

BUSINESS ASSOCIATE AGREEMENT

ADDENDUM TO THE FOUNDATION FOR THE ACCREDITATION OF CELLULAR THERAPY (FACT) ELIBILITY APPLICATION

THIS ADDENDUM is made a part of the Foundation for the Accreditation of Cellular Therapy (“FACT”) Eligibility Application (the “Underlying Agreement”), submitted to FACT by _____ (the “Surveyed Organization”). The Underlying Agreement, when accepted by FACT, establishes the terms of the relationship between FACT and the Surveyed Organization.

RECITALS

WHEREAS, FACT and the Surveyed Organization are parties to the Underlying Agreement, pursuant to which FACT provides an accreditation survey and related services (the “Survey Services”) to the Surveyed Organization;

WHEREAS, in connection with the Survey Services, the Surveyed Organization may disclose to FACT certain Protected Health Information (“PHI”) as that term is defined and is subject to protection under the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”), as amended by the Health Information Technology for Economic and Clinical Health Act Standards (“HITECH Standards”); the HIPAA Privacy Standards; and the HIPAA Security Standards (HIPAA, HITECH, and all pertinent regulations promulgated by the U.S. Department of Health and Human Services, including the Office of the National Coordinator for Health IT, thereunder are collectively referred to herein as “HIPAA”).

WHEREAS, the Surveyed Organization is a “Covered Entity” as that term is defined in the HIPAA Privacy Standards;

WHEREAS, as a recipient to PHI from the Surveyed Organization and a provider of accreditation services to the Surveyed Organization, FACT is a “Business Associate” as that term is defined in the HIPAA Privacy Standards;

WHEREAS, the purpose of this Addendum is to comply with the requirements of HIPAA.

NOW THEREFORE, in consideration of the mutual promise and covenants, herein, and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties agree as follows:

I. Definitions

The following terms used in this Agreement shall have the same meaning as those terms in HIPAA: Breach, Data Aggregation, Designated Record Set, Disclosure, Electronic PHI, Health Care Operations, Individual, Minimum Necessary, Notice of Privacy Practices, Protected Health Information/PHI, Required by Law, Secretary, Security Incident, Subcontractor, Unsecured Protected Health Information, and Use. Specific definitions include:

- A. Affiliate. “Affiliate” shall mean, when used in connection with a particular entity, any corporation, partnership, trust, joint venture, professional association or other entity, directly or indirectly controlling, controlled by, or under common control with such entity. “Control” including “controlling,” “controlled by,” and “under common control with,” shall mean the power to direct

or cause the direction of the management and policies through ownership of voting securities, by contract or otherwise of a corporation, partnership, trust, joint venture, or other entity.

- B. Business Associate. “Business Associate” shall mean the party named above as “FACT” and will generally have the same meaning as the term “Business Associate” at 45 C.F.R. § 160.103 .
- C. Covered Entity. “Covered Entity” shall have the same meaning as the term “covered entity” in 45 C.F.R. § 160.103.
- D. Effective Date. “Effective Date” shall mean the date that this Addendum has been signed by all Parties or April 14, 2003, whichever is later.
- E. HIPAA Privacy Standards. “HIPAA Privacy Standards” shall mean the Standards for Privacy of Individually Identifiable Health Information at 45 C.F.R. Parts 160 and 164 (Subparts A & E).
- F. HIPAA Security Standards. “HIPAA Security Standards” shall mean the regulations promulgated under HIPAA by the United States Department of Health and Human Services to protect the security of electronic Protected Health Information at 45 C.F.R. Parts 160 and 164 (Subparts A & C.)
- G. HITECH Standards. “HITECH Standards” shall mean the privacy, security, and security breach notification provisions applicable to a Business Associate under Subtitle D of the Health Information Technology for Economic and Clinical Health Act (“HITECH”), which is Title XIII of the American Recovery and Reinvestment Act of 2009 (Pub. L. No. 111-5), and any regulations promulgated thereunder.
- H. Protected Health Information (“PHI”) and Electronic Protected Health Information or Electronic PHI. “Protected Health Information” (“PHI”) and “Electronic Protected Health Information” or “Electronic PHI” shall generally have the same meaning as the terms are defined at 45 C.F.R. § 160.103, but for purpose of this Agreement will be limited to the PHI and ePHI created, received, transmitted or maintained by FACT on Surveyed Organization’s behalf.
- I. Unsecured PHI. “Unsecured PHI” shall mean PHI that is not rendered unusable, unreadable, or indecipherable through the use of a technology or methodology specified by the Secretary in the guidance issued under Section 13402(h)(2) of Public Law 111-5 on the HHS website.

II. OBLIGATIONS AND RESPONSIBILITIES OF FACT

FACT agrees to comply with applicable federal and state confidentiality and security laws, including but not limited to the HIPAA Privacy Standards, HIPAA Security Standards, and the HITECH Standards, including without limitation:

- A. Use and Disclosure of PHI. FACT shall not use or disclose PHI except as necessary to fulfill the purposes of the Underlying Agreement and this Addendum; provided, however, that FACT is permitted to use and disclose PHI as necessary for the proper management and administration of FACT or to carry out its legal responsibilities. FACT shall in such cases:

1. provide training to members of the FACT workforce regarding the confidentiality requirements in the HIPAA Privacy Standards and this Addendum;
 2. obtain reasonable assurance from the person or entity to whom the information is disclosed that: (i) the PHI will be held confidential and further used and disclosed only as Required by Law or for the purpose for which it was disclosed to the person or entity; and (ii) the person or entity will notify FACT of any instances of which it is aware in which confidentiality of the PHI has been Breached;
 3. agree to notify the Surveyed Organization within ten (10) business days of becoming aware of any instances in which the PHI is used or disclosed for a purpose that is not otherwise provided for in the Underlying Agreement or this Addendum or for a purpose not expressly permitted by the HIPAA Privacy Standards; and
 4. make all reasonable efforts not to access, Use, or Disclose more than the Minimum Necessary amount of PHI to accomplish the intended purpose of the access, Use, or Disclosure.
- B. Disclosure to Third Parties. If FACT discloses PHI to agents, including subcontractors, FACT shall require the agents to agree to the same restrictions and conditions that apply to FACT under this Addendum. FACT shall ensure that any agent, including a subcontractor, agrees to implement reasonable and appropriate safeguards to protect the confidentiality, integrity, and availability of any electronic PHI that it creates, receives, maintains, or transmits on behalf of Surveyed Organization. Upon Surveyed Organization's request, FACT shall provide Surveyed Organization with a copy of the third party's written assurances.
- C. Data Aggregation. In the event that FACT works for more than one Covered Entity, FACT is permitted to use and disclose PHI for Data Aggregation purposes, but only in order to analyze data for permitted health care operations, and only to the extent that such use is permitted under the HIPAA Privacy Standards. FACT shall not Disclose Surveyed Organization's aggregated data in a manner that identifies Surveyed Organization without Surveyed Organization's prior written consent.
- D. De-Identified Information. Use and Disclosure of de-identified health information is permitted, but only if (i) the precise use is disclosed to the Surveyed Organization and permitted by the Surveyed Organization in its sole discretion and (ii) the de-identification is in compliance with 45 CFR § 164.502(d), and (iii) any such de-identified health information meets the standard and implementation specifications for de-identification under 45 CFR § 164.514(a) and (b), or such regulations as they may be amended from time to time.
- E. Notice of Privacy Practices. FACT agrees that it will abide by the limitations of any Notice of Privacy Practices ("Notice") published by the Surveyed Organization of which it has knowledge. The Surveyed Organization shall provide FACT such Notice when it is adopted or amended. The amended Notice shall not affect permitted uses and disclosures on which FACT relied prior to such Notice.
- F. Withdrawal of Authorization. An individual's authorization is not required when PHI is being used for accreditation purposes pursuant to a business associate agreement. However, if the user or

Disclosure of PHI in this Addendum is based upon an Individual's specific authorization, and the Individual revokes such authorization in writing, or the effective date of such authorization has expired or is found to be defective in any other manner that renders it invalid, FACT agrees, if it has notice of such revocation or invalidity, to cease the use and disclosure of any such Individual's PHI except to the extent it has relied on such use or disclosure or where an exception under the HIPAA Privacy Standards expressly applies.

G. Use or Disclosure that Would Violate HIPAA. FACT shall not use or disclose PHI in a manner that would violate the requirements of the HIPAA Privacy Standards if the PHI were so used or disclosed by the Surveyed Organization.

H. Safeguards. FACT shall maintain appropriate safeguards to ensure that PHI is not used or disclosed other than as provided by this Addendum or as Required by Law. FACT shall implement safeguards that reasonably and appropriately protect the confidentiality, integrity, and availability of any electronic PHI that it creates, receives, or transmits on behalf of Surveyed Organization.

I. Individual Rights.

1. Individual Rights Regarding Designated Record Sets. It is not anticipated that FACT will maintain information in a Designated Record Set that is not also maintained by the Surveyed Organization. However, if there is a circumstance in which FACT maintains a Designated Record Set of information not also maintained by the Surveyed Organization, FACT agrees:

(a) to incorporate any amendments or corrections to PHI maintained by FACT as requested by the Surveyed Organization; and

(b) to make available to the Surveyed Organization the PHI necessary for the Surveyed Organization to respond to an Individual's request to inspect or copy PHI about the Individual in that set under conditions and limitations required under 45 CFR § 164.524 as it may be amended from time to time. Because the Surveyed Organization is required to take action on such requests as soon as possible, but no later than 30 days following receipt of the request, FACT agrees to make reasonable efforts to assist Surveyed Organization in meeting this deadline.

2. Individual Right to Accounting of Disclosures. FACT agrees to document disclosures of PHI, recording such information as would be required for an accounting of disclosures of PHI to an Individual in accordance with HIPAA, the HIPAA Privacy Standards, and the HITECH Standards, including but not limited to 45 CFR § 164.528. Upon request by the Surveyed Organization, FACT agrees to make such documentation available to the Surveyed Organization in order to allow the Surveyed Organization to comply with an Individual's request for accounting of disclosures. Because the Surveyed Organization is required to take action on such requests as soon as possible but no later than 60 days following receipt of the request, FACT agrees to use its best efforts to assist the Surveyed Organization in meeting this deadline.

J. Internal Practices, Books, and Records. FACT shall make available its internal practices, books, and records relating to the use and disclosure of PHI received from, created, or received by FACT

on behalf of the Surveyed Organization to the Secretary or his/her agents for the purpose of determining the Surveyed Organization's compliance with the HIPAA Privacy Standards, the HIPAA Security Standards, and the HITECH Standards.

- K. Knowledge of HIPAA. FACT agrees to review and understand HIPAA as it applies to FACT, and to comply with the applicable requirements of HIPAA and HITECH (including, without limitation, 45 CFR §§ 164.308, .310, .312, and .316), as well as any applicable amendments.
- L. Security Incident. FACT agrees to report to Surveyed Organization a security incident (as defined by the HIPAA Security Regulations) of which FACT becomes aware. In addition, FACT agrees to report to Surveyed Organization a Breach consistent with the HITECH Standards of which FACT becomes aware.
- M. Securing PHI. FACT shall secure any and all electronic PHI covered by this Addendum in accordance with the guidance issued by the Secretary entitled "Guidance Specifying the Technologies and Methodologies that Render Protected Health Information Unusable, Unreadable, or Indecipherable to Unauthorized Individuals," as amended and updated from time to time. In addition, with respect to PHI covered by this Addendum, FACT shall comply with guidance issued by the Secretary under the authority of HITECH Section 13401(c). FACT shall use best efforts to avoid the creation or storage of paper PHI.
- N. Breach Notification. The parties acknowledge and agree that 45 C.F.R. Subpart D (the "Breach Notification Rule") applies to business associates. FACT shall comply with the Breach Notification Rule.
- O. Notification of Breach. Following the discovery of a Breach of Unsecured PHI, FACT shall notify Surveyed Organization without unreasonable delay.
- P. Privacy Provisions of HITECH. FACT acknowledges and agrees that the privacy provisions of HITECH apply to business associates; accordingly, such provisions are herein incorporated into this Addendum.
- Q. Mitigation. FACT shall have procedures in place to mitigate, to the extent practicable, an adverse effect from a use or disclosure of PHI in violation of this Addendum or applicable law.

III. OBLIGATIONS OF THE SURVEYED ORGANIZATION

- A. Notice of Privacy Practices. The Surveyed Organization shall notify FACT of any limitation(s) in its Notice of Privacy Practices to the extent that such limitation(s) may affect FACT's use or disclosure of PHI, and shall promptly notify FACT of any changes or amendments to its Notice of Privacy Practices.
- B. Authorization. The Surveyed Organization shall obtain all necessary authorizations required under the HIPAA Privacy Standards as are necessary to allow FACT to fulfill its obligations under the Underlying Agreement and this Addendum.

- C. Notice of Changes in Authorization. The Surveyed Organization shall notify FACT if an Individual revokes an authorization, the effective date of an authorization has expired, or an authorization is found to be defective in any manner that renders it invalid to the extent that such event affects FACT's use or disclosure of PHI.
- D. Notice of Additional Agreed Restrictions. The Surveyed Organization shall notify FACT of any additional agreed restrictions related to the use or disclosure of PHI to which the Surveyed Organization has agreed under 45 CFR § 164.522 to the extent that such additional agreed restrictions may affect FACT's use or disclosure of PHI.
- E. Redaction. The Surveyed Organization shall redact all PHI from any document submitted to FACT, unless an unredacted copy is specifically requested by FACT.

IV. TERM AND TERMINATION

- A. Term. This Addendum shall be effective as of the Effective Date, and shall remain in effect unless termination by either party is requested and received in writing, until the Underlying Agreement is terminated or expires, or unless this Addendum is terminated for cause under Section IV.C., below.
- B. Effect of Termination. Upon termination of this Addendum or the Underlying Agreement, FACT agrees to return or destroy all PHI received from the Surveyed Organization that FACT maintains in any format and shall comply with federal and state laws as they may be amended from time to time governing the maintenance of retention of PHI. If FACT determines that the return or destruction of PHI is not feasible, FACT shall so inform the Surveyed Organization, and FACT agrees to extend the protections of this Addendum to the information and limit further uses and disclosures of the PHI to those purposes that make the return or destruction of the PHI infeasible, for so long as FACT retains the PHI.
- C. Termination for Cause. If either party terminates a material term of this Addendum, either party may, at its option, terminate this Addendum. The termination of this Addendum shall also terminate the Underlying Agreement.

V. MISCELLANEOUS

- A. No Third Party Beneficiaries. Nothing in this Addendum is intended to confer on any person other than the Parties to this Addendum or their respective successors and assigns, any rights, remedies, obligations or liabilities under or by reason of this Addendum. Nothing in this Addendum shall be considered or construed as conferring any right or benefit on a person not a party to this Addendum nor imposing any obligations on either Party hereto to persons not a party to this Addendum. Neither this Addendum nor the performance hereunder shall be deemed to have created a partnership, agency, joint venture or other business enterprise between the Parties hereto other than that of independent contractors.
- B. Survival. The respective rights and obligations of FACT under Section IV.B. of this Addendum with regard to records management shall survive the termination of this Addendum or the Underlying Agreement.

- C. Inconsistency with Underlying Agreement. To the extent there are inconsistencies between this Addendum and the terms of the Underlying Agreement, the terms of this Addendum will prevail.
- D. Headings. The paragraph headings in this Addendum have been inserted for convenience of reference only, and shall in no way restrict or otherwise affect the construction of the terms or provisions of this Addendum.
- E. Regulatory References. References to the C.F.R. (“Code of Federal Regulations”) in this Addendum mean the cited section of the C.F.R. as that section may be amended from time to time.
- F. Assignment. Neither Party may assign (whether by operation or law or otherwise) any of its rights or delegate or subcontract any of its obligations under this Agreement without the prior written consent of the other Party. Notwithstanding the foregoing, Surveyed Organization shall have the right to assign its rights and obligations hereunder to any entity that is an Affiliate or successor of Surveyed Organization, without the prior approval of Business Associate, provided that Surveyed Organization shall provide FACT notice of such assignment.
- G. Limitation of Liability. FACT shall not be liable to Surveyed Organization for any indirect, incidental, consequential, special, exemplary or punitive damages of any kind or nature, whether such liability is asserted on the basis of contract, tort (including negligence or strict liability), or otherwise, even if Surveyed Organization has been advised of the possibility of such loss or damages. Likewise, Surveyed Organization shall not be liable to FACT for any incidental, consequential, special, or punitive damages of any kind or nature, whether such liability is asserted on the basis of contract, tort (including negligence or strict liability), or otherwise, even if FACT has been advised of the possibility of such loss or damages.
- H. Amendment. This Addendum 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. FACT and the Surveyed Organization agree to take such action as is necessary to amend this Addendum from time to time as necessary for FACT and Surveyed Organization to comply with the requirements of HIPAA and guidance from the Secretary as they may be issued or amended from time to time.
- I. Changes in Law. The parties recognize that this Agreement is at all times subject to applicable state, local, and federal laws. The parties further recognize that this Agreement may become subject to amendments in such laws and regulations and to new legislation, regulatory guidance and instructions and decisional law (“Change in Law”). Any provisions of law that invalidate, or are otherwise inconsistent with, the material terms and conditions of this Agreement, or that would cause one or both of the parties hereto to be in violation of law, shall be deemed to have superseded the terms of this Agreement. In such event, the parties agree to utilize their best efforts to modify the terms and conditions of this Agreement to be consistent with the requirements of such law(s) in order to effectuate the purposes and intent of this Agreement. Within thirty (30) days of a Change in Law, either party may submit to the other party proposed modifications to the terms and conditions of this Agreement in light of the Change in Law. If the parties fail to agree upon proposed modifications to the terms and conditions of this Agreement by executing a written amendment within an additional thirty (30) days, either party may, by giving the other party an additional sixty (60) days written notice, terminate this Agreement, unless it would terminate earlier by its terms. In the event a Change in Law precludes or substantially precludes a contractual

relationship between the parties similar to that expressed in this Agreement, then, under such circumstances, where renegotiation of the applicable terms of this Agreement would be futile, either party may, upon at least sixty (60) days advance written notice, terminate this Agreement, unless it would terminate earlier by its terms. Upon termination of this Agreement as hereinabove provided, neither party shall have any further obligation hereunder except for (i) obligations occurring prior to the date of termination, and (ii) obligations, promises or covenants contained herein which are expressly made and intended to extend beyond the term of this Agreement.

- J. Indemnification. Both FACT and Surveyed Organization hereby agree to indemnify and hold harmless the other, its Affiliates, and their respective officers, directors, managers, shareholders, employees, and agents from and against any and all fines, penalties, damage, claims, or causes of action and expenses (including, without limitation, court costs, and attorney's fees) either Party incurs, arising from violations of the HIPAA Act, the HIPAA Regulations, the HITECH Act, or from any negligence or wrongful acts or omissions, including, but not limited to, failure to perform its obligations that results in a violation of the HIPAA Act, the HIPAA Regulations, or the HITECH Act, by either Party or its employees, directors, officers, subcontractors, agents, or members of its workforce.
- K. Notices. Any notices required or permitted to be given hereunder by either Party to the other shall be given in writing: (1) by personal delivery; (2) by electronic mail or facsimile with confirmation sent by United States first class registered or certified mail, postage prepaid, return receipt requested; (3) by bonded courier or by a nationally recognized overnight delivery service; or (4) by United States first class registered or certified mail, postage prepaid, return receipt requested, in each case, addressed to a Party on the signature page(s) to this Agreement or to such other addresses as the Parties may request in writing by notice given pursuant to this Section. Notices shall be deemed received on the earliest of personal deliver; upon delivery by electronic email or facsimile with confirmation from the transmitting machine that the transmission was completed; twenty-four (24) hours following deposit with a bonded courier or overnight delivery service; or seventy-two (72) hours following deposit in the U.S. mail as required herein.
- L. Attorney's Fees. If any legal action or other proceeding of any kind is brought for the enforcement of this Agreement, or because of any alleged breach, default, or any other dispute in connection with any provision of this Agreement, the successful or prevailing party shall be entitled to recover all reasonable attorney's fees and other costs incurred in any such action or proceedings, in addition to any relief to which it may be entitled.
- M. Counterparts. This Agreement may be executed in one or more counterparts, each of which shall be deemed to be an original, but all of which together shall constitute one and the same instrument.

By Execution hereof by duly authorized representatives of both Parties, the Parties hereby acknowledge, agree to and shall be bound by the terms, provisions and conditions of this Addendum.

[SIGNATURES ON FOLLOWING PAGE]

Agreed to:

FOUNDATION FOR THE ACCREDITATION OF CELLULAR THERAPY (“FACT”)

By: _____

Name: Linda Miller, MPA

Title: FACT Chief Operating Officer

Date: _____

Agreed to:

PROGRAM

By: _____
(Authorized Signature)

Name: _____
(Type or Print)

Title: _____

Date: _____