BUSINESS ASSOCIATE AGREEMENT

This **Business Associate Agreement** ("Agreement"), effective _____, 201__ ("Effective Date"), is entered into by and between _____ [Insert name of physician/practice] ("Covered Entity") and InstantDx, LLC ("InstantDx, LLC" or the "Business Associate"), (each a "Party" and collectively the "Parties").

The Parties have a Subscription Agreement dated _____ (the "Underlying Agreement") under which the Business Associate uses and/or discloses Protected Health Information ("PHI," which, for purposes of this Agreement, includes both Electronic PHI and PHI that is not Electronic PHI) in its performance of the Services described below. The Parties are committed to complying with the Standards for Privacy of Individually Identifiable Health Information (the "Privacy Rule") and the Standards for Security of Electronic Protected Health Information (the "Security Rule") under the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") as well as any obligations arising from changes made to HIPAA or the Security Rule and Privacy Rule pursuant to the American Recovery and Reinvestment Act of 2009 ("ARRA") and its implementing regulations. This Agreement, in conjunction with the Privacy and Security Rules, sets forth the terms and conditions pursuant to which PHI (electronic and non-electronic) that is created, received, maintained, or transmitted by, the Business Associate from or on behalf of Covered Entity, will be handled between the Business Associate and Covered Entity and with third parties during the term of their Underlying Agreement and after its termination.

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

Specific Definitions:

HIPAA Rules. Privacy, Security, Breach Notification, and Enforcement Rules at 45 C.F.R. Part 160 and Part 164.

HITECH Act. Public Law 104-191, the Health Information Technology for Economic and Clinical Health Act.

Electronic Protected Health Information or Electronic PHI. Electronic PHI which is transmitted by Electronic Media (as defined in the HIPAA Security and Privacy Rule) or maintained in Electronic Media.

Privacy Rule. Privacy Rule shall mean the Standards for Privacy of Individually Identifiable Health Information at 45 C.F.R. part 160 and part 164.

Security Rule. Security Rule shall mean the Standards for Security of Electronic Protected Health Information at 45 C.F.R. Parts 160, 162, and 164.

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

The Parties hereby agree as follows:

1. **PERMITTED USES AND DISCLOSURES OF PHI**

1.1 <u>Services</u>. Pursuant to the Underlying Agreement, Business Associate provides or may provide services ("Services") for Covered Entity that involve the Use and Disclosure of PHI. Except as otherwise specified herein, the Business Associate may make any and all uses of PHI necessary to perform its obligations for the Covered Entity under the Underlying Agreement. All other uses not authorized by this Agreement are prohibited. Moreover, Business Associate may disclose PHI for the purposes authorized by this Agreement only to its employees, Subcontractors and agents, in accordance with Section 2.1.6., or as otherwise permitted by or as required by the Privacy or Security Rule, but only for the purpose of performing services for Covered Entity.

1.2. <u>Business Activities of the Business Associate</u>. Unless otherwise limited herein and if such Use or Disclosure of PHI would not violate the Privacy or Security Rules if done by the Covered Entity, the Business Associate may:

1.2.1. Use the PHI in its possession for its proper management and administration and to fulfill any present or future legal responsibilities of the Business Associate to the Covered Entity provided that such uses are permitted under state and federal confidentiality laws.

1.2.2. Disclose the PHI in its possession to third parties for the purpose of its proper management and administration or to fulfill any present or future legal responsibilities of the Business Associate to the Covered Entity, provided that the Business Associate represents to Covered Entity, in writing, that (i) the Disclosures are required by law, as provided for in 45 C.F.R. §103 or (ii) the Business Associate has received from the third party written assurances regarding its confidential handling of such PHI as required under 45 C.F.R. §164.504(e)(4) and §164.314, and the third party notifies the Business Associate of any instances of which it is aware in which the confidentiality of the information has been breached.

1.2.3. Perform data aggregation services as permitted by 45 C.F.R. §164.504(e)(2)(i)(B), and de-identify PHI in accordance with 45 C.F.R. §164.514.

2. **RESPONSIBILITIES OF THE PARTIES WITH RESPECT TO PHI**

2.1 <u>Responsibilities of the Business Associate</u>. With regard to its Use and/or Disclosure of PHI, the Business Associate hereby agrees to do the following:

2.1.1. Not use or disclose PHI other than as permitted or required by this Agreement or the Underlying Agreement or as required by law.

2.1.2. Use reasonable and appropriate safeguards to prevent the Use or Disclosure of PHI, other than as provided for in this Agreement, the Underlying Agreement or as Required by Law.

2.1.3. Implement administrative, physical, and technical safeguards that reasonably and appropriately protect the confidentiality, integrity, and availability of PHI pursuant to 45 C.F.R. §164, Subpart C.

2.1.4. Comply with all applicable requirements of the Security Rule contained

in 45 C.F.R. §164.308, §164.310, §164.312, §164.314 and §164.316.

2.1.5. Report, in writing, to Covered Entity within five (5) business days any Use or Disclosure of PHI not provided for by this Agreement or the Underlying Agreement of which it becomes aware, including Breaches of unsecured PHI as required at 45 C.F.R. §164.410, and any Security Incident of which it becomes aware, and cooperate with the Covered Entity in any mitigation or Breach reporting efforts. Such notification shall include: (i) the individual who has been, may be or is reasonably believed to have been affected by the Breach; (ii) the date of the Breach; (iii) the date of the discovery of the Breach; (iv) the scope and nature of the Breach; and (v) any steps Business Associate has taken to mitigate any harmful effects of the Breach and to protect against any further Breaches. In all cases, the information included in Business Associate's notification shall be in accordance with any regulations and guidance provided by the Secretary of the United States Department of Health and Human Services.

2.1.6. In accordance with 45 C.F.R. §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 Business Associate agree pursuant to a written agreement to the same restrictions, conditions, and requirements that apply to the Business Associate with respect to such information, including but not limited to the implementation of reasonable and appropriate safeguards to protect Covered Entity's PHI.

2.1.7. Within five (5) business days of a request by Covered Entity, make available PHI in a designated record set, if applicable, to Covered Entity, as necessary to satisfy Covered Entity's obligations under 45 C.F.R. §164.524.

2.1.8. Within five (5) business days, make any amendment(s) to PHI, if applicable, in a designated record set as directed or agreed to by the Covered Entity pursuant to 45 C.F.R. §164.526, or take other measures as necessary to satisfy Covered Entity's obligations under 45 C.F.R. §164.526.

2.1.9. Within five (5) business days of receipt of a written request from Covered Entity, make available to Covered Entity information necessary for Covered Entity to make an accounting of Disclosures of PHI about an individual in accordance with 45 C.F.R. §164.528.

2.1.10. To the extent the Business Associate is to carry out one or more of Covered Entity's obligation(s) under Subpart E of 45 C.F.R. Part 164, comply with the requirements of Subpart E that apply to the Covered Entity in the performance of such obligation(s).

2.1.11. Make its internal practices, books, and records available to the Secretary for purposes of determining compliance with the HIPAA Rules.

2.1.12. Comply with minimum necessary requirements under the HIPAA Rules.

2.2 Responsibilities of Covered Entity. With regard to the Use and/or Disclosure of PHI by the Business Associate, Covered Entity hereby agrees to do the following:

2.1.1. Inform the Business Associate of any limitations in the form of Notice of Privacy Practices that Covered Entity provides to individuals pursuant to 45 C.F.R. §164.520, to the extent that such limitation may affect Business Associate's Use or Disclosure of PHI.

2.1.2. Inform the Business Associate of any changes in, or revocation of, the permission by an individual to use or disclose PHI, to the extent that such limitation may affect Business Associate's Use or Disclosure of PHI.

2.1.3. Notify the Business Associate, in writing and in a timely manner, of any restriction on the Use or Disclosure of PHI that Covered Entity has agreed to or is required to abide by under 45 C.F.R. §164.522, to the extent that such restriction may impact in any manner the Use and/or Disclosure of PHI by the Business Associate under this Agreement or the Underlying Agreement, except if the Business Associate will use or disclose PHI for data aggregation or management if provided for by the Underlying Agreement or administration and/or legal responsibilities of the Business Associate.

2.1.4. Not request Business Associate to use or disclose PHI in any manner that would not be permissible under the Privacy and Security Rule if done by the Covered Entity.

3. TERM AND TERMINATION

3.1. Term. The term of this Agreement shall be effective as of the Effective Date and shall terminate when all of the PHI provided by Covered Entity to Business Associate, or created or received by Business Associate on behalf of Covered Entity, is destroyed or returned to Covered Entity, or, if it is infeasible to return or destroy PHI, protections are extended to such information, in accordance with the termination provisions in this section.

3.2. Termination by Covered Entity. Covered Entity may immediately terminate this Agreement and any related agreements, if any, if Covered Entity makes the determination that Business Associate has breached a material term. Alternatively, Covered Entity may choose to provide Business Associate with thirty (30) days written notice of the existence of any alleged material breach; and afford Business Associate an opportunity to cure said alleged material breach upon mutually agreeable terms. Nonetheless, in the event that mutually agreeable terms cannot be achieved within ten (10) days, Business Associate must cure said breach to the satisfaction of Covered Entity within thirty (30) days after the written notice described above. Failure to cure in the manner set forth in this paragraph is grounds for the immediate termination of this Agreement.

3.3. Termination by Business Associate. If Business Associate makes the determination that a material condition of performance has changed under this Agreement or that Covered Entity has breached a material term of this Agreement, Business Associate may provide thirty (30) days' notice of its intention to terminate this Agreement. Business Associate agrees, however, to cooperate with Covered Entity to find a mutually satisfactory resolution to the matter prior to terminating this Agreement.

3.4. <u>Effect of Termination</u>. Upon the event of termination pursuant to Section 3 of this Agreement, Business Associate will promptly return or destroy, in accordance with standards approved by the Department of Health and Human Services, all PHI, in whatever format, maintained by Business Associate and/or its Subcontractors. Business Associate will provide written assurance to Covered Entity that all PHI maintained by Business Associate and/or its Subcontractors has been destroyed in accordance with standards approved by the Department of Health and Human Services, or returned to Covered Entity.

    3.4.1. In the alternative, Business Associate agrees to assess the feasibility of returning and/or destroying all PHI in light of applicable law and reasonable business practices and standards. Business Associate will also assess the feasibility of recovering any PHI in the possession of its Subcontractors or agents.

    3.4.2. If it is not feasible for Business Associate to return and/or destroy said PHI, Business Associate will notify Covered Entity in writing within thirty (30) days from the date of termination. Said notification shall include a statement that Business Associate has determined that it is infeasible to return and/or destroy the PHI in its possession, and the specific reasons for such determination.

    3.4.3. Business Associate further agrees to extend any and all protections, limitations, and restrictions contained in this Agreement to all PHI retained by Business Associate after the termination of this Agreement, and to limit any further Uses and/or Disclosures of PHI to the purposes that make the return and/or destruction of the PHI infeasible for so long as Business Associate maintains the PHI.

    3.4.4. If it is infeasible for Business Associate to obtain, from a Subcontractor or agent, any PHI in the possession of the Subcontractor or agent, Business Associate will also provide a written explanation to Covered Entity. Further, Business Associate will require its Subcontractors and agents to agree to extend any and all protections, limitations, and restrictions contained in this Agreement to all PHI retained by the Subcontractors and/or agents after the termination of this Agreement, and to limit any further Uses and/or Disclosures to the purposes that make the return and/or destruction of the PHI infeasible for so long as the Subcontractors and/or agents maintain the PHI.

    3.4.5. Notwithstanding any provision of the Underlying Agreement, the Underlying Agreement shall terminate immediately upon the termination of this Agreement regardless of the reason for the termination of this Agreement.

4. **AMENDMENT.** In the event there is a change to, or amendment of, the HIPAA Rules or the HITECH Act (or a change in the interpretation of the HIPAA Rules or HITECH Act) that necessitates a change to this Agreement, Covered Entity may amend this Agreement by providing thirty (30) days advance written notice of any amendment to Business Associate by letter or amendment. Such letter or amendment is deemed to have been received by Business Associate on the "Date of Receipt", a date that is five (5) business days after the date Covered Entity has deposited such letter or amendment in the U.S. Mail, first class with postage prepaid, to Business Associate at the address listed on the signature page. Any changes to this Agreement set forth in such letter or amendment will be deemed accepted by

Business Associate if no written response expressly rejecting such amendment is received by Covered Entity (at the address indicated in such letter or amendment) from Business Associate within thirty (30) days of the Date of Receipt. If Business Associate responds in writing within such thirty (30) day time frame that it does not accept such changes, the Parties agree to negotiate in good faith appropriate amendment(s) to this Agreement to give effect to such revised obligations. If the Parties are unable to agree to such amendment(s) within thirty (30) days prior to the effective date of the amendment of the HIPAA Rules (or within ninety (90) days after the publication of the change in interpretation of HIPAA Rules), then either Party may terminate this Agreement consistent with its terms.

5. **FURTHER ASSURANCES.** Each Party shall in good faith execute, acknowledge or verify, and deliver any and all documents which may from time to time be reasonably requested by the other Party to carry out the purpose and intent of this Agreement.

6. **CONFLICTS.** The Parties agree that any ambiguity in this Agreement shall be resolved in favor of a meaning that complies and is consistent with HIPAA Rules or the HITECH Act, including any subsequent amendments or interpretations.

7. **NO THIRD PARTY BENEFICIARIES OR AGENCY.** Nothing express or implied in this Agreement shall confer upon any person, other than Business Associate and Covered Entity and their respective successors or permitted assigns, any rights, remedies, obligations or liabilities whatsoever. It is the intent and agreement of the Parties that in performing this Agreement, Business Associate is an independent contractor of Covered Entity, and not an agent of Covered Entity.

8. **GOOD FAITH.** The Parties agree to exercise good faith in the performance of this Agreement.

9. **NOTICE.** Any notice to be given to Covered Entity pursuant to this Agreement shall be given in writing to Covered Entity's representative signing below at the address provided below. Any notice to be given to Business Associate pursuant to this Agreement shall be given in writing to Business Associate's representative signing below at the address provided below (or, if no address is provided below, to any address Covered Entity reasonably believes will reach Business Associate). Any Party desiring to change its listed address must give written notice in the foregoing manner to the other Party.

[Signature Page Follows]

IN WITNESS WHEREOF, Covered Entity and Business Associate have duly executed this Agreement as of the dates set out beneath their respective signatures.

<mark>_____</mark>   **("Covered Entity")**

By: _____

Name: _____

Title: _____

Date: _____

Address: _____

E-Mail: _____

InstantDx, LLC   **("Business Associate")**

By:_____

Name: _____

Title: _____

Date:_____

Address: 9801 Washington Blvd., Gaithersburg, MD 20878

E-Mail: _____