

APPENDIX I: STANDARD FORM
BUSINESS ASSOCIATE CONTRACT
AND DATA USE AGREEMENT

THIS AGREEMENT is entered into and made effective the _____ day of _____, 20__ (the “Effective Date”), by and between (a) THE SOCIETY OF GYNECOLOGIC ONCOLOGY, a not-for-profit corporation, with its principal place of business at 230 W. Monroe St., Suite 710, Chicago, IL 60606 (“SGO”); and (b) group of gynecologic oncologists whose principal place of business is at, a hospital or _____ (Participant)

WHEREAS, SGO and Participant are parties to that certain Participation Agreement, dated as of _____, 20__, setting forth the terms of Participant’s participation in the SGO Registry (such agreement to be referred to herein as the “Participation Agreement” and such SGO Clinical Outcomes Registry as “Registry”);

WHEREAS, the Participation Agreement permits and provides for the conduct of data analyses that relate to the Participant’s Health Care Operations, including but not limited to Data Aggregation, quality assessment, and peer review functions;

WHEREAS, the Participation Agreement may from time to time require the receipt, Use, and/or Disclosure of Protected Health Information (“PHI”) for SGO to provide services to Participant related to its Health Care Operations;

WHEREAS, the Participation Agreement may from time to time require the Disclosure of PHI in the form of a Limited Data Set (“Limited Data Set Information”) for SGO to provide services to Participant related to its Health Care Operations and for Research purposes; and

WHEREAS, the Parties desire to supplement the Participation Agreement so as to allocate responsibility for the Use and Disclosure of PHI, including Limited Data Set Information, and to comply with applicable requirements of the Health Insurance Portability and Accountability Act of 1996, Public Law 104-191 (“HIPAA”) and the regulations promulgated thereunder by the United States Department of Health and Human Services (“HHS”) codified at 45 CFR Parts 160 and 164, (commonly known as the Privacy and Security Rules) as amended by the Privacy and Security provisions set forth in Section 13400 of the Health Information Technology for Economic and Clinical Health Act, Public law 111-5 (“HITECH Act:”), (collectively referred to herein as the “HIPAA Regulations”), as they pertain to Business Associates and Limited Data Sets;

NOW THEREFORE, in consideration of the mutual promises and conditions contained herein, and for other good and valuable consideration, the Parties agree as follows:

SECTION 1
DEFINITIONS

Section 1.1 Capitalized terms used, but not otherwise defined, in this Agreement will have the meaning ascribed to them in the HIPAA Regulations or the Participation Agreement, as the case may be. Except as otherwise specified herein, the term “Agreement” refers to this

Business Associate Contract and Data Use Agreement and not the Participation Agreement. PHI will have the meaning ascribed to it in the HIPAA Regulations, but for the purposes of this Agreement will refer solely to PHI transmitted from or on behalf of Participant to SGO or a Subcontractor of SGO, or created by SGO or its Subcontractor on behalf of Participant. PHI will include PHI in electronic form (“Electronic PHI”) unless specifically stated otherwise. Limited Data Set Information will have the meaning ascribed to “Limited Data Sets” in the HIPAA Regulations, but for the purposes of this Agreement will refer solely to Limited Data Set Information transmitted from or on behalf of Participant to SGO or a Subcontractor of SGO, or created by SGO or its Subcontractor on behalf of Participant. “Subcontractor” shall refer to a subcontractor that is a business associate as included in the definition of “business associate” in the HIPAA Regulations, provided that SGO is not acting as an agent of Participant in its role as an independent contractor herein.

SECTION 2

EFFECT AND INTERPRETATION

Section 2.1 The provisions of this Agreement shall apply with respect to the Use or Disclosure of any PHI by the Parties under the Participation Agreement. In the event of any conflict or inconsistency between the Participation Agreement and this Agreement concerning the Use or Disclosure of PHI, the terms of this Agreement will prevail unless the Parties mutually agree that the applicable terms of the Participation Agreement would be more protective of PHI. The provisions of this Agreement are intended in their totality to implement 45 CFR 164.504(e) and 45 CFR 164.314(a) as they concern Business Associate Contracts and 45 CFR 164.514(e) as it concerns Data Use Agreements. The provisions of the Participation Agreement will remain in full force and effect and are amended by this Agreement only to the extent necessary to effectuate the provisions set forth herein.

SECTION 3

GENERAL OBLIGATIONS OF SGO

Section 3.1 Business Associate Contract Obligations.

The obligations set out in this Section 3.1 apply with respect to SGO’s Use or Disclosure of PHI, other than Limited Data Set Information.

(a) SGO agrees not to Use or Disclose PHI other than as permitted or required by this Agreement or as Required By Law.

(b) Use or Disclose PHI consistent with Participant’s minimum necessary policy and in accordance with the HIPAA Regulations.

(c) SGO agrees to use appropriate safeguards, and comply with Subpart C of 45 CFR Part 164 with respect to Electronic PHI, to prevent Use or Disclosure of PHI other than as provided for by this Agreement. Without limiting the generality of the foregoing, SGO further agrees to:

(i) implement Administrative, Physical, and Technical Safeguards that reasonably and appropriately protect the Confidentiality, Integrity, and Availability of the

Electronic PHI that it creates, receives, maintains, or transmits on behalf of Participant as required by 45 CFR 164.314(a);

(ii) ensure that any Subcontractor, to whom it provides such PHI agrees to implement reasonable and appropriate safeguards to protect the PHI and comply with Subpart C of 45 CFR Part 164 with respect to Electronic PHI; and

(iii) report promptly to the Participant any Security Incident or Breach of Unsecured PHI of which SGO becomes aware.

(d) SGO agrees to report promptly to Participant any Use or Disclosure of PHI which is not authorized by this Agreement of which SGO becomes aware.

(e) SGO agrees to ensure that any Subcontractor that creates, receives, maintains, or transmits PHI, on behalf of SGO, will agree in writing to comply with the same restrictions and conditions with respect to such information that apply through this Agreement to SGO. For the purposes of this Agreement, all PHI provided at SGO's direction to a Subcontractor of SGO will be deemed to have been provided to SGO.

(f) If PHI provided to SGO, or to which SGO otherwise has access, constitutes a Designated Record Set, SGO agrees to provide Participant with timely access to such PHI, upon reasonable advance notice and during regular business hours, or, at Participant's request, to provide an Individual with access to his or her PHI in order to meet the requirements under 45 CFR 164.524 concerning access of Individuals to PHI. In the event an Individual contacts SGO directly about gaining access to his or her PHI, SGO will not provide such access but rather will forward such request to Participant within five (5) business days of such contact.

(g) If PHI provided to SGO, or to which SGO otherwise has access, constitutes a Designated Record Set, SGO agrees to make timely amendment(s) to such PHI as Participant may direct or agree to pursuant to 45 CFR 164.526. In the event an Individual contacts SGO directly about making amendments to his or her PHI, SGO will not make such amendments, but rather will forward such request to Participant within five (5) business days.

(h) SGO agrees to make internal practices, books and records relating to the Use and Disclosure of PHI and its policies, procedures and documentation required by the Security Rule relating to Safeguards available to the Secretary of the United States Department of Health and Human Services, during regular business hours, for purposes of the Secretary's determining compliance with the HIPAA Regulations.

(i) SGO agrees to document Disclosures of PHI and information related to such Disclosures as would be required for Participant to respond to a request by an Individual for an accounting of Disclosures of PHI in accordance with 45 CFR 164.528. In addition, SGO agrees to provide promptly to Participant or an Individual, upon Participant's reasonable request, information collected in accordance with this Section 3.1(i) in order to permit Participant to respond to a request by an Individual for an accounting of Disclosures of PHI in accordance with 45 CFR 164.528. Notwithstanding the foregoing, this Section 3.1(i) will not apply with respect to Disclosures for which an accounting is not required by 45 CFR 164.528 as amended.

(j) In the event that SGO determines that a “Breach” (as such term is defined by the HIPAA Regulations) has occurred resulting in the use, access, acquisition or disclosure of Unsecured PHI, SGO will notify Participant of the Breach without unreasonable delay and in no case later than sixty (60) business days after Discovery. Such report to Participant shall include:

(i) The identification of each individual whose Unsecured PHI has been or is reasonably believes to have been access, acquired, used, or disclosed during the Breach;

(ii) A description of the incident, including the date of the Breach and the date of Discovery, identification of the individual involved and the circumstances giving rise to the Breach;

(iii) A description of the type of Unsecured PHI that was involved (e.g., name, Social Security number, procedure, diagnosis, treatment, etc.); and

(iv) A description of what SGO and its consultants or subcontractors are doing to investigate, mitigate harm, and protect against future similar breaches.

(k) SGO shall mitigate, to the extent practicable, any adverse effects from any improper Use and/or Disclosure of Protected Health Information by SGO that are known to SGO.

Section 3.2 Data Use Agreement Obligations.

The obligations set out in this Section 3.2 apply only with respect to SGO’s Use or Disclosure of Limited Data Set Information.

(a) Permitted Uses and Disclosures

(i) Except as otherwise specified herein, SGO may make all Uses and Disclosures, including Disclosures to third parties subject to Sections 3.2(e) and (f) hereof, of the Limited Data Set Information necessary to conduct the Research, operate or maintain the SGO Registry or perform the services for the purpose of Participant’s Health Care Operations as described in the Participation Agreement; provided, however, that such Use or Disclosure would not violate the HIPAA Regulations if done by Participant.

(ii) SGO agrees to not Use or further Disclose Limited Data Set Information other than as permitted by this Agreement or as otherwise Required By Law.

(iii) SGO agrees not to Use or Disclose Limited Data Set Information in any way which would violate the HIPAA Regulations if done by Participant.

(b) SGO agrees to use appropriate safeguards to prevent Use or Disclosure of the Limited Data Set Information other than as permitted by this Section 3.2 of this Agreement. Without limiting the generality of the foregoing, SGO further agrees to:

(i) implement Administrative, Physical, and Technical Safeguards that reasonably and appropriately protect the Confidentiality, Integrity, and Availability of the electronic Limited Data Set Information that it creates, receives, maintains, or transmits on behalf of Participant as required by 45 CFR 164.314(a);

(ii) ensure that any Subcontractor, to whom it provides such Limited Data Set Information agrees to implement reasonable and appropriate safeguards to protect such information;

(iii) report within ten (10) business days to the Participant any Security Incident or Breach of Unsecured PHI of which SGO becomes aware.

(c) SGO will report within ten (10) business days to Participant any Use or Disclosure of the Limited Data Set Information not permitted by this Section 3.2 of this Agreement of which SGO becomes aware.

(d) SGO will not attempt to identify the Individuals to whom the Limited Data Set Information pertains, or attempt to contact such Individuals, provided that this restriction will not be interpreted to prevent SGO from conducting such activities under the Business Associate Contract provisions of this Agreement. Under no circumstances will SGO attempt to contact Individuals except with Participant's prior written consent.

(e) SGO agrees to require that any third party to whom it, directly or indirectly, provides Limited Data Set Information will agree in writing to comply with the same restrictions and conditions that apply through this Section 3.2 to SGO.

(f) SGO agrees to enter into a written agreement with each third party to which it Discloses Limited Data Set Information that includes the terms and provisions required by the HIPAA Regulations for such Disclosures.

SECTION 4 **PERMITTED USES AND DISCLOSURES BY SGO**

Section 4.1 **General Business Associate Contract Use and Disclosure Provisions.**

Except as otherwise limited in this Agreement, SGO may Use or Disclose PHI on behalf of, or in order to provide services to, Participant to the extent such Use or Disclosure is reasonably necessary to facilitate Participant's participation in the SGO Registry, consistent with the Participation Agreement, provided that such Use or Disclosure of PHI would not violate the HIPAA Regulations if done by Participant. In providing these services, SGO will be acting as an independent contractor and not as an employee or agent of Participant. SGO shall have no authority, express or implied, to commit or obligate Participant in any manner whatsoever.

Section 4.2 **Specific Business Associate Contract Use and Disclosure Provisions.**

The permitted Uses and Disclosures set out in this Section 4.2 apply only with respect to SGO's Use or Disclosure of PHI other than Limited Data Set Information.

(a) Except as otherwise limited in this Agreement or the Participation Agreement, SGO may Use PHI for the proper management and administration of SGO or to carry out the legal responsibilities of SGO.

(b) Except as otherwise limited in this Agreement or the Participation Agreement, SGO may Disclose PHI for its own proper management and administrative purposes, provided that the Disclosures are either Required By Law, or SGO otherwise obtains reasonable assurances from the person to whom it Discloses the PHI that such person will a) protect the Confidentiality of the PHI; b) Use or further Disclose the PHI only as Required By Law or for the purpose for which it was Disclosed to the person; and c) promptly notify SGO of any instances of which the person is aware that the Confidentiality of the PHI has been breached.

(c) Except as otherwise limited in this Agreement or the Participation Agreement, SGO may Use and Disclose PHI to provide Data Aggregation services to Participant as permitted by 45 CFR 164.504(e)(2)(i)(B).

(d) SGO may de-identify any PHI, provided such de-identification conforms to the requirements of 45 CFR 164.514(b), including without limitation any documentation requirements. SGO may Use or Disclose such de-identified information at its discretion, as such de-identified information does not constitute PHI and is not subject to the terms of this Agreement; provided that such Use or Disclosure is consistent with the Participation Agreement.

(e) SGO may partially de-identify any PHI to create a Limited Data Set, provided such partial de-identification conforms to the Limited Data Set requirements of 45 CFR 164.514(e)(2). A Limited Data Set created pursuant to this Section 4.2(e) is Limited Data Set Information and may be further Used and Disclosed by SGO in accordance with the Data Use provisions of Section 3.2 hereof.

SECTION 5

GENERAL OBLIGATIONS OF PARTICIPANT

Section 5.1 **Participant's Notice of Privacy Practices, Permissions, and Restrictions.**

(a) Participant represents and warrants that it has developed and makes available to all patients a Notice of Privacy Practices that complies with 45 CFR 164.520 and any other applicable provisions of the HIPAA Regulations. Participant will provide SGO with a copy of its then-in-effect Notice of Privacy Practices upon request.

(b) Participant will provide SGO with any changes in, or revocation of, the permission by an Individual to Use or Disclose PHI, if such changes affect SGO's permitted or required Uses and Disclosures.

(c) Participant will ensure on a continuing basis that all Disclosures of PHI made to SGO are permissible under the HIPAA Regulations and are not subject to restrictions that would make the Disclosure of an Individual's PHI to SGO impermissible. Participant will be solely responsible for obtaining any consents and/or authorizations required under the HIPAA Regulations or a more stringent state privacy law of the state in which Participant resides that may be necessary or required prior to transmitting or submitting PHI to SGO. Participant will

notify SGO of any specific or general restrictions on the Use or Disclosure of PHI submitted to SGO that Participant has agreed to in accordance with 45 CFR 164.522.

Section 5.2 Permissible Requests by Participant. Participant will not ask SGO to Use or Disclose PHI in any manner that would not be permissible under the HIPAA Regulations if undertaken by Participant, provided that Participant may, as otherwise permitted under this Agreement, request that SGO Use or Disclose PHI for the purposes of Data Aggregation or the management and administrative activities of SGO, as provided for in 45 CFR 164.504(e) (4).

SECTION 6

TERM AND TERMINATION

Section 6.1 Term. This Agreement will commence as of the Effective Date and will remain in effect for a period that is coterminous with the Participation Agreement, unless (i) this Agreement is terminated sooner in accordance with either Sections 6.2 or 6.3 below; or (ii) the Participation Agreement is amended by written agreement of the Parties in a manner that the Parties mutually agree renders the provisions of this Agreement unnecessary.

Section 6.2 Termination for Material Breach. Either Party may terminate this Agreement based upon a material breach of this Agreement by the other Party, provided that the non-breaching Party gives the breaching Party thirty (30) days written notice and the opportunity to cure such breach, and the breach is not cured during the notice period. In the event such material breach is not cured, the non-breaching Party may terminate this Agreement immediately upon the expiration of the notice period. In the event it is not possible to cure such material breach, the non-breaching Party may terminate this Agreement immediately and without any notice.

Section 6.3 Termination Permitted Due to Change in Law. Either Party may terminate this Agreement as permitted in accordance with Section 8.2 of this Agreement upon a change in an applicable law that causes performance in compliance with this Agreement to violate the law.

Section 6.4 Effect of Termination.

(a) Except as provided in Subsection (b) of this Section 6.4 and except with respect to Limited Data Set Information, upon termination of this Agreement for any reason, SGO will:

(i) retain only that PHI which is necessary for SGO to continue its proper management and administration or to carry out its legal responsibilities;

(ii) continue to use appropriate safeguards and comply with the Security Rule with respect to such PHI to prevent Use or Disclosure of the PHI, other than as provided for in this Section, for as long as SGO retains the PHI;

(iii) not Use or Disclose such PHI retained by SGO other than the purposes for which such PHI was retained and subject to the same conditions set forth herein which applied prior to termination;

(iv) return or destroy the PHI retained by SGO pursuant to this Section 6.4(a)(i) when it is no longer needed by SGO for its proper management and administration or to carry out its legal responsibilities; and

(v) return or destroy all remaining PHI not so retained for SGO's proper management and administration or to carry out its legal responsibilities received from Participant, or created or received by SGO on behalf of Participant. SGO will retain no copies of the PHI, except as provided in Section 6.4(b) or to the extent that the PHI constitutes Limited Data Set Information.

(b) In the event that SGO reasonably determines that returning or destroying the PHI is infeasible, SGO may retain copies of the PHI and will promptly notify Participant of the circumstances that make return or destruction infeasible. Based on such determination, SGO will extend the protections of this Agreement to such PHI and limit any further Use or Disclosure of such PHI to those purposes that make the return or destruction infeasible, for so long as SGO maintains such PHI.

(c) The Parties acknowledge and agree that the provision of any PHI to SGO in accordance with the Participation Agreement is conditioned upon this Agreement being in full force and effect. Therefore, upon termination of this Agreement, the Parties agree that Participant will refrain from submitting PHI to SGO, and SGO will refrain from accepting PHI from Participant. In the event of a termination under either Section 6.4(b) or (c), either Party may also elect to terminate the Participation Agreement. In the event the Parties engage in negotiations undertaken in accordance with Section 8.2 of this Agreement, the Parties will suspend during such period of negotiation any provision of the Participation Agreement requiring or obligating either Party to Use or Disclose PHI in a manner that either Party reasonably believes would violate any applicable state or federal law or regulation, including without limitation the HIPAA Regulations.

(d) The obligations of Section 6.4 will survive any expiration or termination of this Agreement.

SECTION 7

Section 7.1 Each party to this Agreement agrees that it will be responsible for its own acts and omissions and the results thereof; and, shall not be responsible for the acts and omissions of the other party and the results thereof. Each party agrees that it will assume all risk and liability to itself, its agents, or its employees for any injury to persons or property resulting in any manner from conduct of its own operations and the operations of its agents or employees under this Agreement. Under no circumstances will either party be liable to the other for any indirect, consequential, special or punitive 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.

SECTION 8

MISCELLANEOUS

Section 8.1 **Regulatory References.** A reference in this Agreement to a section in the HIPAA Regulations means the section as in effect or as amended from time to time and for which compliance is required.

Section 8.2 **Amendment.** This Agreement may not be amended except by the mutual written agreement of the Parties. Notwithstanding the foregoing, the Parties agree to work together in good faith to take such action as is necessary to make technical amendments to this Agreement from time to time if necessary for Participant and/or SGO to comply with the requirements of HIPAA, the HIPAA Regulations, or any applicable provisions of any other federal or state law, as such laws or regulations may be amended from time to time. However, should any state or federal law or regulation now existing or enacted after the Effective Date of this Agreement, including without limitation HIPAA or the HIPAA Regulations, be amended or interpreted by judicial decision or a regulatory body in such a manner that either Party reasonably determines renders any provision of this Agreement in violation of such law or regulation or adversely affects the Parties' abilities to perform their obligations under this Agreement, the Parties agree to negotiate in good faith to amend this Agreement so as to comply with such law or regulation and to preserve the viability of this Agreement. If, after negotiating in good faith, the Parties are unable to reach agreement as to any necessary amendments, either Party may terminate this Agreement without penalty.

Section 8.3 **Interpretation.** Any ambiguity in this Agreement will be resolved in favor of a meaning that permits Participant and SGO to comply with the HIPAA Regulations. Where provisions of this Agreement are different from those mandated in the HIPAA Regulations, but are nonetheless permitted by the HIPAA Regulations, the provisions of this Agreement will control.

Section 8.4 **Third Party Beneficiaries.** SGO and Participant agree that Individuals whose PHI is Used or Disclosed to SGO or its Subcontractors under this Agreement are not third-party beneficiaries of this Agreement or the Participation Agreement.

Section 8.5 **Waiver.** No provision of this Agreement may be waived except by an agreement in writing signed by the waiving Party. A waiver of any term or provision shall not be construed as a waiver of any other term or provision.

Section 8.6 **Correspondence.** The Parties will send any reports or notices required under this Agreement to the addresses set forth in the notice provision of the Participation Agreement.

IN WITNESS WHEREOF, the Parties hereto have entered into this Agreement on the dates set forth below, so that it may take effect as of the Effective Date.

SOCIETY OF GYNECOLOGIC
ONCOLOGY

PARTICIPANT

By: _____
Print Name: _____
Title: _____
Date: _____

By: _____
Print Name: _____
Title: _____
Date: _____