Access Health CT

All-Payer Claims Database (APCD) Draft Privacy Policy and Procedure

- 1. <u>Purpose of Policy</u>.
 - a. <u>APCD Legislative Mandate and History</u>. Public Act 13-247 enabled the Exchange's creation of the Connecticut All-Payer Claims Database ("APCD"). Pursuant to Public Act 13-247, various Data Submitters are required to report healthcare information to the Exchange for inclusion in the APCD. The Act allows the Exchange: (i) to utilize healthcare information collected from Data Submitters to provide healthcare consumers in Connecticut with information concerning the cost and quality of healthcare services that allows such consumers to make more informed healthcare decisions; and (ii) to disclose Data to state agencies, insurers, employers, healthcare providers, consumers, researchers and others for purposes of reviewing such Data as it relates to health care utilization, costs or quality of healthcare services.
 - b. <u>Purpose of the Policy</u>. The purpose of this Policy is to ensure the integrity, security and appropriate use and disclosure of Data. More specifically, this Policy sets forth the process and procedure by which the Exchange will accept, review and evaluate applications from third parties requesting access to the Data in a manner consistent with the Act.
- 2. <u>Definitions</u>.
 - a. "*Act*" means Connecticut General Statutes Sections 38a-1090 and 38a-1091, as amended from time to time.
 - b. "*Advisory Group*" shall mean the All-Payer Claims Database Advisory Group established pursuant to the Act.
 - c. "*APCD*" means the Connecticut All-Payer Claims Database established by the Act and created and maintained by the Exchange.
 - d. "APCD Personnel" means those Exchange employees, agents and contractors (other than the contractor responsible for receiving healthcare information from the Data Submitters) whom the Executive Director permits, in writing, to access Data through the Managed Environment or Vendor.
 - e. *"Applicant"* means an individual or organization that requests access to Data by submitting a Data Release Application to the Executive Director.

- f. "*Applicant Related Party*" means any individual or entity under common ownership or control of an Applicant.
- g. "*Board*" means the Board of Directors of the Exchange constituted pursuant to Public Act No. 11-53 and the Bylaws of the Exchange.
- h. "*Chief Executive Officer*" means the individual selected by the Board to serve as chief executive officer of the Exchange in accordance with C.G.S. § 38a-1081.
- i. "*Data*" means De-Identified claim information provided to the APCD by Data Submitters and made available through the Vendor or Managed Environment.
- j. "*Data Release Application*" means the written application and supporting documentation or other materials an Applicant submits to the Executive Director or the Data Release Committee in connection with a request to access Data.
- k. "*Data Release Committee*" means the committee responsible for reviewing and making recommendations to the Executive Director regarding the acceptance or denial of Data Release Applications.
- "Data Submitters" means: (i) those entities and/or organizations required to report healthcare claims information to the APCD pursuant to the Act; and (ii) Connecticut state agencies, hospitals, the United States Census Bureau, governmental payers, such as Medicare and Medicaid, and any other third parties who submit healthcare claims information to the APCD.
- m. "*Data Use Agreement*" means the written agreement entered into by and between an Applicant and the Exchange upon acceptance of the Applicant's Data Release Application by the Data Release Committee, which sets forth the obligations and responsibilities of the Applicant with respect to the use of the Data disclosed to it by the Exchange.
- n. "*De-Identified*" refers to healthcare information from which all eighteen (18) identifiers enumerated at 45 C.F.R. § 164.514(b)(2) have been removed.
- o. *"Executive Director"* means the individual appointed by the Exchange to serve as executive director of the APCD.
- p. *"Exchange"* means The Connecticut Health Insurance Exchange d/b/a "Access Health CT".

- q. *"HIPAA"* means the Health Insurance Portability and Accountability Act of 1996 and its implementing regulations, each as amended from time to time.
- r. *"Limited Data Set"* means healthcare information from which all sixteen (16) identifiers enumerated 45 C.F.R. § 164.514(e)(2) have been removed.
- s. *"Managed Environment"* means the computer interface by which the Exchange accesses Data.
- t. *"Project"* means the purpose or program for which Data is disclosed to a Recipient.
- u. *"Recipient"* means an Applicant whose Data Release Application has been approved by the Data Release Committee and which has received Data from the APCD.
- v. *"Recipient Third Party"* means an employee, agent or contractor of a Recipient or any entity or organization to which the Recipient has redisclosed or made available Data.
- w. "State" means the state of Connecticut.
- x. *"Work Product"* means every invention, modification, discovery, design, development, customization, configuration, improvement, process, work of authorship, documentation, formulae, datum, code, technique, reporting logic, know how, secret, or intellectual property right whatsoever or any interest therein (whether patentable or not patentable or registerable under copyright or similar statutes or subject to analogous protection) that is made, conceived, discovered, or reduced to practice by a Recipient or Recipient Third Party.
- y. *"Vendor"* means the entity or organization engaged by the Exchange to provide data management or maintenance services with respect to the APCD.
- 3. Executive Director.
 - a. The Executive Director shall have general oversight responsibility for the privacy, security and access to Data by potential Recipients. In all instances, the Executive Director may delegate functions or responsibilities to other properly qualified Exchange employees, agents or contractors acting in accordance with this Policy.
 - b. The Executive Director shall maintain a list of each member of the Data Release Committee and his or her professional affiliation and shall make

such list available to the public on the Exchange's public-facing website. The Executive Director shall revise and update such list as necessary.

- c. The Executive Director shall establish a meeting schedule for the Data Release Committee and communicate that schedule, and any changes thereto, to each member of the Data Release Committee in a timely manner.
- 4. Data Release Committee.
 - a. <u>Purpose and Mission</u>. The purpose of the Data Release Committee shall be to: (i) review, approve and deny Data Release Applications (in accordance with established guidelines) submitted by Applicants for the release of Data; and (ii) provide support to the Executive Director during the receipt and review of Data Release Applications.
 - b. Governance.
 - i. <u>Committee Members</u>. The Data Release Committee shall consist of not less than eight (8) members and shall be composed of at least the following: (i) one (1) member of the Board who is an *ex officio* member of the Board and a representative of a State agency; (ii) the Executive Director; (iii) an individual with a professional or academic research background involving public health matters; (iv) a representative from the health insurance industry; (v) an attorney with experience in health care, data privacy or research matters; (vi) a healthcare professional, such as a physician, nurse, social worker or psychologist; (vii) an individual with experience in hospital administration, analytics or research; and (viii) a consumer representative (each a "Member" and collectively the "Members").
 - ii. <u>Appointment and Removal</u>. Members shall be appointed by and serve at the pleasure of the Chief Executive Officer. When appointing a Member, the Chief Executive Officer shall consider nominations from the Executive Director. The Chief Executive Officer may remove and replace Members at any time in its discretion.
 - iii. Voting Rights. Each Member shall have one vote.
 - iv. Terms. There shall be no term limits with respect to Members.
 - v. <u>Chairperson</u>. The Chief Executive Officer shall designate a Member of the Data Release Committee to act as chairperson of the Data Release Committee ("Committee Chair"), and may designate one or more vice chairs to act only in the absence of the Committee Chair.

The Committee Chair (or Vice Chair, in the Committee Chair's absence) shall preside at meetings of the Data Release Committee.

- c. Meetings.
 - i. The Data Release Committee normally shall meet at least quarterly, or more frequently as circumstances dictate, in accordance with a schedule set by the Executive Director. Meetings not scheduled on a regular basis in advance may be called by the Executive Director upon reasonable notice provided such notice is not less than five (5) business days. Members may attend a meeting in person or via teleconference; provided that the Member takes reasonable precautions during such teleconference to ensure the confidentiality of the meeting in accordance with this Policy. The Executive Director reserves the right to cancel any scheduled meeting in the event no Data Release Application is available for review and consideration.
 - ii. In order to enhance its ability to fulfill its responsibilities, the Data Release Committee may invite to its meetings, or communicate with, any member of the Board, any member of the Advisory Group, any employee of the Exchange or such other persons as it deems appropriate for the purpose of securing additional guidance and information.
 - iii. All meetings of the Data Release Committee shall be open to the public. Deliberation of confidential information shall be conducted in executive session in accordance with applicable law.
 - iv. In support of the Data Release Committee's meeting schedule, the Executive Director shall arrange for the preparation of meeting agendas, support materials relevant to the Members' review of Data Release Applications and preparing meeting minutes and circulating such minutes to the Members.
- d. Voting.
 - i. <u>Voting/Quorum</u>. A majority of the Members of the Data Release Committee shall constitute a quorum for the transaction of business, and the vote of a majority of Members present shall be required for the Data Release Committee to take formal action.
 - ii. <u>Recusals/Conflicts of Interest</u>. Each Member shall be free from any relationships or conflicts of interest with respect to an Applicant that may impair, or appear to impair, the Member's ability to make independent judgments. In the event of any such relationship or conflict of interest, the Member shall disclose such conflict and if

necessary, recuse him/herself from any review, discussion or deliberation involving or relating to the Applicant's Data Release Application.

- e. <u>Delegation</u>. The Members shall have no right to delegate any functions or responsibilities hereunder to any third party individual or entity.
- 5. Use of Data by the Exchange.
 - a. Access to Data by APCD Personnel.
 - i. The APCD Personnel shall be the only individuals permitted to access Data through the Vendor or Managed Environment.
 - ii. All APCD Personnel shall be credentialed in accordance with applicable Exchange policies and procedures prior to being granted access to the Data through the Vendor or Managed Environment. Access to the Data through the Vendor or Managed Environment shall be subject to the applicable access authentication and audit report requirements of the Exchange's security program and policies, including but not limited to the use of dual-factor authentication.
 - iii. The Executive Director shall review the list of APCD Personnel permitted access to Data through the Vendor or Managed Environment at least every three (3) months and shall revise as necessary.
 - iv. APCD Personnel shall be required to change their password for accessing the Managed Environment every ninety (90) days. APCD Personnel shall be strictly prohibited from disclosing their access credentials, including password, for the Managed Environment to any other individual or entity.
 - b. Use of the Managed Environment and Data
 - i. APCD Personnel may access Data through the Managed Environment or Vendor only (i) to review and analyze such Data for purposes of fulfilling the Exchange's mandate under the Act, including but not limited to the preparation of consumer and publicfacing reports and analyses, or (ii) for Exchange internal business administration or operations.
 - ii. APCD Personnel may not access Data through the Managed Environment or Vendor, or otherwise use or disclose such Data, for (i) any private or illegal purpose, or (ii) any purpose inconsistent with the Act or this Policy.

- iii. When accessing and using the Managed Environment or obtaining Data through the Vendor, APCD Personnel shall: (i) never install any software, application or code in the Managed Environment, unless specific written approval has been provided by the Executive Director; (ii) never link external data with Data from Managed Environment or the Vendor without prior written approval from the Executive Director; and (iii) not re-identify, or attempt to reidentify, Data.
- iv. All Data accessed through the Managed Environment or Vendor by APCD Personnel shall be De-Identified. Notwithstanding, the Executive Director may, in his or her discretion, permit designated APCD Personnel to access a Limited Data Set from the Managed Environment or Vendor. APCD Personnel granted access to a Limited Data Set by the Executive Director shall keep such Limited Data Set strictly confidential and shall not disclose, or provide access to, the Limited Data Set to any other individual, either internal or external to the Exchange, without the prior written consent of the Executive Director.
- v. The Exchange shall maintain: (i) copies of the Managed Environment and Vendor output and make such information available for the purpose of conducting security audits; and (ii) Managed Environment and Vendor access logs.

c. Disclosure of Data by APCD Personnel.

- i. APCD Personnel may not disclose any Data accessed through the Managed Environment or Vendor except: (i) as explicitly permitted by this Policy, including but not limited to disclosure after approval of a Data Release Application by the Data Release Committee; (ii) with the written consent of the Executive Director and after the execution of a written confidentiality agreement between the Exchange and the approved recipient, when such disclosure is reasonably necessary for the Exchange's operations or fulfillment of the purpose of the Act; or (iii) as required by state or federal law, regulation or process.
- ii. Any third-party vendor engaged by the Exchange to maintain, use or disclose the Data, including the Vendor, shall comply with all applicable Exchange policies and procedures and shall implement and maintain technical, physical and administrative standards sufficient to protect and ensure the privacy and security of the Data, including but not limited to: (i) the specifications and requirements set forth in applicable State and federal law; (ii) industry standards and best practices regarding the maintenance and security of

healthcare data, including but not limited to applicable guidance from the National Institutes of Standards and Technology ("NIST"), including but not limited to NIST Special Publication 800-53 Rev 4, as may be amended or superseded from time to time; (iii) the thirdparty vendor's privacy and security policies, procedures and protocols; and (iv) the Exchange's privacy and security policies, procedures and protocols.

- d. Safeguarding Data in the Exchange's Possession.
 - i. All Data in the possession or custody of APCD Personnel shall be maintained on the Exchange's network and servers. APCD Personnel shall not maintain or store Data on any personal electronic device or on any personal or unapproved remote or cloud storage platform or application.
 - ii. All Data shall be maintained in accordance with applicable Exchange security policies, protocols and procedures.
- e. Disposal of Data in the Exchange's Possession.
 - i. All Data maintained on electronic media shall be sanitized in accordance with NIST Special Publication 800-88 ("Guidelines for Media Sanitation"), as may be amended or superseded from time to time, and in accordance with Exchange policy and procedure. Such sanitation shall be performed and/or certified by the Exchange's information technology department.
 - ii. All Data maintained in paper format shall be shredded, pulverized or otherwise destroyed in a manner that prevents re-identification or reassemblage of the Data.
- 6. Data Release Application Process.
 - a. <u>Data Release Application</u>. The Exchange shall develop and maintain a Data Release Application. The Executive Director shall retain the right, in his or her sole discretion, to modify the Data Release Application for particular Applicants or Projects; provided such modification is consistent with this Policy and applicable law.
 - b. <u>Submission</u>. An Applicant must submit a complete Data Release Application to the Exchange and be willing to be interviewed by the Data Release Committee.
 - c. <u>Data Release Application Processing Fees</u>. The Executive Director shall collect a processing fee for each Data Release Application received and

such Data Release Application Processing Fee shall approximate the costs associated with the process of reviewing the Data Release Application. The Executive Director shall create and publish a fee schedule for such processing fees.

- d. <u>Confidentiality</u>. The Executive Director and the Data Release Committee shall take reasonable steps and implement reasonable measures to safeguard the confidentiality of the Applicant and the Data Release Application, subject to applicable law.
- e. Data Release Application Review Process.
 - i. <u>Role of Executive Director.</u>
 - 1. <u>Tasks</u>. Within fifteen (15) calendar days of receipt of a Data Release Application, the Executive Director shall perform the following tasks with respect to his or her review of the Data Release Application:
 - a. Receive Data Release Applications from Applicants;
 - b. Maintain a record of each Data Release Application received; and
 - c. Determine if the Data Release Application is complete and the Applicant has provided all information required by the Data Release Application.
 - 2. <u>Right to reject Data Release Application</u>. The Executive Director may reject a Data Release Application in the event the Executive Director, in his or her sole discretion, determines that the Data Release Application is incomplete.
 - 3. <u>Right to request additional information</u>. The Executive Director may request additional information or clarification from the Applicant, including but not limited to requesting a meeting with the Applicant.
 - 4. <u>Submission to Data Release Committee</u>. Within ten (10) business days of the Executive Director's determination that the Data Release Application is complete, the Executive Director shall submit such Data Release Application to the Data Release Committee. Any complete Data Release Applications received from the Executive Director fifteen (15) or more days prior to the Data Release Committee's

next scheduled meeting, shall be reviewed and considered at such next scheduled meeting. Any complete Data Release Applications received from the Executive Director less than fifteen (15) business days prior to the Data Release Committee's next scheduled meeting shall be reviewed and considered at the meeting following the next scheduled meeting. Such review shall include, but not be limited to, the following:

- a. Determine whether the Data Release Application is consistent with the objectives of the APCD as set forth in the Act;
- b. Review whether the Applicant would be able to reidentify the Data provided;
- c. Determine the adequacy of the Applicant's privacy and security infrastructure and safeguards;
- d. Any other factor or consideration deemed by the Executive Director or Data Release Committee to be relevant to the Data Release Application or Project; and
- e. If the Data Release Application is from a researcher or is otherwise for research purposes, determine whether the research methodology is consistent with established norms and the Data Release Application sets forth a sound research design.
- 5. <u>Right to request additional information</u>. The Data Release Committee shall have the right to direct the Executive Director to request additional information, seek clarification from the Applicant or request a meeting with the Applicant. Any such requests shall be communicated to the Executive Director at least five (5) business days prior to the meeting at which the Data Release Application will be considered.
- 6. <u>Support by Executive Director and Exchange</u>. The Data Release Committee may seek assistance, guidance and technical advice from the Executive Director or the staff of the Exchange at any time during its review and consideration of a Data Release Application. The Data Release Committee may also obtain assistance, guidance and technical advice from third parties including but not limited to dataset design professionals, clinicians, health insurance experts, privacy

experts, attorneys and regulatory authorities; provided it does not delegate its responsibilities hereunder.

- <u>Decisions</u>. (i) Upon completion of its review and consideration of a Data Release Application, the Data Release Committee may issue one of the following three decisions:
 - a. <u>Approval</u>. Approval is to be granted when the Data Release Committee determines, in its sole discretion, that the Data Release Application satisfies each of the requirements and criteria outlined in this Policy and the Data Release Application.
 - b. <u>Conditional Approval</u>. Conditional approval is to be granted when the Data Release Committee requires additional information from, or actions by, the Applicant in order to address outstanding issues, and the Data Release Committee determines, in its sole discretion, that such additional information or actions will (i) adequately address and satisfy any concerns of the Data Release Committee; and (ii) permit the Data Release Committee to determine, in its sole discretion, that the Data Release Application satisfies each of the requirements and criteria outlined in this Policy and the Data Release Application.
 - c. <u>Denial</u>. Denial is to be issued when the Data Release Committee determines, in its sole discretion, that the Data Release Application fails to satisfy one or more requirements or criteria outlined in the Act or this Policy.
- ii. <u>Veto Authority</u>. The Chief Executive Officer reserves the right to veto any decision of the Data Release Committee if he/she determines, in his/her sole discretion, that the Data Release Application fails to satisfy one or more requirements or criteria outlined in the Act or this Policy.
- iii. <u>No Right of Appeal</u>. An Applicant shall have no right to appeal a decision of the Chief Executive Officer, Executive Director or the Data Release Committee.
- iv. <u>Opportunity for Resubmission of Data Release Application</u>. An Applicant which has submitted a Data Release Application that is subsequently denied may re-submit the Data Release Application for

re-consideration; provided that in the event an Applicant or an Applicant Related Party has, in the sole discretion of the Executive Director or Data Release Committee, previously violated any term or condition of a Data Use Agreement entered into between the Exchange and such Applicant or Applicant Related Party, the Executive Director may deny such Applicant or Applicant Related Party the opportunity to re-submit an existing, or submit a new, Data Release Application. The Executive Director also has the discretion to deny consideration of a new Data Release Application if upon preliminary review by the Executive Director, the Data Release Application has not materially changed.

7. <u>Release of Data Pursuant to Approved Data Release Applications</u>.

a. Data Use Agreement.

i. The Executive Director, in consultation with the Exchange and Data Release Committee, shall develop a template Data Use Agreement. The Data Use Agreement shall, at a minimum, require the Recipient to: (i) ensure that Data will be used and re-disclosed only for purposes of the Project; (ii) adequately safeguard the privacy and security of the Data; (iii) grant the Exchange and its designated agents access to the Recipient's premises for purposes of determining compliance with the Data Use Agreement; (iv) agree to all policies and procedures of the Exchange applicable to the APCD, including those addressing cell suppression and this Policy, as applicable; (v) not re-identify, or seek to re-identify, any Data; (vi) if applicable, provide the Executive Director an advance copy of any research or analysis results, publications or manuscripts to determine whether or not the privacy or security of the Data has been compromised in any way; (vii) assign a person to be responsible for the privacy and security of the Data while in Recipient's possession or control; (viii) maintain logs of all individuals and entities who access, use or receive Data, and make such logs available to the Executive Director upon request; (ix) immediately report any unauthorized use or disclosure of Data; (x) not use Data for any unlawful purpose; (xi) require Recipient Related Parties to agree, in writing, to the requirements, terms and conditions of the Data Use Agreement; (xii) notify the Exchange within thirty (30) calendar days of completion of the Project and either return or destroy all Data in accordance with this Policy; (xiii) during all times during which the Data is in the possession or control of the Recipient or a Recipient Related Party, maintain internal written logs recording (a) the date of each use or disclosure of the Data. (b) the identity of each user or recipient of the Data, and (c) the purpose of such use or disclosure; and (xiv) to the extent permitted by law and principles of

sovereign immunity, indemnify, defend and hold the Exchange and the State harmless from any and all claims, losses, liabilities, damages, judgments, fee, expenses, awards, penalties and costs relating to or arising from the use or disclosure of the Data, or the violation of the Data Use Agreement or any applicable law, by the Recipient or Recipient Related Party. In the event that the Recipient is a State agency, and such indemnification is impermissible under State law, such agency shall be required to assume responsibility for any remediation necessary to protect individuals subject to a Data breach that results in re-identification of the subject of the Data.

- Upon approval or conditional approval of a Data Release Application in accordance with Section 6(e)(7) of this Policy, the Executive Director shall provide a Data Use Agreement to the Applicant for review and execution. The Data Use Agreement provided to the Applicant shall be non-negotiable.
- iii. In the event the Executive Director determines that the Recipient has violated any term or condition of the Data Use Agreement, the Exchange may do any of the following in its sole discretion: (i) immediately cancel the Data Use Agreement; (ii) require the immediate return or destruction of the Data; (iii) if access to the Data is provided via the Enclave Model, immediately terminate the Recipient's access to the Data; (iv) deny the Recipient access to any further Data from the Exchange; and/or (v) institute legal proceedings against the Recipient.
- b. <u>Form/Manner of Access</u>. The Exchange shall make Data available to a Recipient through one of two models. The Executive Director, in consultation with the Recipient, shall select the model most appropriate for the Recipient and its approved Project and shall ensure in either case that the access is secure.
 - i. <u>Transmission</u>. The Exchange shall offer a "Transmission Model" of Data access, pursuant to which the Exchange shall collect, format and transmit the Data approved for release by the Data Release Committee to the Recipient.
 - ii. <u>Enclave Model</u>. The Exchange may offer an "Enclave Model" of Data access, pursuant to which the APCD shall permit Recipients remote access to the Data approved for release by the Data Release Committee. Pursuant to this model, all Data will reside exclusively on Exchange servers.
- c. <u>De-Identification</u>. Data released to a Recipient shall not be provided with any key, protocol or map that would allow the Data to be re-identified.

- d. <u>Minimum Necessary</u>. The Exchange shall release only the Data the Executive Director and/or Data Release Committee, in consultation with the Applicant, determines to be the minimum necessary for the Applicant to conduct the Project.
- e. <u>Access Fees</u>. The Exchange, in its discretion, may charge fees to Recipients for access to Data through the Transmission or Enclave Models. In the event such fees are charged, the Executive Director shall create and publish a schedule of such access fees and such fees shall approximate the Exchange's associated costs related to such access.
- f. Posting of Data Release Application Disposition on APCD Website. The Exchange shall post at least the following information on its public-facing website once a completed Data Release Application is received: (i) Applicant name and contact information; (ii) description and purpose of Project; and (iii) disposition of the Data Release Application.

8. <u>Return or Destruction of Data</u>.

- a. <u>Return or Destruction of Data</u>. In the event the Recipient, or any Recipient Related Party, violates any term or condition of the Data Use Agreement entered into by and between the Exchange and the Recipient, or at the end of any Project, the Executive Director may require the Recipient, or any Recipient Related Party, to return to the Exchange or destroy any or all Data in the Recipient's or the Recipient Related Party's possession or control. The Executive Director reserves the right, in his or her sole discretion, to require a particular method and/or schedule of return or destruction.
- b. <u>Standard of Destruction</u>. All Data maintained on electronic media shall be sanitized in accordance with National Institute of Standards and Technology (NIST) Special Publication 800-88 ("Guidelines for Media Sanitation"), as may be amended or superseded from time to time. All Data maintained in paper format shall be shredded, pulverized or otherwise destroyed in a manner that prevents re-identification or re-assemblage of the Data.
- c. <u>Certification of Return or Destruction</u>. The Executive Director may require, in his or her sole discretion, the Recipient to certify, in writing, that all Data in the Recipient's possession or control, or in the possession or control of any Recipient Related Party, has been returned to the Exchange or destroyed in accordance with this Policy.

- 9. Ownership of Data and Work Product.
 - a. <u>Ownership of Data</u>. Neither a Recipient nor a Recipient Related Party shall have any ownership or property rights or interests in the Data received from the Exchange.
 - b. <u>Ownership of Work Product</u>. The Exchange shall not obtain any ownership rights to any Work Product developed or prepared by a Recipient or a Recipient Related Party.
 - c. <u>Publications</u>. Recipient may publish, otherwise publicly disclose or submit for publication an article, manuscript, abstract, report, poster, presentation, or other material that includes the results of the use of the Data, as would be reasonably required for purposes of publication in a peer-reviewed scientific journal (such article, manuscript, abstract, report, poster, presentation, or other material, a "Manuscript").
 - i. Not less than thirty (30) days prior to the earlier of publication or submission for publication of any Manuscript, Recipient shall provide the Exchange with a copy of the Manuscript. Recipient shall delete any Data or other information or content that the Exchange requests in writing be deleted because of concerns with the privacy or confidentiality of the subjects of the Data.
 - ii. Any Manuscript must comply with HIPAA's cell suppression policy and include only De-Identified health information.
 - iii. Recipient shall publicly acknowledge in any Manuscript the Exchange's contribution of the Data, and Recipient may use the Exchange's name for that purpose.
 - iv. Recipient shall grant a worldwide, perpetual, royalty-free, and transferrable license in the Manuscript to the Exchange for the limited purpose of allowing the Exchange to post the Manuscript on its public-facing website or otherwise make the Manuscript publically available. In the event Recipient does not have the legal right to grant such license to the Exchange, the Recipient shall reasonably assist the Exchange in obtaining such license, or an equivalent license, from the appropriate individual or entity.

10. Annual Reporting.

a. The Data Release Committee shall perform a review and evaluation, at least annually, of the performance of the Data Release Committee, including reviewing the compliance of the Data Release Committee with this Policy. In addition, the Data Release Committee shall review and reassess, at least annually, the adequacy of this Policy and recommend to the Board any improvements to this Policy that the Data Release Committee considers necessary or valuable.

b. The Data Release Committee shall submit a report to the Board, at least annually, outlining the Data Release Committee's activities, statistics relating to the volume and type of Data Release Applications received, the review and acceptance or rejection of Data Release Applications and the percentage of Data Release Applications that did and did not result in publication.

11. Conflicts.

- a. In the event of any actual or perceived conflict between an Exchange policy or procedure and this Policy, this Policy shall control, except as may be necessary to comply with any applicable law or regulation.
- b. In the event that any law or regulation is enacted or promulgated that is in any way inconsistent with the terms of this Policy or that interferes with the Exchange's obligations hereunder, this Policy shall be deemed to be automatically amended to comply with such law or regulation.

12. Confidentiality.

Notwithstanding anything herein to the contrary, the Exchange and the Data Release Committee shall comply with all applicable laws and regulations regarding confidentiality, including but not limited to the Connecticut Freedom of Information Act set forth at Connecticut General Statutes Sec. 1-200, *et. seq.*, as may be amended from time to time.