

## **OC CHILDREN'S SCREENING REGISTRY PARTICIPATION AGREEMENT**

This OC CHILDREN'S SCREENING REGISTRY PARTICIPATION AGREEMENT ("Registry Agreement") is made on \_\_\_\_\_ ("Effective Date"), between Children's Hospital of Orange County on behalf of the Help Me Grow program (hereinafter referred to as "Help Me Grow") and [Vendor] ("Participant"). Help Me Grow and Participant shall be referred to herein collectively as the "Parties" and individually as a "Party."

WHEREAS, Help Me Grow has developed the OC Children's Screening Registry ("Registry") to collect and report on developmental, behavioral and trauma screening data of children from birth through seventeen (17) years of age;

WHEREAS, the goal of the Registry is to enable primary care and community-based providers to track developmental screening and proactively identify children with at-risk developmental screening results, reduce duplication of screen efforts, and assist in connecting families with appropriate resources;

WHEREAS, for purposes of this Registry Agreement, Participant may be defined as a corporate entity or organization with a single discrete geographic location; or a corporate entity or organization with multiple geographic locations; or a number of corporate entities or organizations grouped together for the purpose of creating an alliance. Persons executing an agreement on behalf of a Participant must have the appropriate authority to do so;

WHEREAS, Participant desires to participate in the Registry;

WHEREAS, the Parties understand that Help Me Grow's provision of benchmarking and data aggregation services to Participant qualifies CHOC as a "Business Associate" with respect to Participant pursuant to the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") and its implementing regulations (45 C.F.R. Parts 160, 162 and 164, as amended);

NOW, THEREFORE, in consideration of the mutual promises and covenants contained herein, the Parties agree as follows:

1. Participant hereby agrees to participate in the Registry and Help Me Grow hereby agrees to permit Participant to participate in the Registry subject to the terms of this Registry Agreement.
2. Participant Responsibilities:
  - a. Participant will complete the Participant Application to Access the OC Children's Screening Registry, attached hereto as Exhibit A (the "Participant Application"). In the Participant Application, Participant will identify whether it is classified as a "Treating Provider Participant," a "Non-Treating Provider Participant with Authorization Option," or a "Data Entry Access Only Participant," as such terms

are defined in “Level of Registry Use” in the Participant Application. Participant acknowledges and agrees that the final determination of the Level of Registry Use will be at the sole discretion of Help Me Grow.

- b. Participant will designate in the Participant Application a person who will serve as the primary point of contact for participation in the Registry and will supervise the data collection, confirm the accuracy of the data, receive the confidential reports and act as direct liaison with Help Me Grow (the “Participant Contact”). If Help Me Grow determines that any Participant Contact is consistently failing to report data or otherwise is not fulfilling the Participant Contact responsibilities, Participant will identify an alternate individual to serve in that capacity. Participant will notify Help Me Grow of any changes to the Participant Contact within twenty-four (24) hours upon becoming aware of such change.
- c. Participant agrees to furnish developmental, behavioral and trauma screening data of patients for the term of this Registry Agreement in a manner consistent with the requirements of the Registry by securely transmitting the data as prescribed by the specific protocol. Participant acknowledges that patient information will be accessed through the Registry and used by Help Me Grow and Authorized Users (defined below) in accordance with the Registry’s purpose. Participant shall exercise reasonable care to ensure that the information and data that the Participant enters into the Registry (i) is correct, accurate, and complete; (ii) does not violate any privacy rights, intellectual property rights or other rights of a patient or any third party, (iii) does not violate any local, State, or Federal law or regulation. Participant shall ensure that any necessary patient authorization has been obtained and documented. Participant shall promptly notify Help Me Grow of any data that the Participant determines is corrupt, incomplete, erroneous, or otherwise incorrect, or which is otherwise inappropriate for availability through the Registry.
- d. Participant’s data submission will be performed per the specifications posted on the Help Me Grow website located at [www.helpmegrowoc.org](http://www.helpmegrowoc.org) or applicable protocol.
- e. Participant agrees that its submitted data may be audited by or on behalf of Help Me Grow. If Help Me Grow requests an audit, Participant agrees to provide all necessary documents, data and other information, including corroborating evidence of the submitted data in the form of additional supporting documentation. Participant agrees that if an audit process or the application of threshold criteria finds the data does not conform to Help Me Grow standards, the requirements of this Registry Agreement or the Registry, as a condition of continued participation in the Registry, Participant shall submit within forty-five (45) days of notice of the audit an action plan, in a form reasonably acceptable to Help Me Grow, to correct the issues identified through the audit. Furthermore, the non-conforming data submitted by the Participant will be withheld from the Registry database for reporting purposes, until such data conforms to Help Me Grow standards, the requirements of this Registry Agreement or the Registry and is re-submitted to Help Me Grow by Participant.

- f. Participant shall maintain appropriate procedures to safeguard data confidentiality in compliance with applicable law. Participant will be solely responsible for any and all of its acts or omissions regarding the privacy and security of the data it furnishes hereunder. Participant shall maintain appropriate liability insurance for its acts and omissions under this paragraph.
- g. Participant agrees that access to the Registry will be limited to physicians and ancillary providers who are members in good standing of the Participant's medical staff and/or to employees of Participant who have signed the Terms of Use set forth in Exhibit B, who will be supervised and authorized by Participant to access PHI only for purposes set forth in this Registry Agreement in compliance with state and federal law ("Authorized Users"). Participant shall provide Help Me Grow a list in writing identifying all of the Participant's Authorized Users. Participant will communicate to Help Me Grow any changes to Authorized Users within twenty-four (24) hours upon becoming aware of any changes to the Authorized Users, including an Authorized User's voluntary or involuntary termination of employment or other long term or permanent departure from the employment of the Participant. Participant will promptly inform Help Me Grow to deactivate the account of any Authorized User whose responsibilities no longer require access to the Registry.
- h. Help Me Grow shall provide each Authorized User with a unique User Identification ("ID") and password ("Password"). Participant agrees that it and its Authorized Users shall not disclose passwords to anyone or use a User ID not assigned to them. Participant agrees that if an Authorized User account is not accessed for ninety (90) days, the Authorized User account becomes inactive and a new Password will need to be assigned by Help Me Grow following a request from the Authorized User.
- i. Participant acknowledges and agrees that each time an Authorized User signs on to the Registry, the Registry shall identify the Authorized User and record the functions the Authorized User performs.
- j. The Participant Contact shall provide or arrange for appropriate training in the use of the Registry, and as to the requirements of this Registry Agreement and applicable law for all Authorized Users.
- k. Upon designation of an Authorized User to Help Me Grow, Participant agrees and certifies that each designated Authorized User:
  - i. Has executed the Authorized User Terms of Service, a copy of which is attached hereto, and incorporated herein by reference, as Exhibit B;
  - ii. Has completed training relevant to the use of the Registry; and
  - iii. Will be permitted by Participant to use the Registry only as reasonably necessary for performance of Participant's activities at Participant's Level of Registry Use.

Participant will provide to Help Me Grow the copy of the Authorized User Terms of Service signed by the Authorized User prior to Authorized User's use of the Registry. Participant acknowledges and agrees that an Authorized User will not be granted access to use the Registry until Help Me Grow receives the Authorized User's signed copy of the Authorized User Terms of Service.

- l. Participant is responsible for the actions of any former or current Authorized User who accesses the Registry account without proper authority using Participant's User ID or Password. Participant shall immediately notify Help Me Grow of any unauthorized access to or use of the Registry other than in accordance with the requirements this Registry Agreement.
- m. Participant shall be responsible for all acts and omissions, including without limitation privacy or security breaches and/or failures to comply with the requirements of this Registry Agreement by the Participant's Authorized Users, employees, contractors, agents, and any other parties within the Participant who access or use the Registry.
- n. Participant shall be solely responsible for obtaining, installing, and maintaining, at the Participant's expense, the Participant's prerequisite systems needed to access the Registry, including without limitation any computer system, software, interface, hardware, network, or any upgrade or alteration to any of the aforementioned items.
- o. Participant shall not: (i) allow to be transmitted to the Registry any unlawful, threatening, abusive, libelous, defamatory, or otherwise objectionable information of any kind, including without limitation any transmissions constituting or encouraging conduct that would constitute a criminal offense, give rise to civil liability, or otherwise violate any local, State, or Federal law; (ii) knowingly allow to be transmitted to the Registry any data or software that contains malicious electronic code such as a virus, trojan, worm, or other harmful payload, or; (iii) knowingly allow to be transmitted to the Registry any information that violates the proprietary rights, privacy rights, or any other rights of a third party, including without limitation any patient.
- p. Participant shall not make available to Authorized Users through the Registry any patient information or other data containing the following: (i) information relating to a patient's participation in outpatient treatment with a psychotherapist, as defined in Cal. Civ. Code § 56.104; (ii) psychotherapy notes, as defined in 45 CFR §164.501; (iii) records of the identity, diagnosis, prognosis, or treatment of any patient contained in connection with any program or activity relating to alcoholism or alcohol abuse education, training, treatment, rehabilitation, or research, as defined in 42 CFR §2.2 and Cal. Health & Safety Code §11977; (iv) any other data protected from disclosure without valid consent or authorization under State or Federal law or agreement with the patient or their legal representative.

- q. Without limiting any other provisions of this Registry Agreement, the Participant shall notify involved individuals of the Participant's participation in the Registry, the Participant's policies regarding the use and disclosure of patient information through such Registry, and such individual's rights with respect thereto, to the extent required by applicable laws and regulations including, but not limited to, HIPAA.

### 3. Help Me Grow Responsibilities

- a. Help Me Grow agrees to conduct the Registry as described in the Overview of OC Children's Screening Registry, attached hereto as Exhibit C. CHOC reserves the right to terminate all or part of the Registry as described in Section 7, Termination.
- b. Help Me Grow shall exercise commercially reasonable efforts to make the Registry available to Participants twenty-four (24) hours per day, seven (7) days a week, three-hundred sixty-five (365) days per year; provided, however, that the availability of the Registry may be temporarily suspended for maintenance, unscheduled interruptions or other reasons that may be beyond Help Me Grow's control. Help Me Grow shall exercise reasonable efforts to provide the Participant with advance notice of any such suspension or interruption of Registry availability, if possible.
- c. Help Me Grow shall make training and technical support reasonably available to Participants and Authorized Users in the use of the Registry. The coordination of training needs and opportunities related to the Registry for the Participants will be communicated via the Participant Contact.
- d. Help Me Grow shall implement and maintain a mechanism pursuant to which a patient's legal guardian may exercise choice concerning the inclusion and/or availability of their child's patient information in the Registry. If a patient's legal guardian would like to opt-out of participating in the Registry, the patient's legal guardian must notify the Participant in writing prior to Participant entering the patient's information into the Registry. This opt-out notification prevents the Participant from entering any of the child's patient information in the Registry. Once Participant data is entered into the Registry, this data becomes part of the Registry's aggregate data and such data cannot be retracted from the Registry by Participant. If the child's patient information already exists in the Registry at the time the opt-out is received from the legal guardian, the Participant must then notify Help Me Grow in writing of the legal guardian's opt-out request. Upon receipt of the notification, Help Me Grow will remove the patient from the Registry in a timely manner. Notwithstanding the foregoing, if the Patient Information has already been included in any de-identified or aggregate data, or other use permitted under the Participation Agreement which does not identify the patient in any manner, prior to the date of the opt-out notice, Help Me Grow will not be required to remove or cease use of such Patient Information from the pre-existing de-identified or aggregate data or other use permitted under Section 6 and Help Me

Grow may continue to use such de-identified or aggregate data pursuant to the terms of this Registry Agreement provided that the patient is not identified in any manner.

- e. Help Me Grow shall provide Participants with certain information needed to produce Accountings of Disclosures of Patient Information in compliance with HIPAA.
  - f. Help Me Grow shall provide by telephone and/or email, during normal business hours, support and assistance solely in resolving difficulties in accessing and using the Registry. Help Me Grow will not provide problem resolution to solve issues related to the Participant's own computer system, software, interface, hardware, network, or any upgrade or alteration to any of the aforementioned items.
  - g. Help Me Grow agrees to accept Participant's data, except where the submitted data does not conform to this Registry Agreement or other requirements for the Registry, including without limitation the data quality standards established by the Registry as updated from time to time by Help Me Grow. In such cases, Help Me Grow reserves the right to either reject the data submission in its entirety, or to limit the use of such data, if it does not meet Help Me Grow's required standards or the requirements for the Registry.
  - h. Help Me Grow may produce and periodically revise the data elements, definitions and formats used by the Registry. Participant will be notified of any such revisions.
  - i. Help Me Grow will provide a self-training document to guide Participant's data collection activities. Help Me Grow will analyze the Participant's submitted data records by means of electronic data checks, consistency checks and range checks to validate that the data submission conforms to the requirements of this Registry Agreement, the Registry and any related documentation or specifications for the Registry.
  - j. Help Me Grow will accept unique patient identifiers and unique Participant identifiers for each record submitted to the Registry by Participant.
4. Privacy Laws and Security
- a. The Parties agree to abide by all Federal, State and local laws pertaining to confidentiality and disclosure with regard to all information or records obtained and reviewed hereunder. Help Me Grow acknowledges that it is a "Business Associate" as defined and referred to under HIPAA. Accordingly, Help Me Grow shall take reasonable steps to comply with the requirements under HIPAA and the HITECH Act for Business Associates as set forth in the HIPAA Business Associate Agreement (BAA) attached hereto as Exhibit D.
  - b. Help Me Grow will maintain its security policies and procedures to protect Participant data as provided in the BAA. If Help Me Grow determines that a breach

of security has occurred, Help Me Grow will notify Participant in accordance with the provisions of the BAA. Help Me Grow will be responsible for its acts and omissions regarding the privacy and security of the data Help Me Grow maintains under this Registry Agreement.

#### 5. Use of Names and Logos

- a. Without the express prior written consent of Help Me Grow, Participant shall not make any announcements concerning the matters set forth in this Registry Agreement, use the word or symbol, CHOC, Help Me Grow, or OC Screening Registry or any trademarks or service marks of CHOC or make any reference to CHOC or Help Me Grow in any advertising or promotional material, letterhead, symbol or logo, or other communication that is not strictly internal to Participant, or in any other manner, including, without limitation, press releases or lists. Notwithstanding the foregoing, Participant may use the name of CHOC, Help Me Grow, and OC Screening Registry in consent documents and on its clinical research website to advise patients of its participation in the Registry.
- b. Without the express prior written consent of Participant, Help Me Grow shall not use the Participant's logos, trademarks or service marks of Participant.

#### 6. Data and Copyright Ownership

- a. The data for individual patients submitted by Participant shall be the exclusive property of Participant, subject to the rights, if any, of Participant's patients in Protected Health Information, and subject to the rights granted to Help Me Grow in this Registry Agreement, including the HIPAA BAA. Participant hereby agrees the return of that information is not feasible as it has been integrated into the Registry. Participant grants to Help Me Grow a perpetual, enterprise-wide, royalty-free, worldwide license, to use the data submitted by Participant in any manner that is consistent with this Registry Agreement and the HIPAA BAA, in all forms and all media, now known or hereinafter developed, including derivative works. To the extent Help Me Grow develops aggregated de-identified or similar data that are not Protected Health Information from the data submitted by Participant ("aggregate data"), Help Me Grow shall exclusively own such aggregate data and any derivative works derived therefrom, as Intellectual Property Rights (defined below) owned by Help Me Grow. Help Me Grow may use such aggregate data and derivative works for any purpose, including publications and quality improvement research, so long as neither Participant nor any individual patient can be identified from the aggregate data or derivative works. Help Me Grow expressly agrees that such aggregate data and derivative works will exclude any and all Protected Health Information received from Participant, and any information that identifies Participant.
- b. All Intellectual Property Rights and title to all proprietary information in and rights to any software, database, aggregate data and the compilation of the same with any other data received in connection with the Registry and any derivative works using

the Registry including, without limitation, any reports, calculations and models based thereon and de-identified data as described in Section 6(a), including without limitation all copyrights, patent rights, trademarks, trade secret rights, and any other rights and interest in any of the foregoing shall be and remain at all times for all purposes with Help Me Grow or Help Me Grow licensors, as applicable. For purposes of this Registry Agreement, “Intellectual Property Rights” means (i) all, or any intermediate version or portion, of any formulas, processes, outlines, algorithms, ideas, inventions, know how, techniques, intangible, proprietary and industrial property rights and all intangible and derivative works thereof, including without limitation any and all now known or hereafter existing, in and to trademarks, trade name, service marks, slogans, domain names, uniform resource locators or logos; (ii) copyrights, moral rights, and other rights in works of authorship, including, but not limited to, compilations of data, (iii) patents and patent applications, patentable ideas, inventions and innovations; (iv) know-how and trade secrets; and (v) registrations, applications, renewals, extensions, continuations, divisions or reissues of all of the foregoing. Help Me Grow reserves the right to use Participant’s de-identified data in electronic or other format to support ongoing improvements and enhancements to the Registry. Once Participant data are entered into the Registry, these data become part of the Registry’s aggregate data and such data cannot be retracted from the Registry by Participant. Information for which Help Me Grow has ownership under this Section 6 shall not be considered Confidential Information and will not be returned to Participant under Section 8.

- c. If Participant desires to publish or otherwise distribute or use, in whole or in part, any aggregate data or reports provided by Help Me Grow or produced in connection with or derived from the Registry, with the exception of strictly internal use within the Participant as defined in Section 2 Participant must first obtain the prior express written consent of Help Me Grow. To the extent Participant is permitted to publish aggregate data, such aggregate data and any related information published in connection with it must be reviewed and approved by Help Me Grow prior to publication; provided, that such review is intended only to ensure that no Help Me Grow Confidential Information is inappropriately included in such publication. Participant is solely responsible for the accuracy, completeness and reliability of its publications and information using aggregate data or reports derived from the Registry. Help Me Grow shall not be liable for any use of the aggregate data or reports derived from the Registry by Participant, including any publications by Participant. Help Me Grow does not make any representations or warranties as to the Participant data, including the accuracy, completeness or reliability of the Participant data, the reliance on any Participant data or any conclusions drawn from any Participant data.

## 7. Term and Termination.

- a. This Registry Agreement shall begin on the Effective Date and continue for one (1) year. Thereafter, this Registry Agreement will renew automatically for successive

periods of one (1) year each, unless Participant provides Help Me Grow with ninety (90) days advance written notice of its desire to terminate this Registry Agreement in its entirety.

- b. Either Party may terminate this Registry Agreement without cause by providing the other with at least ninety (90) days advance written notice.
- c. Help Me Grow reserves the right to immediately terminate this Registry Agreement and Participant's participation in the Registry if Help Me Grow determines that any one year of the Participant's data are noncompliant with Registry standards or this Registry Agreement or are otherwise unacceptable for inclusion in Registry national reporting data and such non-compliance is not cured as stated in Section 2e.
- d. Notwithstanding anything to the contrary in this Registry Agreement, Help Me Grow may discontinue the Registry at any time in its sole discretion. Such discontinuation shall take effect on a date specified by Help Me Grow in a notice of discontinuation.
- e. Upon termination of this Registry Agreement, Participant shall immediately cease all use of the Registry, including use by Participant's Authorized Users. Upon termination of this Registry Agreement, Participant agrees that it shall not use Registry software or the Registry dataset for collecting and reporting data or any other purpose without Help Me Grow's express written consent, except as necessary to wind down Participant's participation in the Registry.

## 8. Confidentiality

- a. For the purposes of this Registry Agreement, "Confidential Information" means any software, material, data or business, financial, operational, customer, vendor and other information disclosed by one Party to the other and not generally known by or disclosed to the public or known to the receiving Party solely by reason of the negotiation or performance of this Registry Agreement, and shall include, without limitation, the terms of this Agreement. Each Party shall maintain all of the other Party's Confidential Information in strict confidence and will protect such information with the same degree of care that such Party exercises with its own Confidential Information of a similar nature, but in no event with less than a reasonable degree of care. Except as provided in this Registry Agreement, a Party shall not use or disclose any Confidential Information of the other Party in any manner without the express prior written consent of such Party. Access to and use of any Confidential Information shall be restricted to those employees and persons within a Party's organization with a need to use the information to perform such Party's obligations under this Registry Agreement. A Party's consultants, subcontractors and business partners shall be included within the meaning of "persons within a Party's organization," provided that such consultants, subcontractors and business partners are under an obligation of confidentiality.

Notwithstanding anything herein to the contrary, Confidential Information shall not include information that is: (a) already known to or otherwise in the possession of a Party at the time of receipt from the other Party and that was not known or received as the result of violation of any obligation of confidentiality; (b) or becomes publicly available or otherwise in the public domain without breach of this Section by the receiving Party; (c) rightfully obtained by a Party from any third party having a right to disclose such information without restriction and without breach of any confidentiality obligation by such third party; (d) developed by a Party independent of any disclosure hereunder, as evidenced by detailed written records made in the normal course of a Party's business during the development process; or (e) disclosed pursuant to the order of a court or administrative body of competent jurisdiction or a government agency, provided that the Party receiving such order shall notify the other Party prior to such disclosure and shall cooperate with the other Party in the event such Party elects to legally contest, request confidential treatment, or otherwise avoid such disclosure. Notwithstanding anything to the contrary, Protected Health Information is always Confidential Information except when the Protected Health Information becomes aggregated data in accordance with Section 6 and does not identify the patient in any manner.

- b. Except as otherwise provided herein, all of a Party's Confidential Information disclosed to the other Party, and all copies thereof, shall be and remain the property of the disclosing Party. All such Confidential Information and any and all copies and reproductions thereof shall, upon the expiration or termination of this Registry Agreement for any reason, or within fifteen (15) days of written request by the disclosing Party, be promptly returned to the disclosing Party, or destroyed, at the disclosing Party's direction. In the event of such requested destruction, the Party receiving such request shall provide to the other Party written certification of compliance therewith within fifteen (15) days of such written request. Notwithstanding the foregoing, a Party shall not be required to retrieve and destroy or retrieve and return Confidential Information that is stored on backup or archived digital media but shall continue to protect such information under this Section 8. Notwithstanding the provisions of this Section 8, any information governed by Sections 6(a) or 6(b) or the provisions of the HIPAA BAA shall be governed, respectively, by those Sections of this Agreement, as applicable.

## 9. Indemnification

- a. Help Me Grow will indemnify, defend, and hold Participant and its employees, officers, directors, agents, contractors and business partners (collectively the "Participant Indemnitees") harmless from any third party claim, demand, cause of action, lawsuit or proceeding brought against Participant based upon 1) any gross negligence or willful misconduct on the part of Help Me Grow; 2) any errors or inaccuracies contained in the data as created or derived by Help Me Grow, provided that the errors or inaccuracies are caused by Help Me Grow and not caused solely by the data entered into the Registry by Participant; 3) any claim that is based, in whole or in part, on a breach of any warranty, representation or covenant made by

Help Me Grow under this Registry Agreement, including but not limited to any third party lawsuit or proceeding brought against Participant or any of the Participant Indemnitees based upon a claim that any data created or derived by Help Me Grow infringe any third party rights. Such indemnification shall include: (1) all reasonable attorneys' and expert fees and costs associated with defense of such claim; (2) all damages and costs; and (3) the full cost of any settlement. Such indemnification obligation requires that Participant (i) notify Help Me Grow of any such claim within thirty (30) days of Participant's notice of such claim, (ii) provide Help Me Grow with reasonable information, assistance and cooperation in defending the lawsuit or proceeding (to the extent requested by Help Me Grow), and (iii) give Help Me Grow full control and sole authority over the defense and settlement of such claim. Help Me Grow will not enter into any settlement or compromise of any such claim without Participant's prior consent, which shall not be unreasonably withheld.

- b. Participant will indemnify, defend, and hold Help Me Grow and Help Me Grow's employees, officers, and directors (collectively the "Help Me Grow Indemnitees") harmless from any third party claim, demand, cause of action, lawsuit or proceeding brought against one or more Help Me Grow Indemnitees based upon (1) any errors or inaccuracies contained in the data as delivered by Participant to the Registry or Help Me Grow; or (2) any medical treatment, diagnosis or prescription rendered by Participants or its agents (including physicians and healthcare professionals). Participant's indemnification shall include (i) all reasonable attorneys' fees and costs associated with defense of such claim; (ii) all damages and costs awarded; and (iii) the full cost of any settlement entered into by Participant. Such indemnification obligation requires that Help Me Grow (i) notify Participant of any such claim within thirty (30) days of Help Me Grow's notice of such claim, (ii) provide Participant with reasonable information, assistance and cooperation in defending the lawsuit or proceeding (to the extent requested by Participant), and (iii) give Participant full control and sole authority over the defense and settlement of such claim. Participant will not enter into any settlement or compromise of any such claim without Help Me Grow's prior consent, which shall not be unreasonably withheld.

#### 10. Notices.

- a. All notices and demands of any kind or nature which either Party to this Registry Agreement may be required or may desire to serve upon the other in connection with this Registry Agreement shall be in writing, and may be served personally, by registered or certified United States mail, or by nationally recognized overnight courier (e.g., FedEx, DHL, or UPS) to the following addresses:

If to Participant: \_\_\_\_\_  
Address: \_\_\_\_\_  
\_\_\_\_\_  
Phone: \_\_\_\_\_  
Email: \_\_\_\_\_

If to Help Me Grow: Help Me Grow  
Rebecca Hernandez  
1120 W. La Veta Ave., Ste 450  
Orange, CA 92868  
949-267-0300  
[Rehernandez@choc.org](mailto:Rehernandez@choc.org)

With a copy to: Children's Hospital of Orange County  
Chief Legal Officer  
1201 W. La Veta Avenue  
Orange, CA 92868

Service of such notice or demand so made shall be deemed complete on the day of actual delivery. Any Party hereto may, from time to time, by notice in writing served upon the other Party as aforesaid, designate a different mailing address or a different person to which all further notices or demands shall thereafter be addressed.

## 11. General

- a. The relationship of the Parties to this Registry Agreement is that of independent contractors and not that of master and servant, principal and agent, employer and employee, or partners or joint venturers.
- b. This Registry Agreement may be executed in one or more counterparts, each of which shall be deemed an original and all of which taken together shall constitute one and the same instrument. An electronic signature will have the same legal force and effect as though it were the original of such signature.
- c. A waiver by either Party to this Registry Agreement of any of its items or conditions in any one instance shall not be deemed or construed to be a general waiver of such term or condition or a waiver of any subsequent breach. A waiver will not be effective unless it is in writing and signed by the party against whom the waiver is being enforced.
- d. All provisions of this Registry Agreement are severable. If any provision or portion hereof is determined to be unenforceable by a court of competent jurisdiction then

the rest of this Registry Agreement shall remain in full effect, provided that its general purposes remain reasonably capable of being effected.

- e. This Registry Agreement, including the exhibits attached hereto, and any subsequent addendums executed by the Parties (a) constitute the entire agreement between the Parties with respect to the subject matter; (b) supersede and replace all prior and contemporaneous agreements, oral or written, between the Parties relating to the subject matter; and (c), except as otherwise indicated, may not be modified or otherwise changed in any manner except by a written instrument executed by both Parties.
- f. The following sections of this Registry Agreement survive its termination, for any reason: Sections 4, 5, 6, 8, 9, 10 and 11 and the HIPAA BAA.
- g. The parties agree there are no third-party beneficiaries, intended or otherwise, to this Registry Agreement, including without limitation, patients of Participant.
- h. This Registry Agreement shall be governed by and construed in accordance with the laws of the State of California, without regard to its conflict of laws principles.

IN WITNESS WHEREOF, each of the Parties hereto has caused this Registry Agreement to be executed as of the Effective Date.

Children's Hospital of Orange County  
on behalf of the Help Me Grow program

Participant:  
[Vendor]

By: \_\_\_\_\_

By: \_\_\_\_\_

Name: [Signatory Name]

Name: \_\_\_\_\_

Title: [Title]

Title: \_\_\_\_\_

EXHIBIT A  
PARTICIPANT APPLICATION TO ACCESS  
THE OC CHILDREN’S SCREENING REGISTRY

**Participant Application**  
**OC Children’s Screening Registry**

**Overview**

The OC Children’s Screening Registry is an online database designed to enable primary care providers and community-based providers to collect and report on developmental and behavioral screening data of children from birth through seventeen (17) years of age. The OC Children’s Screening Registry accommodates five screening tools (Ages and Stages Questionnaires-3, ASQ: Social Emotional, Parents Evaluation of Developmental Status, M-CHAT, and Pediatric Aces and Related Life-events Screener). The screening information is designed to help clinical and community-based providers proactively identify children with at-risk developmental, behavioral and trauma screening results, reduce duplication of screening efforts, and assist in connecting families with appropriate resources.

**Participant and Authorized Lead Information**

Individual at Participant Organization responsible and authorized to enter into agreements

Participant Name (Organization):
Name:
Role/Title:
Address:
Phone:
Email:

**Participant Liaison Contact Information**

Individual that will have ongoing contact with Help Me Grow regarding user accounts, supervise data entry, confirm accuracy, and act as a direct liaison with Help Me Grow

Name:
Position:
Phone:
Email:

**Type of Participant Registry Use**

(Select One) One of the benefits of the screening registry is to provide a continuum of care for a child between service providers. Child screening results can be shared between service providers IF certain conditions are in place:

<input type="checkbox"/>	Participant is considered a Treating Provider	Service Provider is considered a Treating Provider AND the Service Provider has a treatment relationship with the Child that would warrant a benefit to the child if screening results were shared.
<input type="checkbox"/>	Participant is considered a Non-Treating Provider	Service Provider is NOT a Treating Provider but has obtained a written, valid HIPAA Authorization from the child's parent/legal guardian to allow access to view screening results obtained from another provider AND the Service Provider has a relationship with the Child that would warrant a benefit to the child if screening results were shared. If authorization does not exist for a specific child than only the screening results the participant has entered will be accessible.
<input type="checkbox"/>	Data Entry Only Access	Service Providers may use the data they collect and enter into the OC Children's Screening Registry for internal purposes only and will not view records from other service providers.

**Participant OC Children's Screening Registry Agreement**

<p>On behalf of my organization, I have reviewed, and signed the OC Children's Screening Registry Participation Agreement. This document outlines the terms of use, including responsibilities, benefits, and conditions of the Participant's use of the OC Children's Screening Registry.</p>
<p>Authorized Signature:</p>
<p>Authorized Printed Name:</p>
<p>Date:</p>

EXHIBIT B  
AUTHORIZED USER TERMS OF USE

**OC CHILDREN'S SCREENING REGISTRY**

**TERMS OF USE – FOR AUTHORIZED USERS**

Welcome to the OC Children's Screening Registry, an online database designed to enable primary health care providers and community based providers to view and/or enter developmental and behavioral screening data, and share information on referrals and outcomes ("Registry"). The Registry is provided by Children's Hospital of Orange County on behalf of the Help Me Grow program ("HMG", "We", "Us" or "Our"). Your access and use of the Registry is governed by these Terms of Use ("Terms of Use"). Subject to your compliance with these Terms of Use, We grant you as the Authorized User ("You" or "Your") a limited license to access and use the Registry for Your non-commercial, informational, and personal use.

1. **Definitions:**

1.1 Authorized User –An individual that has been approved by Us and/or the Participant to access and/or use the Registry on behalf of the Participant or Us.

1.2 Participant – The organization that is authorized by Us to participate in the Registry pursuant to an executed OC Children's Screening Registry Participation Agreement between said organization and Us ("Participation Agreement"), and at whose direction You are accessing and/or using the Registry.

1.3 Patient Information – All information relating to a patient, child, or client of a Registry Participant, including, but not limited to, "protected health information," as defined under HIPAA.

1.4 HIPAA – The Health Information Portability and Accountability Act of 1996, as amended, and its implementing regulations.

2. **Patient Participation and Ability to Opt-Out.** HMG operates a Registry pursuant to which a patient's legal guardian may exercise choice concerning the inclusion and/or availability of their child's Patient Information in the Registry. If a patient's legal guardian would like to opt-out of participating in the Registry, the patient's legal guardian must notify the Participant in writing prior to Participant entering the Patient Information into the Registry. This opt-out notification prevents the Participant from entering any of the child's Patient Information in the Registry. Once Patient Information is entered into the Registry, this data becomes part of the Registry's aggregate data and such data cannot be retracted from the Registry by You or Participant. If the child's Patient Information already exists in the Registry, the Participant must then promptly notify HMG in writing of the legal guardian's opt-out request. Upon receipt of the notification, HMG will remove the child's Patient Information from the Registry in a timely manner. Notwithstanding the foregoing, if the Patient Information has already been included in

any de-identified or aggregate data, or other use permitted under the Participation Agreement which does not identify the patient in any manner, prior to the date of the opt-out notice, HMG will not be required to remove or cease use of such Patient Information from the pre-existing de-identified or aggregate data or other use permitted under the Participation Agreement and HMG may continue to use such de-identified or aggregate data pursuant to the terms of the Participation Agreement provided that the patient is not identified in any manner.

### **3. Your Responsibilities:**

Participation in the Registry. You shall access and use the Registry in accordance with the terms and conditions of these Terms of Use and the Participation Agreement.

3.2 Compliance with Laws and Regulations. You agree to comply with all laws and regulations applicable to the activities You conduct pursuant to Your access and use of the Registry.

3.3 Attestation of Status as Authorized User. You attest that You:

- a) Are a current member of the Participant's workforce or medical staff;
- b) Are designated by the Participant as an individual authorized to use the Registry, and;
- c) Are engaging in entry, access, and/or use of Patient Information in the Registry for a legitimate business purpose on behalf of the Participant.

3.4 Limitations Upon Access To and Use of Patient Information. You shall access and use Patient Information through the Registry solely for the purpose of Treatment, as defined under HIPAA, of individuals with whom You have a treatment relationship, or from whom the Participant has received a valid authorization when required under HIPAA or other applicable law or regulation. You may use Patient Information solely in accordance with the Registry's purpose. You shall not engage in any inappropriate use of Patient Information, such as for personal reasons, including but not limited to curiosity or as a favor to others.

3.5 User Identification and Passwords. User IDs and Passwords are intended to protect and maintain the privacy of information in the Registry from unauthorized personnel. You agree that You shall not share Your assigned User ID or Password with others, except to trained technical support personnel for the purpose of technical support. You acknowledge that sharing your User ID or Password with anyone else, or leaving your workstation without logging out of the Registry, is in direct violation of these Terms of Use.

3.6 Limitations Upon Disclosure of Patient Information. You may not disclose Patient Information obtained through the Registry for any reason, except as expressly permitted by applicable laws and regulations, including but not limited to HIPAA, and these Terms of Use.

3.7 Reasonable Safeguards for Privacy and Security. You shall use reasonable safeguards, as required under HIPAA, to maintain the privacy and security of Patient Information. Without

limiting the generality of the foregoing: (i) You shall not use, share, or disclose Your password(s) or other access identification or authentication information with any individual or entity, except as stated in 3.5.

3.8 **Suspension and Termination of Authorized User Status.** You understand and acknowledge that Your status as an Authorized User may be suspended and/or terminated at any time without notice, along with all access privileges, under the following conditions:

- a) Upon termination of the Participant's involvement in the Registry for any reason;
- b) If You are no longer a member of the Participant's workforce or medical staff;
- c) Upon a change to Your roles and/or responsibilities on behalf of the Participant that would make continued access or use inappropriate;
- d) Upon suspicion or confirmation of any inappropriate or unlawful access, use, and/or disclosure occurring by You and/or Your account;
- e) Upon request by the Participant;
- f) At the discretion of HMG;
- g) Upon any act or omission by You that is in violation of these Terms of Use, the Participation Agreement, or any applicable laws or regulations.

3.9 **Monitoring.** You understand and acknowledge that Your access, transactions, and other activities while using the Registry may be monitored.

#### **4. License Restrictions.**

4.1 You shall not:

- (a) Copy any Registry content, except as expressly permitted by the Participation Agreement or these Terms of Use;
- (b) Modify, translate, adapt or otherwise create derivative works or improvements, whether or not patentable, of the Registry or its content;
- (c) Reverse engineer, disassemble, decompile, decode or otherwise attempt to derive or gain access to the source code of the Registry or its content;
- (d) Remove, delete, alter or obscure any trademarks or any copyright, trademark, patent or other intellectual property or proprietary rights notices from the Registry or its content, including any copy thereof; or
- (e) Rent, lease, lend, sell, sublicense, assign, distribute, publish, transfer or otherwise make available the Registry or its content, or any features or functionality of the Registry, to any third party for any reason, including by making the Registry available on a network where it is capable of being accessed by more than one device at any time.

4.2. You acknowledge and agree that the Registry and its content is provided under license, and not sold, to you. You do not acquire any ownership interest in the Registry and its content under these Terms of Use, or any other rights thereto other than to use the Registry and its content in accordance with the license granted, and subject to all terms, conditions and restrictions, under these Terms of Use. We reserve and shall retain Our entire right, title and interest in and to the Registry and its content, including all copyrights, trademarks and other intellectual property rights therein or relating thereto, except as expressly granted to you in this Terms of Use.

**5. Collection and Use of Your Information.** You acknowledge that when You use the Registry, the Registry may use automatic means (including, for example, cookies and web beacons) to collect information about Your use of the Registry. You also may be required to provide certain information about Yourself as a condition to using the Registry or certain of its features or functionality, and the Registry may provide you with opportunities to share information about Yourself with others.

**6. Third Party Materials.** The Registry may display, include or make available third-party content (including data, information, applications and other products services and/or materials) or provide links to third-party websites or services, including through third-party advertising ("Third Party Materials"). You acknowledge and agree that We are not responsible for Third Party Materials, including their accuracy, completeness, timeliness, validity, copyright compliance, legality, decency, quality or any other aspect thereof. We do not assume and will not have any liability or responsibility to You or any other person or entity for any Third Party Materials. Third Party Materials and links thereto are provided solely as a convenience to You and You access and use them at entirely at your own risk and subject to such third parties' terms and conditions.

By signing below, You understand and agree that you will abide by these Terms of Use, and the applicable Participation Agreement.

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Signature

Date

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Print Name

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Employer

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Program or Medical Practice Site

Please return this form to Help Me Grow at the email address below:

Email: [OCscreeningregistry@choc.org](mailto:OCscreeningregistry@choc.org)

Phone: 949-267-0312

EXHIBIT C  
OVERVIEW OF OC CHILDREN'S SCREENING REGISTRY



## Overview of OC Children's Screening Registry

### Healthy Tomorrows Partnership for Children Program Award

The Healthy Tomorrows Partnership for Children Program is a collaborative effort between the American Academy of Pediatrics and Maternal Child Health Bureau that distributes grants to promote community planning and problem solving at the local level.

In March 2014, Help Me Grow Orange County was awarded a Healthy Tomorrows Partnership for Children Program grant. The purpose of the grant is to support the creation of a Developmental Screening Network (DSN), as well as the creation of a Developmental Screening Registry (OC Children's Screening Registry) to improve physician engagement and cross-sector collaboration, link electronic health records among Orange County service providers, and reach out to pediatricians to encourage them to regularly use developmental screening tools and refer children for evaluation and treatment when needed.

### OC Children's Screening Registry

The OC Children's Screening Registry is an online database designed to enable primary health care providers and community-based providers to view and/or enter developmental and behavioral screening data and share information on referrals and outcomes. The OC Children's Screening Registry has been developed to accommodate five screening tools (Ages and Stages Questionnaires (ASQ) -Third Edition, ASQ: Social Emotional-2, Parents Evaluation of Developmental Status, Modified Checklist for Autism in Toddler, Revised with Follow-up, and Pediatric Aces and Related Life-events Screener (PEARLS)).

### Developmental Screening Network

The Developmental Screening Network (DSN) is a collaborative structure of community stakeholders, the primary purpose is to support improved care coordination and connection to developmental services among local service providers serving children birth through eight years.

The DSN has met on a monthly basis since its inception to oversee the development of the Registry. To facilitate this process, the DSN established a subcommittee - the Confidentiality Work Group - to identify barriers to registry utilization, find solutions, examine laws, and outline a methodology that will increase success of the OC Children's Screening Registry.

## Framework for Use of OC Children’s Screening Registry Data

The screening information is designed to help clinical and community based providers proactively identify children with at-risk developmental screening results, reduce duplication of screening efforts, and assist in connecting families with appropriate resources. Information shared may include demographic information (name, date of birth, sex); developmental screening results; and services (types and/or outcomes of referrals made).

**Administrative:** Help Me Grow is the data administrator of the OC Children’s Screening Registry. Help Me Grow will have access to screening information collected on children in the registry for purposes of evaluation, support, and maintenance. Help Me Grow may report aggregate information (*no individuals or individual-level health information will be identified*) from a service provider, group of service providers, or across all service providers. The one exception could be that a participant location such as zip code could be used for purposes of graphing service delivery. Help Me Grow may work with additional data administrators that may only see registry information for purposes of providing technical support for the registry or to authorized service providers, quality assurance for the program, or for removing authorization to share child information.

**Service Provider:** There are two levels of child information access within the OC Children’s Screening Registry. First, is the data collected and entered by each Service Provider and second is the screening data collected by another service provider, but common to both parties.

- **Service Provider Own-entered Child Data.** Service Providers may use the data they collect and enter into the registry for internal purposes only. Providers may prepare and disseminate reports of their own aggregate data for use in program planning and reporting.
- **Screening Results Collected from Another Service Provider.** One of the benefits of the screening registry is to provide a continuum of care for a child between service providers. Individual child screening results on each tool can be viewed within the registry between service providers IF certain conditions are in place:
  1. Service Provider is considered a Treating Provider AND the Service Provider has a treatment relationship with the Child that would warrant a benefit to the child if screening results were shared: **OR**
  2. Service Provider is NOT a Treating Provider, but has obtained a written, valid HIPAA Authorization from the child’s parent/guardian to allow access to view general screening results obtained from another provider. An example of such valid HIPAA Authorization is available on the Help Me Grow website.
  3. Not all Participants utilizing the OC Children’s Screening Registry will have access to view records from other Service Providers.

**Child Data Protections:** Participating in the OC Children’s Screening Registry is voluntary. A parent not wishing to participate may opt out of the registry without any consequences to receiving services. Participant’s staff are subject to follow guidelines set forth by the Health Insurance Portability and Accountability (HIPAA) and California Health and Safety Codes 130200 (AB211) and 1280.15 (SB541) which require the protection and confidential handling of protected health information. All client records are confidential and are protected in a HIPAA compliant, secure database that will only be accessed by authorized OC Children’s Screening Registry users and Help Me Grow staff for administrative purposes. Child data will be maintained in the OC Children’s Screening Registry for Data Entry Only Participants until the child reaches seventeen (17) years of age, at which time data sharing expires and additional access to this record would require parental/guardian authorization. Child data will be maintained in the OC Children’s Screening Registry for Treating Providers until the child reaches 17 years of age, at which time data sharing expires and additional access to this record would require parental/guardian authorization. A request may be made to discontinue sharing information within a child’s record at any time by submitting a written Request to Remove Confidential Information to Help Me Grow at: 1120 W. La Veta Ave., Suite. 450, Orange, CA 92868 .

**EXHIBIT D**  
**BUSINESS ASSOCIATE AGREEMENT**

This Business Associate Agreement (“BAA”) is made and entered into by and between [Vendor] (“Covered Entity” or “CE”) and Children’s Hospital of Orange County d.b.a. CHOC Children’s Hospital (“Business Associate” or “BA”). This BAA is effective as of \_\_\_\_\_ (the “BAA Effective Date”).

**RECITALS**

- A. CE wishes to disclose certain information to BA that may constitute Protected Health Information (“PHI”) (as defined in the HIPAA Rules), in connection with BA’s performance of services for CE.
- B. CE and BA intend to protect the privacy and provide for the security of PHI disclosed to BA in compliance with the Health Insurance Portability and Accountability Act of 1996, Public Law 104-191 (“HIPAA”), the Health Information Technology for Economic and Clinical Health Act, Public Law 111-005 (“the HITECH Act”), and regulations promulgated thereunder by the U.S. Department of Health and Human Services (the “HIPAA Regulations”) and other applicable state and federal laws and regulations.
- C. As part of the HIPAA Regulations, the Privacy Rule and the Security Rule (defined below) require CE to enter into a contract containing specific requirements with BA prior to the disclosure of PHI, as set forth in, but not limited to, Title 45, Sections 164.314(a), 164.502(e) and 164.504(e) of the Code of Federal Regulations (“C.F.R.”) and contained in this BAA.

In consideration of the mutual promises below and the exchange of information pursuant to this BAA, the parties agree as follows:

**AGREEMENT**

**A. Definitions**

1. Catch-all definition:

The following terms used in this Agreement shall have the same meaning as those terms in the HIPAA Rules: Breach, Data Aggregation, Designated Record Set, Disclosure, Health Care Operations, Individual, Minimum Necessary, Notice of Privacy Practices, PHI, Required by Law, Secretary, Security Incident, Subcontractor, Unsecured PHI, and Use.

2. Specific definitions:

- a. Business Associate. “Business Associate” (“BA”) shall generally have the same meaning as the term “business associate” at 45 CFR 160.103.
- b. Covered Entity. “Covered Entity” (“CE”) shall generally have the same meaning as the term “covered entity” at 45 CFR 160.103.

- c. HIPAA Rules. “HIPAA Rules” shall mean the Privacy, Security, Breach Notification, and Enforcement Rules at 45 CFR Part 160 and Part 164.

## **B. Obligations and Activities of Business Associate**

### Business Associate agrees to:

1. Not use or disclose PHI other than as permitted or required by the Agreement or as required by law;
2. Use appropriate safeguards, and comply with Subpart C of 45 CFR Part 164 with respect to electronic PHI, to prevent use or disclosure of PHI other than as provided for by the Agreement;
3. Report, in writing, to covered entity any use or disclosure of PHI not provided for by the Agreement of which it becomes aware, including breaches of unsecured PHI as required at 45 CFR 164.410, and any security incident of which it becomes aware, without unreasonable delay and in no case later than three (3) days after discovery;
4. Breach notifications to individuals, The HHS Office for Civil Rights (OCR), and potentially the media, will be handled by the CE. BA agrees to pay the actual costs of CE for such notifications, as long as the nature of the breach has been determined to have been caused by the BA or BA’s Subcontractor(s).
5. In accordance with 45 CFR 164.502(e)(1)(ii) and 164.308(b)(2), if applicable, ensure that any subcontractors that create, receive, maintain, or transmit PHI on behalf of the BA agree to the same or more stringent restrictions, conditions, and requirements that apply to the BA with respect to such information;
6. Make available PHI in a designated record set to the CE for inspection and copying within five (5) days of a request by CE to enable CE to fulfill its obligations under 45 CFR 164.524;
7. Make any amendment(s) to PHI in a designated record set as directed or agreed to by the CE pursuant to 45 CFR 164.526, within thirty (30) days of receipt of a request from the CE or take other measures as necessary to satisfy CE’s obligations under 45 CFR 164.526;
8. Maintain and make available, within thirty (30) days of notice by CE or a request, the information required to provide an accounting of disclosures to the CE as necessary to satisfy CE’s obligations under 45 CFR 164.528;
9. To the extent the BA is to carry out one or more of CE's obligation(s) under Subpart E of 45 CFR Part 164, comply with the requirements of Subpart E that apply to the CE in the performance of such obligation(s); and
10. Make its internal practices, books, and records available to CE and the Secretary for purposes of determining compliance with the HIPAA Rules.

**C. Permitted Uses and Disclosures by Business Associate**

1. BA may only use or disclose PHI for the sole purpose of performing BA's obligations as directed by CE and as permitted under this BAA.
2. BA may use or disclose PHI as required by law.
3. BA agrees to make uses and disclosures and requests for only the minimum amount of PHI necessary to accomplish the purpose of the request, use or disclosure.
4. BA may not use or disclose PHI in a manner that would violate Subpart E of 45 CFR Part 164 if done by CE, except for the specific uses and disclosures set forth in paragraphs 5 and 6 below.
5. BA may disclose PHI for the proper management and administration of BA or to carry out the legal responsibilities of the BA, provided the disclosures are required by law, or BA obtains reasonable written assurances from the third party to whom the information is disclosed that the information will remain confidential and used or further disclosed only as required by law or for the purposes for which it was disclosed to the third party, and a written agreement from the third party is in place outlining that the third party immediately notifies BA of any instances of which it is aware in which the confidentiality of the information has been breached.
6. BA may provide data aggregation services relating to the health care operations of the CE.
7. BA shall (i) not use or disclose PHI for fundraising or marketing purposes, except as provided in a separate contract between CE and BA, and consistent with the requirements of 42 U.S.C. 17936; (ii) 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 (iii) not directly or indirectly receive remuneration in exchange for PHI, except with the prior written consent of CE and as permitted by the HITECH Act, 42 U.S.C Section 17935 (d)(2); however, this prohibition shall not affect payment by CE to BA for services provided at the direction of CE.

**D. Provisions for Covered Entity to Inform Business Associate of Privacy Practices and Restrictions**

1. CE shall notify BA of any limitation(s) in the notice of privacy practices of CE under 45 CFR 164.520, to the extent that such limitation may affect BA's use or disclosure of PHI.
2. CE shall notify BA of any restriction on the use or disclosure of PHI that CE has agreed to or is required to abide by under 45 CFR 164.522, to the extent that such restriction may affect BA's use or disclosure of PHI.

## **E. Termination**

1. Material Breach. If either Party (CE or BA) knows of a pattern of activity or practice of the other Party that constitutes a material breach or violation of the BAA, or other arrangement, then the non-breaching Party shall provide written notice of the breach or violation to the other Party that specifies the nature of the breach or violation. The breaching Party must cure the breach or end the violation on or before thirty (30) days after receipt of the written notice. In the absence of a cure reasonably satisfactory to the non-breaching Party within the specified time frame, or in the event the breach is reasonably incapable of cure, then the non-breaching Party may do the following: (a) if feasible, terminate the arrangement; or (b) if termination of the arrangement is infeasible, report the issue to the Secretary of the HHS.
2. Obligations of BA Upon Termination.
  - a. Upon termination of this Agreement for any reason, BA shall return to CE (or, if agreed to by CE, destroy) all PHI received from CE, or created, maintained, or received by BA or its agents or subcontractors on behalf of CE, that the BA or its agents or subcontractors still maintain in any form. BA shall retain no copies of the PHI. BA shall certify in writing to CE that such PHI has been destroyed.
  - b. If return or destruction of said PHI is not feasible, as determined by CE, BA shall continue to use appropriate safeguards and comply with Subpart C of 45 CFR Part 164 with respect to electronic PHI to prevent use or disclosure of the PHI other than for those purposes that make the return or destruction of such PHI infeasible.
3. Survival. The obligations of BA under this Section shall survive the termination of this Agreement.

## **F. Miscellaneous**

1. Amendment. The Parties agree to take such action as is necessary to amend this Agreement from time to time as is necessary for compliance with the requirements of the HIPAA Rules and any other applicable law.
2. Assistance in Litigation. BA shall make itself and any subcontractors, employees or agents assisting BA in the performance of its obligations under this BAA or any other arrangements between CE and BA available to CE, at no cost to CE, to testify as witnesses, or otherwise, in the event of litigation or administrative proceedings being commenced against CE, its directors, officers or employees based upon a claim of violation of HIPAA, the HITECH Act, or other laws related to security and privacy, except where BA or its subcontractor, employee or agent is named as an adverse party.
3. Indemnification; Limitation of Liability. Business Associate shall defend, indemnify and hold harmless Covered Entity, its parent and subsidiary corporations, officers, directors, employees, and agents from any and all claims, inquiries, investigations, costs, reasonable attorneys' fees, monetary penalties, and damages incurred by Covered Entity to the extent resulting directly or indirectly from any acts or

omissions of Business Associate, including without limitation breach of this Agreement by Business Associate.

Covered Entity shall defend, indemnify and hold harmless Business Associate, its parent and subsidiary corporations, officers, directors, employees, and agents from any and all claims, inquiries, investigations, costs, reasonable attorneys' fees, monetary penalties, and damages incurred by Business Associate to the extent resulting directly or indirectly from any acts or omissions of Covered Entity, including without limitation breach of this Agreement by Covered Entity.

This provision shall survive the termination of the BAA.

4. Interpretation. Any ambiguity in this Agreement shall be interpreted to permit compliance with the HIPAA Rules.
5. No Third-Party Beneficiaries. Nothing express or implied in the BAA is intended to confer, nor shall anything herein confer upon any person other than CE, BA and their respective successors or assigns, any rights, remedies, obligations or liabilities whatsoever.
6. Notices. All notices or other communications required or permitted hereunder shall be in writing and shall be deemed given or delivered (a) when delivered personally, against written receipt, (b) if sent by registered or certified mail, return receipt requested, postage prepaid, when received, (c) when received by facsimile transmission, and (d) when delivered by a nationally recognized overnight courier service, prepaid, and shall be sent to the addresses set forth below or at such other address as each party may designate by written notice to the other by following this notice procedure.

a. Written notice to CE under this BAA shall be addressed to:

\_\_\_\_\_  
Attn: \_\_\_\_\_

\_\_\_\_\_  
\_\_\_\_\_

Facsimile: ( ) \_\_\_\_\_

b. Written notice to BA under this BAA shall be addressed to:

Children's Hospital of Orange County dba  
CHOC Children's Hospital  
Attn: Chief Compliance Officer  
1201 W. La Veta Avenue  
Orange, CA 92868  
Phone: (714) 509-3014

7. Regulatory References. A reference in this Agreement to a section in the HIPAA Rules means the section as in effect or as amended.

**IN WITNESS WHEREOF**, the parties hereto have duly executed this BAA as of the BAA Effective Date.

**COVERED ENTITY:**

**[VENDOR]**

By: \_\_\_\_\_

Name: \_\_\_\_\_

Title: \_\_\_\_\_

**BUSINESS ASSOCIATE:**

**CHILDREN'S HOSPITAL OF ORANGE  
COUNTY d.b.a. CHOC CHILDREN'S  
HOSPITAL**

By: \_\_\_\_\_

Name: [Signatory Name]

Title: [Signatory Title]