

Memorandum of Understanding

Between

Center for Disease Analysis Foundation, Inc

and

Cherokee Nation Health Services

This Memorandum of Understanding (MOU) sets forth the terms and understanding between Center for Disease Analysis Foundation, Inc (CDAF) and the Cherokee Nation Health Services (CNHS) to analyze the epidemiology, disease burden, economic burden, and strategies to eliminate hepatitis C virus (HCV) and hepatitis B virus (HBV) in the Cherokee Nation.

Background

CDAF is a non-profit organization committed to the elimination of viral hepatitis. It has conducted similar analyses in over 85+ countries around the world. In each country, close collaboration with a panel of local clinical, research and health system experts is crucial for ensuring the highest quality of work.

The Cherokee Nation is one of the first nations to implement a program to eliminate hepatitis C and it can play a vital role in collaborating to collect epidemiology data to model the hepatitis disease burden. In turn, the results of the analyses hold important implications for health policy decision makers on how to best manage HCV and HBV infection at the population level.

Roles and Responsibilities

The above goals will be accomplished by undertaking the following activities:

- CDAF shall conduct an exhaustive literature search for available data.
- CDAF shall develop a computer model using Microsoft Excel^{® 10} track the historical burden of disease and forecast the future burden of disease.
- CNHS shall assist in providing data specific to the Cherokee Nation and list of experts interested in collaborating.
- CDAF shall invite the experts to collaborate on the project and shall set up a teleconference, approximately 3 hours in length.
- CDAF shall facilitate the teleconference, with the purpose of presenting findings from the literature search and seeking additional data and consultation from the expert panel.
- CDAF shall update the computer model with any additional data and recalibrate the model.
- CDAF shall coordinate a second meeting, this time in-person, with the purpose of (a) reaching consensus from the expert panel on all data inputs and (b) developing potential strategies for reducing the burden of HCV and HBV through various treatment and screening interventions.
- CDAF shall report the findings of the analysis, in collaboration with the expert panel, to CNHS and provide a report that summarized the findings.

Funding

CDAF and CNHS will collaborate to secure a grant to support conducting the analyses outlined above.

Duration

CDAF shall make every effort to complete the project in a 4-8 week period. This MOU is at-will and may be modified by mutual consent of CDAF and CNHS.

Confidentiality:

The NATION represents that it is a covered entity (CE) as defined by the Health Insurance Portability and Accountability Act of 1996 (HIPAA). Both parties agree to abide by the Business Associate Attachment, incorporated herein as Attachment "A".

Data Ownership and Data Sharing Plan

As a domestic sovereign nation, the tribe insists upon retention of intellectual ownership of the data and all aspects of the research and complete control over usage of tribal data, including the sharing, presentation, and/or publication of individual or aggregated data analyses.

The CDAF and the funding agency will be granted a royalty free, nonexclusive right to reproduce, publish or otherwise use the data for educational and research purposes in furtherance of the aims of the research project, but **only after** the tribal publication review committee had an opportunity to review and approve such requests.

IRB Approval Requirement- Before any primary data are collected or secondary data are analyzed, an IRB application will be reviewed and approved by Cherokee Nation IRB and then submitted to and approved by other relevant IRBs.

Publication and Dissemination – Researchers aim to disseminate project findings in peer-reviewed journals and at scientific research conferences must submit for review manuscripts, posters or any form of publication for tribal publication committee’s review and approval in a timely fashion.

Data sharing with Outside Researchers and the Public – We are aware of the goal to share data with researchers and in some cases the public, such as through provisions of the Office of Management and Budget circular A-110 to provide public access to research data through the Freedom of Information Act under some circumstances. However, federally recognized tribes enjoy special protections as domestic dependence sovereignties, so we will follow procedures for access to all data generated under this program. Any entity other than the Cherokee Nation or its research intensive partner or the sponsor of the project wishing to access, view or use the data from this study will need to ask for explicit permission from the Cherokee Nation and proceed through a Cherokee Nation review process. A key feature of this process will be an agreement by the outside entity to submit all public presentations and manuscripts to the appropriate tribal authorities for review and approval prior to dissemination and publication. In some instances, the Cherokee Nation may require that their communities not be identified; this precaution is taken to protect the community harm, which may occur due to careless disclosure of sensitive information about a small socially identifiable population.

Contact Information

Center for Disease Analysis Foundation, Inc.
Dr. Homie Razavi
Managing Director
+1 720.890.4848
homie.razavi@cdafound.org

Cherokee Nation Health Services
Dr. Jorge Mera
Director of Infectious Diseases
+1 918 525 2194
jorge-mera@cherokee.org

Signatures

Homie Razavi

Dr. Homie Razavi
Managing Director
Center for Disease Analysis Foundation

March 1, 2019

Date

Jorge Mera

Dr. Jorge Mera
Director of Infectious Diseases
Cherokee Nation

2/21/2019

Date

Stephen Jones 2/1

Dr. R. Stephen Jones, Interim Executive Director,
Health Services

2/19/19

Date

Rebecca Mitchell, Director of Acquisition
Management

Date

ATTACHMENT "A"

CHEROKEE NATION BUSINESS ASSOCIATE AGREEMENT CONFIDENTIALITY AND SECURITY OF PROTECTED HEALTH INFORMATION

This Business Associate Agreement is entered into between Cherokee Nation Health Services (NATION) and _____ (Business Associate). Business Associate may have or obtain access to confidential protected health information (PHI) as defined below, including but not limited to individually identifiable health information, some of which may be maintained in electronic format (e-PHI). The functions or activities authorized to be performed by Business Associate for or on behalf of the NATION are described below or in the underlying agreement between the parties, incorporated herein:

Additional Definitions:

Business Associate. "Business Associate" shall generally have the same meaning as the term "Business Associate" at 45 CFR 160.103.

HIPAA Rules. "HIPAA Rules" shall mean the Privacy, Security, Breach Notification, and Enforcement Rules at 45 CFR Part 160 and Part 164, all as may be amended.

The following terms used in this Agreement shall have the same meaning as those terms in the HIPAA Rules: Access, Acquisition, Allowed, Breach, Data Aggregation, Designated Record Set, Disclosure, Discovery, Health Care Operations, Individual, Marketing, Minimum Necessary, Notice of Privacy Practices, Protected Health Information, Required By Law, Research, Reasonable Diligence, Secretary, Security Incident, Subcontractor, Unsecured PHI, and Use.

Obligations of Business Associate:

Business Associate may use Electronic PHI and PHI (collectively, "PHI") solely to perform its duties and responsibilities under this Agreement and only as provided in this Agreement. Business Associate acknowledges and agrees that PHI is confidential and shall not be used or disclosed, in whole or in part, except as provided in this Agreement or as required by law. Business Associate will:

1. use or further disclose PHI only as permitted in this Agreement or as Allowed or Required by Law, including, but not limited to the Privacy and Security Rule;
2. 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;
3. implement and document appropriate administrative, physical, and technical safeguards to protect the confidentiality, integrity, and availability of PHI that it creates, receives, maintains, or transmits for or on behalf of NATION in accordance with 45 CFR 164;
4. implement and document administrative safeguards to prevent, detect, contain, and correct Security violations in accordance with 45 CFR 164;
5. make its policies and procedures required by the Security Rule available to NATION solely for purposes of verifying BA's compliance and the Secretary of the Department of Health and Human Services (HHS);
6. not receive remuneration from a third party in exchange for disclosing PHI received from or on behalf of NATION;
7. not use PHI for marketing;
8. not use PHI for research without prior written approval of the NATION's Internal Review Board;
9. report to NATION in writing any impermissible access, use or disclosure of PHI within five (5) working days of becoming aware of it and mitigate, to the extent practicable and in cooperation with NATION, any harmful effects known to it of a use or disclosure made in violation of this Agreement;

10. report to NATION in writing within five (5) working days of any Security Incident, as defined in the Security Rule, with respect to Electronic PHI;
11. notify NATION in writing within five (5) working days, upon the discovery of a breach of Unsecured PHI. Such notice shall include, to the extent possible, the name of each individual whose Unsecured PHI has been, or is reasonably believed by Business Associate to have been, accessed, acquired, or disclosed during such Breach. Business Associate shall be responsible for notification of the Secretary, media or individuals required under Sections 13402(e)2 and 13402(f) of the HITECH Act arising from its own actions or inactions.
12. indemnify and hold NATION harmless from all claims, liabilities, costs, and damages arising out of or in any manner related to the impermissible acquisition, access, use or disclosure by Business Associate of any PHI or to the breach by Business Associate of any obligation related to PHI;
13. document disclosure of PHI and information related to such disclosure as would be required for NATION to respond to a request by an Individual for an accounting of disclosures of PHI, in accordance with 45 CFR 164.528, and within five (5) working days of receiving a request from NATION, make such disclosure documentation and information available to NATION. In the event the request for an accounting is delivered directly to Business Associate, Business Associate shall forward such request to NATION within five (5) working days;
14. make its internal practices, books, and records related to the use and disclosure of PHI received from or created or received by Business Associate on behalf of NATION available to the Secretary of the Department of HHS, authorized governmental officials, and NATION for the purpose of determining Business Associate's compliance with the Privacy Rule. Business Associate shall give NATION advance written notice of requests from DHHS or government officials and provide NATION with a copy of all documents made available; and
15. in accordance with 45 CFR 164.502(e)(1) and 164.308(b), ensure that all of its subcontractors, vendors, and agents to whom it provides PHI or who create, receive, use, disclose, maintain, or have access to NATION's PHI shall agree in writing to requirements, restrictions, and conditions at least as stringent as those that apply to Business Associate under this Agreement, including but not limited to implementing reasonable and appropriate safeguards to protect PHI, and shall ensure that its subcontractors, vendors, and agents agree to indemnify and hold harmless NATION for their failure to comply with each of the provisions of this Agreement.

16. Permitted Uses by Business Associate:

Except as otherwise provided in this Agreement, Business Associate may use or disclose PHI on behalf of or to provide services to NATION for the purposes specified in this Agreement, if such use or disclosure of PHI would not violate the Privacy Rule if done by NATION. Business Associate may:

1. use PHI for its proper management and administration of healthcare operations or to fulfill any present or future legal responsibilities of Business Associate;
2. disclose PHI to fulfill any present or future legal responsibilities of Business Associate, provided that (i) the disclosure is Required by Law; or (ii) Business Associate obtains written assurances from any person to whom the PHI is disclosed that such PHI will be kept confidential and will be used or further disclosed only as Allowed or Required by Law or for the purpose(s) for which it was disclosed to the person, and the person commits to notifying Business Associate of any instances of which it is aware in which the confidentiality of the PHI has been breached;
3. disclose PHI to report violations of law to appropriate federal and state authorities; or
4. make uses and disclosures and requests for protected health information consistent with NATION's minimum necessary policies and procedures.

Obligations of NATION:

1. NATION shall notify Business Associate of any limitation(s) in the Notice of Privacy Practices of NATION or disclosure of PHI.
2. NATION shall notify Business Associate of any changes in, or revocation of, the permission by an individual to use or disclose his or her PHI, to the extent that such changes may affect Business Associate's use or disclosure of PHI.
3. NATION shall notify Business Associate of any restriction on the use or disclosure of PHI that NATION has agreed to or is required to abide by under 45 CFR 164.522, to the extent that such restriction may affect Business Associate's use or disclosure of protected health information.

Term and Termination:

1. Term. The Term of this Agreement shall be effective as of the date of the underlying agreement, and shall terminate on the date the underlying agreement terminates or on the date NATION terminates for cause as authorized in paragraph (b) of this Section, whichever is sooner.
2. Termination for Cause. Business Associate authorizes termination of this Agreement by NATION, if NATION determines Business Associate has violated a material term of the Agreement (and Business Associate has not cured the breach or ended the violation within the time specified by NATION if a cure period is specified).
3. Obligations of Business Associate Upon Termination.

Upon termination of this Agreement for any reason, Business Associate, with respect to PHI received from NATION, or created, maintained, or received by Business Associate on behalf of NATION, shall:

- a. Retain only that PHI that is necessary for Business Associate to continue its proper management and administration of healthcare operations or to carry out its legal responsibilities;
 - b. Return to NATION (or, if agreed to by NATION, destroy) the remaining PHI that the Business Associate still maintains in any form;
 - c. Continue to use appropriate safeguards and comply with Subpart C of 45 CFR Part 164 with respect to PHI to prevent use or disclosure of the PHI, other than as provided for in this Section, for as long as Business Associate retains the PHI
 - d. Not use or disclose the PHI retained by Business Associate other than for the purposes for which such PHI was retained and subject to the same conditions set out at above under "Permitted Uses and Disclosures By Business Associate" that applied prior to termination; and
 - e. Return to NATION (or, if agreed to by NATION, destroy) the PHI retained by Business Associate when it is no longer needed by Business Associate for its proper management and administration or to carry out its legal responsibilities.
4. All other obligations of Business Associate under this Agreement shall survive termination.

Miscellaneous:

1. Business Associate recognizes that any material breach of this Agreement or breach of confidentiality or misuse of PHI may result in the termination of this Agreement and/or legal action. Said termination may be immediate and need not comply with any termination provision in the parties' underlying agreement, if any.
2. The parties agree to amend this Agreement from time to time as is necessary for NATION or BA to comply with the requirements of the Privacy Rule and related laws and regulations.

3. CONTRACTOR's Notice of Privacy Practices is available on its website(s): The Nation's Notice of Privacy Practices is available on its website: <http://www.cherokee.org/Services/Health/NoticeofHealthInformationPractices.aspx>
4. Any ambiguity in this Agreement shall be resolved in a manner that causes this Agreement to comply with HIPAA.
5. This Agreement embodies and constitutes the entire agreement and understanding between the parties with respect to the subject matter hereof and supersedes all prior Business Associate agreements, oral or written agreements, commitments, and understandings pertaining to the subject matter hereof.
6. If Business Associate maintains a designated record set in an electronic format on behalf of NATION, then Business Associate agrees that within 30 days of expiration or termination of the parties' agreement, Business Associate shall provide to NATION a complete report of all disclosures of and access to the designated record set covering the three years immediately preceding the termination or expiration. The report shall include patient name, date and time of disclosures/access, description of what was disclosed/accessed, purpose of disclosure/access, name of individual who received or accessed the information, and, if available, what action was taken within the designated record set.