



Data Release Policy

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1. Purpose

- a. Legislative Mandate. Connie, Connecticut's designated health information exchange, is subject to and acts in a manner consistent with applicable state law. Among these applicable state laws are C.G.S.A. § 17b-59d and C.G.S.A. § 17b-59g which are referred to herein as the "Legislative Mandate". The Legislative Mandate requires Connie to: (i) "empower consumers to make effective health care decisions, promote patient-centered care, improve the quality, safety and value of health care, reduce waste and duplication of services, support clinical decision-making, keep confidential health information secure and make progress toward the state's public health goals"; and (ii) "assist the state, health care providers, insurance carriers, physicians and all stakeholders in empowering consumers to make effective health care decisions, promote patient-centered care, improve the quality, safety and value of health care, reduce waste and duplication of services, support clinical decision-making, keep confidential health information secure and make progress toward the state's public health goals." One way in which Connie fulfills the Legislative Mandate is by Disclosing Data to appropriate third parties for legitimate purposes.
- b. Policy Purpose and Scope. In furtherance of the Legislative Mandate, Connie has adopted this Data Release Policy (this "Policy") to govern the appropriate and secure disclosure of Data. More specifically, this Policy sets forth the process and procedure by which Connie will consider Data release programs and accept, review, evaluate, and decide upon requests from third parties to access Data, all in a manner consistent with the Legislative Mandate. This Policy does not address or apply to disclosures of Data to patients, which are subject to Connie's then-current Patient Access Policy.

2. Definitions

"**Board**" means the Board of Directors of Connie constituted pursuant to C.G.S.A. § 17b-59g and the Bylaws of Connie.

"**Connie**" refers to Health Information Alliance, Inc. d/b/a Connie, Connecticut's designated health information exchange.

"**Connie Management**" means the individuals approved or authorized by the Board to serve in leadership and management roles and their respective designees.

"**Contributing Organizations**" means: (i) those entities and organizations required to submit Data to Connie pursuant to the Legislative Mandate; and (ii) other third parties who submit Data to Connie.



“Data” means the health care information provided to Connie by Contributing Organizations. Data does not include health care information subject to a consumer opt-out request.

“De-Identified” refers to Data from which all eighteen (18) identifiers enumerated at 45 C.F.R. § 164.514(b)(2) have been removed.

“Disclosure” (and its variants) means the release, transfer, provision of access to, or divulging in any manner of Data outside of Connie.

“Health Care Provider Access” means a health care provider accessing Data of its patients through Connie in a manner consistent with Connie policy and applicable law.

“HIPAA” means the Health Insurance Portability and Accountability Act of 1996 and its implementing regulations, as amended from time to time.

“Institutional Review Board” means a group that has been formally designated to review and monitor research involving human subjects. In accordance with federal regulations, an Institutional Review Board has the authority to approve, require modifications in (to secure approval), or disapprove research. This group review serves an important role in the protection of the rights and welfare of human research subjects.

“Legislative Mandate” has the meaning given to it in Section 1 of this Policy.

“Limited Data Set” means Data from which all sixteen (16) identifiers enumerated 45 C.F.R. § 164.514(e)(2) have been removed.

“Permitted Disclosure” shall have the meaning given to the term in Section 3(a) of this Policy.

“Policy” means this Data Release Policy as approved by the Board.

“Required by Law” means a mandate contained in law that compels Connie to Disclose Data, including, but not limited to, court orders and court-ordered warrants; subpoenas or summons issued by a court, grand jury, a governmental or tribal inspector general, or an administrative body authorized to require the production of information; a civil or an authorized investigative demand; and statutes or regulations that require the production of Data.

“Research” means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.

“Research Disclosure Agreement” means the agreement entered into by and between Connie and a Research Recipient.

“Research Disclosure Application” means the documentation developed by Connie pursuant to which a third party may request access to Data for Research Purposes.

“Research Evaluation Committee” shall refer to one or more standing or ad-hoc committees formed by the Board to fulfill the applicable obligations set forth in this Policy.



“Research Recipient” means an individual or entity whose application for access to Data for Research purposes has been approved in accordance with this Policy.

“Research Recipient Third Party” means an employee, agent, or contractor of a Research Recipient or any entity or organization to which the Research Recipient has re-disclosed or made available Data.

“Service” means any function or activity for which Connie is engaged by a third party that is not included within the scope of Health Care Provider Access.

“State” means the state of Connecticut.

3. **Authorized Data Disclosures**

- a. **Permitted Disclosures**. The Board recognizes that the appropriate Disclosure of Data by Connie is an essential element of Connie’s fulfillment of the Legislative Mandate. Specifically, Connie may Disclose Data (i) to “assist” health care providers, insurance carriers, the State and other stakeholders; (ii) to “empower” consumers by making Data available to them and to others to allow them to gain knowledge and make decisions; (iii) to “support” academic research, care coordination, reduction in health care costs, promote interoperability, population health, public health reporting, quality improvement, and health care delivery and payment reform; and (iv) otherwise in a manner consistent with the Legislative Mandate (each a “Permitted Disclosure”). The Board further recognizes that a Disclosure of Data may be initiated by Connie or requested by a third party.
- b. **Required Disclosures**. The Board also recognizes that Connie may Disclose Data when Required by Law.

4. **Permitted Disclosures**

- a. **Role of Connie Management**. Connie Management shall have the authority to approve or deny contemplated or requested Permitted Disclosures. In doing so, Connie Management may rely upon Connie staff, consultants, legal counsel, committees, and the Board.
- b. **Disclosure Type**. Connie Management shall designate a Permitted Disclosure as either a Health Care Provider Access Disclosure, Service Disclosure, or Research Disclosure.
- c. **Role of Committees**
 - i. **Research Evaluation Committee**. Connie shall designate an existing committee or establish a new committee to serve the function of the Research Evaluation Committee as described in this Policy.
 - ii. **Additional Committees**. Connie Management may form ad-hoc committees for the purpose of reviewing one or more Permitted Disclosures generally or specifically or to assess, evaluate, and issue recommendations for the approval or denial of a Permitted Disclosure.
- d. **Minimum Approval Criteria**. Connie Management may approve a Permitted Disclosure upon assessment and documentation that such Permitted Disclosure meets the following minimum approval



criteria: (i) the Permitted Disclosure is consistent with Connie's mission, values, and Legislative Mandate; (ii) the Permitted Disclosure is consistent with applicable law; (iii) the Permitted Disclosure is not prohibited by applicable agreements to which Connie is a party; and (iv) if the Permitted Disclosure is a Service Disclosure or a Research Disclosure, it is consistent with the requirements of Section 4(f) or 4(g), as applicable.

- e. Fees. Connie may charge fees for Health Care Provider Access and Service Disclosures. Connie may charge fees for Research Disclosures in accordance with Section 4(g) of this Policy.
- f. Service Disclosures
 - i. Minimum Assessment Criteria. In addition to other minimum requirements set forth herein, Connie Management may authorize a Service Disclosure upon a finding that the Service Disclosure (a) is consistent with, and would not jeopardize, Connie's tax-exempt status; (b) is consistent with Connie's resources, expertise, and organizational capacity; (c) would not expose Connie to undue legal or contractual risk; (d) does not violate Connie's then-current Conflicts of Interest Policy; (e) is anticipated to be economically beneficial or neutral for Connie, or that any loss incurred by Connie by virtue of the Service Disclosure is reasonable and appropriate; and (f) would be to a third-party entity with commercially reasonable administrative, technical, and physical safeguards to ensure the proper protection of the Data and minimize the risk of unauthorized use, disclosure, or access to the Data.
 - ii. Procedural Requirements. Connie shall enter into a written agreement with each recipient of Data in a Service Disclosure arrangement. The Service Disclosure agreement shall, at a minimum, require the third party to which Data is Disclosed to: (a) ensure that Data will be used and re-disclosed only for purposes of the Service; (b) adequately safeguard the privacy and security of the Data; (c) if the Data Disclosed is De-Identified, not re-identify, or seek to re-identify, any such Data; (d) report any unauthorized use or disclosure of Data to Connie; (e) not use Data for any unlawful purpose; and (f) with the exception of any applicable work product, return or destroy all Data upon cessation of the Service or termination or expiration of the applicable Service agreement.
- g. Research Disclosures
 - i. Minimum Assessment Criteria. In addition to other minimum requirements set forth herein, Connie Management may authorize a Research Disclosure upon a finding that the Research Disclosure is for Research that has (a) a purpose consistent with the mission and values of Connie and that furthers the Legislative Mandate; and (b) been approved by an Institutional Review Board and that such approval has not been revoked or suspended.
 - ii. Procedural Requirements
 - a. Application Process
 1. Connie shall develop and maintain a Research Disclosure Application. Connie Management shall retain the right, in their sole discretion, to modify the Research Disclosure Application for particular applicants or Research; provided such modification is consistent with this Policy and applicable law.



2. An applicant must submit a complete Research Disclosure Application to Connie and be willing to be interviewed by Connie Management and/or the Research Evaluation Committee.
3. Connie Management may collect a processing fee for each Research Disclosure Application received and such fee shall approximate the costs associated with the process of reviewing the Research Disclosure Application. Connie Management may create and publish a fee schedule for such processing fees.
4. Connie Management and the Research Evaluation Committee shall take reasonable steps and implement reasonable measures to safeguard the confidentiality of the applicant and the Research Disclosure Application, subject to applicable law.

b. Role of Connie Management

1. Tasks. Within fifteen (15) business days of receipt of a Research Disclosure Application, Connie Management shall perform the following tasks with respect to their review of the Research Disclosure Application:
 - a. Maintain a record of each Research Disclosure Application received; and
 - b. Determine if the Research Disclosure Application is complete and the applicant has provided all information required by the Research Disclosure Application.
2. Right to Reject Research Disclosure Application. Connie Management may reject a Research Disclosure Application in the event Connie Management determines that the Research Disclosure Application is incomplete.
3. Right to Request Additional Information. Connie Management may request additional information or clarification from the applicant, including but not limited to requesting a meeting with the applicant.
4. Submission to Research Evaluation Committee. Within ten (10) business days of Connie Management's determination that the Research Disclosure Application is complete, Connie Management shall submit such Research Disclosure Application to the Research Evaluation Committee. Any complete Research Disclosure Applications received from Connie Management fifteen (15) or more days prior to the Research Evaluation Committee's next scheduled meeting shall be reviewed and considered at such next scheduled meeting. Any complete Research Disclosure Applications received from Connie Management less than fifteen (15) business days prior to the Research Evaluation 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 Research Disclosure Application is consistent with the requirements of this Policy;
 - b. Determine the adequacy of the applicant's privacy and security infrastructure and safeguards;
 - c. If identifiable Data is requested, consider whether the applicant has sufficiently justified the need for such Data rather than De-Identified Data or a Limited Data Set;
 - d. Any other factor or consideration deemed by Connie Management or the Research Evaluation Committee to be relevant to the Research Disclosure Application or Research; and
 - e. Determine whether the Research methodology is consistent with established norms and the Research Disclosure Application sets forth a sound Research design.



5. Right to Request Additional Information. The Research Evaluation Committee may request that Connie Management request additional information from an applicant, seek clarification from the applicant, or request a meeting with the applicant. Any such requests shall be communicated to Connie Management at least five (5) business days prior to the meeting at which the Research Disclosure Application will be considered.
 6. Support by Connie Management and Connie. The Research Evaluation Committee may seek assistance, guidance, and technical advice from Connie Management or the staff of Connie at any time during its review of a Research Disclosure Application. The Research Evaluation 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 that the Research Evaluation Committee does not delegate its responsibilities hereunder.
- c. Recommendations. Upon completion of its review of a Research Disclosure Application, the Research Evaluation Committee may issue one of the following three recommendations to Connie Management:
1. Approval. Approval is to be recommended when the Research Evaluation Committee determines that the Research Disclosure Application satisfies each of the requirements and criteria outlined in this Policy and the Research Disclosure Application.
 2. Conditional Approval. Conditional approval is to be recommended when the Research Evaluation Committee requires additional information from, or actions by, the applicant in order to address outstanding issues, and the Research Evaluation Committee determines that such additional information or actions will (a) adequately address and satisfy any concerns of the Research Evaluation Committee; and (b) permit the Research Evaluation Committee to determine that the Research Disclosure Application satisfies each of the requirements and criteria outlined in this Policy and the Research Disclosure Application.
 3. Denial. Denial is to be recommended when the Research Evaluation Committee determines that the Research Disclosure Application fails to satisfy one or more requirements or criteria outlined in this Policy.
- d. No Right of Appeal. An applicant shall have no right to appeal a decision of Connie Management.
- e. Opportunity for Resubmission of Research Disclosure Application. An applicant which has submitted a Research Disclosure Application that is subsequently denied may re-submit the Research Disclosure Application for re-consideration; provided that in the event an applicant has, in the sole discretion of Connie Management, previously violated any term or condition of a Research Disclosure Agreement entered into between Connie and such applicant, Connie Management may deny such applicant the opportunity to re-submit an existing, or submit a new, Research Disclosure Application. Connie Management also has the discretion to deny consideration of a new Research Disclosure Application if upon preliminary review by Connie Management, the Research Disclosure Application has not materially changed.



iii. Research Disclosure Agreement

- a. Connie Management, in consultation with the Research Evaluation Committee, shall develop a template Research Disclosure Agreement. The Research Disclosure Agreement shall, at a minimum, require a Research Recipient to: (a) ensure that Data will be used and re-disclosed only for purposes of the Research; (b) adequately safeguard the privacy and security of the Data; (c) if the Data Disclosed is De-Identified, not re-identify, or seek to re-identify, any such Data; (d) if applicable, provide Connie Management 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; (e) assign a person to be responsible for the privacy and security of the Data while in Research Recipient's possession or control; (f) report any unauthorized use or disclosure of Data; (g) not use Data for any unlawful purpose; (h) require Research Recipient Third Parties to agree, in writing, to the requirements, terms and conditions of the Research Disclosure Agreement; (i) notify Connie within thirty (30) calendar days of completion of the Research and either return or destroy all Data; (j) during all times during which the Data is in the possession or control of the Research Recipient or a Research Recipient Third Party, maintain internal written logs recording (1) the date of each use or disclosure of the Data, (2) the identity of each user of the Data, and (3) the purpose of such use or disclosure; and (k) to the extent permitted by law and principles of sovereign immunity, indemnify, defend and hold Connie 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 Research Disclosure Agreement or any applicable law, by the Research Recipient or Research Recipient Third Party; provided that, in the event that the Research 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 breach of Data.
- b. Upon approval or conditional approval of a Research Disclosure Application in accordance with this Policy, Connie Management shall provide a Research Disclosure Agreement to the applicant for review and execution.
- c. In the event Connie Management determines that the Research Recipient has violated any term or condition of the Research Disclosure Agreement, Connie may do any of the following in its sole discretion: (i) immediately cancel the Research Disclosure Agreement; (ii) require the immediate return or destruction of the Data; (iii) if applicable, immediately terminate the Research Recipient's access to the Data; (iv) deny the Research Recipient access to any further Data from Connie; and/or (v) institute legal proceedings against the Research Recipient.

iv. Data Transmission

1. Form and Manner. Connie shall establish a secure and accessible method by which Data is to be disclosed to a Research Recipient.
2. Minimum Necessary. Connie shall release only the Data Connie Management and/or the Research Evaluation Committee, in consultation with the applicant, determines to be the minimum necessary for the applicant to conduct the Research.



- v. **Fees.** Connie, in its discretion, may charge fees to a Research Recipient for access to or receipt of Data for Research Disclosures. In the event such fees are charged, Connie shall create and publish a schedule of such fees and such fees shall approximate Connie's associated costs.

5. **Disclosures Required by Law**

- a. **Role of Connie Management.** Connie Management shall have the authority to approve or deny purported Disclosures Required by Law. In doing so, Connie Management may rely upon Connie staff, consultants, legal counsel, the Board, or Connie committees.
- b. **Minimum Assessment Criteria.** Connie Management may approve a Disclosure Required by Law only upon assessment and documentation that such purported Disclosure Required by Law meets the following minimum approval criteria: (i) confirmation that the requesting entity has proper authority and jurisdiction; (ii) confirmation that the request complies with any necessary documentation, notice, and/or other legal requirements; and (iii) confirmation that fulfillment of the requested Disclosure is not prohibited by other law or regulation.
- c. **Fulfillment.** In the event Connie Management has approved a Required by Law disclosure, Connie Management shall (i) ensure that the release of Data is limited to the minimum necessary to satisfy the legal requirement; and (ii) work with the requesting entity to ensure a safe and secure Data transmission process.

6. **Reporting and Board Oversight**

- a. Connie Management shall submit a report to the Board, at least annually, outlining statistics relating to the volume and type of Disclosures, including by category.
- b. The Board shall retain oversight of and direction over this Policy and Connie's Disclosure programs and processes.

7. **Waiver.** A Disclosure may not be authorized unless such Disclosure complies in full with the applicable requirements set forth in this Policy; provided that the Board may waive any requirement that it determines in good faith would not materially jeopardize the privacy and security of Data or the legal obligations of Connie.