BUSINESS ASSOCIATE AGREEMENT

ADDENDUM TO THE FOUNDATION FOR THE ACCREDITATION OF CELLULAR THERAPY (FACT) ELIGIBILITY 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 discloses to FACT certain Protected Health Information ("PHI") that 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 the regulations promulgated by the U.S. Department of Health and Human Services 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 of 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 HIPAA Privacy Standards require a Covered Entity to receive adequate assurances, in the form of a written agreement, that its Business Associates will comply with certain obligations with respect to the PHI received in the course of providing services on behalf of the Covered Entity; and

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

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

I. Definitions

Capitalized terms not otherwise defined herein shall have the following meanings:

A. Breach. "Breach" shall mean the acquisition, access, use or disclosure of PHI in a manner not permitted under the Privacy Rule which "compromises the security or privacy of the PHI" as set forth in 45 C.F.R. § 164.402; provided however, that a Breach shall not include (i) any unintentional acquisition, access, or use of PHI by a workforce member or person acting under the authority of Surveyed Organization or FACT, if such acquisition, access, or use was made in good faith and within the scope of authority and does not result in a further use or disclosure in a manner not permitted under the Privacy Rule; (ii) any inadvertent disclosure by a person authorized to access PHI at Surveyed Organization or FACT to another person authorized to access PHI at Surveyed Organization or FACT, or an organized health care arrangement in which Surveyed Organization participates, and the information received as a result of such disclosure is not further used or disclosed in a manner not permitted under the Privacy Rule; or (iii) a disclosure of PHI where Surveyed Organization or FACT has a good faith belief that the unauthorized person to whom the disclosure was made would not have reasonably been able to retain the disclosed information.

B. Business Associate. "Business Associate" shall have the same meaning as the term "business associate" in 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. Data Aggregation. "Data Aggregation" shall have the same meaning as the term "data aggregation" in 45 C.F.R. § 164.501.

E. Designated Record Set. "Designated Record Set" shall have the same meaning as the term "designated record set" in 45 C.F.R. § 164.501.

F. Individual. "Individual" shall have the same meaning as the term "individual" in 45 C.F.R. § 160.103 and shall include a personal representative under 45 C.F.R. § 164.502(g).

G. Effective Date. "Effective Date" shall mean the date that this Addendum has been signed by all Parties or April 14, 2003, whichever is later.

H. HIPAA. "HIPAA" shall mean the Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191, codified at 42 U.S.C. Section 1320d et. seq.

I. 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).

J. 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).

K. 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.

L. Protected Health Information ("PHI"). "Protected Health Information" ("PHI"), shall have the same meaning as the term "protected health information" in 45 C.F.R. § 160.103, limited to the information created or received by FACT from or on behalf of the Surveyed Organization.

M. Required by Law. "Required by Law" shall have the same meaning as the term "required by law" in 45 C.F.R. § 164.103.

N. Secretary. "Secretary" shall mean the Secretary of the Department of Health and Human Services.

O. 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 assurances 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 of any instances of which it is aware 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. ensure that all disclosures of PHI are subject to the principle of "minimum necessary use and disclosure," *i.e.*, only PHI that is the minimum necessary to accomplish the intended purpose of the use, disclosure, or request may be disclosed.

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.

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.

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 to 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 use 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 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, maintains, 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 not later than 30 days following receipt of the request, FACT agrees to make reasonable efforts to assist the 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 not 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 C.F.R. §§ 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 C.F.R. § 164.522 to the extent that such additional agreed restrictions may affect FACT's use or disclosure of PHI.

IV. TERM AND TERMINATION

A. Term. This Addendum shall be effective as of the Effective Date, and shall terminate upon termination of the Underlying Agreement, unless sooner terminated for cause under Section IV.C., below.

B. Effective 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 form and shall comply with federal and state laws as they may be amended from time to time governing the maintenance or 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.

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.

Agreed to:

FOUNDATION FOR THE ACCREDITATION OF CELLULAR THERAPY ("FACT")

By:_____

Name: Phyllis I. Warkentin, M.D.

Title: FACT Chief Medical Officer

Date:_____

Agreed to:

PROGRAM

By:_____
(Authorized Signature)

Name:_____
(Type or Print)

Title:_____

Date:_____