BUSINESS ASSOCIATE/LIMITED DATA SET USE AGREEMENT

This Business Associate/Limited Data Set Use Agreement (“BAA”) supplements and is made a part of the Inflexxion Behavioral Health Tools Standard Software License Agreement (“License”) entered into by and between ______________________________________ (“Covered Entity”) and Inflexxion, Inc. (“Business Associate”). This BAA is effective as of ____________________, 20__.

RECITALS

Whereas, the administrative simplification provisions of the Health Insurance Portability and Accountability Act of 1996, Public Law 104-191 and regulations promulgated thereunder by the U.S. Department of Health and Human Services, as amended from time to time (“HIPAA”) require that contracts between covered entities and their business associates contain certain enumerated elements;

Whereas, Business Associate’s interaction with Covered Entity makes it a “business associate” as defined under HIPAA;

Whereas, the purpose of this BAA is to satisfy the HIPAA requirements, and the substance abuse treatment confidentiality requirements of 42 CFR Part 2 and state law, as they apply to Covered Entity;

Whereas, this BAA is intended to supplement the primary contract between the parties, documented in the License agreed to by the Covered Entity prior implementing the Inflexxion Behavioral Health Tools, which includes the Addiction Severity Index Multimedia Version (“ASI-MV”), the Behavioral Health Index Multimedia Version (“BHI-MV”), and the Comprehensive Health Assessment for Teens (“CHAT”);

Now therefore, in consideration of the mutual promises below, Covered Entity and Business Associate agree as follows:

Article One

1.1 Operation of ASI-MV Connect Standard Software License Agreement. This BAA shall be subject to the terms of the ASI-MV Connection Standard Software License Agreement (“License”), a form of which agreement is attached.

1.2 Protected Health Information (“PHI”) shall have the same meaning as defined in the HIPAA privacy and security rules, including but not limited to, Title 45, Sections 160.103, 164.308(b), 164.314(a), 164.502(e) and 164.504(e) of the Code of Federal Regulations, as amended from time to time. All other capitalized terms not defined in this BAA shall have the meaning ascribed to them in the HIPAA privacy and security rules unless the context clearly indicates otherwise. Business Associate shall use and disclose PHI in compliance with the HIPAA privacy and security rules, other applicable federal law (including 42 USC § 290dd-2 and regulations promulgated thereunder applicable to substance abuse treatment records), and applicable state privacy law (including state laws protecting the confidentiality of substance abuse treatment records).
1.3 Permitted Uses and Disclosures.

a. Business Associate shall use and/or disclose PHI received by Business Associate from Covered Entity only as necessary to perform the tasks and activities described herein.

b. All uses and disclosures of Protected Health Information shall be limited to the minimum amount of information necessary to carry out a purpose permitted by this BAA.

c. Business Associate shall not use or further disclose PHI received from Covered Entity in any manner except as permitted or required by this BAA and only as Required by Law. “Required by Law” shall have the same meaning as the term “required by law” in 45 CFR 164.103.

d. Business Associate may use and disclose PHI received from Covered Entity (i) for the proper management and administration of the Business Associate, (ii) to carry out the Business Associate’s legal responsibilities, (iii) to de-identify PHI, (iv) to provide data aggregation services relating to Covered Entity’s Treatment and Healthcare Operations as requested by Covered Entity, (v) to create a limited data set without any of the identifiers listed in 45 C.F.R. § 164.514(e) (“Limited Data Set”) for research, public health and Health Care Operations purposes.

e. Covered Entity agrees to provide Business Associate with data from the Addiction Severity Index Multimedia Version (“ASI-MV”), and/or from the Behavioral Health Index Multimedia Version (“BHI-MV”), and/or from the Comprehensive Health Assessment for Teens (“CHAT”), as Covered Entity’s Business Associate, consistent with 45 C.F.R. § 164.502(d)(1), so that Covered Entity’s Data (i) can be aggregated by Business Associate on a de-identified basis with Inflexxion Behavioral Health Tools Data from other clients of Business Associate to create benchmark information against which the Covered Entity’s Inflexxion Behavioral Health Tools Data will be compared by Business Associate and reported to Covered Entity for quality assurance, other Health Care Operations, and research purposes of the Covered Entity and (ii) identifiers listed in 45 C.F.R. § 164.514(e) can be removed from the Inflexxion Behavioral Health Tools Data and that Data can be aggregated by Business Associate in a Limited Data Set for its own or general research purposes, public health purposes, and/or for Health Care Operations purposes of the Covered Entity (“Authorized Purposes”). Covered Entity also understands and acknowledges that Business Associate may use, sell, rent and otherwise disseminate the Inflexxion Behavioral Health Tools Data in aggregated, de-identified form for any purpose, or in the form of a Limited Data Set for Authorized Purposes, or in the form of analyses of such de-identified or Limited Data Set information, in its sole discretion, and that Covered Entity will not be entitled to any compensation for such use of Inflexxion Behavioral Health Tools Data. Business Associate agrees to use and disclose the Limited Data Set only for the Authorized Purposes, and not to use or disclose the Limited Data Set in a manner that would violate the HIPAA privacy rule or applicable state law if the use or disclosure was made by the Covered Entity. Business Associate agrees not to use the Limited Data Set in such a way as to identify any individual whose data is incorporated in the Limited Data Set and further agrees not to contact any such individual.

f. The aggregated de-identified Inflexxion Behavioral Health Tools Data produced by Business Associate either (i) will not include any identifiers listed in 45 C.F.R. § 164.514(b)(2)(i), (ii) will be in the form of a Limited Data Set, without any of the identifiers listed in 45 C.F.R. § 164.514(e) and used for Authorized Purposes and/or (iii) will have been determined by a person with appropriate
knowledge of and experience with generally accepted statistical and scientific principles and methods for rendering information not individually identifiable and applying such principles and methods, that the risk is very small that the aggregated de-identified Inflexxion Behavioral Health Tools Data generated by Business Associate under this BAA could be used, alone or in combination with other reasonably available information, by an anticipated recipient, to identify an individual who is a subject of the information, thereby forming a “statistically de-identified data set” and rendering the information not PHI under HIPAA.

1.4 Appropriate Safeguards. Business Associate agrees that it will implement reasonable and appropriate safeguards to prevent its use or disclosure of PHI or Limited Data Set received from Covered Entity other than as set forth in this BAA. Business Associate further agrees that it will appropriately safeguard electronic PHI in accordance with the standards specified at 45 CFR §164.314(a). In particular, Business Associate will implement administrative, physical and technical safeguards that reasonably and appropriately protect the confidentiality, integrity and availability of electronic PHI that it creates, receives, maintains or transmits on behalf of Covered Entity.

1.5 Reporting of Disclosures of PHI. Business Associate shall report to Covered Entity any suspected or actual breach of security, intrusion or unauthorized use of disclosure of PHI or a Limited Data Set and/or any actual or suspected use or disclosure of PHI or a Limited Data Set in violation of any applicable federal or state laws or regulations, or this BAA, as soon as possible after becoming aware of it. Business Associate also agrees to report in writing to Covered Entity any security incident (as defined in 45 CFR §164.304) as soon as possible after Business Associate becomes aware of such an incident. Business Associate shall take (i) prompt corrective action to cure any deficiencies that caused the security incident or unauthorized use or disclosure, (ii) any corrective action required by applicable federal and state law and (iii) to mitigate, to the extent practicable, any harmful effect that is known to Business Associate of a use or disclosure of PHI by Business Associate in violation of the requirements of this BAA.

1.6 Agents and Contractors. Business Associate shall ensure that any agent or contractor that will have access to PHI or a Limited Data Set obtained from Covered Entity agrees to be bound by the same restrictions, terms and conditions that apply to Business Associate pursuant to the BAA. To the extent that Business Associate discloses PHI or a Limited Data Set to an agent or contractor, Business Associate (i) will obtain, prior to making any such disclosure, reasonable assurances from such third party that such PHI or Limited Data Set will be held confidential pursuant to the same restrictions, terms and conditions that apply to Business Associate under this BAA, (ii) will obtain reasonable assurance from such third party that the PHI or Limited Data Set will be disclosed by such third party only as required by law or for the purposes for which it was disclosed to such third party, and (iii) obtain an agreement from such third party to immediately notify Business Associate of any breach of confidentiality of the PHI or Limited Data Set, to the extent it has obtained knowledge of such breach.

1.7 Retention of PHI. Business Associate shall maintain and retain PHI for the term of the BAA and make such PHI available to Covered Entity as set forth in this BAA.

1.8 Access to and Availability of PHI. Within 7 days of a request by Covered Entity, Business Associate shall:

a. Make available to Covered Entity PHI in Business Associate’s possession as needed to permit Covered Entity to respond to an individual’s request for access to PHI. If Business Associate
received a request directly from the individual, the Business Associate shall within 7 days forward the request to the Covered Entity along with the requested PHI. Covered Entity shall be responsible for responding to all individual requests for access to the PHI.

b. Provide to Covered Entity PHI as needed to respond to a request for amendment of PHI, and shall incorporate any amendment to the PHI held by Business Associate received from Covered Entity.

c. Make available to Covered Entity the information required to permit Covered Entity to respond to an individual’s request for an accounting of disclosures of PHI to the extent required by HIPAA. If Business Associate receives a request for an accounting directly from the individual, the Business Associate shall within seven (7) days forward the request to the Covered Entity along with the information needed to respond to the request for accounting. Covered Entity shall be responsible for responding to all individual requests for accounting of disclosures.

d. Business Associate agrees to implement an appropriate record keeping process to enable it to comply with the requirements of this Section 1.7.

1.9 Availability of Business Associate’s Internal Practices, Books and Records. Business Associate agrees to make its internal practices, policies and procedures, books and records relating to the use and disclosure of PHI available to the Secretary of Health and Human Services and to Covered Entity for the purposes of determining Covered Entity’s and Business Associate’s compliance with this BAA and the HIPAA privacy standards.

1.10 Conforming Amendments. Business Associate agrees that this BAA shall be amended from time to time as necessary to comply with amendments to the HIPAA and/or the substance abuse treatment confidentiality requirements of 42 CFR Part 2 and applicable state law.

Article Two

2.1 Termination of Business Relationship.

a. Notwithstanding any inconsistent provision of any other agreement between Covered Entity and Business Associate, Covered Entity may terminate the business relationship outlined in the License between Covered Entity and Business Associate if Covered Entity determines that Business Associate has materially breached this BAA and Business Associate fails to cure said breach within such thirty (30) day period or such longer period as may be required to cure such breach using reasonable diligence.

b. If Business Associate’s efforts to cure such breach is unsuccessful, Covered Entity shall terminate this BAA, if feasible or (ii) if termination of this Agreement is not feasible, Covered Entity shall report the breach or violation to the Secretary of the Department of Health and Human Services.

c. Covered Entity may terminate the business relationship upon ninety (90) days notice if Business Associate refuses to amend this BAA as necessary to comply with federal or state laws or regulations relating to the administrative simplification, privacy, or information security provisions of HIPAA or substance abuse treatment confidentiality requirements under 42 CFR Part 2 or applicable state law.
d. In the event of any termination of the business relationship between the parties, Business Associate shall return or destroy all PHI and Limited Data Set information obtained from or on behalf of Covered Entity that Business Associate still maintains in any form and shall retain no copies. If return or destruction is not feasible, Business Associate may retain such PHI and Limited Data Set information but shall continue to protect the confidentiality of such PHI and Limited Data Set information as required by this BAA and limit any use or disclosure of such PHI and Limited Data Set information to those purposes that make the return of destruction of the same infeasible.

2.2 Term and Termination of BAA. This BAA shall remain in effect so long as Business Associate and Covered Entity have a business relationship that requires the use, disclosure, maintenance or transmission of PHI. Upon termination of the underlying License or business relationship, this BAA shall terminate, except for sections 2.1(b), 2.3 and 2.4, which shall survive termination of this BAA.

2.3 Retention of Protected Information. Business Associate and its contractors or agents shall retain communications and documents required to be maintained as required by HIPAA.

2.4 Applicable Law; Disputes. This BAA shall be construed under the laws of the Commonwealth of Massachusetts. All disputes arising under this BAA shall be resolved by a State or Federal Court located in Boston, Massachusetts, and both parties agree to the venue and jurisdiction of such courts.

2.5 Entire BAA. Apart from the separate terms identified in the License, this BAA constitutes the complete agreement of the parties relating to the matters specified herein and supersedes all prior representations or agreements, whether oral or written, with respect to such matters. No oral modification or waiver of any of the provisions of this BAA shall be binding on either party. Only a written instrument signed by both parties may amend this BAA. This BAA for the benefit of, and shall be binding upon, only the parties hereto and their respective successors and assigns.

2.6 Notice. Any notice required to be given by one party to the other under this BAA shall be deemed received when sent if sent by United States mail, certified mail return receipt requested, postage prepaid, or shall be deemed received as of the next business day after faxing the written notice to the last known fax number of the receiving party and obtaining oral confirmation of receipt from an individual answering the phone at the receiving party’s last known telephone number. Notices shall be addressed as follows:

To Covered Entity at:  
Agency: ________________________________
Address: ________________________________
City/State/Zip: ________________________________
Facsimile: ________________________________
Phone: ________________________________
Attn: ________________________________

To Business Associate at:  
Name: Inflexxion, Inc.
Address: 320 Needham Street, Suite 100
City/State/Zip: Newton, MA 02464
IN WITNESS WHEREOF, Covered Entity and Business Associate have duly executed this BAA as of the date listed below.

Business Associate: Inflexxion, Inc.

    Signature: ______________________________________
    Print Name: ______________________________________
    Print Title: ______________________________________
    Date: ____________________________________________

Covered Entity:

    Signature: ______________________________________
    Print Name: ______________________________________
    Print Title: ______________________________________
    Date: ____________________________________________
Addendum

Inflexxion Behavioral Health Tools Standard Software License Agreement (“License”)

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NOTE: The BAA is intended to address the requirements of HIPAA governing Covered Entities and Business Associates (as defined under HIPAA). The BAA is NOT the primary agreement for use of the Software between You and Inflexxion. This License is the primary agreement for use of the Software.

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