

## MASTER PARTICIPATION AGREEMENT FOR ASPS/PSF DATA REGISTRIES

[September 2016]

The undersigned, ("You" or "Participant") has chosen to participate in one or more clinical data registries owned and operated by the American Society of Plastic Surgeons ("ASPS") or the Plastic Surgery Foundation ("PSF") (each such clinical data registry, a "Registry").

You have selected to participate in one or more Registries as identified in your user profile.

If you do not agree to all of the terms below, then you will not be permitted access to enter cases into the applicable Registry.

### Data Warehousing Services

As a condition of participation in any Registry, you must agree to the terms and conditions of the following:

1. Data Warehousing Agreement and Business Associate Agreement (collectively, the "Vendor Agreement") with FIGmd, Inc. ("Vendor").

2. The Terms and Conditions of the applicable Registry(ies) in which Participant has chosen to participate (individual and collectively, the "Exhibit") which are attached hereto.

### Definitions

For purposes of this participation agreement (this "Agreement"), the following terms shall have the meaning ascribed to them below:

"Participant Data" shall mean that information, including PHI, requested in the applicable case report form for the applicable Registry which is submitted by Participant to Vendor. For avoidance of doubt, Participant Data specifically does not include Registry Data.

"Registry Data" shall mean that data derived from Participant Data which has been de-identified in accordance with the requirements of 45 C.F.R. § 160.514.

"Protected Health Information" or "PHI" shall have the same meaning ascribed to it at 45 C.F.R. § 160.103, but as used herein shall refer only to that PHI of Participant submitted to Vendor for purposes of participating in a Registry.

### Ownership

You agree that you will own, subject to the individual's rights as applicable, the Participant Data; provided, however, that you agree that you will not have any right, title or interest in the Registry Data (other than as provided herein or in an Exhibit), which shall be the exclusive property of ASPS or PSF, as applicable, in all respects.

You agree that you shall not have any right, title or interest in or to the Registry, which shall be the exclusive property of ASPS or PSF, as applicable, in all respects. All patents, copyrights, trademarks, trade secrets and other ownership rights in the Registry are and shall remain with ASPS or PSF, as applicable. As between the parties, the source code of the Registry and all information regarding the design, structure or internal operation of the Registry are trade secrets of ASPS or PSF, as applicable.

Ownership of services and software provided pursuant to the Vendor Agreement shall be determined in accordance with the terms thereof.

### **Publication**

All requests for publication based upon or utilizing Registry Data are subject to ASPS or PSF approval, as applicable. Request must be in written form and submitted to [RESEARCH@plasticsurgery.org](mailto:RESEARCH@plasticsurgery.org) and may be subject to the terms and conditions of a data release agreement.

### **Restrictions**

YOU MAY NOT:

- a. Access Registry Data or Participant Data other than your own.
- b. Translate, reverse engineer, decompile or disassemble any Registry or any software of Vendor, except to the extent, if any, as permitted under the Vendor Agreement.
- c. Rent, lease or assign your access to any Registry.
- d. Access, analyze, publish or in any way utilize Registry Data without submitting a research request form and approval of such request from ASPS or PSF, as applicable.
- e. Transfer your rights under this Agreement to anyone else, including an affiliate, without the signed written consent of ASPS and PSF, as applicable.
- f. Permit any of your employees and/or agents to perform any of the activities listed in (a)-(e) above, and you agree to maintain reasonable safeguards to prevent others from performing any of the activities listed in (a)-(e) above.

### **Vendor Agreement**

You agree to notify ASPS or PSF, as applicable, within ten (10) days of any termination, amendment or knowledge of a breach (whether actual or alleged) of the Vendor Agreement by either you or Vendor.

### **Term**

Once accepted by both parties, the terms of this Agreement shall commence and remain in effect until such time as this Agreement is terminated by either party in accordance with the below provisions.

### **Termination by ASPS/PSF**

ASPS or PSF, as applicable, may terminate this Agreement at any time if

(a) Participant fails to submit Participant Data or to submit Participant Data in conformance with PSF or Vendor's submission requirements, (b) Participant violates the Ownership or Confidentiality provisions of this Agreement, (c) Participant becomes ineligible to participate in the Registry, (d) Participant materially breaches this Agreement without having cured such breach within thirty (30) days following notice thereof, (e) Participant terminates the Vendor Agreement or (f) ASPS or PSF elects to discontinue the Registry for any reason.

#### **Termination by Participant**

Participant may terminate participation in any Registry at any time upon thirty (30) days' notice to PSF and ASPS, as applicable. Such notice shall be sent to RESEARCH@plasticsurgery.org or such other notice address as may be provided to Participant by ASPS or PSF from time to time.

#### **Confidentiality**

Participant agrees to treat all information relating to the operation of the Registry that are disclosed to Participant under this Agreement, including the Protocol (if applicable) and authorized persons' usernames and passwords, as confidential and in accordance with the Vendor Agreement. Participant agrees to protect such information using the same degree of care with which he/she/it protects his/her/its own confidential information, but in no event using less than reasonable care. Participant will not disclose, reveal or give such information to anyone except those who have a need to have such information, including an Institutional Review Board (as necessary), in connection with the participation in the Registry(ies) and who have assumed an obligation of confidentiality at least to the extent that Participant is bound hereunder.

The foregoing obligation of confidentiality will not apply to information that: (a) can be demonstrated to have been in the public domain or publicly known and readily available prior to disclosure; (b) can be demonstrated to have been in Participant's possession or readily available to Participant from another source, not subject to the terms of confidentiality, prior to the disclosure; (c) becomes part of the public domain or publicly known by publication or otherwise, not due to any unauthorized act by Participant, or Participant's employees or agents; (d) is independently developed or acquired by Participant without use of or reliance upon the information provided by ASPS or PSF; or (e) is required to be disclosed by law, provided that Participant notifies ASPS or PSF, as applicable, before the disclosure is made to allow such party to seek the advice of counsel.

#### **Independent Contractor**

Participant and ASPS or PSF, as applicable, agree that this Agreement is not intended to create, and does not establish, a partnership, joint venture, agency or other arrangement between or among the parties, and that the relationship of the parties is that of independent contractors. No party, by virtue of this Agreement, shall have any right, power or authority, expressed or implied, to act on behalf of or enter into any undertaking binding another party.

#### **Compliance with Laws**

While participating in any Registry, Participant shall comply with all applicable

federal, state and local rules and guidelines including, but not limited to, the requirements of HIPAA. Where applicable, Participant shall be exclusively responsible for obtaining and complying with Institutional Review Board approvals and determinations in connection with the collection and transfer of Participant Data in connection with participation in the Registry.

#### **Limitation of Liability**

Under no circumstances will either party be liable to the other for any indirect, special, punitive or consequential damages of any kind, including lost profits (whether or not the parties have been advised of such loss or damage), arising in any way in connection with this Agreement.

#### **Several Liability**

Participant recognizes that ASPS and PSF, and each subsidiary and affiliate entity thereof, are separate legal entities. None of the liabilities and obligations of ASPS shall be treated as a joint liability of PSF, and none of the liabilities and obligations of PSF shall be treated as a joint liability of ASPS.

#### **Entire Agreement**

This Agreement, including all applicable Exhibits, constitutes the entire agreement between or among the parties with respect to the subject matter contained herein and supersedes all previous oral or written negotiations, understandings or proposals and may be modified only by an agreement executed in writing by the authorized representatives of both parties. In the event of any inconsistency between this Agreement and any Exhibit, the terms of this Agreement shall govern.

#### **Amendment to Exhibits**

ASPS and PSF, in their sole discretion, may amend the terms and conditions specific to each Registry as set forth on the applicable Exhibit from time to time during the term of this Agreement. Such amended Exhibit will be distributed to Participant at least thirty (30) days prior to the effective date thereof, either by electronic copy or notification that an updated version is available on the Registry website, and such amended Exhibit shall replace the existing Exhibit for such Registry and be made a part of this Agreement without requiring further action by the parties.

#### **Waiver**

No term or provision of this Agreement shall be deemed waived or any breach excused unless such waiver or consent shall be in writing and signed by the party claimed by the other to have waived or consented. Any consent by any party to, or waiver of, a breach by the other, whether express or implied, shall not constitute a consent to, waiver of or excuse for any other different or subsequent breach.

#### **Severability**

The invalidity, illegality or unenforceability of any one or more of the provisions of this Agreement, including any Exhibit hereto, shall in no way affect or impair the validity, legality or enforceability of the remaining provisions hereof, which shall

remain in full force and effect. Any invalid, illegal or unenforceable provisions shall be deemed to be severed from this Agreement.

### **HIPAA Compliance**

In addition to this Agreement, Participant will be asked to electronically accept a Vendor Agreement, which includes a Business Associate Agreement or data use agreement (where applicable), as required by HIPAA. Participant will not be able to participate in the Registry or to enter Participant Data until Participant has clicked through and agreed to the terms of the Vendor Agreement, including the Business Associate Agreement or data use agreement, as applicable.

Termination of the Business Associate Agreement or data use agreement, whether by Vendor or Participant, shall immediately and simultaneously result in the termination of this Agreement and of participation in any and all Registries.

### **Authorizations**

Participant agrees that the signatory below is duly authorized to bind the named Participant to the terms and conditions of this Agreement and the Exhibits hereto.

Further, other than the legal obligations imposed upon Participant by HIPAA and other applicable state and federal privacy laws, if you are an individual and not a legal entity, you represent that you are duly authorized to submit Participant Data, and such submission is not in violation of any other contractual or legal obligation upon you, including the policies and procedures of your employer (if applicable).

THE PLASTIC SURGERY FOUNDATION

SIGNATURE  
Keith M. Hume  
Executive Director  
The Plastic Surgery Foundation

DATE

SIGNATURE

Name

Title

Participant Name

Participant Address

DATE

AMERICAN SOCIETY OF PLASTIC  
SURGEONS

IF REQUIRED:

ASPS Member Name

SIGNATURE  
Keith M. Hume  
Senior Vice President, Programs & Policy  
American Society of Plastic Surgeons

ASPS Member Number

DATE