

## SeleCT Portal Terms and Conditions

(revised: July 2020)

Welcome to Imbio Portal (the “Portal”), a website and online service of Imbio, LLC (collectively “Imbio”, “We”, “Us” and “Our”). This Portal Terms and Conditions Agreement (the “Agreement”) is made by and between Imbio, LLC, a Minnesota corporation located at 1015 Glenwood Avenue, Floor 4, Minneapolis MN 55413, and the customer accepting this agreement (customer hereinafter referred to as “Customer”, “You” and “Your”).

You have indicated that You wish to subscribe to the Portal software services offered by Imbio as defined herein, and Imbio agrees to make services, software or applications owned, controlled, or offered by Imbio (which may include, as applicable, content and offline components such as associated media, printed materials, and electronic documentation) (collectively the “Services”) available to You for the purpose of either (i) a limited time (the “Trial Period”) for the purpose of evaluating the Services, or (ii) an ongoing use of the Services, subject to the completion of any additional subscription, research, beta or other use agreement as may be required by Imbio. If You have a separate fully executed and current subscription, research, beta or other use agreement with Imbio, such other agreement takes precedence over this Portal agreement where any conflicts may exist.

BY ACCEPTING THIS AGREEMENT, EITHER BY CLICKING A BOX INDICATING YOUR ACCEPTANCE OR BY EXECUTING ANOTHER AGREEMENT, ORDER FORM OR QUOTATION THAT REFERENCES THIS AGREEMENT, YOU AGREE TO THE TERMS OF THIS AGREEMENT. IF YOU ARE ENTERING INTO THIS AGREEMENT ON BEHALF OF A COMPANY OR OTHER LEGAL ENTITY, YOU REPRESENT THAT YOU HAVE THE AUTHORITY TO BIND SUCH ENTITY AND ITS AFFILIATES TO THESE TERMS AND CONDITIONS, IN WHICH CASE THE TERMS “YOU” OR “YOUR” SHALL REFER TO SUCH ENTITY AND ITS AFFILIATES. IF YOU DO NOT HAVE SUCH AUTHORITY, OR IF YOU DO NOT AGREE WITH THESE TERMS AND CONDITIONS, YOU MUST NOT ACCEPT THIS AGREEMENT AND MAY NOT USE THE SERVICES.

### 1. TERM AND TERMINATION.

1.1 Term and Termination. This Agreement commences on the date You first accept it and continues until (i) any Trial Period set forth herein has expired or has been terminated, or (ii) any related subscription, research, beta or other use agreement expires or is terminated.

1.2 Trial Periods. If You are subscribing to the Services for a Trial Period, such Trial Period for this agreement begins upon your first login to Portal and continues for the lesser of (a) the number of days indicated on the Imbio web site as the offered trial period at the time at which You request Your trial, or (b) the expiration of the trial credits offered to You to utilize the Services. In no circumstance, will a Trial Period exceed ninety (90) days. Either party may terminate a Trial Period for any reason or no reason upon seven (7) days notice to the other party.

1.3 Cessation of Use. Upon expiration or termination of this Agreement, You may no longer utilize the Services and We will terminate your access to the Services. We will delete all of Your data and any outputs You generate as you utilize the Services within thirty (30) days of the expiration or termination of this Agreement.

## 2. USE OF SERVICES

2.1 Your Responsibilities. Subject to Your use of Services in accordance with the terms of this Agreement, Imbio hereby grants You a non-exclusive, non-transferable right to permit Your employees or other users authorized by You (“Users”) to use the Services during the term of this Agreement solely for Your internal business operations. You will (a) be responsible for Users’ compliance with this Agreement and be responsible for any breach of this Agreement by the Users, (b) be solely responsible for the accuracy, quality, integrity and legality of Your data and the means by which You acquired Your data, (c) use Services only in accordance with any documentation provided by Imbio and applicable laws and government regulations.

2.2 Usage Restrictions; Reservation of Rights. All title, rights, ownership and copyrights in and to the software used in providing the Services, the accompanying media and printed materials are owned at all times by Imbio or its licensors. You will not (a) make any Service available to, or use any Service or Content for the benefit of, anyone other than You or Your Users, (b) use a Service to store or transmit infringing, libelous, or otherwise unlawful or tortious material, or to store or transmit material in violation of third-party privacy rights (including, but not limited to, the PHI of patients, as defined by the laws and regulations commonly referred to as HIPAA), or (c) attempt to defeat, avoid, by-pass, remove, deactivate, or otherwise circumvent any software protection mechanisms in the Services. Subject to the limited rights expressly granted hereunder, We and Our licensors reserve all of Our/their right, title and interest in and to the Services, including all of Our/their related intellectual property rights. No rights are granted to You hereunder other than as expressly set forth herein.

2.3 Olympus Spiration® Valve System (SVS) Usage Restrictions. The following additional usage restrictions apply for Olympus Corporation SeleCT Services. You may permit Your employees or other users authorized by You (“Users”) to use the Services during the Term solely for evaluating potential patients for Bronchoscopic Lung Volume Reduction treatment with the Olympus Spiration® Valve System (SVS) (“Purpose”). You will not use the Services for any purpose other than the exclusive Purpose. Further, you acknowledge that based on the EMPROVE randomized clinical trial data, the use of the Services consistent with the Purpose should result in approximately twenty-five percent (25%) of patients qualifying for treatment with the Olympus SVS (“Patient Qualification Ratio”). IMBIO RESERVES THE RIGHT, WITHOUT LIABILITY TO YOU, TO DISABLE YOUR ACCESS TO THE SERVICES FOR MATERIAL DEVIATION FROM THE EMPROVE PATIENT QUALIFICATION RATIO.

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2.4 Medical Use. You understand that the Services offered by us involve software used to supplement the treatment of patients undergoing medical procedures. The Services are only to be used as a supplement to standard methods of interpreting radiological images. If any of the Services You utilize under the terms of this Agreement are identified by Imbio as a beta application (for example, identified as Beta Products, Beta Software, Beta Applications, Research Use Only, or Investigational Use Only) (collectively, “Beta Services”), You understand that such Beta Services are not intended for clinical usage, and You agree that You will not use the Beta Services for clinical patient treatment purposes. Any Beta Services will be identified by Imbio on the Portal website or will produce outputs labeled to indicate beta, research or investigational use only.

## 3. PATIENT PRIVACY AND PROTECTED HEALTH INFORMATION

3.1 HIPAA Compliance. Imbio represents that, to the extent required by law, the Services provided under this Agreement will comply in all material respects with the privacy standards adopted by the U.S. Department of Health and Human Services as they may be amended from time to time, 45 C.F.R. parts 160 and 164, subparts A and E (“the Privacy Rule”) and the security standards adopted by the U.S. Department of Health and Human Services as they may be amended from time to time, 45 C.F.R. parts 160, 162 and 164, subpart C (“the Security Rule”). Collectively, the Privacy Rule and the Security Rule are referred to herein as “HIPAA Rules.”

3.2 Business Associate Agreement. To the extent that HIPAA Rules (45 C.F.R. Section 164.504(e)) may require a “Business associate contract” between You or the Legal Entity that You represent as a covered entity, and Imbio as a business associate, attached and incorporated herein and agreed to by the parties is Exhibit A, “HIPAA Business Associate Agreement”. Terms of Exhibit A shall be considered binding upon your acceptance of this Agreement and shall remain in effect during the term of the Agreement including any extensions. To the extent You require a “Business associate contract” with Olympus America Inc., as a business associate (as defined in this section 3) and provider of medical devices relating directly to the Services and section 2.3 of this Agreement, the terms of Exhibit B, “Olympus Business Associate Agreement”) shall be considered binding upon your acceptance of this Agreement and shall remain in effect during the term of the Agreement including any extensions.

3.3 GDPR Compliance. Imbio represents that, to the extent required by law, the Services provided under this Agreement will comply in all material respects with the EU General Data Protection Regulation 2016/679 referred to herein as “GDPR”. If You are a User to which GDPR protections apply, You acknowledge that Imbio collects your personal information through the Portal registration process and through Your Portal online user profile. This information is retained to document and support Your subscription and may be used by Imbio to contact You regarding Your subscription, Your use of the Services and product notices or other marketing communications related to the Services You are using so long as You maintain an active subscription to the Services. Imbio shall not sell, share or otherwise transfer any of Your personal information to any 3rd party other than as may be required for performing the Services and Imbio communications authorized herein. You may contact IMBIO at support@imbio.com to edit, correct, change, or delete your personal information at any time, or to terminate your use of the Services under a Trial Period at any time.

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3.4 Non-U.S. and EU Users or Entities. IMBIO DOES NOT WARRANT OR REPRESENT that the Services provided hereunder meet all international laws and regulations regarding personal or patient privacy and protected health information, except for the representations in sections 3.1 and 3.3 of this Agreement. IMBIO DOES REPRESENT that We shall take substantially the same measure of care and apply the same internal policies, procedures and standards in managing and protecting Your data as We do to meet the HIPAA compliance standards per section 3.1 of this agreement, for all users of the Services. If You or the Legal Entity you represent are not subject to or protected by the representations in sections 3.1 and 3.3 of this Agreement, You are responsible to ensure that Your use of the Services and any data that You may uploaded to Imbio shall comply with Your internal processes and policies, and any applicable governmental laws or regulatory requirements pertaining to patient privacy and protected patient health information. You hereby accept sole liability for non-compliance with laws or regulations regarding patient privacy and protected health information.

## 4. CONFIDENTIALITY

The parties agree that the data exchanged by the parties under the terms of this Agreement, including but not limited to the data uploaded to and downloaded from the Portal website, as well as the information contained on the Portal website itself, are considered Confidential Information. In addition, any data, including the existence of, the user interface of, Your use of and outputs of any Beta Services shall be considered Confidential. The receiving party will use the same degree of care that it uses to protect the confidentiality of its own confidential information of like kind (but not less than reasonable care) not to use any Confidential Information of the disclosing party for any purpose outside the scope of this Agreement,. The obligations under this Section 3 shall remain in force for a term expiring two (2) years after the expiration of this Agreement.

## 5. INDEMNIFICATION & LIMITATION OF LIABILITY

5.1 Indemnification by Us. We will defend You against any claim, demand, suit or proceeding made or brought against You by a third party alleging that the use of the Services in accordance with this Agreement infringes or misappropriates such third party's intellectual property rights (a "Claim Against You"), and will indemnify You from any damages, attorney fees and costs finally awarded against You as a result of a Claim Against You, provided You (a) promptly give Us written notice of the Claim Against You, (b) give Us sole control of the defense and settlement of the Claim Against You, and (c) give Us all reasonable assistance, at Our expense. The above defense and indemnification obligations do not apply to the extent a Claim Against You arises from Your use of the Services in a manner contrary to the instructions given to You by Us, or Your breach of this Agreement. In addition, Imbio shall not be responsible for any compromise or settlement made without its written consent. THE FOREGOING STATES THE ENTIRE LIABILITY OF IMBIO FOR INFRINGEMENT AND SHALL BE CUSTOMER'S SOLE AND EXCLUSIVE REMEDY AND IMBIO'S SOLE OBLIGATION AND LIABILITY FOR ANY ALLEGED INFRINGEMENT.

5.2 Indemnification by You. Except as is specified in Section 5.1, You will defend us and hold us harmless against any claim, demand, suit or proceeding made or brought against us by a third party resulting from Your use of the Services under the terms of this Agreement, including indemnifying us against any damages, costs or attorney fees as a result of any such claim.

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5.3 Limitation of Liability. IMBIO ACCEPTS NO LIABILITY WITH RESPECT TO ANY INCIDENT ARISING OUT OF OR RELATED TO THIS AGREEMENT EXCEPT FOR LIABILITY ARISING DIRECTLY FROM INFRINGEMENT OR MISAPPROPRIATION OF A THIRD PARTY'S INTELLECTUAL PROPERTY RIGHTS BY IMBIO.

5.4 Exclusion of Consequential and Related Damages. IN NO EVENT WILL EITHER PARTY HAVE ANY LIABILITY TO THE OTHER PARTY FOR ANY LOST PROFITS, REVENUES OR INDIRECT, SPECIAL, INCIDENTAL, CONSEQUENTIAL, COVER OR PUNITIVE DAMAGES. THIS DISCLAIMER WILL NOT APPLY TO THE EXTENT PROHIBITED BY LAW.

## 6. GENERAL

6.1 Surviving Provisions. The Sections titled "Usage Restrictions," "Patient Privacy and Protected Health Information," "Reservation of Rights," "Confidentiality," "Indemnification & Limitation of Liability," and "General Provisions" will survive any termination or expiration of this Agreement.

6.2 General Provisions. The parties mutually agree i) this Agreement shall be governed by the laws of the State of Minnesota, each party agrees to the applicable governing law without regard to choice or conflicts of law rules, and to the exclusive jurisdiction of the applicable courts above; ii) neither party may assign any of its rights or obligations hereunder, without the other party's prior written consent (not to be unreasonably withheld), except that Imbio may assign this Agreement in its entirety without the other party's consent to its affiliate or in connection with a merger, acquisition, corporate reorganization, or sale of all or substantially all of its assets. used in the performance of the services hereunder; iii) the parties are independent contractors, this Agreement does not create a partnership, franchise, joint venture, agency, fiduciary or employment relationship between the parties; iv) no failure or delay by either party in exercising any right under this Agreement will constitute a waiver of that right; and v) if any provision of this Agreement is held by a court of competent jurisdiction to be contrary to law, the provision will be deemed null and void, and the remaining provisions of this Agreement will remain in effect.

6.3 Third Party Terms. To the extent You require a "Business associate contract" with Olympus America Inc., as a business associate (as defined in section 3) and provider of medical devices relating directly to the Services and section 2.3 of this Agreement, the terms of Exhibit B, "Olympus Business Associate Agreement") shall be considered binding upon your acceptance of this Agreement, incorporated herein by reference, shall apply, (as applicable,) and shall remain in effect during the term of the Agreement including any extensions

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## **EXHIBIT A HIPAA BUSINESS ASSOCIATE AGREEMENT**

This Business Associate Agreement (this “Agreement”) is made by and between Imbio, LLC, a Minnesota corporation located at 1015 Glenwood Avenue Floor 4, Minneapolis MN 55405, hereinafter referred to as “Imbio” or “Business Associate”, and the customer accepting the Portal Terms and Conditions Agreement into which it is incorporated, hereinafter referred to as “Covered Entity”, (individually, a “Party” and collectively, the “Parties”).

WHEREAS, Covered Entity may from time to time enter into agreements with Imbio for the provision of services (“Service Agreements”), pursuant to which Imbio will act as a business associate (“Business Associate”) within the meaning of the Health Insurance Portability and Accountability Act of 1996 and its implementing regulations, as the same may be amended from time to time (“HIPAA”); and

WHEREAS, both Parties are required to comply with the Health Information Technology Economic and Clinical Health (“HITECH”) Act, as well as the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”) and the privacy regulations promulgated pursuant to HIPAA, including, but not limited to, 45 C.F.R. Parts 160 and 164 Subpart E (the “Privacy Regulation”), and the security regulations promulgated pursuant to HIPAA, including, but not limited to 45 C.F.R. Parts 160 and 164 Subpart C (the “Security Regulation”), as may be amended from time to time.

NOW, THEREFORE, This Agreement sets forth the terms and conditions pursuant to which Protected Health Information, including electronic Protected Health Information will be handled by Business Associate and third parties during the term of the Agreement and after its termination. The Parties agree as follows:

## **DEFINITIONS**

Except as otherwise defined herein, any and all capitalized terms in this Agreement shall have the definitions set forth by HIPAA. In the event of an inconsistency between the provisions of this Agreement and mandatory provisions of HIPAA, HIPAA shall control. Where provisions of this Agreement are different from those mandated by HIPAA, but are nonetheless permitted by HIPAA, the provisions of this Agreement shall control.

## **OBLIGATIONS AND ACTIVITIES OF BUSINESS ASSOCIATE**

Business Associate agrees to:

- (a) Not use or disclose protected health information other than as permitted or required by this Agreement or by law;
- (b) Use appropriate safeguards, and comply with Subpart C of 45 CFR Part 164 with respect to electronic protected health information, to prevent use or disclosure of protected health information other than as provided for by the Agreement;

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- (c) Report to Covered Entity any use or disclosure of protected health information not provided for by the Agreement of which it becomes aware, including breaches of unsecured protected health information as required at 45 CFR 164.410, and any security incident of which it becomes aware within seventy-two (72) hours. Covered Entity shall be responsible for any required notifications to individuals, regulatory bodies or government agencies as required by law on behalf of Covered Entity;
- (d) 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 protected health information on behalf of the Business Associate agree to the same restrictions, conditions, and requirements that apply to the Business Associate with respect to such information;
- (e) Make available protected health information in a designated record set to the Covered Entity as necessary to satisfy Covered Entity's obligations under 45 CFR 164.524. Should Business Associate receive a request for protected health information from any individual, Business Associate shall forward such request to Covered Entity, and Covered Entity shall, in its sole discretion fulfill such requests as required by applicable law and regulations;
- (f) Make any amendment(s) to protected health information in a designated record set as directed or agreed to by the Covered Entity pursuant to 45 CFR 164.526, or take other measures as necessary to satisfy Covered Entity's obligations under 45 CFR 164.526;
- (g) Maintain and make available the information required to provide an accounting of disclosures to the Covered Entity" as necessary to satisfy Covered Entity's obligations under 45 CFR 164.528. Should Business Associate receive a request for an accounting of disclosures from any individual, Business Associate shall forward such request to Covered Entity, and Covered Entity shall, in its sole discretion fulfill such requests as required by applicable law and regulations;
- (h) To the extent the Business Associate is to carry out one or more of Covered Entity's obligation(s) under Subpart E of 45 CFR Part 164, comply with the requirements of Subpart E that apply to the Covered Entity in the performance of such obligation(s); and
- (i) Make its internal practices, books, and records available to the Secretary for purposes of determining compliance with the HIPAA Rules.

## **PERMITTED USES AND DISCLOSURES BY BUSINESS ASSOCIATE**

- (a) Business Associate may only use or disclose protected health information as necessary to perform its obligations under any Service Agreement between the Parties, subject to the terms of this Agreement.
- (b) Business Associate may use or disclose protected health information as required by law.
- (c) Business Associate agrees to make uses and disclosures and requests for protected health information consistent with Covered Entity's minimum necessary policies and procedures.
- (d) Business Associate may not use or disclose protected health information in a manner that would violate Subpart E of 45 CFR Part 164 if done by Covered Entity.



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## TERM AND TERMINATION

- (a) Term. This Agreement shall be effective upon your acceptance of the Portal Terms and Conditions Agreement into which it is incorporated, and will continue until either (i) the expiration or termination of all Service Agreements between the Parties, or (ii) termination for cause as authorized in paragraph (b) of this Section.
- (b) Termination for Cause. Business Associate authorizes termination of this Agreement by Covered Entity, if Covered Entity determines Business Associate has violated a material term of the Agreement, and Business Associate has not cured the breach or ended the violation within thirty (30) days of receiving written notice of such violation from Covered Entity. Termination of this agreement does not in any manner affect, reduce or eliminate Covered Entity's payment obligations under any Service Agreement between the Parties.
- (c) Obligations of Business Associate Upon Termination. Upon termination of this Agreement for any reason, Business Associate, with respect to protected health information received from Covered Entity, or created, maintained, or received by Business Associate on behalf of Covered Entity, shall:
1. Retain only that protected health information which is necessary for Business Associate to carry out its legal responsibilities or otherwise required by law. Business Associate shall continue to use appropriate safeguards and comply with Subpart C of 45 CFR Part 164 with respect to electronic protected health information to prevent use or disclosure of the protected health information;
  2. Return to Covered Entity or, if agreed to by Covered Entity, certify to the destruction of all other protected health information that the Business Associate still maintains in any form;
  4. Not use or disclose the protected health information retained by business associate other than for the purposes for which such protected health information was retained;
  5. Return to Covered Entity [or, if agreed to by Covered Entity, destroy] the protected health information retained by business associate when it is no longer needed by business associate to carry out its legal responsibilities.
- (d) Survival. The obligations of Business Associate under this Section shall survive the termination of this Agreement.

## Miscellaneous

- (a) Except as expressly stated herein or in HIPAA, the Parties to this Agreement do not intend to create any rights in any third parties. The obligations of Business Associate under this Section shall survive the expiration, termination, or cancellation of this Agreement, the Service Agreements and/or the business relationship of the Parties, and shall continue to bind Business Associate, its agents, employees, contractors, successors, and assigns as set forth herein.
- (b) This Agreement sets forth the entire understanding of the parties regarding the subject matter covered herein, and may be modified or amended only by a written Amendment signed by both Parties.



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- (c) This Agreement will be interpreted and construed in accordance with the laws of the State of Minnesota, and each party agrees to the applicable governing law without regard to choice or conflicts of law rules, and to the exclusive jurisdiction of the applicable courts above.
- (d) If any provision of this Agreement is held invalid, illegal or unenforceable in any respect, such invalidity, illegality or unenforceability will not affect any other provisions of this Agreement, and this Agreement will be construed as if such invalid, illegal or unenforceable provision had never been contained herein. Further, if any provision of this Agreement is held to be unenforceable as written, it will be construed, by limiting and reducing it, so as to be enforceable to the extent compatible with applicable law.

## **EXHIBIT B**

### **OLYMPUS BUSINESS ASSOCIATE AGREEMENT**

This Business Associate Agreement (this "Agreement") is made by and between Olympus America Inc. a New York corporation with a registered address at 3500 Corporate Parkway, hereinafter referred to as "Business Associate", and the customer accepting the Portal Terms and Conditions Agreement into which it is incorporated, hereinafter referred to as "Covered Entity", (individually, a "Party" and collectively, the "Parties").

WHEREAS, the purpose of this Agreement is to address the measures that Business Associate shall take to protect the confidentiality of certain individually identifiable health information that the Covered Entity may disclose to Business Associate or that the Business Associate may create, receive, maintain, or transmit on behalf of the Covered Entity or its Affiliates in connection with the service, repair, trouble shooting and maintenance activities associated with the products identified at <http://medical.olympusamerica.com/baaproducts> (the "Services"). This Agreement applies only if and to the extent Olympus is a "business associate" (as that term is defined in 45 C.F.R. § 160.103) of Covered Entity.

WHEREAS, the use and disclosure, electronic transmission and maintenance, and security of certain individually identifiable health information is regulated by the Administrative Simplification Provisions of the Health Insurance Portability and Accountability Act of 1996, Pub. L. 104-191, as amended by Health Information Technology for Economic and Clinical Health Act, Section 13400, et. seq. of the American Recovery and Reinvestment Act of 2009 ("HITECH"), and the regulations promulgated thereunder, all as may subsequently be amended (collectively referred to as "HIPAA").

WHEREAS, the Covered Entity may from time to time disclose individually identifiable health information to the Business Associate, and the Business Associate may from time to time create, receive, maintain, and/or transmit such individually identifiable health information.

WHEREAS, both Parties are committed to complying with HIPAA, including without limitation, the HIPAA Standards for Privacy of Individually Identifiable Health Information (the "Privacy Rule"), the HIPAA Security Standards (the "Security Rule"), and the HIPAA Standards for Notification in the Case of Breach of Unsecured Protected Health Information (the "Breach Notification Rule") (all as set forth in 45 C.F.R. Parts 160, 162 and 164), and any applicable guidance from the Department of Health and Human Services ("HHS" or the "Secretary").

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NOW THEREFORE, for and in consideration of the foregoing premises, the Covered Entity and Business Associate hereby agree as follows:

## 1. PERMITTED USES AND DISCLOSURES OF PHI

**1.1 Definitions.** Except for the below, all terms used in this Agreement shall have the same meaning as set forth in HIPAA.

- a. "Affiliate" shall mean any company directly or indirectly through one or more intermediate companies which now or hereafter may control, be controlled by or be under common control with the relevant party. "Control" of a company means the power to exercise 50 percent or more of the voting rights of such company.
- b. "Covered Entity" shall have the meaning given to that term under 45 C.F.R. § 160.103 but shall be limited to entities receiving Services from the Business Associate pursuant to a written agreement.
- c. "Protected Health Information" or "PHI" shall have the meaning given to that term under 45 C.F.R. § 160.103 but shall be limited to the information created, received or maintained by the Business Associate from or on behalf of the Covered Entity.

**1.2 Use and Disclosure.** The Business Associate shall not use or further disclose PHI other than as permitted or required by this Agreement or as Required by Law, as that term is defined in 45 C.F.R. § 164.103 ("Required by Law"). All other uses or disclosures not authorized by this Agreement are prohibited.

**1.3 Disclosure to perform Services.** Except as otherwise limited herein, the Business Associate may use or disclose PHI as necessary to perform the Services, provided that such use or disclosure would not violate the Privacy Rule if done by the Covered Entity.

**1.4 Business Activities of the Business Associate.** Unless otherwise limited herein, the Business Associate may:

- a. Use PHI for the Business Associate's proper management and administration and to carry out any of its legal responsibilities.
- b. Disclose PHI to third parties for the purpose of the Business Associate's proper management and administration and to carry out any of its legal responsibilities, if and only if (1) Required by Law, or (2) the Business Associate obtains reasonable assurances from the third party to whom the information is disclosed that it shall be held confidentially and be used or further disclosed only as Required by Law or the purpose for which it was disclosed to that third party. In addition, the third party will notify Business Associate of any instances of which it is aware in which the confidentiality of the information has been breached.
- c. Provide data aggregation services to the Covered Entity as permitted by 45 C.F.R. § 164.504(e)(2)(i)(B).
- d. Report violations of law to appropriate Federal and State authorities, consistent with 45 C.F.R. § 164.502(j)(1).

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

**2.1 Responsibilities of the Business Associate.** With regard to its use and/or disclosure of PHI and the privacy and security of PHI, the Business Associate hereby agrees to the following:

a. Privacy and Security.

(i) The Business Associate shall not use or further disclose PHI other than as permitted or required by this Agreement or as Required by Law.

(ii) In carrying out an obligation of the Covered Entity under the Privacy Rule, the Business Associate shall comply with the requirements of the Privacy Rule that apply to the Covered Entity in the performance of such obligation.

(iii) The Business Associate shall use appropriate safeguards and comply with the Security Rule with respect to electronic PHI to prevent use or disclosure of PHI other than as provided for by this Agreement and as Required by Law.

**b. Mitigation.** The Business Associate shall take reasonable measures requested by the Covered Entity to mitigate, to the extent practicable, any harmful effects to the individual who is the subject of the PHI of a use or disclosure of PHI by the Business Associate that violates this Agreement.

**c. Agents and Subcontractors.** The Business Associate shall, in accordance with 45 C.F.R. §§ 164.502(e)(1)(ii) & 164.308(b)(2), as applicable, require all of its agents and subcontractors that create, receive, maintain, or transmit PHI on behalf of the Business Associate to agree, in a writing substantially the same as this Agreement, to the same (or more stringent) restrictions and conditions that apply to the Business Associate under this Agreement.

**d. Reporting.**

(i) The Business Associate shall, without unreasonable delay, and in no event longer than ten (10) business days, report to the Covered Entity's Privacy Officer or other representative identified by Covered Entity, any use and/or disclosure of PHI that is not permitted by this Agreement of which it becomes aware, including instances in which an agent or subcontractor has improperly used or disclosed PHI

(ii) The Business Associate shall, without unreasonable delay, and in no event more than ten (10) business days, report to the Covered Entity's Privacy Officer or other representative identified by Covered Entity, any Security Incident (as defined in 45 C.F.R. § 164.304) involving electronic PHI of which it becomes aware.

(iii) The Business Associate shall report to the Covered Entity, as required by the Breach Notification Rule, any Breach (as defined in 45 C.F.R. § 164.402) of Unsecured Protected Health Information (as defined in 45 C.F.R. § 164.402). Such report shall be made without unreasonable delay, and in no event longer than ten (10) business days after Business Associate discovers the Breach.

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- (iv) Any reports given to Covered Entity by Business Associate shall identify at a minimum: (i) the nature of the non-permitted use or disclosure, (ii) the PHI used or disclosed, (iii) party or parties who made the non-permitted use or received the non-permitted disclosure, (iv) what corrective actions the Business Associate took or will take to prevent further non-permitted use or disclosures, (v) what Business Associate did or will do to mitigate any harmful effect of the nonpermitted use or disclosure, (vi) and any such other information HHS may prescribe by regulation.
- e. Access to Internal Practices. The Business Associate shall make its internal practices, books and records (including policies and procedures, and PHI) relating to the use and/or disclosure of PHI available to the Secretary for purposes of the Secretary's determining compliance with HIPAA.
- f. Access to PHI. The Business Associate shall make an individual's PHI available for inspection and copying in accordance with 45 C.F.R. § 164.524. Further, at the Covered Entity's request, and within fifteen (15) days of the Covered Entity's request, the Business Associate shall provide the Covered Entity with the PHI requested by an individual pursuant to 45 C.F.R. § 164.524.
- g. Amendments to PHI. The Business Associate shall make an individual's PHI available for amendment and shall incorporate any amendments to the PHI in accordance with 45 C.F.R. § 164.526. Further, at the Covered Entity's request, and within fifteen (15) days of the Covered Entity's request, the Business Associate shall provide the Covered Entity with the PHI that an individual seeks to amend pursuant to 45 C.F.R. § 164.526.
- h. Accounting of Disclosures. The Business Associate shall make available the information required to provide an accounting of disclosures to an individual pursuant to 45 C.F.R. § 164.528, and, as applicable, 42 U.S.C. § 17935(c) and any regulations promulgated thereunder. Further, at the Covered Entity's request, and within fifteen (15) days of the Covered Entity's request, the Business Associate shall provide the Covered Entity with such information. To fulfill this obligation, the Business Associate agrees to document those disclosures of PHI and related information that would be necessary for the Covered Entity to respond to an individual's request for an accounting of disclosures.
- i. Restrictions/Alternatives. The Business Associate shall abide by any arrangements that the Covered Entity has made with an individual regarding restricting the use or disclosure of the individual's PHI, or providing the individual with confidential communications of PHI by alternative means or at an alternative location pursuant to 45 C.F.R. § 164.522, provided that the Covered Entity has notified the Business Associate in writing of such restrictions or alternative means of communication.
- j. Minimum Necessary. The Business Associate shall request, use and disclose the minimum amount of PHI necessary to accomplish the purpose of the request, use or disclosure in accordance with 45 C.F.R. § 164.502(b).

## **2.2 Responsibilities of the Covered Entity.**

- a. Notification Requirement. With regard to the use and/or disclosure of PHI by the Business Associate, the Covered Entity shall:

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- (i) Provide the Business Associate with its Notice of Privacy Practices (the “Notice”), which the Covered Entity provides to its participants in accordance with 45 C.F.R. § 164.520, as well as any changes to or limitations in such Notice to the extent that the changes or limitations affect the Business Associate’s use or disclosure of PHI.
  - (ii) Inform the Business Associate of any changes in, or revocation of, the permission by an individual to use or disclose his or her PHI, if such changes or revocation may affect the Business Associate’s uses or disclosures of the PHI.
  - (iii) Notify the Business Associate of any arrangements the Covered Entity has agreed to that restrict disclosures or provide individuals with confidential communications pursuant to 45 C.F.R. § 164.522 that may affect the Business Associate’s use or disclosure of PHI.
- b. No Impermissible Requests. The Covered Entity shall not request that the Business Associate use or disclose PHI in any manner that would not be permissible under the Privacy Rule if done by the Covered Entity, except as permitted by Section 1.4(a), (b) and (c) above.

## 3. TERM AND TERMINATION

**3.1 Term.** This Agreement shall become effective as of the Effective Date, and shall continue unless terminated as provided below.

**3.2 Termination for Cause by Covered Entity.** If the Covered Entity determines that the Business Associate has breached a material term of this Agreement, the Covered Entity may:

- a. Provide the Business Associate with written notice of the material breach, and afford the Business Associate thirty (30) days to cure such breach. If the breach is not cured within the thirty (30)-day period, the Covered Entity may terminate this Agreement.
- b. Immediately terminate this Agreement or any other agreement for Services if the Business Associate has breached a material term of this Agreement and cure is not possible.

**3.3 Effect of Termination.** Upon termination of this Agreement for any reason, the Business Associate shall, with respect to PHI received, created, maintained, or transmitted on behalf of the Covered Entity:

- a. Retain only that PHI which is necessary for the Business Associate to continue its proper management and administration or to carry out its legal responsibilities;
- b. Continue to use appropriate safeguards and comply with the Security Rule with respect to electronic PHI to prevent use or disclosure of the PHI, other than as provided for in this section, for as long as the Business Associate retains the PHI;
- c. Not use or disclose the PHI retained by the Business Associate other than for the purposes for which such PHI was retained and subject to the same conditions set out in Section 1.4(a) and (b) which applied prior to termination; and

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d. Destroy the PHI retained by the Business Associate when it is no longer needed by the Business Associate for its proper management and administration or to carry out its legal responsibilities.

## 4. INDEMNIFICATION.

Business Associate agrees to indemnify and defend Covered Entity and their respective employees, officers and directors, ("Indemnified Parties") from and against any and all losses or costs the Indemnified Parties may suffer, pay or incur as a result of third party claims, demands or actions ("Claim") against any of the Indemnified Parties to the extent such losses are attributable to the actions of the Business Associate or the failure of the Business Associate to comply with this Agreement or applicable laws, rules and regulations. Notwithstanding the aforesaid, the indemnifying party shall not be liable to the Indemnified Parties to the extent that the Claim is based on or arises out of the negligence, omissions, or other misconduct of the Indemnified Party.

THE FOREGOING SETS FORTH THE PARTIES' EXCLUSIVE REMEDY AND THE INDEMNIFYING PARTY'S SOLE OBLIGATION WITH RESPECT TO ANY CLAIMS RELATING TO THE SUBJECT MATTER DESCRIBED HEREIN. IN NO EVENT SHALL THE INDEMNIFYING PARTY BE RESPONSIBLE, WHETHER UNDER THIS SECTION, IN CONTRACT, TORT, OR OTHERWISE, FOR ANY INDIRECT, INCIDENTAL, SPECIAL, OR CONSEQUENTIAL LOSSES OR DAMAGES, WHETHER OR NOT THE INDEMNIFYING PARTY SHALL BE OR SHOULD BE AWARE OF THE POSSIBILITY OF SUCH POTENTIAL LOSS OR DAMAGE.

## 5. MISCELLANEOUS

**5.1 Regulatory References.** A reference in this Agreement to a provision in HIPAA means the provision as in effect or as amended, and for which compliance is required.

**5.2 Survival.** The provisions of this Agreement shall survive the expiration or any termination of the term of this Agreement to the extent that the Business Associate continues to maintain PHI.

**5.3 Interpretation.** Any ambiguity in this Agreement shall be resolved to permit the Covered Entity and the Business Associate to comply with HIPAA.

**5.4 Amendments; Waiver.** This Agreement may not be modified, nor shall any provision hereof be waived or amended, except in a writing duly signed by authorized representatives of the Parties. The Parties agree to take such action as is necessary to amend this Agreement from time to time as is necessary for the Parties to comply with the requirements of, or conform to, any changes in HIPAA. A waiver with respect to one event shall not be construed as continuing, or as a bar to or waiver of any right or remedy as to subsequent events.

**5.5 No Third Party Beneficiaries.** Nothing express or implied in this Agreement is intended to confer, nor shall anything herein confer, upon any person other than the Parties and the respective successors or assigns of the Parties, any rights, remedies, obligations, or liabilities whatsoever.

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**5.6 Counterparts; Facsimiles.** This Agreement may be executed in any number of counterparts, each of which shall be deemed an original. Facsimile copies hereof shall be deemed to be originals.

**5.7 Disputes.** If any controversy, dispute or claim arises between the Parties with respect to this Agreement, the Parties shall make good faith efforts to resolve such matters informally.

**5.8 Notices.** Any notices to be given hereunder to Olympus shall be given to:

Olympus America Inc.  
3500 Corporate Parkway  
Center Valley, PA 18034  
Attention: OCA Privacy Officer  
Email: [leslie.cox@olympus.com](mailto:leslie.cox@olympus.com)

With a copy to:

Olympus Corporation of the Americas  
3500 Corporate Parkway  
Center Valley, PA 18034  
Attention: General Counsel

Covered Entity shall send its notification address, along with all other contact information to [BAA@olympus.com](mailto:BAA@olympus.com).

Notification shall be made via U.S. mail or express courier to such Party's provided address. Each Party named above may change its notification address and that of its representative by giving notice thereof in the manner herein provided.

**5.9 Entire Agreement.** This Agreement contains the entire agreement and understanding between the Parties relating to the subject matter herein and supersedes all prior agreements, understandings, and representations relating to that subject matter.

Olympus is a registered trademark of Olympus Corporation, Olympus America Inc., and/or their affiliates.



**OLYMPUS AMERICA INC.**  
3500 Corporate Parkway, PO BOX 610, Center Valley, PA 18034

For more information, contact your Olympus sales representative, or call 800-848-9024.  
[www.medical.olympusamerica.com](http://www.medical.olympusamerica.com)

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