



Contract Number

21-765 A-2

SAP Number

Department of Public Health

Department Contract Representative	<u>Michael Shin, HS Contracts</u>
Telephone Number	<u>(909) 386-8146</u>
Contractor	<u>EqualTox, LLC</u>
Contractor Representative	<u>Dr. Ali Kohzad</u>
Telephone Number	<u>(714) 598-7467</u>
Contract Term	<u>June 30, 2022 – June 29, 2023</u>
Original Contract Amount	<u>Not to Exceed \$5,000,000</u>
Amendment Amount	<u>\$0</u>
Total Contract Amount	<u>Not to Exceed \$5,000,000</u>
Cost Center	<u>9300002759</u>

IT IS HEREBY AGREED AS FOLLOWS:

AMENDMENT NO. 1:

It is hereby agreed to amend Contract No. 21-765, effective upon execution, as follows:

SECTION VII. TERM

Amend Section VII. Term to read as follows:

This Contract amendment is effective upon execution by both parties and is amended from its original expiration date of June 30, 2022, to expire on June 29, 2023, but may be terminated earlier in accordance with provisions of Section VIII of the Contract. The Contract term may be extended for up to two (2) additional one-year periods by mutual agreement of the parties.

ATTACHMENTS:

Add **Attachment C – Business Associate Agreement** (Attached).

All other terms and conditions of the Contract No. 21-765 shall remain in full force and effect.

This Contract may be executed in any number of counterparts, each of which so executed shall be deemed to be an original, and such counterparts shall together constitute one and the same Contract. The parties shall be entitled to sign and transmit an electronic signature of this Contract (whether by facsimile, PDF or other email transmission), which signature shall be binding on the party whose name is contained therein. Each party providing an electronic signature agrees to promptly execute and deliver to the other party an original signed Contract upon request.

IN WITNESS WHEREOF, the San Bernardino County and Contractor have each caused this Contract to be subscribed by its respective duty authorized officers, on its behalf.

SAN BERNARDINO COUNTY

EQUALTOX, LLC

(Print or type name of corporation, company, contractor, etc.)

▶

Curt Hagman, Chairman, Board of Supervisors

By ▶ _____
(Authorized signature - sign in blue ink)

Dated: _____

Name _____ Ali Kohzad, PharmD.
(Print or type name of person signing contract)

SIGNED AND CERTIFIED THAT A COPY OF THIS DOCUMENT HAS BEEN DELIVERED TO THE CHAIRMAN OF THE BOARD

Title _____ Chief Operating Officer
(Print or Type)

Lynna Monell
Clerk of the Board of Supervisors
San Bernardino County

By _____
Deputy

Dated: _____

Address _____ 1562 Parkway Loop, Suite B
_____ Tustin, CA 92780

FOR COUNTY USE ONLY

Approved as to Legal Form	Reviewed for Contract Compliance	Reviewed/Approved by Department
▶ Adam Ebright, Deputy County Counsel	▶ Patty Steven, HS Contracts Manager	▶ Joshua Dugas, Director
Date _____	Date _____	Date _____

BUSINESS ASSOCIATE AGREEMENT

Except as otherwise provided in this Agreement, EqualTox, LLC (EqualTox), hereinafter referred to as Business Associate, may use, access, maintain or disclose Protected Health Information to perform functions, activities or services for or on behalf of the Department of Public Health, hereinafter referred to as the Covered Entity, as specified in this Agreement and the attached **CONTRACT**, provided such use, access, maintenance or disclosure does not violate the Health Insurance Portability and Accountability Act (HIPAA), 42 United States Code (USC) 1320d et seq., and its implementing regulations, including but not limited to, 45 Code of Federal Regulations (CFR) Parts 160, 162, and 164, hereinafter referred to as the "Privacy and Security Rules" and patient confidentiality regulations, including but not limited to, Title 42 of the Code of Federal Regulations Part 2 and the requirements of the Health Information Technology for Economic and Clinical Health Act, as incorporated in Title XIII of the American Recovery and Reinvestment Act of 2009 (ARRA), Public Law 111-5 (HITECH) and any regulations adopted or to be adopted pursuant to HITECH that relate to the obligations of business associates. Business Associate recognizes and agrees it is obligated by law to meet the applicable provisions of HITECH.

I. Definitions

- A. "Breach" means the acquisition, access, use or disclosure of Protected Health Information (PHI) in a manner not permitted under HIPAA (45 CFR Part 164, Subpart E), which compromises the security or privacy of the PHI. An impermissible use or disclosure of PHI is presumed to be a Breach unless the Covered Entity or Business Associate demonstrates that there is a low probability that the PHI has been compromised. A breach shall not include:
1. Any unintentional acquisition, access or use of PHI by a workforce member or person acting under the authority of Covered Entity or the Business Associate, if such acquisition, access or use was made in good faith and within the scope of authority and does not result in further use or disclosure in a manner not permitted under the Privacy Rules; or
 2. Any inadvertent disclosure by a person who is authorized to access PHI at Covered Entity or Business Associate to another person authorized to access Protected Health Information at Covered Entity or Business Associate, respectively, and the information received as a result of such disclosure is not further used or disclosed in a manner not permitted under the Privacy Rule; or
 3. A disclosure of PHI where Covered Entity or Business Associate has a good faith belief that an unauthorized person to whom the disclosure was made would not reasonably have been able to retain such information.
- B. "Business Associate" means with respect to a Covered Entity, a person who:
1. On behalf of such Covered Entity, but other than in the capacity of a member of the workforce of such Covered Entity creates, receives, maintains or transmits PHI for a function or activity involving the use or disclosure of Personally Identifiable Health Information, including claims processing or administration, data analysis, data storage, utilization review, quality assurance, billing, benefit management, practice management, and repricing; or
 2. Provides, other than in the capacity of a member of the workforce of such Covered Entity, legal, actuarial, accounting, consulting, data aggregation, management, administrative,

accreditation or financial services to or for Covered Entity where the provision of the service involves the disclosure of PHI from such Covered Entity to the person.

A Covered Entity may be the Business Associate of another Covered Entity.

- C. “Covered Entity” means a health plan, a health care clearinghouse or a health care provider who transmits any health information in electronic form in connection with a transaction covered by the Privacy and Security Rules.
- D. “Data Aggregation” means, with respect to PHI created or received by a Business Associate in its capacity as the Business Associate of a Covered Entity, the combining of such PHI by the Business Associate with the PHI received by the Business Associate in its capacity as a Business Associate of another Covered Entity, to permit data analyses that relate to the health care operations of the respective Covered Entities.
- E. “Discovered” means a Breach shall be treated as discovered by Covered Entity or Business Associate as of the first day on which such Breach is known to such Covered Entity or Business Associate, respectively, (including any person, other than the individual committing the Breach, that is an employee, officer or other agent of such entity or associate, respectively) or should reasonably have been known to such Covered Entity or Business Associate (or person) to have occurred.
- F. “Electronic Protected Health Information” or “Electronic PHI” means PHI that is transmitted by or maintained in electronic media as defined in the Security Rules.
- G. “HIPAA” means the Health Insurance Portability and Accountability Act of 1996, Public Law 104-191.
- H. “HITECH” means the privacy and security Breach notification provisions applicable to Business Associate under Title XIII of ARRA.
- I. “Individual” means the person who is the subject of PHI, and shall include a person who qualifies as a personal representative in accordance with 45 CFR 164.502(g).
- J. “Individually Identifiable Health Information” means information that is a subset of health information, including demographic information collected from an individual, and;
 - 1. is created or received by a health care provider, health plan, employer or health care clearinghouse; and
 - 2. relates to the past, present or future physical or mental health condition of an individual; the provision of health care to an individual; or the past, present or future payment for the provision of health care to an individual; and
 - (a) that identifies the individual; or
 - (b) with respect to which there is a reasonable basis to believe the information can be used to identify the individual.
- K. “Privacy Rule” means the regulations promulgated under HIPAA by the United States Department of Health and Human Services to protect the privacy of Protected Health Information, including, but not limited to, 45 CFR Part 160 and 45 CFR Part 164, Subpart A and Subpart E.
- L. “Protected Health Information” or “PHI” means Individually Identifiable Health Information transmitted or maintained in any form or medium that (i) is received by Business Associate from Covered Entity, (ii) Business Associate creates for its own purposes from Individually Identifiable

Health Information that Business Associate received from Covered Entity, or (iii) is created, received, transmitted or maintained by Business Associate on behalf of Covered Entity. Protected Health Information excludes Individually Identifiable Health Information in education records covered by the Family Educational Rights and Privacy Act, as amended, 20 U.S.C. Section 1232(g), records described at 20 U.S.C. Section 1232g(a)(4)(B)(iv), and employment records held by the Covered Entity in its role as employer.

- M. "Security Rule" means the regulations promulgated under HIPAA by the United States Department of Health and Human Services to protect the security of the Electronic Protected Health Information, including, but not limited to, 45 CFR Part 160 and 45 CFR Part 164, Subpart A and Subpart C.
- N. "Unsecured PHI" means PHI that is not secured through the use of a technology or methodology specified by the Secretary of the U.S. Department of Health and Human Services.
- O. Any terms capitalized, but not otherwise defined, in this Agreement shall have the same meaning as those terms have under HIPAA, the Privacy Rule, the Security Rule and HITECH.

II. Obligations and Activities of Business Associate

A. Prohibited Uses and Disclosures

Business Associate shall not use, access or further disclose PHI other than as permitted or required by this Agreement and as specified in the attached **CONTRACT** or as required by law. Further, Business Associate shall not use PHI in any manner that would constitute a violation of the Privacy Rule or HITECH. Business Associate shall disclose to its employees, subcontractors, agents, or other third parties, and request from Covered Entity, only the minimum PHI necessary to perform or fulfill a specific function required or permitted hereunder.

Business Associate shall not use or disclose PHI for fundraising or marketing purposes. Business Associate shall not disclose PHI to a health plan for payment or health care operations purposes if the patient has requested this special restriction, and has paid out of pocket in full for the health care item or service to which the PHI solely relates; 42 U.S.C. Section 17935(a) and 45 C.F.R. Section 164.522(a)(1)(i)(A). Business Associate shall not directly or indirectly receive remuneration in exchange for PHI, except with the prior written consent of Covered Entity and as permitted by HITECH, 42 U.S.C. Section 17935(d)(2); and 45 C.F.R. Section 164.508 however, this prohibition shall not affect payment by Covered Entity to Business Associate for services provided pursuant to this Agreement.

B. Permitted Uses and Disclosures

1. Except as otherwise limited in this Agreement, Business Associate may use PHI for the proper management and administration of the Business Associate or to carry out the legal responsibilities of the Business Associate.
2. Except as otherwise limited in this Agreement, Business Associate may use PHI to provide Data Aggregation service to Covered Entity as permitted by 45 CFR Section 164.504(e)(2)(i)(B).
3. Business Associate may use PHI to report violations of law to appropriate Federal and State authorities, consistent with 45 CFR Section 164.502(j)(1).

C. Appropriate Safeguards

Business Associate shall implement the following administrative, physical, and technical safeguards that reasonably and appropriately protect the confidentiality, integrity and availability of PHI that Business Associate creates, receives, maintains or transmits on behalf of Covered Entity; and to ensure that any agent or subcontractor to whom Business Associate provides such information agrees to implement reasonable and appropriate safeguards to protect PHI in accordance with the Security Rule under 45 C.F.R., Sections 164.308, 164.310, 164.312, 164.314 and 164.316:

1. Implement policies and procedures to prevent, detect, contain and correct security violations; identify the security official who is responsible for the development and implementation of the policies and procedures required by this subpart for the Business Associate; implement a security awareness and training program for all members of its workforce; implement policies and procedures to prevent those workforce members who should not have access from obtaining access to Covered Entity's Electronic PHI; implement policy and procedures to address security incidents; establish policies and procedures for responding to an emergency or other occurrence that damages systems that contain Electronic PHI; and perform a periodic technical and nontechnical evaluation in response to environmental or operational changes affecting the security of Electronic PHI, including conducting accurate and thorough assessments of the potential risks and vulnerabilities to the confidentiality, integrity and availability of Electronic PHI, that establishes the extent to which an entity's security policies and procedures meet the requirements of this subpart.
2. Implement policies and procedures to limit physical access to Business Associate's electronic information systems and the facility or facilities in which they are housed, while ensuring that properly authorized access is allowed; implement policies and procedures that specify the proper functions to be performed, and the physical attributes of the surroundings of a specific workstation or class of workstations that can access Electronic PHI; implement physical safeguards for all workstations that access Electronic PHI; restrict access to authorized users; implement policies and procedures that govern the receipt and removal of hardware and electronic media that contain Electronic PHI into and out of a facility and the movement of these items within the facility.
3. Implement technical policies and procedures for electronic information systems that maintain Electronic PHI to allow access only to those persons or software programs that have been granted access rights as specified in 45 C.F.R., Section 164.308 implement hardware, software and/or procedural mechanisms that record and examine activity in information systems that contain or use Electronic PHI; implement policies and procedures to protect electronic PHI from improper alteration, destruction, unauthorized access or loss of integrity or availability; including but not limited to, encryption of all workstations, laptops and flash drives that store PHI.
4. Enter into written agreements with agents and subcontractors to whom Business Associate provides Covered Entity's PHI that impose the same restrictions and conditions on such agents and subcontractors that apply to Business Associate with respect to such PHI, and that require compliance with all appropriate safeguards as found in this Agreement.

D. Mitigation

Business Associate shall have procedures in place to mitigate, to the extent practicable, any harmful effect that is known to Business Associate of a use, access or disclosure of PHI by Business Associate, its agents or subcontractors in violation of the requirements of this Agreement.

E. Reporting of Improper Access, Use or Disclosure or Breach

Business Associate shall report to Covered Entity's Office of Compliance any unauthorized use, access or disclosure of unsecured PHI or any other security incident with respect to PHI no later than one (1) business day upon the discovery of a Breach or suspected Breach consistent with the regulations promulgated under HITECH by the United States Department of Health and Human Services, 45 CFR Part 164, Subpart D. Upon discovery of a Breach or suspected Breach, the Business Associate shall complete the following actions:

1. Provide Covered Entity's Office of Compliance with the following information to include but not limited to:
 - (a) Date the Breach or suspected Breach occurred;
 - (b) Date the Breach or suspected Breach was discovered;
 - (c) Number of staff, employees, subcontractors, agents or other third parties and the titles of each person allegedly involved;
 - (d) Number of potentially affected Patients/Clients; and
 - (e) Description of how the Breach or suspected Breach allegedly occurred.
2. Conduct and document a risk assessment by investigating without reasonable delay and in no case later than five (5) calendar days of discovery of the Breach or suspected Breach to determine the following:
 - (a) The nature and extent of the PHI involved, including the types of identifiers and likelihood of re-identification;
 - (b) The unauthorized person who used PHI or to whom it was made;
 - (c) Whether the PHI was actually acquired or viewed; and
 - (d) The extent to which the risk to PHI has been mitigated.
3. Provide a completed risk assessment and investigation documentation to Covered Entity's Office of Compliance within ten (10) calendar days of discovery of the Breach or suspected Breach with decision whether a Breach has occurred.
 - (a) If a Breach has not occurred, notification to Individual(s) is not required.
 - (b) If a Breach has occurred, notification to the Individual(s) is required and Business Associate must provide Covered Entity with affected Individual(s) name and contact information so that Covered Entity can provide notification.
4. Make available to Covered Entity and governing State and Federal agencies in a time and manner designated by Covered Entity or governing State and Federal agencies, any policies, procedures, internal practices and records relating to a Breach or suspected Breach for the purposes of audit or should the Covered Entity reserve the right to conduct its own investigation and analysis.

F. Access to Protected Health Information

Business Associate shall provide access to PHI in a Designated Record Set to Covered Entity or to an Individual, at the request or direction of Covered Entity and in the time and manner designated by the Covered Entity. If Business Associate maintains PHI in an electronic format,

and an individual requests a copy of such information in electronic form, Business Associate shall provide such information in electronic form as required by of 45 CFR Section 164.524.

G. Amendment of Protected Health Information

If Business Associate maintains a Designated Record Set on behalf of the Covered Entity, Business Associate shall make any amendment(s) to PHI in a Designated Record Set that the Covered Entity directs or agrees to, pursuant to 45 CFR Section 164.526, in the time and manner designated by the Covered Entity.

H. Access to Records

Business Associate shall make internal practices, books, and records, including policies and procedures and PHI, relating to the use, access and disclosure of PHI received from, or created or received by Business Associate on behalf of, Covered Entity available to the Secretary of the U.S. Department of Health and Human Services, in a time and manner designated by the Secretary, for purposes of the Secretary determining Covered Entity's compliance with the Privacy and Security Rules and patient confidentiality regulations. Anything provided to the Secretary shall also be provided to the Covered Entity upon Covered Entity's request.

I. Accounting for Disclosures

Business Associate, its agents and subcontractors shall document such disclosures of PHI and information related to such disclosures as would be required for Covered Entity to respond to a request by an Individual for an accounting of disclosures of PHI. Further, Business Associate shall provide to Covered Entity or an Individual, in the time and manner designated by the Covered Entity, information collected in accordance with provision (F.), above, to permit Covered Entity to respond to a request by the Individual for an accounting of disclosures of PHI in accordance with 45 CFR Section 164.528.

J. Destruction of Protected Health Information

Upon termination of this Agreement, Business Associate shall return all PHI required to be retained and return or destroy, with certification of destruction by an officer of Business Associate, all other PHI received from the Covered Entity, or created or received by the Business Associate or its subcontractors, employees or agents on behalf of the Covered Entity. In the event the Business Associate determines that returning the PHI is not feasible, the Business Associate shall provide the Covered Entity with written notification of the conditions that make return not feasible. Business Associate further agrees to extend any and all protections, limitations, and restrictions contained in this Agreement, to any PHI retained by Business Associate or its subcontractors, employees or agents after the termination of this Agreement, and to limit any further use, access or disclosures to the purposes that make the return or destruction of the PHI infeasible.

K. Breach Pattern or Practice by Covered Entity

Pursuant to 42 U.S.C. Section 17934(b), if the Business Associate knows of a pattern of activity or practice of the Covered Entity that constitutes a material Breach or violation of the Covered Entity's obligations under this Agreement, the Business Associate must take reasonable steps to cure the Breach or end the violation. If the steps are unsuccessful, the Business Associate must terminate the Agreement if feasible, or if termination is not feasible, report the problem to the Secretary of DHHS.

L. Costs Associated to Breach

Business Associate shall be responsible for reasonable costs associated with a Breach. Costs shall be based upon the required notification type as deemed appropriate and necessary by the Covered Entity and shall not be reimbursable under the Agreement at any time. Covered Entity shall determine the method to invoice the Business Associate for said costs. Costs shall incur at the current rates and may include, but are not limited to the following:

1. Postage;

2. Alternative means of notice;
3. Media notification; and
4. Credit monitoring services.

M. Direct Liability

Business Associate may be held directly liable under HIPAA for impermissible uses and disclosures of PHI; failure to provide breach notification to Covered Entity; failure to provide access to a copy of Electronic PHI to covered entity or individual; failure to disclose PHI to the Secretary of the U.S. Department of Health and Human Services when investigating Business Associate's compliance with HIPAA; failure to provide an accounting of disclosures and failure to enter into a business associate agreement with subcontractors.

N. Termination for Cause

Covered Entity may, upon written notice to Business Associate, immediately terminate this agreement, and any related agreements, if Covered Entity determines that Business Associate has breached a material term of this agreement. Covered Entity may, upon written notice to Business Associate, allow Business Associate five (5) business days to cure such breach.

III. Obligations of Covered Entity

- A. Covered Entity shall notify Business Associate of any limitation(s) in its notice of privacy practices of Covered Entity in accordance with 45 CFR Section 164.520, to the extent that such limitation may affect Business Associate's use, access or disclosure of PHI.
- B. Covered Entity shall notify Business Associate of any changes in, or revocation of, permission by an individual to use, access or disclose PHI, to the extent that such changes may affect Business Associate's use, access, maintenance or disclosure of PHI.
- C. Covered Entity shall notify Business Associate of any restriction to the use, access or disclosure of PHI that Covered Entity has agreed to in accordance with 45 CFR Section 164.522, to the extent that such restriction may affect Business Associate's use, access, maintenance or disclosure of PHI.

IV. General Provisions

A. Remedies

Business Associate agrees that Covered Entity shall be entitled to seek immediate injunctive relief as well as to exercise all other rights and remedies which Covered Entity may have at law or in equity in the event of an unauthorized use, access or disclosure of PHI by Business Associate or any agent or subcontractor of Business Associate that received PHI from Business Associate.

B. Ownership

The PHI shall be and remain the property of the Covered Entity. Business Associate agrees that it acquires no title or rights to the PHI.

C. Regulatory References

A reference in this Agreement to a section in the Privacy and Security Rules and patient confidentiality regulations means the section as in effect or as amended.

D. Amendment

The Parties agree to take such action as is necessary to amend this Agreement from time to time as is necessary for Covered Entity to comply with the requirements of the Privacy and Security

Rules and the Health Insurance Portability and Accountability Act and patient confidentiality regulations.

E. Interpretation

Any ambiguity in this Agreement shall be resolved to permit Covered Entity to comply with the Privacy and Security Rules and patient confidentiality regulations.

F. Indemnification

Business Associate agrees to indemnify, defend and hold harmless Covered Entity and its authorized officers, employees, agents and volunteers from any and all claims, actions, losses, damages, penalties, injuries, costs and expenses (including costs for reasonable attorney fees) that are caused by or result from the acts or omissions of Business Associate, its officers, employees, agents and subcontractors, with respect to the use, access, maintenance or disclosure of Covered Entity's PHI, including without limitation, any Breach of PHI or any expenses incurred by Covered Entity in providing required Breach notifications.