Regulatory References. A reference in this Agreement to a section in a federal, state, or local statute, law, or regulation means the section as in effect or as amended.

Section 13.14 Ethical and Religious Directives. The Parties acknowledge that the operation of St. Francis Hospital and Health Centers and St. Vincent Hospital and Health Care Center, Inc. (a member of Ascension Health) and their participation in the Network in accordance with the Ethical and Religious Directives and the principles and beliefs of the Roman Catholic Church ("Directives") are matters of conscience. It is the intent and agreement of the Parties that neither this Agreement nor any part hereof shall be construed to require St. Francis or St. Vincent to violate said Directives in their operation and all parts of this Agreement must be interpreted in a manner that is consistent with said Directives.

Section 13.15 Corporate Compliance. The Parties acknowledge that some or all of them have in place a Corporate Compliance Program ("Program") which has as its goal to ensure that the Party complies with federal, state, and local laws and regulations. These Programs focus on risk management, the promotion of good corporate citizenship, including the commitment to uphold a high standard of ethical and legal business practices, and the prevention of misconduct. The Parties acknowledge one another's respective commitments to their Programs and agree to conduct all business transactions which occur pursuant to this Agreement in accordance with the underlying philosophy of Program Compliance adopted by the respective Parties.

Section 13.16 Waiver of Breach. No failure or delay by any party in exercising its rights under this Agreement shall operate as a waiver of such rights, and no waiver of any breach shall constitute a waiver of any prior, concurrent, or subsequent breach.

IN WITNESS WHEREOF, the Parties have executed this Agreement as of the dates indicated below.

CLARIAN HEALTH PARTNERS, INC.

By: _____
Signature

Printed

Title

Date

Address

COMMUNITY HOSPITAL OF INDIANA, INC.

By: _____
Signature

Printed

Title

Date

Address

**HEALTH AND HOSPITAL CORPORATION OF MARION COUNTY on behalf of
WISHARD MEMORIAL HOSPITAL**

By: _____
Signature

Printed

Title

Date

Address

I.U. MEDICAL GROUP — PRIMARY CARE

By: _____
Signature

Printed

Title

Date

Address

REGENSTRIEF INSTITUTE, INC.

By: _____
Signature

Printed

Title

Date

Address

ST. FRANCIS HOSPITAL AND HEALTH CENTERS

By: _____
Signature

Printed

Title

Date

Address

ST. VINCENT HOSPITAL AND HEALTH CARE CENTER, INC.

By: _____
Signature

Printed

Date

Title

Address

INDY 1385321v1