



## Patient-Authorized Research Use Case

Version	Approval Date	Owner
1.0	March 26, 2020	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 for:

**Patient-Authorized 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, self-care, health systems planning, wider public health activities, behaviors and 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.<sup>1</sup>

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:

**“Such other Uses and Disclosures pursuant to an Authorization provided by the individual who is the subject of the PHI or such individual’s personal representative and prepared in accordance with 45 CFR 164.508(c) of the HIPAA Regulations.”**

<sup>1</sup> 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

### 2.1. Member Participation in this use case is defined by the following:

#### Inclusion:

##### **HSX Members/Participants 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 PAR”).
- b) **Contribute Data to HSX equitable to the Data being requested.** The determination of whether an HSX Member/Participant is eligible for access to Data under this use case shall be made by HSX.
- c) **“Covered Entity” under HIPAA.** Such HSX Member/Participants may access Data on their patient/member population available in the HSX Clinical Data Repository contributed from other HSX Members/Participants.
- d) **Research must be approved through an institutional review board (IRB).**
- e) **Research must be accompanied by a signed HIPAA-Compliant Patient Authorization.**

#### 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. [PAR Ref. §6.3.4]
- b) HSX Members/Participants are prohibited from utilizing this use case for purposes of identifying potentially eligible subjects, or for recruitment or marketing purposes.

In accordance with the HSX Participation Agreement, as a non-Treatment Use Case, members have the ability to 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

#### **Inclusion: This use case pertains to the following data:**

- a) 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”).



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- b) Only such Identifiable Data, including Protected Health Information (PHI), that is described in the Research Study documentation approved by the IRB and consistent with HIPAA-Compliant Authorizations.
- c) 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 unless the HIPAA-Compliant Authorization signed by the patient/member meets the specific applicable federal and/or State law elements required.
- d) Health plans may have access to self-pay encounter Data only with the appropriate type of signed HIPAA-Compliant Authorization.

**Exclusions:**

- Financial Data, including but not limited to Data concerning billed and paid amounts.

## 2.3. Compliance and Authorization

Identifiable Data may be disclosed to an HSX Member/Participant and an HSX Member/Participant may access Identifiable Data only when the following criteria are met:

- a) A HIPAA-Compliant Authorization has first been obtained from the patient/member for the intended use and disclosure of such Identifiable Data, and has been documented and retained in accordance with the procedures set forth in this use case.
- b) The patient/member’s permission to use/share his/her Identifiable Data for specific purpose(s) will be documented in the HIPAA-Compliance Authorization and will explicitly address that the patient/member grants the Investigator(s) permission to obtain their health records from a Health Information Exchange, such as HealthShare Exchange (HSX).
- 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. To the extent that an HSX Member/Participant requires a patient/member to opt into data sharing with HSX, no identifiable data about the patient/member will be contributed to the HSX CDR and available for this use case unless the patient/member opts into data sharing with HSX at the Member/Participant organization.

### 3. Policy

HSX and its Members/Participants support Patient-Authorized Research conducted by HSX Members/Participants strictly in accordance within the scope, procedures and limitations of this use case, the PAR (*or substantively equivalent participation agreement*) and a HIPAA-Compliant Authorization signed by the patient/member.

### 4. Procedures

- An HSX Member/Participant 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 Patient-Authorized Research on prostate cancer, HSX Member/Participant may ask HSX to confirm whether the CDR contains sufficient Data on prostate cancer.
- HSX shall determine whether HSX Members/Participants accessing Identifiable Data pursuant to this use case for Patient-Authorized Research purposes may be charged a reasonable cost-based fee to prepare and transmit the PHI under this use case. 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)].
- Each Research Study which an HSX Member/Participant is seeking to conduct under this use case must be approved through an institutional review board (IRB) 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.
- 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’s rules, 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>
- Every individual who wishes to participate in a Research Study and/or who wants their Identifiable Data to be disclosed or made available to the designated HSX Member/Participant must complete and sign a HIPAA-Compliant Authorization for each research study. For purposes of this use case, a “HIPAA-Compliant Authorization” must meet the following minimum criteria:



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- a. In instances where no Super Protected Data will be accessed or disclosed, a HIPAA-Compliant Authorization which contains the minimum required elements as set forth in HIPAA, as restated in the attached *Checklist of Required Elements of Compliant Consent* (see Appendix B), signed by the individual who wishes to participate in the research study ) or such individual's legally recognized Personal Representative (as defined by HIPAA);
  - b. In instances where Super Protected Data will be accessed or disclosed, a legally compliant Authorization form which contains the minimum required elements of HIPAA and meets all additional specific elements and notices required by applicable law (see Appendix B),
    - i. Identifiable Data originates from a Part 2 facility or program (as defined in 42 C.F.R. Part 2 or under applicable State licensing laws) may be accessed/used only with the individual/patient's signed HIPAA-Compliant Authorization which strictly complies with 42 C.F.R. Part 2 and applicable State law (**NOTE:** 42 C.F.R. Part 2 requirements may be **waived** for IRB-approved Research Studies conducted by a Covered Entity on Data originating from a facility or program governed **only by 42 CFR Part 2**; HOWEVER, any State Law requirements applicable to licensed substance abuse facilities, units or programs would still apply);
    - ii. Identifiable Data which contains HIV/AIDS related information may be accessed/used only with the individual/ patient's signed HIPAA-Compliant Authorization which strictly complies with State law, or otherwise pursuant to an exception(s) under State law which allows such information to be accessed without such authorization;
    - iii. Identifiable Data which contains information originating from a mental health facility or program regulated by applicable State law may be accessed/used only with the individual/ patient's signed HIPAA-Compliant Authorization which strictly complies with State law, or otherwise pursuant to an exception(s) under State law which allows such information to be accessed without such consent.
  - c. The HIPAA-Compliant Authorization form which is intended to be used for a particular Research Study must be reviewed by and approved by the applicable IRB before being implemented for use, with the guidance of legal counsel as appropriate.
  - d. HSX will verify that the IRB-approved, HIPAA-Compliant Authorization meets these requirements as outlined above and in Appendix B.
  - e. Sample language addressing the patient's authorization to obtain their records from other providers through HSX is included in Appendix C.
- Once the HSX Member/Participant's application is approved, the Principal Investigator, or his/her designee, shall ensure the following:
    - A signed HIPAA-Compliant Authorization, as set forth in the *Checklist of Required Elements for Compliant Consent to Disclosed Identifiable Data*, attached as [Appendix B](#), is obtained from each patient/member before accessing or using his/her Identifiable Data for Patient-Authorized Research under this use case;
    - HIPAA-Compliant Authorizations are obtained in accordance with this use case and the processes described in the *Consumers' Right to Direct and Control Transmission of Their Personal Data Use Case*, and the processes which afford the patient/member greater control over their data and provide for the best safeguards shall control; and

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- Signed HIPAA-Compliant Authorizations are securely maintained for the duration of the study and for a minimum of six (6) years thereafter.
- HSX staff will encrypt all transmissions of Personal Health Information (“PHI”) in accordance with the HHS Secretary’s *Guidance to Render Insecure 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*.
- 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.
- 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 Compliant Consents are/were properly obtained and maintained.

## Enforcement

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

## Definitions

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

- **Patient-Authorized Research:** For purposes of this use case, Patient-Authorized Research is limited to the access and/or disclosure of Identifiable Data from the HSX Clinical Data Repository to an covered entity HSX Member/Participant for a Research Study approved in accordance with this use case and which is authorized by the patient/member individual as captured and set forth in a HIPAA-Compliant Authorization signed and retained for a minimum of six (6) years after the end of the study, or longer as required by the IRB.
- **Research Study:** 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:*
- HIPAA Ref. 164.508(a)(4)(i) 164.508(a)(4)(i) *Authorization required: Sale of protected health information.*

<b>Policy Owner</b>	Privacy Officer Chief Information Security Officer	<b>Contact</b>	Don.reed@healthshareexchange.org
<b>Approved By</b>	Privacy/Security HSX Board	<b>Approval Date</b>	2/18/20 3/26/20
<b>Date in Effect</b>	3/26/20	<b>Version #</b>	1
<b>Original Issue Date</b>	3/26/20	<b>Last Review Date</b>	
<b>Related Documents</b>	Audit and Monitoring Policy Data Misuse Policy Encryption Policy Glossary HSX Opt-Out and Opt-Back-In Policy HSX Participation Agreement Secure Disposal Policy		



## Appendix A

### External IRB Approval Attestation and Application

#### Instructions

This form is required before any Patient-Authorized 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 Patient Authorized Research Use Case.

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

#### Background Information

<p><b>Principal Investigator</b></p> <p><i>The PI's responsibility includes ensuring the collection and retention of patient consents.</i></p>	<p><i>Full name and degree of Principal Investigator</i></p> <p><i>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</i></p> <p><i>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</i></p>
<b>Protocol Title</b>	<i>Full protocol title</i>
<b>Funding Sponsor</b>	<i>Identify the agency, organization, company or person providing funds for the Research Study</i>
<b>Regulatory Sponsor</b>	<i>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. For clinical trials (studies involving drugs or devices) this is typically the FDA IND holder, for device studies, this is the FDA IDE holder.</i>
<b>IRB of Record</b>	<i>Insert name of institution serving as the IRB of record</i>





## Procedural Information

<b>Data Confidentiality and Security</b>	<p><i>Data Confidentiality and Security</i> relates to how the confidentiality, integrity and availability of all research data created, received, maintained, or transmitted will be ensured by the Research Study.</p> <p>In this section, the following must be included:</p> <ul style="list-style-type: none"><li>• 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.</li><li>• A description of any additional controls that will be implemented for the storage, handling, and sharing of data.</li><li>• The long-range plan for protecting the confidentiality of research data, including a schedule for destruction of identifiers associated with the data.</li><li>• Explain how <b>HIPAA Privacy</b> compliance will be achieved.</li><li>• Explain how <b>HIPAA Security</b> compliance will be achieved, including reporting and notifying affected individuals about Data breaches.</li></ul>
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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 Patient-Authorized 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 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. As long as HSX Participants follow the legal requirements for obtaining patient authorization or consent for the release of Super Protected Data when and if consent is legally-required, such Data is included in the "Permitted Purposes" as described in this Agreement. HSX shall create necessary HSX Policies and/or structure its Use Cases to facilitate compliance with laws protecting 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



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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.

\_\_\_\_\_  
Signature of Principal Investigator

\_\_\_\_\_  
Date



## Appendix B

### Checklist of Required Elements of HIPAA-Compliant Authorization to Disclose Identifiable Data

#### HIPAA-Compliant AUTHORIZATION

- Identify the **name** of the patient/subject
- Describe the information**, that will be accessed/used, in a specific and meaningful fashion
- Describe **each purpose** of the disclosure and/or use of the information.
  - If the information will be used directly or indirectly for **marketing purposes**, this must be **expressly stated**.
- Identify the specific person or **class of persons disclosing** the information
- Identify the specific person or **class of persons receiving** the information
- Include a **specific expiration date OR trigger event** (*trigger event cannot be "when/if patient revokes authorization"*) relating to the individual or purpose of the disclosure/use which causes the authorization to expire.
- Must contain the following **statements** and explanations:
  - You have the **right to revoke** your authorization
  - Describe **how** authorization can be revoked
  - Right to revoke authorization **excludes disclosures already made** relying on signed authorization
  - The disclosing entity/person and the receiving entity/person **will not condition treatment, payment, enrollment or eligibility for benefits** on signing the authorization. *Exceptions*, if they apply, must be **expressly stated** for:  
(1) research-related treatment (2) where health plan conditions enrollment or eligibility for benefits on authorization if (a) for eligibility and enrollment determinations, underwriting or risk determinations and (b) psychotherapy notes are not included (3) treatment/care is created *solely* for the purpose of creating such information for disclosure to a third party (i.e., employment prescreening).
  - Your information disclosed may be **subject to redisclosure** by the recipient and NOT protected by HIPAA.
  - If the entity disclosing the information receives **remuneration** in exchange for the information, this must be **expressly stated** in the form (unless an exception applies).
- Must be **signed by the Patient** or **Personal Representative** (*legally recognized under applicable state law i.e., Guardian; Power of Attorney; Parent*). Personal Representative's specific legal authority must be described.
- Date of signature** must be included
- Cannot "compound" or "combine"** multiple HIPAA Authorizations **EXCEPT**: (1) can combine HIPAA Authorization for psychotherapy notes with another HIPAA Authorization for psychotherapy notes, (2) **can** combine **multiple HIPAA Authorization for research studies** (3) can combine multiple HIPAA Authorizations so long as NOT general HIPAA Authorization + HIPAA Authorization for psychotherapy notes, and NOT with HIPAA Authorization that impose allowed conditions.

#### ADDITIONAL Required Elements for Super Protected Data

A HIPAA-Compliant Authorization to access/use Identifiable Data which contains Super Protected Data must include all of the required elements listed above for a HIPAA-Compliant Authorization **but also** meet the more stringent requirements, set forth below, which apply to the applicable Super Protected Data to be accessed/used.

**42 CFR Part 2** (data originating from Substance Abuse Facilities/Programs, including those licensed under PA & NJ) [NOTE: private facilities/programs and facilities/programs that do not accept any federal dollars/funds may be excluded from these additional requirements]



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- Must state *how much, what kind* and **explicitly describe the “Part 2 Information”** to be disclosed/used.
- Entity receiving** the Part 2 information must be described as follows:
  - Name of Person** (for all *non-Treatment* purposes) OR
  - Name of Entity BUT ONLY IF Patient has “*treatment relationship*” with Entity OR
  - Name of Entity** facilitating disclosures (i.e., **HSX**) **AND**
    - (a) *Names* of individual participants; *or*
    - (b) *Names* of entity participants (i.e., entity or program) that have Treatment relationship w/ Patient; *or*
    - (c) **General Designation** of individuals or entities (i.e., *all my providers*) with a **treating provider relationship** with Patient (**BUT** HSX must be able to produce a List of Disclosures of the names of each/every Entity that received Part 2 info).
- Must include *date, event or condition* which, if met, will be the *expiration date* of the authorization. Length of durability of authorization *can be “no longer than reasonably necessary”* to serve the purpose for which the authorization is given.
- Must contain a specific **Notice to Recipient**:

**“42 CFR Part 2 prohibits unauthorized disclosure of these records”.**

- If using General Designation of Recipients (allowed only for treatment), authorization must contain a **statement** that the patient/individual **confirms understanding** that upon their request and consistent with Part 2, they will be provided with a **List of Entities** to which their Part 2 info was disclosed pursuant to the general designation.

### **HIV/AIDS Information (PA)**

- Must describe **how much** and **what kind** of information (i.e., HIV/AIDS) is to be disclosed.
- Name or **title of the individual** OR **Name of the organization** that will receive the HIV/AIDS info
- Each disclosure made with the subject’s written authorization must be accompanied by the following **written statement**:

***This information has been disclosed to you from records protected by Pennsylvania law. Pennsylvania law prohibits you from making any further disclosure of this information unless further disclosure is expressly permitted by the written consent of the person to whom it pertains or is authorized by the Confidentiality of HIV-Related Information Act. A general authorization for the release of medical or other information is not sufficient for this purpose.***

### **Mental Health Facility (PA)**

- Statement of the **specific purpose(s)** for which the released records are to be used.
- The **person obtaining the authorization** from the client/patient/parent/guardian **must** also **sign and date** the consent form.
- Must **identify the agency or person to whom** the records are to be released.
- Include a time limit on the validity of the authorization that shows **starting and ending date**
- Statement that authorization is **revocable at the written request** of the person who have the authorization (or oral request with 2 witnesses IF patient physically unable to give written authorization).
- All disclosures of patient information from a mental health facility must be accompanied by a **written statement**:



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***This information has been disclosed to you from records whose confidentiality is protected by State statute. State regulations limit your right to make any further disclosure of this information without prior written consent of the person to whom it pertains.***

- Signature of the client/patient or parent or guardian. [If **person is physically unable to provide a signature, the signatures of two witnesses** who witnessed that the client/ patient understood the nature of the release and freely gave his verbal authorization.] ALSO, the person obtaining the authorization from the client/patient/parent/guardian must sign and date the consent form.
- Must include a **statement** that the **person understands the nature of his release**.

### **HIV/AIDS Information (New Jersey)**

- Must state *how much, what kind* and **explicitly describe the “HIV/AIDS Information”** which will be disclosed/used.
- Entity receiving** the HIV/AIDS Information must be described as follows:
  - **Name of Person** (for all *non-Treatment* purposes) OR
  - Name of Entity BUT ONLY IF Patient has “*treatment relationship*” with Patient OR
  - **Name of Entity** facilitating disclosures (i.e., **HSX AND**)
    - (a) *Names* of Individuals with Tx relationship w/ Pt; *or*
    - (b) *Names* of participants (i.e., entity or program) that have Tx relationship w/ Pt; *or*
    - (c) **General Designation** of individuals or entities (i.e., *all my providers*) with a **treating provider relationship** with Patient (**BUT** HSX must be able to produce a List of Disclosures of the names of each/every Entity that received HIV/AIDS Info.
- Must include *date, event or condition* which, if met, will be the *expiration date* of the authorization. Length of durability of authorization *can be “no longer than reasonably necessary”* to serve the purpose for which the authorization is given.
- Must contain a specific **Notice to Recipient**:

***“New Jersey prohibits unauthorized disclosure of these records”.***

- If using General Designation of Recipients (*allowed only for treatment*), authorization must contain a **statement** that the patient/individual **confirms understanding** that upon their request and consistent with NJ law, they will be provided with a **List of Entities** to which their HIV/AIDS Information was disclosed pursuant to the general designation.

### **Mental Health Facilities/Programs (New Jersey):**

- Describe the purpose of the disclosure/use **and** the “**predictable outcome.**”
- Name** of the **agency/entity disclosing** the info.
- Name or Title** of the **Person or Organization receiving** the information.
- Include an **expiration date** or defined a **termination event**. [NOTE! **Automatic expiration after 4 months if expiration date is not indicated**]
- Must contain statement that individual has the right to revoke consent at any time by **written** communication to custodian of records.
- Must contain a **specific Notice to Recipient** of the information:

***“Disclosure without the authorization of the person who is the subject of the records,***



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***or as otherwise provided by law, is prohibited.”***

- Statement of Understanding. Must include statement that signing individual understands the nature of the Authorization and has been informed of right to revoke.

**Genetic Information (New Jersey):**

- Must include statement that signing individual explicitly consents to release of genetic test results for the purpose(s) of the study and that that the consent form also serves as notice to the individual of the intended access and use by intended recipients. (NJ Statute 10:5-48, Notice to persons receiving genetic testing.)

**IMPORTANT**

**IF IDENTIFIABLE DATA WILL ORIGINATE FROM ANY OTHER STATE THAN PENNSYLVANIA OR NEW JERSEY, THE LAWS OF THE STATE FROM WHICH THE DATA ORIGINATES MUST BE REVIEWED AND FULLY SATISFIED FOR THE HIPAA-COMPLIANT AUTHORIZATION TO BE VALID.**



## Appendix C

### Sample Language for Patient Authorization to Obtain Records from Other Providers Through HSX

- In addition to information our staff collect from you directly, our staff will also review your medical records to get information about your medical history, emergency room visits and hospitalizations, and the medications that you take, medical procedures you have... *[to reflect the scope of the specific study]*
- If you seek treatment at another healthcare facility, we request permission to obtain records from any outside hospital, healthcare provider, or insurer, including any records available through a Health Information Exchange. By signing this document, you consent to the release of your medical records from all the parties above for the purpose of review by the study team...