190 N. Independence Mall West, Suite 701, Philadelphia PA, 19106 www.healthshareeexchange.org

# Consent-Waived/Medical Records Research Use Case

| Version | Approval Date | Owner |
|---|---|---|
| 1.0 | 5/23/24 | Privacy/Security |

## 1. Purpose

The purpose of this use case is to establish the policy and procedures for authorizing HSX to disclose data to HSX Members/Participants or others engaged in healthcare-related research for:

**Consent Waived/Medical Records Research (as defined below in Section 6) in accordance with this use case.**

Patients' data maintained by HSX has the strong potential for public benefit through research across the spectrum: informing prevention and treatment strategies, health promotion efforts, evaluations of health quality and equity, self-care, health systems planning, wider public health activities, behaviors, decisions, validation, and monitoring of populations and more.

As a result, the outcomes of such research are generalizable and relevant to a variety of sectors including, academic researchers, industry representatives, healthcare professionals and providers, patients and the public, payers and policymakers, regulators, charities, and the third sector.[1]

This use case extends HSX's capabilities of contributing to the public benefit thereby providing value for the HSX Members/Participants and the overarching community.

This use case is in alignment with the HSX Participation Agreement, Schedule 6.2, which includes the following as a Permitted Purpose:

*Exceptional use of Protected Health Information for otherwise non-Permitted Purposes (i.e. pay-for-performance; benchmarking, analytics, and comparative purposes; and/or research) may be granted on a case-by-case basis upon review and approval of HSX with Notice to and approval by Data-Contributing Participants for each and every non-Permitted Purpose. Data Contributing Participants have the opportunity to opt-out of exceptional use of Personal Health Information ("PHI").*

[1] Sonja M, Ioana G, Miaoqing Y, Anna K. Understanding value in health data ecosystems: A review of current evidence and ways forward. *Rand Health Q*. 2018;7(2):3. Published 2018 Jan 29.

# 2. Scope

The scope of this use case covers access to data by HSX Members/Participants or other extramural researchers, that are qualified under the inclusion criteria set forth in this use case, for non-patient-consented research aligned with HSX's mission of supporting preventive and cost-effective healthcare, improving the quality of patient care, and facilitating care transitions. The requirements for research involving documented patient consent (**such as a clinical trial) is covered in a separate use case: Patient-Authorized Research.**

This use case covers uses of HSX data that may still constitute research, but which involve using only aggregate anonymized data or which receives an Institutional Review Board (IRB) determination of exemption and/or waiver of informed consent. Such research would typically involve retrospective use of existing medical/administrative records, would not involve an active experimental intervention, and would not affect the care delivered to patients whose records were used in the Research Study.

## 2.1. Access to data under this use case is defined by the following:

**Inclusion:**

HSX Members/Participants requesting data for research under this use case must meet the following requirements:

a) Entered into participation agreements with HSX. Agreements must materially contain the same terms and conditions as the HSX Founding Member Participation Agreement ("the HSX PAR").
b) Contribute data to HSX and allow it to be made available for research purposes in a manner equitable to the data being requested by such HSX Member/Participant.
c) The determination of whether an HSX Member/Participant is eligible for access to data under this use case shall be made by HSX according to the Procedures (Section 4) below.
d) HSX Members/Participants with data that could be used in the proposed Research Study will be advised of the proposed Research Study and be provided an opportunity to opt out.

All parties requesting data for research under this use case must meet the following requirements:

a) The Research Study must align with HSX's mission and purpose as a community asset for activities that benefit patient care.
b) The questions being addressed in the Research Study must be aligned with the data being requested, and HSX must be confident the data needed for the study is likely to be in HSX's databases in sufficient quantity.
c) If not covered by an HSX PAR, the researcher(s) requesting the data must be currently affiliated with a recognized academic or research institution, and that institution must be signatory to the Data Use Agreement (Appendix B) described in (e) below.
d) If not covered by an HSX PAR, researcher(s) requesting a HIPAA Limited Data Set must undergo background checks performed and retained by HSX prior to approval of the Proposed Research Study. A background check may not be required when the data requested is aggregated or completely anonymized.

e) Even if covered by an HSX PAR, the organization or institution must enter into a Data Use Agreement (Appendix B) with HSX covering its obligations to keep the data secure, to use the data only for the stated permitted purpose(s), to certify destruction of the data when no longer needed and to fulfill the other obligations of the HSX PAR.

f) The Research Study must have documented either: (i) IRB exemption from review, or (ii) IRB approval with waiver of informed consent. Evidence of IRB determination must be submitted to HSX.

**Exclusions:**

a) Health Plan Participants may not access Data provided by Hospital/Health System Participants for the purpose of analysis of the costs, rates, charges, utilization levels or for steering or tiering of Hospital/Health System Participants. [HSX PAR Ref. §6.3.4]

b) All parties are prohibited from utilizing this use case for purposes of identifying potentially eligible research subjects, or for recruitment or marketing purposes.

In accordance with the HSX PAR, as a non-treatment use case, HSX Members/Participants can opt out of this use case. Members who opt out will not be eligible to receive data under this Use Case.

## 2.2. Data Set Definition

**The following conditions apply to data requested under this use case:**

a) Fully identifiable Data will **only be available to HSX Members/Participants for research for their own** patients/members. Fully identifiable data will not be available to researchers who are not contracted HSX Members/Participants.

b) Data stored centrally within the HSX databases and patient/member data that can be accessed includes, but is not limited to, allergies, care team, demographics, health history, lab results, medications, problems, procedures, immunizations, and vitals (“Identifiable Data”).

c) Only such Identifiable Data, including Protected Health Information (PHI), that is described in the Research Study documentation approved by the IRB.

d) Super Protected Data (i.e., HIV/AIDS; 42 CFR Part 2; genetic information etc., “SPD”) shall not be included in the Identifiable Data disclosed to an HSX Member/Participant because a patient does not have an opportunity to authorize access to such data in research that is approved for a waiver of consent.

e) Health Plans may not have access to self-pay encounter data because a patient does not have an opportunity to authorize access to such data in research that is approved for a waiver of consent.

**Exclusions:**

a) Financial data, including but not limited to data concerning billed and paid amounts.
b) Data originating from any HSX Member(s)/Participant(s) that have opted out of participation in this use case.

## 2.3. Compliance and Authorization

a) Identifiable Data is not available to extramural researchers who are not affiliated with an HSX Member/Participant.

b) Identifiable Data may be disclosed to an HSX Member/Participant and an HSX Member/Participant may access Identifiable Data under this use case only pursuant to an IRB waiver of HIPAA Authorization requirement obtained strictly in accordance with the procedures set forth in this use case.

c) If a patient/member has previously opted out at HSX of its Clinical Data Repository ("CDR"), the patient/member's Identifiable Data shall not be shared until such individual opts back-in to the HSX CDR by contacting HSX directly.

d) HSX Members/Participants may choose to maintain a list of patients/members who have opted out of research activities through its opt-out procedures, and to provide this opt out list to HSX. No data from these opted-out patients/members will be shared for research activities.

# 3. Policy

HSX and its Members/Participants support use of clinical and administrative data for research conducted by HSX Members/Participants or other HSX-approved researchers strictly in accordance within the scope, procedures and limitations of this use case, and the HSX PAR (*or substantively equivalent participation agreement*) and the IRB-approved documents of the waiver of Informed Consent requirements. It is the responsibility of Members/Participants to indicate to patients/members in their HIPAA Notice of Privacy Practices that patient/member data may be used for research purposes within the scope of legally permitted use under applicable federal and state law.

The following table outlines the scope and granularity of data potentially available to requestors of HSX-approved research.

| Data Type | HSX Participants/ Members | Credentialed Extramural Researchers | Example |
|---|---|---|---|
| Aggregate, Not Patient-Level, Anonymized/Deidentified | Yes | Yes | A table providing counts of individuals with diabetes stratified by demographic cohorts |

| Data Type | HSX Participants/ Members | Credentialed Extramural Researchers | Example |
|---|---|---|---|
| Patient-Level, Anonymized to the HIPAA Deidentification Safe Harbor Standard or by HIPAA's Expert Determination Method | Yes | Yes | A table providing a line listing of results of A1c tests with no HIPAA identifiers included and with a synthetic ID to link multiple observations from the same patient and dates of service altered. |
| Patient-Level, (e.g, a HIPAA Limited Data Set) | Yes | Yes | A table providing a line listing of results of A1c tests with no direct HIPAA identifiers included and with a synthetic ID to link multiple observations from the same patient. Indirect identifiers may be included if necessary (e.g., zip code, dates of service, dates of birth). |
| Patient-Level, Fully Identifying Data | Yes (only for their own patients/members) | Not permitted | A table providing a line listing of results of A1c tests from clearly identified individuals. |

## 4. Procedures

a) An organization or institution contemplating a Research Study, as defined in the definitions section below, may initially submit an informal inquiry to HSX for high-level aggregated and de-identified descriptive information regarding the information held within the HSX CDR. For example, if interested in performing research on prostate cancer, the organization or institution may ask HSX to confirm whether the CDR contains sufficient Data on prostate cancer screening and treatment.

b) HSX shall determine whether the organization or institution that will be accessing data pursuant to this use case **may be charged a reasonable cost-based fee** to prepare and transmit the data. The fee will be a mutually agreed upon and negotiated fee in compliance with HIPAA provisions governing and prohibiting the "sale of PHI" [HIPAA Ref. 164.502(a)(5)(ii); 164.508(a)(4)(i)]. Not all data exchanged under this use case will include PHI.

c) Each Research Study which an organization or institution is seeking to conduct under this use case must be approved through an institutional review board (IRB) with consent requirements waived, and the Principal Investigator (PI) must submit a completed *IRB Approval and Application and Attestation* and *Certification of Principal Investigator* (see Appendix A).

- Applications and other supporting documentation shall be sent to HSX for review and approval.
- Applications must demonstrate fully and satisfactorily completed forms and submission of supplemental information requested.

d) In order to ensure compliance with HIPAA and to prevent uses and disclosures of PHI which fall outside the scope of this use case and HIPAA, the Principal Investigator shall ensure that each and every individual who

may access Identifiable Data for an HSX-approved Research Study is educated on HIPAA and other laws governing and/or affecting how PHI may be legally accessed, used and disclosed for research. To effectuate the forgoing, among other resources, the following HHS Guidance, or the successor to such HHS Guidance, shall be carefully reviewed and leveraged for such education and training:

- DHHS Guidance on Health Services Research & the HIPAA Privacy Rule:

  https://privacyruleandresearch.nih.gov/pdf/healthservicesresearchhipaaprivacyrule.pdf

- DHSS Guidance on HIPAA & Individual Authorization of Uses & Disclosures of PHI:

  https://www.hhs.gov/sites/default/files/hipaa-future-research-0authorization-guidance-06122018%20v2.pdf

e) Because this use case is focused on research where IRB review may not be required or where an IRB has approved a waiver of informed consent requirements, explicit written patient authorization is not expected. However, HSX encourages all Members/Participants to include language in their Notice of Privacy Practices that patients' data may be used for research purposes as permitted by applicable laws and regulations.

f) Evidence of IRB approval, and waiver of informed consent requirements if applicable, or documentation of the rationale for the Research Study being exempt from IRB review will be provided to and saved by HSX. Copies will be made available to HSX Members/Participants participating in this use case upon request to meet their HIPAA documentation requirements.

g) HSX will establish a Research Activity Advisory Committee ("Committee") comprised of representatives of HSX Members/Participants knowledgeable in health-related research and privacy concerns to review proposed Research Studies on behalf of the entire Membership. The purpose of the Committee is to evaluate whether:

1. The proposed Research Study addresses valid and meaningful question(s) that have the potential to benefit the healthcare community and/or society consistent with HSX's mission.
2. The proposed Research Study is permitted under the conditions of the HSX PAR and this use case.
3. The data held by HSX would be useful in answering the proposed research questions.
4. The researchers are appropriately credentialed and affiliated with a recognized academic or research institution in good standing, and the researcher is conducting this proposed research as a representative of the institution and not individually.

For a Research Study that has been reviewed by an IRB, the Committee need not re-evaluate the risk to human subjects, the appropriateness of the analytic methods, or the decision to waive consent requirements (if applicable). The Committee will rely on the IRB's determination on these issues.

h) Unless an HSX Member/Participant has waived out all participation in all activities and research studies under this use case, HSX Members/Participants who may have data that could be used in the proposed Research Study will be advised of the proposed Research Study and be provided an opportunity to opt-out of each proposed Research Study,

i) HSX staff will encrypt all transmissions of PHI in accordance with the HHS Secretary's *Guidance to Render Unsecure Protected Health Information Unusable, Unreadable, or Indecipherable to Unauthorized Individuals* and encryption shall be maintained throughout all storage and transmission processes as per the HSX *Encryption Policy.*

j) Upon conclusion or termination of the Research Study subject to this use case, PHI shall be disposed of by the HSX Member/Participant in alignment with standards provided within the HSX *Secure Disposal Policy*,

unless the disposal of PHI is not technically or legally feasible in which case the PHI shall be maintained in a secure environment in compliance with HIPAA and shall not be accessed or be made available for any other secondary uses.

k) HSX shall have the right to audit the applicable HSX Member/Participant at any time during its Research Study and for 6 years thereafter to confirm the requirements of this use case and any related Data Use Agreement are followed.

# 5. Enforcement

a) HSX monitors the use of data in accordance with the *Audit and Monitoring Policy* as applicable and dependent on the mechanism of delivery of the patient/member consented Identifiable Data.

b) HSX's Chief Security and Chief Privacy Officer(s) are responsible for ensuring compliance with this use case under the direction of the HSX President.

*c)* Non-compliance with this use case is subject to enforcement (i.e., suspension from access to data) per HSX policies and the HSX PAR (or equivalent), including the HSX *Data Misuse Policy.*

# 6. Definitions

For a complete list of definitions, refer to the *Glossary*.

a) **Consent Waived/Medical Records Research:** For purposes of this use case, Consent Waived/Medical Records Research is Research that is: a) categorically exempt from the Common Rule, b) is IRB-approved with a waiver of informed consent requirements, or c) exempt from IRB review. It is exclusive of patient-authorized research (covered in a separate use case).

b) **Research Study**: For the purpose of this use case, a Research Study is research approved in accordance with this use case and: which is intended to generate or contribute to generalizable knowledge outside the scope of providing the participating institution information that is needed to assess or improve the health of the individuals or populations they serve; and where the data collected exceeds requirements for care of the study participants or extend beyond the scope of the activity. Generalizable knowledge means new information that has relevance beyond the population or program from which it was collected, or information that is added to the scientific literature. Knowledge that can be generalized is collected under systematic procedures that reduce bias, allowing the knowledge to be applied to populations and settings different from the ones from which it was collected.

### References


- U.S. Department of Health and Human Services Guidance to Render Unsecured Protected Health Information Unusable, Unreadable or Indecipherable to Unauthorized Individuals. https://www.hhs.gov/hipaa/for-professionals/breach-notification/guidance/index.html


Regulatory References:


- HHS 45 CFR part 46 Federal Policy for the Protection of Human Subjects ('Common Rule')
- HIPAA Ref. 164.502(a)(5)(ii) 164.502(a)(5) *Prohibited uses and disclosures:*

*Sale of protected health information:*

| | | | |
|---|---|---|---|
| **Policy Owner** | Privacy Officer<br>Chief Information Security Officer | **Contact** | Don.reed@healthshareexchange.org |
| **Approved By** | Privacy/Security<br>Clinical Advisory<br>HSX Board | **Approval Date** | 5/23/24<br>5/2/24<br>5/17/24 (Exec Com) |
| **Date in Effect** | 5/23/24 | **Version #** | 1 |
| **Original Issue Date** | 5/23/24 | **Last Review Date** | 5/23/24 |
| **Related Documents** | Audit and Monitoring Policy<br>Data Misuse Policy<br>Encryption Policy<br>Glossary<br>HSX Opt-Out and Opt-Back-In Policy<br>HSX Participation Agreement<br>Secure Disposal Policy<br>Patient-Authorized Research Use Case | | |

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Appendix A

## External IRB Approval Attestation and Application

### Instructions

This form is required before any Consent-Waived Research may be completed using HSX assets and is an attestation by the Principal Investigator that he/she will comply with applicable law when conducting research using data obtained from HSX under its Consent Waived/Medical Records Research Use Case.

*Remove the blue text prior to submitting the application*.

### Background Information

| | |
|---|---|
| **Principal Investigator**<br><br>***The PI's responsibility includes ensuring the collection and retention of patient consents.*** | *Full name and degree of Principal Investigator*<br><br>*Insert name of individual or overseeing committee/body charged with ensuring the privacy and confidentiality of data collected on research subjects if not the Principal Investigator*<br><br>*Insert name of individual or overseeing committee/body charged with ensuring the privacy and confidentiality of data collected on research subjects if not the Principal Investigator* |
| **Protocol Title** | *Full protocol title* |
| **Funding Sponsor** | *Identify the agency, organization, company or person providing funds for the Research Study* |
| **Regulatory Sponsor** | *Identify the agency, organization, or person primarily responsible for initiating and overseeing the research and ensuring the study complies with research standards and federal regulations.* |
| **IRB of Record** | *Insert name of institution serving as the IRB of record, if not exempt* |

## Procedural Information

| | |
|---|---|
| **Data Confidentiality and Security** | *Data Confidentiality and Security* relates to how the confidentiality, integrity and availability of all research data created, received, maintained, or transmitted will be ensured by the Research Study.<br><br>In this section, the following must be included:<br>• A detailed description of how research data will be handled, managed, and transmitted including a description of how this plan complies with any specific requirements for data security and storage that stem from institutional policies, state or federal regulations, requirements of funding agencies, contractual obligations or data access agreements.<br>• A description of any additional controls that will be implemented for the storage, handling, and sharing of data.<br>• The long-range plan for protecting the confidentiality of research data, including a schedule for destruction of identifiers associated with the data.<br>• Explain how **HIPAA Privacy** compliance will be achieved.<br>• Explain how **HIPAA Security** compliance will be achieved, including reporting and notifying affected individuals about Data breaches. |

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Appendix B

## Data Use Agreement

This Data Use Agreement ("Agreement"), effective as of Month, Day, Year ("Effective Date"), is entered into by and between _____ (collectively "Recipient") and HealthShare Exchange of Southeastern Pennsylvania, Inc. in its capacity as a business associate to various covered entities ("HSX"). The purpose of this Agreement is to provide Recipient with access to clinical data for a panel of patients for the permitted purposes described in Section 6 of this Agreement ("Permitted Purposes").

1. Background. Recipient has requested that HSX make certain data available to it in order that it can undertake the project described in Schedule "A" (the "Permitted Purposes"). This project shall be subject to HSX's Consent-Waived Medical Records Research Use Case (the "Use Case") and applicable HSX policies ("Policies") as contained on the HSX's website at https://healthshareexchange.org/hsx-approved-policies/.

2. Definitions. Unless otherwise specified in this Agreement, all capitalized terms used in this Agreement not otherwise defined have the meaning established for purposes of the "HIPAA Regulations" codified at Title 45 parts 160 through 164 of the United States Code of Federal Regulations, as amended from time to time.

3. Preparation of the Data Set. HSX shall prepare and furnish to Recipient the Data Set forth in Schedule "B" to this Agreement, in accordance with the Health Insurance Portability Accountability Act and regulations ("HIPAA"). All Data to be provided to Recipient shall be "as is" and "as available".

4. Minimum Necessary Data Fields in the Data Set. In preparing the Data Set, HSX shall include the data fields specified by the parties from time to time, which are the minimum necessary to accomplish the purposes set forth in Section 6 of this Agreement.

5. Responsibilities of Recipient.

   Recipient agrees to:

   a. Comply with the Use Case and applicable Policies in all respects;

   b. Obtain and maintain patient authorization to the extent required by 45 CFR Part 46 Protection of Human Subjects, requirements established by the Institutional Review Board approving or waiving approval of the project, the Use Case and applicable law and to provide copies of such patient authorization (or IRB waiver of consent if applicable) to HSX upon request;

   c. Use or disclose the Data Set only for Permitted Purposes and as permitted by this Agreement or as required by law and to not re-use, attempt to re-identify, or redisclose the Data Set for any other purpose;

   d. Use appropriate safeguards to prevent use or disclosure of the Data Set other than as permitted by this Agreement or required by law;

   e. Report to HSX any use or disclosure of the Data Set of which it becomes aware that is not permitted by this Agreement or required by law;

   f. Require any of its subcontractors or agents that receive or have access to the Data Set to agree to the same restrictions and conditions on the use and/or disclosure of the Data Set that apply to Recipient under this Agreement; and

   g. Extend the provisions of this Agreement to its investigators.

6. Permitted Uses and Disclosures of the Data Set. Recipient may use and/or disclose the Data Set only for the Permitted Purposes described in Schedule "A" to this Agreement or as required by law.

7. Term and Termination.

   a. Term. The term of this Agreement shall commence as of the Effective Date and terminate two (2) years from Effective Date. Should the Recipient desire to keep the Data Set for a longer period, a justification in writing should be made to HSX whose decision shall be final. In such event, the term of this Agreement shall be extended to such longer period as approved by HSX.

   b. Automatic Termination. This Agreement shall be automatically terminated upon the first to occur of the termination of Recipient's participation agreement with HSX, the termination of approval of the research project by an institutional review board, the cessation of Recipient's research project, and, as to the use of the Data Set for any patient, upon rescission of the patient's consent. Recipient shall be required to provide HSX with immediate written notice of any event(s) giving rise to automatic termination.

   c. Termination by Recipient. Recipient may terminate this Agreement at any time effective upon written notice to HSX.

   d. Termination by HSX. HSX may terminate this Agreement at any time by providing thirty (30) days prior written notice to Recipient.

   e. For Breach. HSX shall provide written notice to Recipient of any determination that Recipient has breached a material term of this Agreement. HSX shall afford Recipient an opportunity to cure said alleged material breach upon mutually agreeable terms. Failure of Recipient to cure the breach within thirty (30) days of the sending of notice shall be grounds for the immediate termination of this Agreement by HSX. Nothing in this Agreement shall require HSX to continue to supply Recipient with the Data Set during the cure period. In the event that the breach is not susceptible to cure, HSX may terminate this Agreement immediately effective upon written notice to Recipient.

   f. Effect of Termination. Within thirty (30) days of the termination or expiration of this Agreement, Recipient shall destroy or return the Data Set to HSX. Unless the Data Set is returned, Recipient shall supply HSX with a certificate of destruction. The provisions of this Agreement which, by their nature, would reasonably be expected to survive termination or expiration of this Agreement shall survive its termination or expiration.

   g. Certification of Destruction. Upon termination or expiration, Recipient will provide a written Certificate of Destruction to HSX.

8. Security. The Data Set will be encrypted in transmission and at rest and shall be subject to reasonable standards of security including reasonable security requirements contained in the Policies.

9. Publication. Recipient shall have the right to use a) the analyzed, de-identified data derived from the use of the Data Set; and b) information and results arising out of analysis of the Data Set, as part of a publication or presentation of the results related to Permitted Purposes. The Recipient shall not include any personally identifying information or the names of any of HSX's data sources/data providers in any publication or presentation. HSX and its investigator's contribution shall be acknowledged appropriately in any such publication or presentation in accordance with academic standards. Recipient's publication shall contain a disclaimer similar to the following: "The findings and conclusions in this report are those of the author(s) and should not be construed to represent HSX's endorsement of any analysis or conclusion contained herein."

10. Miscellaneous.

a. Change in Law. The parties agree to negotiate in good faith to amend this Agreement to comport with changes in federal law that materially alter either or both parties' obligations under this Agreement. If the parties are unable to agree to mutually acceptable amendment(s) by the compliance date of the change in applicable law or regulations, either Party may terminate this Agreement as provided in section 7.

b. Choice of Law. The interpretation of this Agreement and the resolution of any disputes arising out of this Agreement shall be governed by the laws of the Commonwealth of Pennsylvania, without regard to conflict of law principles, and determined exclusively by the state or federal courts of the Commonwealth of Pennsylvania.

c. Construction of Terms. The terms of this Agreement shall be construed to give effect to applicable federal interpretative guidance regarding HIPAA Regulations.

d. No Third Party Beneficiaries. Nothing in this Agreement shall confer upon any person other than the parties and their respective successors or assigns, any rights, remedies, obligations, or liabilities whatsoever.

e. Counterparts. This Agreement may be executed in one or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

f. No Offshoring. The Data Set may not be stored, maintained, transmitted, accessed, used or disclosed beyond the boundaries and jurisdiction of the United States.

g. No Exclusion. During the term of this Agreement, no party shall be excluded, debarred, suspended or otherwise ineligible to participate in federal or state healthcare programs.

h. Hold Harmless. Each party to this Agreement shall be solely responsible for the claims, damages, costs, losses, and liabilities occurring as a result of or arising from its own acts and/or omissions, and those of its officers, employees, and agents, arising from, or in relation to, this Agreement and the services hereunder. Under no circumstances shall either party be responsible for any acts or omissions of the other party, its officers, employees, and agents, or for the acts and/or omissions of those entities or individuals not a party to this Agreement.

i. Indemnification. Recipient shall indemnify and hold HSX and its data sources harmless from and against any and all claims, damages, costs, losses, and liabilities arising from or as a result of its own acts and/or omissions, and those of its officers, employees, and agents.

j. Insurance. Recipient represents that it has sufficient insurances to protect itself and HSX from and against claims that may arise as a result of this Agreement. Recipient shall supply HSX with a certificate of insurance upon request.

IN WITNESS WHEREOF, each of the undersigned has caused this Agreement to be duly executed in its name and on its behalf.

**HEALTHSHARE EXCHANGE OF SOUTHEASTERN PENNSYLVANIA, INC.**

By: _____

Print Name: Martin Lupinetti

Print Title: President & CEO

**RECIPIENT:** _____

_____

By: _____

Authorized Signatory

Print Name: _____

Print Title: _____

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Schedule “A”

Permitted Purposes

**Project Lead:** _____

**Project Title:** _____

**Project Objective/Purposes:**

_____

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Schedule "B"

Data Set

[SAMPLE DESCRIPTION BELOW: REPLACE]

The Data Set provided to Recipient shall contain only the following Identifiers of patients whose consent is provided or waived by an IRB to participate in this project: Names; dates of birth, MRN, HSX Community ID, and Dates of Service.

Data Requested:

For Adults included in the study, up to a maximum of 1,000 participants:

- The patient group of interest will be identified by Recipient and sent to HSX as a panel based on HSX Panel Specifications.
- Encounter Types will include: inpatient or emergency. Ambulatory and non-ED outpatient will be excluded.
- Fields in the output file will include:
    - MRN
    - HSX Community ID
    - First Name
    - Last Name
    - DOB
    - Encounter Start Date
    - Encounter End Date (usually null for ED visits)
    - Encounter Type
    - Provider Organization

**Attestation and Certification of Principal Investigator**

I, the individual named below, hereby attest and certify the following:

1. I have personally completed or overseen the completion of the information requested in this application for Consent Waived/Medical Records Research and have undertaken the due diligence necessary, through consultation with subject-matter experts, review of relevant documentation, and other steps, to ensure that the information provided herein is true and accurate;

2. I hereby certify that I am responsible for overseeing and ensuring that the Research Study described in this Application remains contained to the original scope and comports with the standards self-described here;

3. I hereby certify that I am responsible, together with the individuals designated to oversee Privacy and Security compliance for the Research Study, for overseeing and ensuring that the Research Study complies with this use case, the Data Use Agreement, HIPAA Privacy and Security standards, FDA regulations (where applicable) and common law governing research subject confidentiality and consent, including ensuring the collection and retention of patient consents, as well as all other applicable federal and State laws governing patient data;

4. I will comply with the *HSX Encryption Policy*, Applicable Law, and the HSX Participation Agreement which states:

    a. PAR §8.1 Participant and HSX shall comply with Applicable Law including the federal standards governing the confidentiality, security, and use of patient health information, including without limitation Protected Health Information defined in HIPAA and HITECH and 42 CFR Part 2, which definitions are incorporated herein by reference, and with the HSX Policies, as may be amended from time to time.

    b. PAR §8.2 HSX: Participant shall comply with the requirements for the privacy, security, and use of individually identifiable health information imposed under the laws of the Commonwealth of Pennsylvania

    c. PAR Schedule 6.2 (Super Protected Data): Certain drug and alcohol abuse, mental health and HIV/AIDS records patient information ("Super Protected Data") is protected under Applicable Law including 42 CFR Part 2 and Pennsylvania's confidentiality laws that restrict the release of Super Protected Data.

5. I hereby declare under penalty of perjury that the answers and statements provided are true and correct, to the best of my knowledge; and

6. I agree to immediately report all material changes from the date of submission of this Application to HSX until the date that the Research Study is fully complete.

Name of Research Study:

_____

Signature of Principal Investigator

_____

Date