

Agreement ID: 2023-0104-D

<b>FDP Data Transfer and Use Agreement (“Agreement”)</b>	
<b>Provider:</b> Napa County	<b>Recipient:</b> The Regents of the University of California on behalf of its Davis campus
<b>Provider Scientist</b> Name: Felix Bedolla Email: felix.bedolla@countyofnapa.org	<b>Recipient Scientist</b> Name: Dr. Tara Niendam Email: tniendam@ucdavis.edu
<b>Agreement Term"</b> Start Date: "Date of last signature below End Date: June 30th, 2024 after the Start Date"	<b>Project Title:</b> Collaborative Statewide Early Psychosis Learning <b>Attachment 2 Type:</b> Limited Data Set

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- 1) Provider shall provide the data set described in Attachment 1 (the “Data”) to Recipient for the research purpose set forth in Attachment 1 (the “Project”). Provider shall retain ownership of any rights it may have in the Data, and Recipient does not obtain any rights in the Data other than as set forth herein.
- 2) If applicable, reimbursement of any costs associated with the preparation, compilation, and transfer of the Data to the Recipient will be addressed in Attachment 1.
- 3) Recipient shall not use the Data except as authorized under this Agreement. The Data will be used solely to conduct the Project and solely by Recipient Scientist and Recipient’s faculty, employees, fellows, students, and agents (“Recipient Personnel”) and Collaborator Personnel (as defined in Attachment 3) that have a need to use, or provide a service in respect of, the Data in connection with the Project and whose obligations of use are consistent with the terms of this Agreement (collectively, “Authorized Persons”).
- 4) Except as authorized under this Agreement or otherwise required by law, Recipient agrees to retain control over the Data and shall not disclose, release, sell, rent, lease, loan, or otherwise grant access to the Data to any third party, except Authorized Persons, without the prior written consent of Provider. Recipient agrees to establish appropriate administrative, technical, and physical safeguards to prevent unauthorized use of or access to the Data and comply with any other special requirements relating to safeguarding of the Data as may be set forth in Attachment 2.
- 5) Recipient agrees to use the Data in compliance with all applicable laws, rules, and regulations, as well as all professional standards applicable to such research.
- 6) Recipient is encouraged to make publicly available the results of the Project. Before Recipient submits a paper or abstract for publication or otherwise intends to publicly disclose information about the results of the Project, the Provider will have thirty (30) days from receipt to review proposed manuscripts and ten (10) days from receipt to review proposed abstracts to ensure that the Data is appropriately protected. Provider may request in writing that the proposed publication or other disclosure be delayed for up to thirty (30) additional days as necessary to protect proprietary information.

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- 7) Recipient agrees to recognize the contribution of the Provider as the source of the Data in all written, visual, or oral public disclosures concerning Recipient's research using the Data, as appropriate in accordance with scholarly standards and any specific format that has been indicated in Attachment 1.
- 8) Unless terminated earlier in accordance with this section or extended via a modification in accordance with Section 13, this Agreement shall expire as of the End Date set forth above. Either party may terminate this Agreement with thirty (30) days written notice to the other party's Authorized Official as set forth below. Upon expiration or early termination of this Agreement, Recipient shall follow the disposition instructions provided in Attachment 1, provided, however, that Recipient may retain one (1) copy of the Data to the extent necessary to comply with the records retention requirements under any law, and for the purposes of research integrity and verification.
- 9) Except as provided below or prohibited by law, any Data delivered pursuant to this Agreement is understood to be provided "AS IS." PROVIDER MAKES NO REPRESENTATIONS AND EXTENDS NO WARRANTIES OF ANY KIND, EITHER EXPRESSED OR IMPLIED. THERE ARE NO EXPRESS OR IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, OR THAT THE USE OF THE DATA WILL NOT INFRINGE ANY PATENT, COPYRIGHT, TRADEMARK, OR OTHER PROPRIETARY RIGHTS. Notwithstanding, Provider, to the best of its knowledge and belief, has the right and authority to provide the Data to Recipient for use in the Project.
- 10) Except to the extent prohibited by law, the Recipient assumes all liability for damages which may arise from its use, storage, disclosure, or disposal of the Data. The Provider will not be liable to the Recipient for any loss, claim, or demand made by the Recipient, or made against the Recipient by any other party, due to or arising from the use of the Data by the Recipient, except to the extent permitted by law when caused by the gross negligence or willful misconduct of the Provider. No indemnification for any loss, claim, damage, or liability is intended or provided by either party under this Agreement.
- 11) Neither party shall use the other party's name, trademarks, or other logos in any publicity, advertising, or news release without the prior written approval of an authorized representative of that party. The parties agree that each party may disclose factual information regarding the existence and purpose of the relationship that is the subject of this Agreement for other purposes without written permission from the other party provided that any such statement shall accurately and appropriately describe the relationship of the parties and shall not in any manner imply endorsement by the other party whose name is being used.
- 12) Unless otherwise specified, this Agreement and the below listed Attachments embody the entire understanding between Provider and Recipient regarding the transfer of the Data to Recipient for the Project:
  - I. Attachment 1: Project Specific Information
  - II. Attachment 2: Data-specific Terms and Conditions
  - III. Attachment 3: Identification of Permitted Collaborators (if any)
- 13) No modification or waiver of this Agreement shall be valid unless in writing and executed by duly-authorized representatives of both parties.

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14) The undersigned Authorized Officials of Provider and Recipient expressly represent and affirm that the contents of any statements made herein are truthful and accurate and that they are duly authorized to sign this Agreement on behalf of their institution.

By an Authorized Official of Provider:"

Name: Belia Ramos  
Title: Chair of the Board of Supervisors  
Contact Information for Formal Notices:

Name:" Latoya Akil  
Address: Napa County Health and Human Services  
2751 Napa Valley Corporate Drive, Bldg B  
Napa CA 94558  
Email:" Latoya.Akil@countyofnapa.org  
Phone:" (707) 253-4715

By an Authorized Official of Recipient:"

DocuSigned by: Dianna L. Francis 3/2/2023  
Name: Dianna L. Francis  
Title: Intellectual Property Officer  
Contact Information for Formal Notices:

Name:" Executive Director  
Address:" UC Davis Innovation Access  
1850 Research Park Drive, Suite 100  
Davis, CA 95618-6134  
Email:" mta@ucdavis.edu  
Phone:" 1(530)754-8649

Read & Acknowledged:

DocuSigned by: Tara Niendam  
Dr. Tara Niendam  
Associate Professor, UC Davis

Approved as to form:  
Napa County Counsel  
Dated: 1/24/2023

/S/ Rachel L. Ross  
Rachel L. Ross, Deputy County Counsel

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## Attachment 1

### Data Transfer and Use Agreement Project Specific Information

#### 1. Description of Data:

Data on consumers of behavioral health services from the Provider. This will include past and current clients in the Napa County Aldea SOAR program, as well as individuals with similar diagnoses who utilized other behavioral health services in Napa County. The exact variables we collect will depend on what is available through the county:

Year and month of birth (not date)

Zip code

Demographics including: age, race, ethnicity, sex, gender, sexual orientation, insurance status (i.e. privately insured or Medi-Cal, not MRNs), education level, marital status, employment status, living arrangement, military service/veteran status, foster care/adoption, and preferred language

All diagnosis(es) (psychiatric, substance use, physical health) and date of diagnosis, including outcomes of eligibility assessments, e.g. intake and referral assessments

Dates and types of service provided (limited to dates of service between January 1, 2013 and December 31, 2019 and between June 1, 2021 and December 31, 2024), including information on the following types of services: outpatient, crisis residential, crisis stabilization, urgent care, long-term care, hospitalizations, substance use, referral, outreach, medications, any service-related data/code including but not limited to: service code, location code, facility code, EBP/supported services code, providers, provider types, and clinics associated with services received, law enforcement contacts, forensic services, and jail services, and self-reported data on symptoms, functioning, and other metrics of treatment goals and progress for a subset of clients (collected on surveys)

#### 2. Description of Project:

The Early Psychosis Learning Health Care Network is a multi-year project that connects early psychosis (EP) programs across California to improve early identification, diagnosis, clinical assessment, intervention effectiveness, service delivery, and health outcomes in clinics offering evidence-based specialty care to persons in the early stages of psychotic illness. Another major goal of the EP LHCN is to develop a sustainable network of California EP programs via a collaborative statewide evaluation to clarify the effect of the network and these programs on the consumers and communities that they serve. The EP LHCN is led by UC Davis in collaboration with UCSF, UCSD, and multiple California Counties. The initial infrastructure has been developed using MSHA Innovation funds and thus the proposal must comply with the regulatory and funding guidelines for evaluation as stipulated by the applicable MSHA funding regulations, contract deliverables, and best practices.

The EP LHCN will link multiple early psychosis clinical service programs and create a network using a core assessment battery of valid, low-burden measures and mHealth technology platform to collect client-level information as part of standard care, visualize such information via clinician dashboard for treatment planning, and integrate across clinics to provide de-identified data for evaluating statewide outcomes data. The core assessment battery will include standard measures of early psychosis clinical features, services, and treatment outcomes.

The design and approach of the different components of the EP LHCN must be shaped by the input of stakeholders, including mental health consumers and family members. This will be accomplished in part by collecting qualitative data that will include focus groups, stakeholder meetings & qualitative interviews with consumers, families, county staff and EP program staff to inform the implementation of LHCN and the evaluation, present findings, and assess satisfaction. We will assess consumer and provider skills, beliefs and attitudes around measurement-based care and use of LHCN in service delivery (pre- and post-LHCN implementation).

The proposed California network will contribute these systematically collected clinical outcomes from participating community and university EP clinics, to enhance the development of a national EP network, supported by the NIMH EPINET program. EPINET The Early Psychosis Intervention Network (EPINET) is a 5-year project that connects regional hubs to a national network of EP programs. EPI-CAL is California's regional hub. Data collected within the LHCN requires individuals to make choices about sharing their data outside the clinic, including with UC Davis for the statewide evaluation and to the EPINET National Data Coordinating Center for research. This is optional and data will only be shared if users opt in. The project will also include development and validation of a measure of the Duration of Untreated Psychosis (DUP) that is feasible for use in community settings.

An additional component of the LHCN project is to identify, describe, and analyze the costs incurred by providing early psychosis clinical services, the outcomes associated with such a program, and the costs associated with those outcomes for individuals served by each program in each county. We will also examine services and costs associated with similar individuals served elsewhere in the county. This is will include past and current clients in the EP program, as well as individuals with similar diagnoses who utilized other behavioral health services in Napa County.

This Statewide EP Evaluation, LHCN, and NIMH EPINET all primarily aim to 1) increase the quality of mental health services, including measurable outcomes, and 2) introduce a mental health practice or approach that is new to the overall mental health system.

#### 3. Provider Support and Data Transmission:

Provider shall transmit the Data to Recipient: (select one)  electronically or  by mail to:

Name:	GoAnywhere Portal
Address:	For questions please contact Valerie Tryon and/or Tara Niendam
Email:	vltryon@ucdavis.edu; tniendam@ucdavis.edu
Phone:	

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Upon execution of this Agreement, Provider shall send any specific instructions necessary to complete the transfer of the Data to the contact person listed above, if not already included below in this section of Attachment 1.

For the Provider Data, the format of the Data and a provision of a data dictionary will be finalized after meetings between the Provider and Recipient regarding available Data.

While Data transferred between EP program staff and Provider data analysts, it may be identifiable, all information will be de-identified and provided with a unique numeric ID before being submitted to the Recipient's evaluation team. Data will be shared through an encrypted and password protected server, which is housed on the Recipients secure servers. The Provider will not have access to any identifiable Data from the other participants. The Provider will receive instructions for uploading their Data to the secure portal (GoAnywhere, managed by the Recipients IT team). Each Provider personnel is given a unique login and is able to securely login into the GoAnywhere portal and upload their Data directly to the Recipients server. Upon receipt, Recipient will confirm with the Provider that all the Data was received

4. Reimbursement of Costs:

None

As governed by a separate written agreement between the parties

Reimbursement Agreement Reference # (if required):

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As set forth herein:

5. Disposition Requirements upon the termination or expiration of the Agreement:

Data should be destroyed after it has been utilized for the Learning Health Care Network.

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**Attachment 2**  
Data Transfer and Use Agreement  
Data-specific Terms and Conditions:  
Limited Data Set

**Additional Terms and Conditions:**

1. Nothing herein shall authorize the Recipient to use or further disclose the Data in a manner that would violate the requirements of Provider under 45 CFR 164.514.
2. Recipient shall not use or further disclose the Data other than as permitted by this Agreement or as otherwise required by law.
3. Recipient shall report to the Provider any use or disclosure of the Data not provided for by this Agreement within 5 business days of when it becomes aware of such use or disclosure.
4. Provider is a HIPAA Covered Entity, and the Data will be a Limited Data Set as defined by the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"). In accordance with Section 164.514(e)(2) of the HIPAA Privacy Rule, the Data shall exclude the following direct identifiers of the individual or of relatives, employers, or household members of the individual:
  - (i) Names;
  - (ii) Postal address information, other than town or city, State, and zip code;
  - (iii) Telephone numbers;
  - (iv) Fax numbers;
  - (v) Electronic mail addresses;
  - (vi) Social security numbers;
  - (vii) Medical record numbers;
  - (viii) Health plan beneficiary numbers;
  - (ix) Account numbers;
  - (x) Certificate/license numbers;
  - (xi) Vehicle identifiers and serial numbers, including license plate numbers;
  - (xii) Device identifiers and serial numbers;
  - (xiii) Web Universal Resource Locators (URLs);
  - (xiv) Internet Protocol (IP) address numbers;
  - (xv) Biometric identifiers, including finger and voice prints; and
  - (xvi) Full face photographic images and any comparable images.

If the Data being provided is coded, the Provider will not release, and the Recipient will not request, the key to the code.

5. Recipient will not use the Data, either alone or in concert with any other information, to make any effort to identify or contact individuals who are or may be the sources of Data without specific written approval from Provider and appropriate Institutional Review Board approval, if required pursuant to 45 CFR 46. Should Recipient inadvertently receive identifiable information or otherwise identify a subject, Recipient shall promptly notify Provider and follow Provider's reasonable written instructions, which may include return or destruction of the identifiable information.
6. By signing this Agreement, Recipient provides assurance that relevant institutional policies and applicable federal, state, or local laws and regulations (if any) have been followed, including the completion of any IRB or ethics review or approval that may be required.
7. The parties agree to take such action as is necessary to amend this Agreement, from time to time, in order for the Provider to remain in compliance with the requirements of HIPAA.

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**Attachment 3**  
Data Transfer and Use Agreement  
Identification of Permitted Collaborators (if any)

For all purposes of this Agreement, the definition of “Collaborator Personnel” checked below will pertain:

“Collaborator Personnel” means: None. No collaborators are permitted on the Project.

-OR-

“Collaborator Personnel” means as set forth below and agreed upon between the Parties:

“Collaborator Personnel” means faculty, employees, fellows, or students of the University of San Francisco and the University of San Diego, which (i) has agreed to collaborate in the Project, (ii) has faculty, employees, fellows, or students who have a need to use or provide a service in respect of the Data in connection with its collaboration in the Project, and (iii); has executed agreements that are substantially similar to this Agreement with the Recipient.