

 FOUNDATION FOR THE ACCREDITATION OF CELLULAR THERAPY Policies and Procedures	Policy	Document #: 11.HQC.POL.005 Revision: 4 Approval Date: 21/October/2026 Page 1 of 2 Effective Date: 21/October/2026
FACT Business Associate Agreement Policy		

1.0 Purpose

This policy establishes the terms governing the relationship between the Foundation for the Accreditation of Cellular Therapy (FACT) and a Surveyed Organization for the purpose of FACT providing accreditation surveys and related services to the Surveyed Organization.

2.0 Scope

This policy applies to FACT personnel who are responsible for conducting accreditation surveys and providing related services to Surveyed Organizations.

3.0 Responsibility

3.1 The Senior Coordinator, Business Services is responsible for:

- 3.1.1 Ensuring that Surveyed Organizations have a fully executed Business Associate Agreement (BAA) on file with FACT.
- 3.1.2 Reviewing Business Associate Agreements provided by a Surveyed Organization to ensure compliance with HIPAA and applicable federal privacy and security regulations.

3.2 Surveyed organizations are responsible for complying with this policy.

4.0 References

- 4.1 [FACT Business Associate Agreement](#), 11.HQC.FRM.005
- 4.2 FACT Record Retention Policy for Surveyed Organizations, 11.HQC.POL.007
- 4.3 Privacy and Security Policy, 11.HQC.POL.011

5.0 Definitions and Abbreviations

- 5.1 Covered Entity: individuals or organizations engaged in the electronic creation, reception, maintenance, or transmission of Protected Health Information (PHI).
- 5.2 HIPAA: Health Insurance Portability and Accountability Act of 1996.
- 5.3 HITECH Standards: Health Information Technology for Economic and Clinical Health Act Standards.
- 5.4 Protected Health Information (PHI): any health information that can identify an individual that is in possession of or transmitted by a "covered entity" or its business associates that relates to a patient's past, present, or future health.
- 5.5 Surveyed Organization: Clinical program, cellular therapy collection facility, cellular therapy processing facility, cord blood bank (including cord blood collection sites and cord blood

processing facilities), or immune effector cellular therapy program, that is undergoing accreditation or re-accreditation by FACT.

6.0 Policy

6.1 Business Associate Agreement Requirement

6.1.1 FACT shall comply with the HIPAA Privacy Rule, applicable HITECH amendments, and the *Privacy and Security Policy* by requiring all Surveyed Organizations to maintain a signed Business Associate Agreement with FACT.

6.1.2 FACT is a Business Associate of the Surveyed Organization when performing services on behalf of the Surveyed Organization that involve the use or disclosure of Protected Health Information (PHI).

6.2 Execution of Business Associate Agreements

6.2.1 A Business Associate Agreement shall be requested at the initiation of the accreditation or re-accreditation process.

6.2.2 The Business Associate Agreement may be either [*FACT Business Associate Agreement*](#) or an agreement provided by the Surveyed Organization, subject to review and approval by FACT.

6.2.3 Business Associate Agreements are effective for the duration of the relationship between FACT and the Surveyed Organization and do not require routine renewal unless materially amended or terminated.

6.3 Review and Compliance

6.3.1 Business Associate Agreements provided by a Surveyed Organization shall be reviewed by the FACT Senior Coordinator, Business Services to ensure compliance with HIPAA and applicable federal privacy and security regulations.

6.3.2 FACT reserves the right to require modifications to a Surveyed Organization's agreement if necessary to ensure regulatory compliance.

6.4 Record Retention

6.4.1 Executed Business Associate Agreements shall be maintained in accordance with *FACT Record Retention Policy for Surveyed Organizations*.

6.5 Termination

6.5.1 Failure of a Surveyed Organization to execute or maintain a compliant Business Associate Agreement may result in denial, suspension, or termination of accreditation-related services at the discretion of FACT.

Approved by (date):

Heather Conway (Director, Quality Improvement & Compliance) (21/October/2026), Linda Miller (Chief Operating Officer) (22/September/2026)