This Product Evaluation “Agreements Module” is intended for use with Ottobock representatives conducting product “field testing”, evaluations or other routine product fittings in the field. Ottobock representatives routinely fit customers with prosthetics, which may include pre-launch and post-launch activities as well as developmental and marketing activities. Particular care should be taken to observe the proper legal and regulatory obligations while conducting those activities. However, representatives should realize that the obligations and legal requirements may change given the circumstances, including but not limited to: (a) whether the product is already “on the market” or commercially available, (b) is the feedback going to be made public, put into a commercial/marketing study, or a FDA-submitted study, (c) is a CPO going to be present, (d) are parties to be compensated, and (e) will the patient’s photo or testimony be needed for future publication purposes? These factors will determine the elements of this “module” that are included in the ultimate documents provided to the present CPO and/or user/tester, and whether modifications of the text are needed.

**HOW TO USE THIS DOCUMENT:**

This document contains several separate “modules” covering various obligations that accrue to the user/tester and Ottobock. Certain components of this document will be included or not depending on the nature of the evaluation activities. Each module is explained below:

1. A Product Evaluation Agreement will be needed from those individuals who are being compensated, and whose evaluation may lead to intellectual property development. This module will be used by R&D who is evaluating the products to obtain feedback for development purposes. This document also sets forth a place to input the product, study, dates of the study and the compensation for each study and should be filled out by the R&D team as appropriate prior to use.
2. A Confidentiality Agreement will be used in cases where users are using products that are pre-launch but will not be paid. In the cases where a Product Evaluation Agreement is used, the Confidentiality Agreement is not required. However, in cases where the Product Evaluation Agreement is not used, but nevertheless, confidentiality terms are to be observed (e.g., Marketing still does not want information disclosed), then the Confidentiality Agreement should be included. Note that, in some cases, the patient user may be compensated, but an accompanying CPO may not be compensated—they might still need to sign the Confidentiality Agreement, so evaluators should determine if CPOs need a confidentiality agreement.
3. A General Consent and Release will be used with all testers, whether compensated or not. Depending on the use of the data, a short form can be used in all cases where the information will not be published or submitted to the FDA. This module contains first a short form general consent and liability release. If the product is investigational and regulated by FDA for approval then a longer tailored Consent is required, and the Legal/Clinical teams should be consulted. This third page also includes an optional Media Consent and Patient Health Information Authorization. These are optional and may or may not be needed. If applicable, a user must sign to consent to these items, so that Ottobock can use their name and likeness or follow up with their healthcare provider.
4. This document can be configured either by the Legal department or the R&D/Marketing teams as needed. If the R&D or Marketing teams are modifying the documents, they can delete inapplicable parts of the document, but should not modify text of the agreements without Legal involvement. Users of this document should evaluate the study and delete this explanatory page, along with the Product Evaluation Agreement and/or Confidentiality Agreement, before making copies for users to use.
5. Once signed agreements are obtained, the signed documents should be scanned and emailed to the Legal department for safe keeping. Email such agreements to **Kristin.ballobin@ottobock.com**.

To the extent any users are unsure as to which components are to be used, or have questions about this document, they should consult with Al Li (512-806-2660) or Kristin Ballobin (512-806-2658).

☐ PRODUCT/SERVICE EVALUATION AGREEMENT (this “Agreement”)

Otto Bock HealthCare LP (“OTTOBOCK”) wishes to thank you (“TESTER”) for agreeing to participate in the testing of one or more product(s) or service (s) presently being considered by OTTOBOCK, described asfollows (*Ottobock to Complete*):

PRODUCT:

STUDY:

DATES OF STUDY:

COMPENSATION RATE: $ P/HR

For good and valuable consideration received hereunder, OTTOBOCK and TESTER (collectively, the “Parties”) agree to the following terms and conditions, effective as of \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (*insert date)*:

1. The Information disclosed by and between OTTOBOCK and TESTER under this Agreement (“Information’) is technical and/or business information relating to product or service concepts that may or may not be later commercialized. When OTTOBOCK discloses Information to TESTER, TESTER will provide feedback and information to OTTOBOCK regarding these concepts, which may be prompted by questions from OTTOBOCK.
2. No product, service, or aspect thereof is being sold or offered for sale by OTTOBOCK in connection with this Agreement or activities related thereto, and TESTER acknowledges and agrees that these services provided are not exchanged for any referral or inducement for future purchases of products or services from OTTOBOCK.
3. TESTER shall keep such Information confidential and shall not disclose it to any third party or use the Information it receives from OTTOBOCK for any purpose beyond providing feedback to OTTOBOCK relating to the Information without the express written consent of OTTOBOCK. TESTER shall use its best efforts to prevent the disclosure of Information shared under this Agreement. TESTER shall not make any commercial use of or attempt to analyze or “reverse engineer,” in whole or in part, any Information provided by OTTOBOCK or use such Information for any purpose other than the purposes of this Agreement.
4. All Information, including questionnaires, feedback surveys, reports, communications, product-related images and recordings, material, information, innovations, or inventions (whether or not patentable or copyrightable) made or documented by TESTER in connection with the evaluation conducted hereunder shall be promptly disclosed to and be the sole property of OTTOBOCK, and TESTER hereby assigns to OTTOBOCK all right, title and interest therein.
5. TESTER’s duties under this Agreement shall apply to all Information disclosed in writing, or in another tangible form including but not limited to a prototype, electronically, orally, or visually.
6. The obligations herein will not apply to any Information that is (a) available to the public other than by breach of this Agreement by TESTER; (b) rightfully received by TESTER from a third party without proprietary limitations; (c) independently developed by TESTER without use of Information; or (d) known to TESTER prior to first receipt of same from OTTOBOCK.
7. TESTER acquires no license under any intellectual property rights under this Agreement. If TESTER conceives of or expresses any ideas, inventions, improvements, variations, or alternative embodiments (whether or not patentable or copyrightable subject matter) as a result of receiving Information, TESTER agrees to inform OTTOBOCK and assign (and hereby does assign) all rights, title, and interest to OTTOBOCK in such ideas, inventions, improvements, variations, alternative embodiments, expressions, or the like. TESTER shall execute such documents and take such other actions as OTTOBOCK deems necessary or appropriate to obtain, record or assign intellectual property thereof in OTTOBOCK’s name.
8. Waiver by a Party of a breach of any provision of this Agreement shall not constitute or be construed as a waiver of any future breach of any provision(s) in this Agreement.
9. The Parties do not intend that any employment, agency or partnership relationship be created between them by this Agreement.
10. This Agreement constitutes the entire agreement of the parties with respect to the subject matter hereof. All additions or modifications to this Agreement must be made in writing and must be signed by both Parties.
11. This Agreement shall be governed by, and interpreted and construed in accordance with, the laws of the state of Texas, and adjudicated within the venue of Texas courts located in Travis County, Texas.
12. TESTER may not assign this Agreement without prior written consent of OTTOBOCK. OTTOBOCK may freely assign this Agreement without any consent of TESTER.
13. After and in consideration of receiving Information and providing feedback to OTTOBOCK, TESTER shall receive from OTTOBOCK compensation equal to the number of hours as documented by OTTOBOCK multiplied by the compensation rate specified above. Further, OTTOBOCK shall reimburse TESTER for mileage and/or pre-approved travel expenses incurred for travel to an evaluation site, upon OTTOBOCK receiving appropriate documentation from TESTER. TESTER shall solely be responsible for any reporting, withholdings, taxes, or other sums resulting from OTTOBOCK’s payments.

**TESTER**

AUTHORIZED SIGNATURE

PRINTED NAME

DATE

**OTTO BOCK HEALTHCARE LP**

AUTHORIZED SIGNATURE

PRINTED NAME

DATE

**☐ CONFIDENTIALITY AGREEMENT**

**(this “Agreement”)**

This Agreement is made this \_\_\_\_\_\_\_ day of \_\_\_\_\_\_\_\_, 20\_\_ (the “Effective Date”) by and between Otto Bock HealthCare LP, whose address and principal place of business is Austin, TX (“OTTOBOCK”) and \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (Insert Legal Name), whose address is \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (“RECIPIENT”).

WHEREAS, OTTOBOCK desires to share with RECIPIENT and RECIPIENT may receive certain business and/or technical information and/or product(s) for temporary use relating to one or more OTTOBOCK products and/or services (“Confidential Information”) so that the RECIPIENT may demonstrate and discuss RECIPIENT’s impressions and evaluation of such products and/or services with OTTOBOCK for its business efforts (the “Purposes of the Agreement”).

WHEREAS, RECIPIENT acknowledges that OTTOBOCK considers such disclosed information confidential and proprietary and desires to keep such information confidential, limit its use, and protect it from unauthorized dissemination and use.

THEREFORE, in consideration of the promises and covenants set forth hereinafter, and for good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties agree as follows:

1. RECIPIENT acknowledges that, in the course of all activities regarding the Purposes of the Agreement, he/she will receive Confidential Information.

2. RECIPIENT shall keep such Confidential Information confidential and shall not disclose it to any third party or use the Confidential Information it receives from OTTOBOCK for any purpose beyond the Purposes of the Agreement without the express written consent of OTTOBOCK. RECIPIENT shall use its best efforts to prevent the disclosure of Confidential Information received under this Agreement. RECIPIENT shall not make any commercial use of or attempt to analyze or “reverse engineer,” in whole or in part, any Confidential Information provided to it or use such Confidential Information for any purpose other than the Purposes of the Agreement.

Any Confidential Information permitted to be disclosed under this Agreement may be disclosed in an oral, electronic, or written form, or in another form. If RECIPIENT is uncertain whether any information disclosed by OTTOBOCK is within the definition of Confidential Information as used in this Agreement, such information shall be deemed to be Confidential Information hereunder.

3. Notwithstanding anything to the contrary, the definition of Confidential Information shall exclude information that RECIPIENT can prove with documentation:

(a) is in the public domain at the time of disclosure or later becomes part of the public domain through no fault of RECIPIENT;

(b) was in its lawful possession prior to receiving any Confidential Information from OTTOBOCK;

(c) is received by RECIPIENT from a third party without a breach of confidentiality owed by the third party to OTTOBOCK;

(d) was developed by RECIPIENT who had no knowledge of OTTOBOCK’s information that otherwise qualifies as Confidential Information; or

(e) the disclosure of which may be necessary by reason of legal or regulatory requirements, provided RECIPIENT first gives reasonable notice to OTTOBOCK to permit it to oppose such requirement.

4. The disclosure of Confidential Information does not (i) give any right or license under any patent, patent application or know-how now held, or which may be obtained by, or which may be licensed by OTTOBOCK; (ii) give any express or implied right or license to use such information for any purpose other than the Purpose of the Agreement; or (iii) constitute an offer or promise to enter into any other contract or relationship.

5. RECIPIENT shall return all Confidential Information and any copies of Confidential Information received upon conclusion of activities contemplated under the Purposes of the Agreement.

6. The disclosure period for this Agreement shall begin as of the Effective Date and shall terminate when (a) a Party notifies the other Party in writing that it terminates the disclosure period of this Agreement, which either Party may do at will, or (b) two years from the Effective Date, whichever occurs first. Neither termination of the disclosure period nor any termination or expiration of this Agreement shall relieve RECIPIENT of any obligation or restriction with respect to Confidential Information disclosed hereunder.

7. This Agreement shall be governed by, and interpreted and construed in accordance with, the laws of the state of Texas, and adjudicated within the venue of Texas courts located in Travis County, Texas.

8. No failure or delay by either party to take any action or assert any right hereunder shall be deemed to be a waiver of such action or right or a subsequent action or right in the event of the continuation or repetition of the circumstances giving rise to such first action or right.

9. This Agreement constitutes the entire agreement of the parties with respect to the subject matter hereof. This Agreement may only be amended in writing, which may be in the form of facsimile or electronic transmission in one or more counterparts.

IN WITNESS WHEREOF, the undersigned parties have caused this Agreement to be executed on the date first above written.

**RECIPIENT**

AUTHORIZED SIGNATURE

PRINTED NAME

DATE

**OTTO BOCK HEALTHCARE LP**

AUTHORIZED SIGNATURE

PRINTED NAME

DATE

GENERAL CONSENT AND RELEASE (All Parties)

For good and valuable consideration, receipt of which is hereby acknowledged, I, the undersigned, do hereby agree and consent to allow Otto Bock HealthCare LP, its officers, employees, agents, licensees, subsidiaries, affiliates and related entities and their successors and assigns and any other related persons (collectively, “OTTOBOCK”), to evaluate its products and/or services through my activities (collectively, the “Activities”). Further, I acknowledge that these Activities are undertaken by my own volition or choice and that these products and services have not been prescribed or recommended by OTTOBOCK. I do hereby release OTTOBOCK of any and all claims and demands of whatever nature, actions and causes of action, damages, costs, loss of services, expenses and compensation on account of or in any way growing out of personal injuries and property damage that may result at any time in the future, whether or not contemplated at the present time and whether or not they arise following the execution of this release, as the result of and by reason of my participation in the Activities.

I do, for myself and my heirs, administrators, executors and assigns, covenant with OTTOBOCK to indemnify OTTOBOCK from all claims and demands or damages, costs, loss of services, expenses and compensation on account of, or in any way growing out of my participation in the Activities. This release expresses a full and complete settlement of a liability claimed and denied, and, regardless of the adequacy of the compensation, is intended to avoid litigation.

There is absolutely no agreement on the part of any or all of the persons, firms, partnerships or corporations released to make any payment or to do any act or thing other than is expressly stated and clearly agreed to in this Consent and Release.

I understand that information used or disclosed pursuant to this Consent and Release may not be protected by federal or state law.

As this Consent and Release will be acted upon by OTTOBOCK forthwith, it is irrevocable. I am either over 18 years of age or my parent or guardian signed below on my behalf.

**In addition to this foregoing Consent and Release, with my signature given on the following sections entitled, “Media Consent and Release” and “Patient Health Information Authorization” I hereby further consent and agree to those consents, authorizations and releases.**

**SIGNATURE DATE** (☐ GUARDIAN OR ☐ AUTHORIZED REPRESENTATIVE)

**PRINTED NAME OF PARTY, GUARDIAN OR AUTHORIZED REPRESENTATIVE**

MEDIA CONSENT AND RELEASE

(For user who allows his/her information to be released in Media)

SIGNATURE

For good and valuable consideration, receipt of which is hereby acknowledged, I do hereby agree and consent to allow OTTOBOCK to use, publish, circulate, distribute, copyright, copy, transfer and assign, in any print and/or electronic mode of reproduction or distribution, my name, image, likeness, words, biographical information, and other personal identification, any and/or all photographs, digital images, film, videotape, statements, testimonials, voice recordings, engravings, pictures, drawings, and any written, engraved, painted or printed reproduction or likeness of me, whether alone or apart from, or in connection with or illustrative of any written or printed subject matter, story or news item or advertised matter of any kind, nature, or description (collectively, my “Name and/or Likeness”), and do hereby agree and consent that my Name and/or Likeness shall be the absolute property of OTTOBOCK for all time and that OTTOBOCK shall have all rights of every kind in connection with the uses of my Name and/or Likeness hereunder, including, without limitation, all copyrights and other rights therein, without condition, limitation or reservation, and full right of distribution and assignment to any other person, corporation or company whatsoever and for any use or purpose whatsoever, including but not limited to marketing and the creation of derivative works.

I hereby release OTTOBOCK from any and all claims, demands or causes of action for damages for libel, slander, invasion of privacy or any other claim, demand or cause of action based on my Name and/or Likeness.

**PROTECTED HEALTH INFORMATION AUTHORIZATION**

**(For patient user who authorizes their healthcare provider(s) to share medical information)**

**SIGNATURE**

NAME DOB SSN

ADDRESS

CITY STATE ZIP

TELEPHONE

I hereby authorize any health plan, physician, health care professional, hospital, clinic, laboratory, pharmacy, medical facility, or other health care provider that has provided payment, treatment, or services to me or on my behalf and all other medical sources (each being a “Covered Entity”), to use or disclose my protected health information (“PHI”), including the history of my amputation and the resulting care, as indicated below to:

Otto Bock HealthCare LP

3820 W. Great Lakes Dr. | Salt Lake City, UT  84120

801.956.2504 (Telephone) | 801.952.2904 (Fax)

The purpose of the disclosure authorized herein is “at the request of the individual.” I understand that this authorization is voluntary and made to confirm my direction. I understand that my PHI may be subject to re-disclosure, and this redisclosure may not be protected by federal or state health information privacy laws.

I understand that this authorization will expire two (2) years from the date signed below. I understand that I may revoke this authorization in writing at any time by sending a signed and dated written statement to OTTOBOCK, saying that I am revoking my authorization to disclose health records, except to the extent that OTTOBOCK or any other entity or person has taken action in reliance on this authorization.

I have had the opportunity to read and consider the contents of this authorization. I confirm that the contents are consistent with my direction.