

Research Policy & Procedure

PURPOSE:

To identify the procedures and process for organizations or individuals to request Message Content through the HIN and to establish the parameters of Permitted Purposes related to Research.

All Permitted Purposes related to Research must be in accordance with this Policy and applicable law. The impermissible use and disclosure of Message Content provided for Research will not be tolerated by the HIN and will result in the denial of future access and potential legal action.

DEFINITIONS:

Data Use Agreement means an agreement which sets forth the permissible use of and required safeguards of a Limited Data Set for Research purposes without patient authorization and meets the requirements set forth at 45 C.F.R. § 164.514(e)(4)(ii).

De-Identified Data Set means information that excludes the specific identifiers set forth at 45 C.F.R. § 164.514(b)(2) and for which there is no knowledge that such information could be used to identify the subject of the information.

Identified Data Set means information which includes one or more of the direct identifiers set forth at 45 C.F.R. § 164.514(e).

IRB or Institutional Review Board means a committee that has been formally designated by Participant to approve, monitor, and review biomedical and behavioral Research involving humans, as defined and governed by 45 C.F.R. Part 46, implementing the provisions of the National Research Act of 1974.

Limited Data Set means information which excludes the specific direct identifiers set forth at 45 C.F.R. § 164.514(e).

Participant Organization means an individual or organization that has entered into a mutually agreed upon data sharing agreement with HIN.

Requestor means a person or entity that requests information for a Permitted Purpose related to Research.

Research means the use of data of multiple individuals for purposes beyond treatment, payment, and healthcare operations, as defined under the HIPAA Privacy Rule, and used for purposes such as for data analytics, quality and safety measurement, and research as defined under 45 C.F.R. § 164.501.

PROCEDURE:

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1. Eligible Requestors. To be eligible to request information for Research, the Requestor must be a Participant connected to HIN.
2. Date Request Process. The process for requesting information for Research is as follows:
 - A. For each request for Research, the Requestor must complete a data request form, as set forth on Appendix A, which contains the basic information necessary for the HIN to evaluate and fulfill the request. On the data request form, the Requestor must indicate whether access to (i) a De-Identified Data Set, (ii) a Limited Data Set, or (iii) an Identified Data Set is required.
 - B. The HIN Board or the HIN Board's designee will then review the request to determine whether it fits into one of the following broad categories:
 - Research
 - Clinical best practices/evidence-based medicine
 - Public health
 - C. If the request is for the aforementioned purposes, then the activity may be granted in accordance with this Policy.
 - D. HIN Board or HIN Board's designee must ensure Appendix A, Appendix B, and Appendix C if applicable, and the HIN Application Security Architecture have been completed and are in compliance with this policy. Appendix D contains relevant sections of the Application Security Architecture and a template to be populated with suggestions by HIN's Privacy and Security team.
3. Form of Data Use. The HIN may share and/or provide reports of data for Research in the following forms:
 - A. A De-Identified Data Set;
 - B. A Limited Data Set; or
 - C. An Identified Data Set.
4. Research Using a De-Identified Data Set. If a Requestor requires access to a De-Identified Data Set, IRB or HIN approval may not be required so long as the method set forth in 45 CFR 164.514(b)(2) (the "Safe Harbor method") is utilized for deidentification. If the method set forth in 45 CFR 164.514(b)(1) (the "Expert Determination method") is utilized either by HIN or third-party subcontractor, the IRB or equivalent of the Participant Organization must approve the methodology for deidentification before information is shared.
5. Research Using a Limited Data Set

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- A. If a Requestor requires access to a Limited Data Set, the Requestor must comply with the parameters defined by the Participant's IRB. HIN Board or HIN Board's designee will take parameters under advisement and determine if a Research Access Acknowledgement, as set forth on Appendix B, and Data Use Agreement with the HIN, as set forth on Appendix C, is required. Conversely, if determined by the IRB, an authorization from the patient may suffice to allow sharing of a Limited Data Set for Research purposes and supplemental documentation may not be required.
 - B. If required, The Data Use Agreement must clearly describe the intended use of the Limited Data Set and meet the requirements set forth in 45 C.F.R. § 164.514(e)(4)(ii).
6. Research with an Identified Data Set.
- A. If a Requestor requires access to an Identified Data Set, the Requestor must comply with the parameters defined by the Participant's IRB. This may include a requirement that (i) the Requestor has obtained a HIPAA-compliant authorization from the relevant individual(s) authorizing the disclosure of the PHI to the Requestor for the stated purpose and provided the authorization(s) to the HIN; (ii) Requestor provides the HIN with documentation showing IRB waiver of the authorization requirement in accordance with 45 C.F.R. § 164.512(i) and other applicable laws and regulations (only if the request is for Research purposes).
 - B. A Requestor making a request for an Identified Data Set for Research purposes must also provide the HIN with the following related to the Research:
 - Curriculum vitae for the principal investigator
 - Current IRB letter of approval
 - Copy of IRB application, including the approved patient consent form, if applicable
 - A description of the proposed research, including the purpose of the study, the population/sample size, including inclusion and exclusion criteria, gender, and location, and the process of any recruitment and consent process.
 - A description of any special needs or other support required from the HIN for the Requestor to conduct the proposed research project.
 - C. If a Requestor is provided with access to an Identified Data Set, the Requestor must also sign a Research Access Acknowledgement, as set forth on Appendix B.
7. Information Not Provided for Research. No data or report provided for Research will include any information of individuals who have opted-out of the HIN or who have been treated by a Participant that is subject to 42 C.F.R. Part 2 without the required consent in place.

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8. Data Sets that Identify Participants Prohibited Without Authorization. Any request for data that identifies a Participant as the source of the data, which is not made by the data-source Participant, must be approved in writing by an authorized representative of the data-source Participant. The data-source Participant shall be provided with information regarding the identity of the Requestor, information requested by the Requestor, and the Requestor's proposed use of the data at the time the authorization is sought from the data source Participant.
9. Prohibited Use of Data. A Requestor must limit its use of the data it receives from the HIN in response to a request for Research solely to the information indicated by the Requestor on the data request form it submitted to the HIN, and in accordance with the Minimum Necessary rule, as defined under 45 CFR §§ 164.502(b) and 164.514(d). Further, under no circumstance, even if indicated on the data request form, may a Requestor use or disclose data received from the HIN for its own commercial purposes or to improve its competitive position. Any violation of this prohibition shall be subject to the remedies and/or penalties set forth in this Policy and/or in a separate written agreement between the Requestor and the HIN.
10. No Further Disclosures. A Requestor may not further disclose any data it receives from the HIN to any third party or to any individuals not identified on the data request form the Requestor submitted to the HIN, unless required by applicable federal and/or state law.
11. Notification of an Unauthorized Access, Use or Disclosure. In the event a Requestor becomes aware of any access, use or disclosure of data it received from the HIN, regardless of whether the unauthorized access, use or disclosure was intentional or inadvertent and regardless of the form of the data (e.g., a De-Identified Data Set, a Limited Data Set, or an Identified Data Set), the Requestor must immediately, and in no event later than three (3) business days after discovery, notify the HIN in writing of the unauthorized access, use or disclosure. Failure to so timely notify the HIN will result in the remedies and/or penalties set forth in this Policy and/or in a separate written agreement between the Requestor and the HIN.
12. Remedies for Violations. In addition to any remedies set forth in an agreement between the HIN and a Requestor, if a Requestor violates this Policy, the HIN may deny any future requests made by the Requestor, as well as entities under common control or ownership as the Requestor. Further, by submitting a request for data access, a Requestor acknowledges that a violation of this Policy by the Requestor may cause substantial and continuing damage to the HIN (and its participant Members), the value of which will be difficult or impossible to ascertain, and therefore, the HIN reserves the immediate right to seek both temporary and permanent injunctive relief necessary to prevent the Requestor's violation of this Policy without the need to prove damage or post bond.
13. Record-Keeping Requirements. The HIN will institute and follow appropriate procedures for maintaining a record of all information released pursuant to this Policy, including all agreements and materials related to this Policy. Such records and documentation will be maintained by the HIN for a period of six (6) years.

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**APPENDIX A
DATA REQUEST FORM FOR RESEARCH**

Date of Request: _____

Requestor: *(primary contact):*

Name: _____

Organization: _____

Email: _____

Telephone: _____

Background on Requestor's Organization Relevant to Research _____

Purpose of Request: *(Indicate all that apply):*

- Research
- Quality improvement/assurances
- Clinical best practices/evidence-based medicine
- Public health

Describe the Intended Data Use: *(Include relevant background information, goals of data analysis, where and how the data/data analytics will be presented, and who the audience will be (e.g., internal use, public forum, conference, published article, etc.):* _____

What Type of Data Set is Requested? *(Please choose one):*

- De-Identified Data Set
- Limited Data Set
- Identified Data Set

List the Specific Data Elements Requested: *(Simply indicating all available information or all health information is not acceptable):* _____

Describe the Desired Report Format: _____

Describe the Desired Method of Data Delivery:

- ADT
- CCD
- Direct Secure Message (DSM)
- FHIR

Requested Delivery Date: *(The actual date may vary based on the complexity of the request):*

Is there Grant-Funding Related to this Request or is this Request Related to a Grant-Funded Project?

- No Yes

Names of Individuals or Titles at Requestor with Access to the Requested Data: _____

Describe Requestor's Plan for Securing the Privacy and Security of the Requested Data: _____

Additional Comments: _____

To be Completed by the HIN:

The HIN does not approve this request. Please contact _____ for an explanation of why this request was not approved.

The HIN approves this request. the HIN's cost estimate for fulfilling this request is:

Cost estimate: _____

The HIN will not begin to fulfill this request until the HIN has receives Requestor's signature below indicating acceptance of the cost estimate, along with all other required documentation and signed agreements.

To be Completed by Requestor after Receipt of Cost Estimate:

Requestor hereby accepts the cost estimate set forth above and wishes to proceed with this request.

Requestor does not accept the cost estimate set forth above and wishes to cancel this request.

Signature of Requestor's Authorized Representative

Date

Name of Authorized Representative

Title of Authorized Representative

**APPENDIX B
RESEARCH ACCESS ACKNOWLEDGEMENT**

In consideration for receipt of Data (as defined below) from _____ (the “HIN”) pursuant to the Research Policy & Procedure (the “Policy”), the “Requestor” identified in the signature block hereby agrees to the terms and conditions set forth herein. Terms otherwise not defined herein shall have the same meaning given to such terms in the Policy.

1. Eligibility. Requestor represents and warrants that Requestor is a Participant of the HIN.
2. Prohibited Use of Data. Requestor agrees to limit its use of the data it receives from the HIN pursuant to the Policy (the “Data”) solely to the specific Research indicated by Requestor on the data request form it submitted to the HIN and in accordance with the Minimum Necessary rule, as defined under 45 CFR §§ 164.502(b) and 164.514(d). Requestor further agrees, even if indicated on the data request form, that Requestor will not use or disclose the Data for its own commercial purposes or to improve its competitive position.
3. Further Disclosures Prohibited. Requestor acknowledges and agrees that it may not further disclose any Data to any third party, or to any individuals not identified on the data request form Requestor submitted to the HIN, unless required by applicable federal and/or state law.
4. Notification of an Unauthorized Access, Use or Disclosure. In the event Requestor becomes aware of any unauthorized access, use or disclosure of Data, regardless of whether the unauthorized access, use or disclosure was intentional or inadvertent and regardless of the form of the Data (e.g., a De-Identified Data Set, a Limited Data Set, or an Identified Data Set), Requestor agrees to immediately, and in no event later than three (3) business days after discovery, notify the HIN in writing of the unauthorized access, use or disclosure.
5. Remedies for Violations. Requestor acknowledges and agrees that if Requestor violates the terms of this Acknowledgement or the Policy, the HIN may deny any future requests made by the Requestor, as well as entities under common control or ownership as the Requestor. Further, Requestor acknowledges and agrees that a violation of this Acknowledgement or the Policy by Requestor may cause substantial and continuing damage to the HIN (and its Participants), the value of which will be difficult or impossible to ascertain, and therefore, the HIN shall have the immediate right to seek both temporary and permanent injunctive relief necessary to prevent Requestor’s violation of this Acknowledgement or the Policy without the need to prove damage or post bond.
6. Indemnification. To the extent permitted by law, Requestor shall indemnify, defend and hold harmless the HIN and its employees, contractors, agents, or other Participant Members from and against any and all liability, claim, lawsuit, injury, loss, expense or damage resulting from or relating to the acts or omissions of Requestor in connection with the representations, duties, and obligations of Requestor under this Acknowledgement or the Policy.

Agreed and acknowledged to this ___ day of _____, 20__

REQUESTOR:

By: _____

Name: _____

Title: _____

HIN:

By: _____

Name: _____

Title: _____

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**APPENDIX C
DATA USE AGREEMENT FOR LIMITED DATA SET**

This Data Use Agreement (this “Agreement”) is effective as of the _____ day of _____, 2014 (the “Effective Date”), by and between _____ (the “HIN”), and _____ (“Requestor”).

RECITALS

WHEREAS, pursuant to the Health Insurance Portability and Accountability Act of 1996 and the implementation regulations thereunder (“HIPAA”), the HIN and Requestor are required to enter into a data use agreement to set forth the terms and conditions upon which the HIN will disclose to Requestor, and Requestor will use for purposes of public health, healthcare operations or research, information which comprises a Limited Data Set (as defined at 45 C.F.R. § 164.514(e)(2)) (“Information”); and

WHEREAS, this Agreement is intended to comply with the requirements of HIPAA.

NOW, THEREFORE, in consideration of the foregoing, and for other good and valuable consideration, the receipt and adequacy of which is hereby acknowledged, the parties agree as follows:

ARTICLE I.

Requestor OBLIGATIONS

1.1 Use and Disclosure of Information. Requestor agrees it shall use Information only for the activity indicated by Requestor on the data request form it submitted to the HIN for the Information. Requestor agrees not to use or further disclose Information other than as permitted by this Agreement or as required by law and in accordance with the Minimum Necessary rule, as defined under 45 CFR §§ 164.502(b) and 164.514(d).

1.2 Safeguarding and Limiting Access to Data. Requestor agrees to establish and implement proper safeguards against unauthorized use and disclosure of Information. Requestor shall establish proper administrative, technical, procedural, and physical safeguards to protect the confidentiality of Information and to prevent the unauthorized access to Information.

1.3 Report of Unauthorized Access, Use or Disclosure. Requestor shall promptly report to the HIN within three (3) business days if Requestor becomes aware of any unauthorized access, use or disclosure of Information. This report shall identify the nature of the unauthorized access, use or disclosure, what corrective action Requestor has or will take to prevent further violations, including any mitigation, and provide any other information as the HIN may reasonably request.

1.4 Disclosure to Agents. Requestor shall not disclose Information, or any portion thereof, to any subcontractors or agents, unless such subcontractor or agents are identified on the data request form Requestor submitted to the HIN for the Information. In the event a disclosure to an agent or subcontractor is permissibly made, Requestor shall ensure that such subcontractor or agent agrees to the same terms, conditions, and restrictions as those that apply to Requestor

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pursuant to this Agreement. Requestor shall be responsible to the HIN for any breach by a contractor or subcontractor of Requestor of any of the foregoing.

1.5 Identification of Information. Requestor shall not attempt to identify the individuals whose information is contained in Information or attempt to contact the individuals.

1.6 Survival. The duties and responsibilities imposed upon Requestor shall survive termination or expiration of this Agreement with respect to any Information that remains in the possession of Requestor.

ARTICLE II. TERM AND TERMINATION

2.1 Term. The terms of this Agreement shall be effective upon the Effective Date and shall continue until terminated by the parties in writing, or the HIN terminates the Agreement for a breach as described below. In the event the HIN becomes aware of a material breach of Requestor's obligations with respect to use and disclosure of Information, the HIN may (i) provide an opportunity for Requestor to cure the breach or end the violation and terminate this Agreement in the event Requestor does not cure the breach or end the violation within the time specified by the HIN or (ii) immediately terminate this Agreement.

2.2 Effect of Termination. Upon termination of this Agreement for any reason, Requestor shall return or destroy all Information received by Requestor from the HIN. This provision shall also apply to Information that is in the possession of subcontractors or agents of Requestor. Requestor shall retain no copies of the information. In the event that return or destruction of the information is not feasible, Requestor shall provide to the HIN notification of the conditions that make return or destruction not feasible. In such case, Requestor shall extend the protections required under this Agreement and limit further uses and disclosures to those purposes that make the return or destruction not feasible, for as long as Requestor maintains such information.

ARTICLE III. INDEMNIFICATION; LIMITATION OF LIABILITY

To the extent permitted by law, Requestor shall indemnify, defend and hold harmless the HIN from any and all liability, claim, lawsuit, injury, loss, expense or damage resulting from or relating to the acts or omissions of Requestor in connection with the representations, duties, and obligations of Requestor under this Agreement. This provision shall survive the termination of the Agreement.

ARTICLE IV. MISCELLANEOUS

4.1 Compliance with Laws. Each party agrees to comply with all applicable laws, rules and regulations in connection with its obligations under the Agreement.

4.2 No Agency. Nothing in this Agreement shall be construed to create a partnership, joint venture, agency or other legal relationship between Requestor and the HIN that could result in

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either party being responsible or liable for the acts or omissions of the other party. Requestor and the HIN are independent contractors with respect to the any obligations being performed hereunder. In no event shall this Agreement be construed to imply or provide that any party has granted another party any express or implied right to create any obligation on behalf of or in the name of the other, or to bind the other in any manner with respect to either party's relation with third parties. Nothing in this Agreement shall be interpreted or construed as creating or establishing the relationship of employer and employee between the parties or their respective employees, agents or contractors.

4.3 Third Party Rights. There are no third party beneficiaries to this Agreement.

4.4 Amendment. No alteration, amendment, or modification of the terms of this Agreement shall be valid or effective unless in writing and signed by the HIN and Requestor.

4.5 Waiver. A failure by any party to enforce at any time any term, provision or condition of this Agreement, or to exercise any right or option herein, shall in no way operate as a waiver thereof, nor shall any single or partial exercise preclude any other right or option herein; in no way whatsoever shall a waiver of any term, provision or condition of this Agreement be valid unless in writing, signed by the party, and only to the extent set forth in such writing.

4.6 Assignment. Neither party may assign this Agreement, or any of its rights hereunder, in whole or in part, without the prior, written consent of the non-assigning party. Any assignment in violation of the foregoing will be null and void.

4.7 Entire Agreement. This Agreement represents the entire agreement between the parties with respect to the subject matter hereof, and no party shall be entitled to benefits other than those described herein. There are no representations, warranties, promises, agreements, terms or conditions, written or oral, other than those contained herein.

4.8 Section Headings. The section headings contained herein are for convenience and reference and are not intended to define or limit the scope of any provision of this Agreement.

4.9 Counterparts. This Agreement may be executed in one or more counterparts, each of which shall be deemed an original, and will be effective and binding upon the parties as of the Effective Date. Facsimile copies shall be deemed valid as an original.

4.10 Notices. All notices, demands and communications made under this Agreement shall be given in writing to the HIN or Participation Organization's representatives at the address listed below, and will be deemed given: if mailed certified mail, restricted delivery to the addresses below. Notices will be effective on the date of delivery indicated on the return receipt. Notices may also be given by courier or express mail service (e.g. Federal Express). Other notices, including for operational or administrative issues, should be addressed to the notice address as set forth below.

4.11 Governing Law. This Agreement shall be governed and construed in accordance with the laws of the State of _____ (without regard to principles of conflicts of laws).

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IN WITNESS WHEREOF, the parties hereto have executed this Agreement effective of the date stated above.

REQUESTOR

HIN

By: _____

By: _____

Print Name:

Print Name:

Title:

Title: _____

Date: _____

Date: _____

Notice Address:

Notice Address:

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APPENDIX D
APPLICATION SECURITY ARCHITECTURE FOR HIN BOARD REVIEW

HIN BOARD CONSIDERATIONS	Applicability	Maturity	Exception?	Control Comments/To-Do's/Responsibility
Access can be aligned with patient consent requirements (full opt-out, sensitive information, etc).	Highly Restricted			
Access is aligned with legal and contractual 'initial' and 'future' permissible use and disclosure requirements.	Highly Restricted			
Logs provide sufficient information to identify data owner/contributing organization for breach notification.	Highly Restricted			
Application logs and can report access and disclosures by patient that include identification of user and organization.	Highly Restricted			
Patient matching uses existing MPI or implements conservative matching criteria	Highly Restricted			

Full Application Security Architecture Template included below. HIN Security and Privacy Team to provide HIN Board or HIN Board designee with suggestions prior to review.



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