## **ART DATA COLLECTION AGREEMENT**

- THIS ART DATA COLLECTION AGREEMENT ("Agreement") is made and entered into as of the Effective Date listed on the signature page hereto by and between the Society for Assisted Reproductive Technology ("SART") and the assisted reproductive technology clinic listed on the signature page hereto ("ART Clinic").
- WHEREAS, ART Clinic is an entity covered by HIPAA. ART Clinic requests SART to provide certain goods and/or services to ART Clinic as set forth herein, and in connection with those goods and/or services SART may create, receive, maintain or transmit PHI that is subject to protection under HIPAA.
- **NOW, THEREFORE**, in consideration of the foregoing and of the covenants and agreements set forth herein, the parties, intending to be legally bound, agree as follows:
- **Section 1. Definitions.** The terms used, but otherwise not defined in this Agreement, shall have the same meaning as those terms in HIPAA and the FCSRC Act, as applicable.
- (a) "Breach" shall have the meaning set forth in HIPAA, including, without limitation, the unauthorized acquisition, access, use, or disclosure of Protected Health Information in a manner not permitted by HIPAA.
- (b) "CDC" means the Centers for Disease Control and Prevention and, as appropriate, any contractor working on behalf of the CDC to collect data pursuant to the FCSRC Act.
- (c) "Clinic Reporting Data" means patient treatment and outcome data which is collected by ART Clinic for the time period beginning January 1 of the year in which the Effective Date occurs.
- (d) "Data Aggregation" shall have the meaning set forth in HIPAA, including, without limitation, the combining of Protected Health Information received by SART from ART Clinic with Protected Health Information received by SART from other assisted reproductive technology clinics for which SART acts as a business associate, to permit data analysis that relates to the health care operations of ART Clinic.
- (e) "Designated Record Set" shall have the meaning set forth in HIPAA, including, without limitation, a group of records maintained by or for ART Clinic that consist of: (i) the medical records and billing records about individuals maintained by or for ART Clinic; (ii) the enrollment, payment, claims adjudication, and case or medical management record systems maintained by or for a health plan; or (iii) records used, in whole or in part, by or for ART

- Clinic to make decisions about individuals. For purposes of this definition, the term "record" means any item, collection or grouping of information that includes Protected Health Information and is maintained, collected, used or disseminated by or for ART Clinic.
- (f) "Fertility Clinic Success Rate and Certification Act of 1992" or "FCSRC Act" shall mean Public Law 102-493, 42 USC 263a-1, *et seq.*, including any implementing regulations.
- (g) "HIPAA" shall mean: (i) the Health Insurance Portability and Accountability Act of 1996, and regulations promulgated thereunder, including the Privacy, Security, Breach Notification and Enforcement Rules at 45 CFR Parts 160 and 164, and any subsequent amendments or modifications thereto, and (ii) the HITECH Act, and regulations promulgated thereunder, and any subsequent amendments or modifications thereto.
- (h) "Historical Clinic Reporting Data" means patient treatment and outcome data collected by ART Clinic for the time period prior to January 1 of the year in which the Effective Date occurs.
- (i) "HITECH Act" shall mean the Health Information Technology for Economic and Clinical Health Act, found in the American Recovery and Reinvestment Act of 2009, Public Law 111-5.
- (j) "PHI" means Protected Health Information which SART creates, receives, maintains, or transmits on behalf of ART Clinic in connection with the performance of goods and/or services pursuant to this Agreement, including the Clinic Reporting Data and Historical Clinic Reporting Data.
- (k) "Protected Health Information" shall have the meaning set forth in HIPAA, including, without limitation, any information, whether oral or recorded in any form or medium, including an electronic format: (i) that relates to the past, present or future physical or mental health or condition of an individual; (ii) the provision of health care to an individual; or (iii) the past, present or future payment for the provision of health care to an individual; and (iv) that identifies the individual or with respect to which there is a reasonable basis to believe the information can be used to identify the individual.
- (l) "Required by Law" shall have the meaning set forth in HIPAA, including, without limitation, a mandate contained in law that compels ART Clinic or SART to make a use or disclosure of Protected Health Information and that is enforceable in a court of law.

1274232 v14 (Rev. 5/2018) Page 1 of 6

- (m) "Secretary" shall mean the Secretary of the U.S. Department of Health and Human Services or his/her designee.
- (n) "Security Incident" shall have the meaning set forth in HIPAA, including without limitation, the attempted or successful unauthorized access, use, disclosure, modification or destruction of electronic PHI.
- (o) "Unsecured PHI" shall have the meaning set forth in HIPAA, including, without limitation, PHI not secured through the use of encryption, destruction or other technologies and methodologies identified by the Secretary to render such information unusable, unreadable, or indecipherable to unauthorized persons.
- Section 2. Goods and/or Services Provided by SART. As of the Effective Date, SART will provide to the ART Clinic the following goods and/or services in accordance with the terms and conditions of this Agreement:
- (a) ART Data Collection Website. SART shall provide ART Clinic with access to SART's secure ART Data Collection website ("Website"). ART Clinic will input its Clinic Reporting Data and Historical Clinic Reporting Data into the Website. If necessary to obtain Historical Clinic Reporting Data, SART will use best efforts to provide software to ART Clinic to enable ART Clinic to transfer its Historical Clinic Reporting Data from an electronic database into the Website. For the health care operations of the ART Clinic, including quality assessment and improvement activities, and for the purpose of SART providing services in accordance with this Agreement, SART will arrange for the Clinic Reporting Data and Historical Clinic Reporting Data to be stored and maintained. ART Clinic will be able to access its own data contained on the Website for its health care operation activities.
- (b) Clinic Data Reporting Assistance. SART will convert the Clinic Reporting Data (and any Historical Clinic Reporting Data for the data year then collected by the CDC) contained on the Website into a format acceptable to the CDC and will submit the data to the CDC on the ART Clinic's behalf in accordance with the FCSRC Act. SART shall also assist ART Clinic in preparation of an annual reporting package as required by the FCSRC Act.
- (c) <u>De-Identification of Health Information</u>; <u>Data Aggregation</u>. In accordance with HIPAA, SART may remove from the Clinic Reporting Data and the Historical Clinic Reporting Data all individually identifiable health information ("De-Identified Clinic Data") and may use or disclose such De-Identified Clinic Data in SART's discretion. SART may also use Clinic Reporting Data and Historical Clinic Reporting Data to provide Data Aggregation Services to ART Clinic.
- (d) <u>Publication of ART Clinic Summary Reports.</u> SART will prepare a profile of ART Clinic for publication

- on a website maintained by SART or the App, as defined below. The profile will only contain De-Identified Clinic Data.
- (e) <u>Use of Data for Research Purposes</u>. SART will make De-Identified Clinic Data available to individuals or entities who will use the data for research purposes ("Researchers"). SART will also make PHI available to Researchers as permitted by HIPAA. As required by HIPAA, ART Clinic agrees to maintain and distribute to its patients a Notice of Privacy Practices which references the possible disclosure of ART Clinic's PHI for research purposes.
- (f) SART Mobile App. SART will provide certain mobile services to ART Clinic and its patients or potential patients through the use of a mobile application ("App"). In the event ART Clinic uses the App to communicate with patients, potential patients, or other users of the App or participates in the App in any other manner, the provisions of this Section 2(f) of this Agreement shall apply. SART may use Clinic Reporting Data or other information entered by ART Clinic into the Website in connection with the App. ART Clinic is solely responsible for ensuring that its use of the App and the information ART Clinic discloses through the App complies with all applicable state and federal rules, regulations, and laws. If state law requires certain actions, representations, or obligations by SART, as ART Clinic's business associate and/or the entity offering the App, in addition to those actions, representations, or obligations stated in the Agreement, ART Clinic is responsible for providing SART with written notification of such actions, representations, or obligations. ART Clinic is solely responsible for obtaining any and all patient consents or authorizations that are required by state or federal rules, regulations, or laws for use of the App. By participating in the App, ART Clinic acknowledges and consents to the transmission of information, which may include PHI, via the App, and consents to the storage of any information entered into the App, which may include PHI, by SART. By making the App available to ART Clinic, SART makes no representation or warranty to ART Clinic regarding the accuracy of the information entered into the App by a patient, potential patient, or other user of the App.

## Section 3. Obligations of SART.

- (a) <u>Permitted Uses</u>. SART shall not use PHI in any manner except for the purpose of permitting SART to provide goods and/or services pursuant to this Agreement; provided, however, that SART shall not use PHI in any manner that would constitute a violation of HIPAA if so used by ART Clinic. Notwithstanding, SART may use PHI: (i) for the proper management and administration of SART; (ii) to carry out the legal responsibilities of SART; or (iii) as Required by Law.
- (b) <u>Permitted Disclosures</u>. SART shall not disclose PHI in any manner except for the purpose of permitting SART to provide goods and/or services pursuant to this Agreement;

1274232 v14 (Rev. 5/2018)

Page 2 of 6

provided, however, that SART shall not disclose PHI in any manner that would constitute a violation of HIPAA if so disclosed by ART Clinic. Notwithstanding, SART may disclose PHI: (i) for the proper management and administration of SART if such disclosure is Required by Law or if "Reasonable Assurances" are obtained; (ii) to carry out the legal responsibilities of SART if such disclosure is Required by Law or if "Reasonable Assurances" are obtained; or (iii) as Required by Law. To the extent that SART discloses PHI to a third-party pursuant to Section 3(b)(i) or (ii) above under Reasonable Assurances, SART must obtain from the third-party in writing, prior to making any such disclosure: (x) reasonable assurance from the thirdparty that such PHI will be held in a confidential manner; (y) reasonable assurance from the third-party that such PHI will be used or further disclosed only as Required by Law or for the purpose for which it was disclosed to such third-party; and (z) an agreement from the third-party to immediately notify SART of any breaches of confidentiality of such PHI, to the extent the third-party has obtained knowledge of such breach (collectively, "Reasonable Assurances"). Upon notice from ART Clinic, and except as Required by Law, SART shall not disclose PHI to a health plan for payment or health care operations if the individual subject to the PHI has requested such restriction and the individual (or a designee) pays out of pocket in full for the health care item or service to which the PHI relates.

- (c) Appropriate Safeguards. In accordance with HIPAA, SART shall implement appropriate administrative, technical, physical, and security safeguards that reasonably and appropriately safeguard and protect the confidentiality, integrity and availability of electronic PHI that SART creates, receives, maintains or transmits on behalf of ART Clinic. As required by HIPAA, SART shall maintain policies, procedures and documentation that address these safeguards, and which are appropriate to the size and complexity of SART's operations and the nature and scope of its services for ART Clinic.
- (d) <u>SART's Subcontractors and/or Agents</u>. To the extent SART uses one or more subcontractors or agents to perform a function, activity or service for ART Clinic, and such subcontractors or agents create, receive, maintain, or transmit PHI, SART shall require in accordance with HIPAA that each subcontractor or agent agree in writing to be bound by the terms that apply through this Agreement and HIPAA to SART. SART shall report to ART Clinic in writing, as soon as possible, the discovery of noncompliance by a subcontractor or agent of any of its obligations with respect to PHI.
- (e) Access to PHI. SART shall make PHI (including electronic PHI) maintained by SART in a Designated Record Set available to ART Clinic for inspection and/or copying to enable ART Clinic to fulfill its obligations under HIPAA.
- (f) Amendment of PHI. SART shall amend PHI maintained by SART in a Designated Record Set as directed

by ART Clinic to enable ART Clinic to fulfill its obligations under HIPAA.

- (g) <u>Accounting of PHI Disclosures</u>. SART agrees to document disclosures of PHI and information related to such disclosures as would be required for ART Clinic to respond to a request by an individual for an accounting of disclosures in accordance with HIPAA.
- (h) <u>Governmental Access to Records</u>. SART shall make PHI and its facilities, internal practices, books, records, accounts, and other information relating to the use and disclosure of PHI available to the Secretary in a time and manner designated by the Secretary and shall cooperate with the Secretary concerning any investigation designed to determine ART Clinic's or SART's compliance with HIPAA.
- (i) Minimum Necessary Use and Disclosure Requirement. SART shall only request, use and disclose the minimum amount of PHI necessary to reasonably accomplish the purpose of the request, use or disclosure in accordance with HIPAA. Further, SART will restrict access to PHI to those employees, workforce members, subcontractors or agents of SART who are actively and directly participating in providing goods and/or services pursuant to this Agreement and who need to know such PHI in order to fulfill such responsibilities.
- (j) <u>Retention of PHI</u>. SART shall retain all PHI throughout the term of this Agreement and shall continue to maintain the information required under Section 3(g) of this Agreement for a period of six (6) years from its creation.
- (k) Notification Obligation; Mitigation. During the term of this Agreement, SART shall promptly notify ART Clinic of any use and/or disclosure of PHI not permitted by this Agreement or HIPAA, a Breach of Unsecured PHI, or any material Security Incident of which it becomes aware. This notification obligation shall include the information required by HIPAA and, at a minimum, shall provide ART Clinic with the following information to the extent known: (i) a description of the facts and circumstances concerning the improper use or disclosure, Breach or Security Incident; (ii) a description of the PHI affected; and (iii) the name and identity of the individual(s) affected. SART shall take prompt corrective action to mitigate and cure, if possible, any harmful effect that is known to SART of an improper use and/or disclosure of PHI, Breach or material Security Incident, SART shall cooperate with ART Clinic regarding any Breach notification to third parties. SART shall be deemed to discover a Breach of Unsecured PHI as of the first day on which such Breach is known, or by exercising reasonable diligence should have been known, by SART.
- (l) <u>Additional Obligations</u>. SART shall comply with the requirements of HIPAA, which are applicable to business associates, including all guidance and regulations which are issued to implement such requirements, as may be amended, modified or superseded from time to time. To the extent SART carries out one or more of ART Clinic's

1274232 v14 (Rev. 5/2018) Page 3 of 6

obligation(s) under 45 CFR Part 164, Subpart E, in the performance of such obligations, SART shall comply with the requirements of 45 CFR Part 164, Subpart E, that apply to ART Clinic to the same extent as required by ART Clinic.

## Section 4. <u>Obligations of ART Clinic.</u>

- (a) Notification of Amendment(s). ART Clinic shall promptly notify SART of any amendments to PHI that SART is relying on for purposes of providing the goods and/or services pursuant to the terms and conditions of this Agreement.
- (b) Notification of Limitation(s). ART Clinic shall promptly notify SART of any limitation(s) which may affect SART's use or disclosure of PHI, including limitations imposed by ART Clinic's Notice of Privacy Practices or any changes in, or revocation of, permission by individuals to use and/or disclose PHI, to the extent such changes or revocations affect SART's permitted or required uses and/or disclosures of PHI.
- (c) <u>Compensation to SART</u>. In return for the services provided by SART pursuant to this Agreement, ART Clinic will pay SART an annual fee as determined by SART from time to time. Payment of the annual fee by ART Clinic is due upon receipt of invoice from SART.
- (d) <u>Compliance with Reporting Deadlines</u>. ART Clinic will comply will all reporting deadlines established by SART, or its agents, for submission of Clinic Reporting Data so as to allow for compliance with the FCSRC Act. SART shall not be responsible for untimely or incomplete submission of reporting data to the CDC due to a failure of ART Clinic to comply with SART's, or its agents', deadlines, policies or directions.

## Section 5. Term and Termination.

- (a) <u>Term</u>. This Agreement shall commence on the Effective Date and will remain effective for one (1) year, unless terminated in accordance with the terms herein. Thereafter, this Agreement will automatically renew for successive one (1) year periods.
- (b) <u>Termination Without Cause</u>. Either party may, in its sole discretion, terminate this Agreement without cause by giving the other party at least ninety (90) days prior written notice.
- (c) For Cause Termination Due to Material Breach. ART Clinic may terminate this Agreement by notice in writing to SART in the event SART materially breaches this Agreement in any manner and such material breach continues for a period of thirty (30) days after written notice is given to SART by ART Clinic specifying the nature of the breach and requesting that it be cured. Where termination is not feasible, ART Clinic shall report SART's breach to the Secretary, if required by HIPAA.

- (d) Change of Circumstances. If: (i) any federal, state or local law, rule, regulation or interpretation at any time during the term of this Agreement prohibits, restricts or in any way materially and adversely affects the arrangement contemplated in this Agreement, (ii) there is any change in any federal, state, or local law, rule, regulation or interpretation which materially and adversely affects either party, including, without limitation, a material and adverse change in the economic benefit to be received pursuant to this Agreement, or (iii) any court of competent jurisdiction determines that any material provision of this Agreement is invalid, void, or unenforceable in whole or in part, ((i) (ii), (iii) separately and in the aggregate a "Material Change"), then the parties shall use their good faith best efforts to amend this Agreement in a manner which is consistent with any such Material Change and which substantially preserves for the parties the relative economic benefits of this Agreement. If the parties cannot reach agreement on such amendment within thirty (30) days following notice by one party to the other of the Material Change, with such notice to be accompanied by an opinion of counsel regarding the Material Change and its impact on the Agreement, this Agreement shall terminate as of the expiration of the thirty (30) day period.
- (e) Effect of Termination. Upon termination of this Agreement, SART shall return or destroy all PHI (regardless of form or medium), including all copies thereof and any data compilations derived from PHI and allowing identification of any individual who is the subject of the information, not to include De-Identified Clinic Data and PHI disclosed to and used by Researchers pursuant to Section 2(e). The obligation to return or destroy all PHI shall also apply to PHI that is in the possession of subcontractors or agents of SART. If the return or destruction of PHI is not feasible, SART shall provide ART Clinic with written notification of the conditions that make return or destruction not feasible. Upon such notification, SART shall continue to extend the protections of this Agreement to such information and limit further uses or disclosures of such PHI to those purposes that make the return or destruction of such PHI not feasible, for as long as SART maintains such information.
- Section 6. <u>Construction</u>. This Agreement shall be construed as broadly as necessary to implement and comply with HIPAA. The parties agree that any conflict between this Agreement and HIPAA or any ambiguity in this Agreement shall be resolved in favor of a meaning that complies and is consistent with HIPAA.
- Section 7. Notice. All notices and other communications required or permitted pursuant to this Agreement shall be in writing, addressed to the party at the mailing address, E-mail address or facsimile number set forth at the end of this Agreement, or to such other mailing address, E-mail address, or facsimile number as any party may designate from time to time in writing in accordance with this Section. All notices and other communications shall be sent by: (a) First Class Mail, postage pre-paid; (b) facsimile; or (c) E-mail. All notices shall be effective two (2)

1274232 v14 (Rev. 5/2018) Page 4 of 6

days following the date of mailing if sent by First Class Mail and as of the date of delivery if sent by facsimile or E-mail.

Section 8. Assignment. This Agreement and the rights and obligations hereunder shall not be assigned, delegated, or otherwise transferred by any party without the prior written consent of the other party and any assignment or transfer without proper consent shall be null and void. Notwithstanding, ART Clinic hereby agrees and acknowledges that SART may retain one or more agents or subcontractors to provide services to ART Clinic pursuant to this Agreement. Such agents or subcontractors will comply with Section 3(d) of this Agreement.

Section 9. Governing Law; Venue. This Agreement shall be governed by, and interpreted in accordance with, HIPAA and the internal laws of the State of Alabama, without giving effect to any conflict of law's provisions. Venue for any dispute relating to this Agreement shall be in Jefferson County, Alabama.

Section 10. <u>Binding Effect; Modification.</u> This Agreement shall be binding upon, and shall inure to the benefit of, the parties hereto and their respective permitted successors and assigns. SART may unilaterally amend this Agreement at any time by providing notice of the amendment to ART Clinic and such amendment will become effective not less than thirty (30) days following notice to the ART Clinic. In the event ART Clinic does not agree with the amendment, ART Clinic may terminate this Agreement as of the effective date of the amendment upon notice to SART; provided, however, that such notice of

termination must be received by SART no later than the effective date of the amendment. Except as set forth above, this Agreement may only be amended or modified by mutual written agreement of the parties.

Section 11. Waiver. The failure of any party at any time to enforce any right or remedy available hereunder with respect to any breach or failure shall not be construed to be a waiver of such right or remedy with respect to any other breach or failure by the other party.

Section 12. Severability. In the event that any provision or part of this Agreement is found to be totally or partially invalid, illegal, or unenforceable, then the provision will be deemed to be modified or restricted to the extent and in the manner necessary to make it valid, legal, or enforceable, or it will be excised without affecting any other provision of this Agreement, with the parties agreeing that the remaining provisions are to be deemed to be in full force and effect as if they had been executed by the parties subsequent to the expungement of the invalid provision.

Section 13. <u>Entire Agreement.</u> This Agreement constitutes the entire agreement between the parties with respect to the matters contemplated herein and supersedes all previous and contemporaneous oral and written negotiations, commitments, and understandings relating thereto.

Section 14. <u>Counterparts.</u> This Agreement may be executed in multiple counterparts, each of which shall constitute an original and all of which together shall constitute but one Agreement.

[Signatures on following page]

1274232 v14 (Rev. 5/2018) Page 5 of 6

**IN WITNESS WHEREOF**, SART and ART Clinic have each caused this Agreement to be executed in their respective names by their duly authorized representatives as of the Effective Date.

ART CLINIC	SART
(Print Name of ART Clinic) Signature:	The Society for Assisted Reproductive Technology  Signature:
Print Name/Title:	Print Name/Title: Jared C. Robins, MD, MBA, CEO SART
Address:	Address: 1209 Montgomery Highway
	Birmingham, Alabama 35216-2809
Telephone:	Telephone: (205) 978-5000 ext. 109
Facsimile:	Facsimile: (205) 978-5018
Email:	Email: jmarshall@asrm.org
Contact Person:	Contact Person: SART, Executive Administrator
Date: ("Effective Date")	

1274232 v14 (Rev. 5/2018) Page 6 of 6