



CRISP Research Initiative Data Use Agreement

Version 1.1 FINAL – 2017-04-12

This Data Use Agreement (“Agreement”) is made between the Chesapeake Regional Information System for our Patients (“CRISP”), located at 7160 Columbia Gateway Circle, Suite 100, Columbia, MD 21046 and **Johns Hopkins University on behalf of its School of Medicine** (“Data Recipient”), located at **Hampton House 606, 624 N. Broadway, Baltimore, MD 21025**, (each a “Party” and, collectively, the “Parties”) for the purpose of supporting the research study **Addressing Suicide Research Gaps; Understanding Mortality Outcomes, aka JHU Suicide Outcomes** (“Research Study”) approved by the CRISP Research Subcommittee on **April 30, 2019** under the approved use case, **Linking and Enhancing Multiple External Data Sets Using CRISP IDs and Geocodes for Research**. The terms of this agreement are governed by the relevant provisions of the CRISP Participation Agreement of the Data Recipient. For the purposes of this agreement, the CRISP Participation Agreement signatory organization is **Johns Hopkins Hospital**. The conduct of the Research Study will be subject to the applicable state and federal law and regulations, including the Maryland HIE Regulations, COMAR 10.25.18.10B, governing secondary use of data available through the CRISP. Applicable state and federal law and regulations will control over any inconsistent provision of the Participation Agreement or of this Agreement, including the Attachments.

The specific data request under which this agreement is made is specified in the approved Data Request Form, included here as Attachment A.

The cost recovery fee structure for the data request is summarized in Attachment E.

WHEREAS, applicable state and federal law and regulations permits health information exchange to disclose de-identified data, a limited data set, or identifiable data to a qualified research organization for research purposes;

WHEREAS, the research study described in the approved Data Use Request meets the requirements of applicable state and federal law and regulations;

WHEREAS, CRISP data to be made available may include patient-specific data containing both protected health information (“PHI”) and personally identifiable information (“PII”), including unique patient identification numbers, dates of birth, sex of patient, zip code of residence, provider identification numbers, diagnosis codes, dates of service, and insurer plan and type of product information; and

WHEREAS, the Research Study has been approved by an IRB and each subject has executed a research consent including, unless waived by the IRB, a HIPAA-compliant Research Authorization.

NOW THEREFORE, in consideration of the mutual promises and covenants, the sufficiency of which is hereby acknowledged, the Parties agree as follows:

1. DATA TO BE RELEASED

- 1.1 CRISP agrees to provide access to electronic data to the Data Recipient as such electronic data is specifically identified in the Data Request Form in Attachment A (“Covered Data”). Covered Data may be provided through access to the CRISP Query Portal or through a Data Extract, when available from CRISP.



- 1.2 CRISP will provide the Covered Data for the number of years indicated in Attachment A.
- 1.3 Data Recipient will maintain measures to protect the privacy, security and confidentiality of the Covered Data (unless the Covered Data constitutes a de-identified data set as defined in HIPAA) in paper or electronic form that are no less stringent than would be required to protect Protected Health Information under HIPAA. Data Recipient will promptly report any unauthorized use or disclosure of the Covered Data in accordance with Section 15.03 ("Report of Unpermitted Data Use or Disclosure) of the Participation Agreement. Without limitation, to the extent CRISP makes the Covered Data available through a Data Extract, Data Recipient agrees to maintain an appropriate secure location to download the Covered Data in compliance with this Agreement and the Data Management Plan contained in Attachment B.
- 1.4 CRISP and Data Recipient agree that CRISP or the original data owners retain all ownership rights to the Covered Data and any derivations, and that Data Recipient does not obtain any right, title, or interest in any of the Covered Data furnished by CRISP, except for the rights granted in this Agreement in connection with the Research Study, including the necessary rights to publish the results of the Research study, if described in the approved Data Request Form, the sole consideration for which are the fees specified in Attachment E, "Fee Schedule". The right of Data Recipient to publish results of its Research Study or otherwise disclose the results of the Research outside its own organization, if any such third-party publication or disclosure is intended, must be described Data Request Form and be reasonably acceptable to CRISP.
- 1.5 Data Recipient represents and warrants that it is requesting Data for Research, as defined in COMAR 10.25.18.02B (Maryland HIE Regulations), and that Data Recipient is authorized to receive such data, under the IRB approval or waiver and, as applicable, the patient consent/authorization, in de-identified, limited data set or identified form, as specified in the Data Request Form, and will remain so for the duration of this Data Use Agreement.

2. *PERMITTED USES OF THE COVERED DATA*

- 2.1 The Covered Data shall be used solely to support the Research Study as described in Attachment A. Any uses of the Covered Data outside the scope of Attachment A are strictly prohibited unless approved in writing by CRISP in advance, in its sole discretion and in accordance with the applicable IRB approval, patient consent, HIPAA-compliant Research Authorization, and state and federal law and regulations.
 - 2.1.1 Data Recipient shall submit an annual written brief summarizing any analyses or reports for which Covered Data was used. The brief could also include a formal request to CRISP to amend the Data Request for an expansion of use for any new hypotheses or questions generated from the use of the data. This request for an amendment is subject to review and approval by the Research Subcommittee to determine whether it is permissible under the scope of applicable Maryland HIE



Regulations, Patient Consent/Authorization, Research Authorization, and IRB approval.

- 2.1.2 CRISP reserves the right to review these written summaries for determination as to whether the activities reported are within the scope of Attachment A. If CRISP determines, within its sole discretion, that any use of the Covered Data is outside the scope of Attachment A, and therefore unauthorized, CRISP reserves the right to terminate this Agreement pursuant to Section 5.
- 2.2 Data Recipient may retain the Covered Data and utilize such data for the specific purposes described in Attachment A or, with approval from the Research Subcommittee, in its sole discretion as set forth in Section 2.1.1, any subsequent amendments to the Data Request approved by the Research Subcommittee during the effective dates of this Agreement.
- 2.3 If the Covered Data is provided in identified or limited data set form, Data Recipient agrees not to disclose findings, listings, or information derived from the Covered Data, where such findings, listings, or information can, by themselves or in combination with other data, be used to determine an individual patient's identity. Examples of data elements that must be excluded from findings, listings or information include direct identifiers, such as name or address, or indirect identifiers, such as geographic location, age (if > 89), sex, diagnosis and procedure, admission/discharge date(s), or date of death. The Data Request Form must specify what other data and data sources, if any, will be used in combination with the Covered Data.
- 2.4 For data releases involving de-identified data or limited datasets, Data Recipient agrees not to attempt to re-identify individuals whose information is contained in the Covered Data.
- 2.5 Data Recipient understands that this Agreement is non-exclusive and that CRISP may make all or a portion of the Covered Data available to others for Research or other permitted purposes. Covered Data made available to the Data Recipient by CRISP is subject to the limitations described in the Participation Agreement, and may not include Data Subject to Special Restrictions, as defined in the CRISP Participation Agreement, or Data on individuals that have Opted-Out, as both are defined in the Participation Agreement. In the event that a patient opts out after a Data Recipient receives data from CRISP, that opt-out is prospective only and data from the opted-out individual will not be included in the Covered Data subsequently made available by CRISP pursuant to this Data Use Agreement.
- 2.6 Data Recipient acknowledges that, without limitation, the Disclaimer of Warranties and the Limitation of Damages contained in the Participation Agreement apply to this Agreement.

3. *PERMITTED USERS OF THE COVERED DATA*

- 3.1 Data Recipient shall comply with the approved uses and requirements of the study as described in Attachment A including any IRB, privacy board, or individual consent or authorization. In accordance with applicable federal and state laws and regulations, Data Recipient may not reuse Covered Data that constitutes PHI (including a Limited Data Set) or



disclose Covered Data that constitutes PHI (except where permitted by HIPAA). Disclosures of Covered Data to a third party may not be done without a contractual agreement with the third-party binding the third-party to the terms of this Data Use Agreement, or authorization from the patient who is the subject of the Covered Data, which authorization may be included in the consent to participate in the Research Study. Any disclosures of Covered Data to a third party must be specified in the Data Request, including the individuals who will have access to the Covered Data through the third party, and must comply with the approved Data Management Plan contained in Attachment B.

- 3.2 Within Data Recipient, access to the Covered Data, the Covered Data documentation, and any files derived from the Covered Data shall be limited to the minimum number of individuals necessary, as determined within the reasonable discretion of Data Recipient, as necessary to achieve the purposes set out in Attachment A, and access to the Covered Data shall be granted only on a need-to-know basis.
- 3.3 All credentialed individuals accessing Covered Data through the Query Portal shall have their own User Name and Password. Data Recipient shall also provide a list of authorized users who are permitted to access CRISP Covered Data along with appropriate credentials as required by the CRISP to allow CRISP to monitor access the Covered Data, including Covered Data provided in the form of a Data Transfer as specified in the Provider Bulk Load spreadsheet. Under no circumstances are credentials to access Covered Data through the Query Portal or in a Data Transfer to be shared. Individuals with access to CRISP data through the HIE for treatment or for other Permitted Uses as Authorized Users under the Participation Agreement may not use such credentials to obtain data for the purposes of the Research Study.
- 3.4 Data Recipient shall keep a log of the identity of each employee, contractor and/or subcontractor (including their individual personnel) who is authorized to access the Covered Data provided under this Agreement through the Query Portal or through a Data Transfer (“Credentialed Individuals”). Data Recipient will provide updates of the log to CRISP at least two (2) business days before authorizing any Credentialed Individual to access the Covered Data and within two (2) business days of termination of the right to access Covered Data by a Credentialed End User Individual.
- 3.5 All employees, contractors and subcontractors with access to the Covered Data shall be advised of the confidential nature of the information and the safeguards required to protect the information as well as the other obligations referred to in the End User Agreement (Attachment C) that are binding on Credentialed End Users Individuals. Data Recipient will require all Credentialed Individuals to comply with this Agreement and the End User Agreement. Data Recipient will provide documentation of the foregoing to CRISP upon request.



4. *DATA SECURITY*

- 4.1 Data Recipient agrees to comply, at a minimum, with any applicable state and federal privacy and security requirements regarding collection, maintenance, and use of the Covered Data, including The Health Insurance Portability and Accountability Act (“HIPAA”) of 1996, and implementing regulations of 45 C.F.R. Parts 160 and 164.
- 4.2 Subject to the foregoing and to Section 1.3, Data Recipient will maintain the electronic security of the Covered Data in accordance with the Data Management Plan (“DMP”) submitted by Data Recipient (Attachment B).
- 4.3 Data Recipient will submit to CRISP a revised DMP, approved by the relevant IRB, if there are any changes to the plan, including, but not limited to, storage location and security protocols within two (2) business days of approval of the revisions.
- 4.4 At the termination of this Agreement for any reason, Data Recipient agrees to destroy the Covered Data unless retention is required by law, regulation or sponsor or funding agreement, including any products directly derived from the Covered Data, and all back-up and archived copies of the Covered Data in a manner that renders the Covered Data permanently unrecoverable. For Covered Data in electronic form, the destruction process shall involve using software that is capable of destroying data on a drive in a manner that meets the data destruction standards specified by the National Institute of Standards and Technology (“NIST”) Special Publication 800-88, Guidelines for Media Sanitation (http://csrc.nist.gov/publications/nistpubs/800-88/NISTSP800-88_with-errata.pdf). Data Recipient will send a fully executed Certificate of Data Destruction (Attachment D) within 30 days of the termination of this Agreement.

5. *BREACH OF AGREEMENT*

- 5.1 Data Recipient shall give CRISP written notice immediately or as soon as reasonably practicable upon having reason to know that a breach, as defined in Section 6.2, has occurred, but in no event less than five (5) business days after Data Recipient has actual knowledge of a breach.
- 5.2 Any failure of Data Recipient to comply with the terms and obligations of this Agreement shall constitute a breach of this Agreement, including any unauthorized use of the Covered Data, and any violation of State or federal law or regulation with respect to disclosure of the Covered Data. Any breach of the privacy or security of Covered Data by Data Recipient shall be reported and handled as required under Section 15.03 “Report of Unpermitted Data Use of Disclosure” under the Participation Agreement unless reported and handled under other applicable law, including HIPAA.
- 5.3 In addition to the actions specified under Section 6.3, in the event that CRISP reasonably believes that the security or confidentiality of the Covered Data has been breached, CRISP



may: investigate the matter, including an on-site inspection for which Data Recipient shall provide access; and require Data Recipient to develop a plan of correction to ameliorate or minimize the damage caused by the breach of confidentiality and to prevent future breaches of the confidentiality of the Covered Data.

- 5.4 In the event of a material breach of this Agreement, CRISP may seek any appropriate remedy for breach of the Participation Agreement, including termination of this Agreement, and disqualification of Data Recipient from receiving PHI or PII from CRISP in the future and require actions specified in the HIE Regulations, (COMAR 10.25.18.10.C “Enforcement and Reporting”). CRISP will provide Data Recipient with written notice of the breach and, unless cure is infeasible or irreparable harm would result, in both cases in the reasonable judgment of CRISP, the notice will provide the Data Recipient with a period not to exceed ten (10) days to cure the breach to the reasonable satisfaction of CRISP.

6. *FEES*

- 6.1 CRISP agrees to provide access to Covered Data to Data Recipient per the fee schedule described in Attachment E. CRISP will invoice Data Recipient annually to support the research study described in Attachment A.
- 6.2 No reimbursement will be made by either Party to the other Party for expenses related to accessing, maintaining, or upgrading their information technology infrastructure, or for any expenses related to extracting, using, or storing the Covered Data, or for any other expense otherwise arising out of this Agreement.

7. *PROJECT MANAGERS AND NOTICE*

- 7.1 The Project Manager for Data Recipient is Click or tap here to enter text. or his/her successor, as designated by the Data Recipient. The Project Manager for CRISP is Dr. Ross Martin, Program Director, Research and Transformation, or his successor, as designated by CRISP.
- 7.2 The Project Manager’s responsibilities shall include: serving as liaison in negotiating any procedures necessary for the implementation of this Agreement, including establishing the project plan and implementation strategy; coordinating requests for information and other cooperative activities between the Parties; and communicating and working with information technology staff to resolve logistical and technical problems related to accessing the Covered Data.
- 7.3 Any notice given pursuant to this Agreement must be in writing and addressed to:

If to CRISP:
Dr. Ross D. Martin
Program Director, CRISP Research Initiative
7160 Columbia Gateway Drive
Suite 230
Columbia, MD 21046
ross.martin@crisphealth.org



202-697-3077

If to Data Recipient:
Hadi Kharrazi, MD, PhD
Assistant Professor
Hampton House 606, 624 N. Broadway
Baltimore, MD 21025
kharrazi@jhu.edu
410-614-3957

8. GOVERNING LAW

8.1 This Agreement shall be construed in accordance with and governed by the laws of the State of Maryland.

9. EFFECTIVE DATE, AMENDMENTS AND TERMINATION

- 9.1 This Agreement is effective as of the date of its execution, and shall remain in effect for the period specified in the Data Use Request in Attachment A.
- 9.2 The Agreement may be extended by mutual agreement and upon approval of the Research Subcommittee. Any such extension must be in documented in writing and submitted at least 45 days in advance of the end of the Agreement.
- 9.3 This Agreement may be modified in writing as mutually agreed to by the Parties.
- 9.4 This Agreement may be terminated by either Party, with or without cause, provided that written notice is given to the non-terminating Party at least 30 days before the determined termination date.
- 9.5 This Agreement will automatically terminate, without further notice or action, on the effective date of termination of the Participation Agreement between the parties. Termination of this Agreement will not, however, automatically terminate the Participation Agreement.

IN WITNESS WHEREOF, the duly authorized representatives of the Parties have executed this Data Use Agreement effective **30 April 2019**.

For CRISP

For Johns Hopkins University

Brandon Neiswender
Brandon Neiswender (Jun 4, 2019)

Michael McGrath
Michael McGrath
cn=Michael McGrath, o=JHU,
ou=JHURA,
email=mcgra11@jhu.edu, c=US
2019.05.21 15:27:36 -04'00'

Name: Brandon Neiswender

Name: Michael McGrath

Title: Chief Operating Officer

Title: Snr. Contracts Associate

Date: Jun 4, 2019

Date: 5/21/2019



Appendix A - CRISP Research Data Request Form

Version 1.6 – Last Updated 02/27/18

Section A: Research project demographic summary

1. Name of CRISP Participating Organization (must signer of the CRISP Participation Agreement): <u>Johns Hopkins University on behalf of its School of Medicine</u>		
2. Title of study: <u>Addressing Suicide Research Gaps: Understanding Mortality Outcomes</u>		
3. Collaborating institutions, if any: <u>Maryland Health Care Commission, Maryland Health Services Cost Review Commission, Maryland Office of the Medical Examiner</u>		
4. Initial Submission Date: <u>8/14/2018</u>		
5. Principal Investigator: Name: <u>Hadi Kharrazi</u> Title: <u>Assistant Professor</u> Email: <u>kharrazi@jhu.edu</u>	Address: <u>Hampton House 606, 624 N. Broadway</u> City, ST, ZIP: <u>Baltimore, MD 21025</u> Phone: <u>443-287-8264</u> Link to Bio: <u>http://www.jhsph.edu/faculty/directory/profile/2762/hadi-h-k-kharrazi</u>	
6. Co-investigator(s) (include email, title, phone, affiliation and, as available, link to bio): Holly Wilcox, PhD, Associate Professor, JHSPH hwilcox1@jhmi.edu, 410-502-0629 https://www.jhsph.edu/faculty/directory/profile/1588/holly-c-wilcox Paul Nestadt MD, Assistant Professor, JHSOM Department of Psychiatry, pnestadt@jhmi.edu https://www.hopkinsguides.com/hopkins/view/Johns_Hopkins_Author_Bios/550079/all/PaulNestadtM_D_		
7. Research Administrator / Primary Contact: Name: <u>Elyse Lasser</u> Title: <u>Senior Project Manager</u> Email: <u>elasser1@jhu.edu</u>		Address: <u>624 N Broadway</u> City, ST, ZIP: <u>Baltimore MD 21205</u> Phone: <u>(410) 614-3957</u>
8. Financial Point of Contact (for invoicing): Name: <u>Rachel Jones</u> Title: <u>Financial Expert / Senior Admin</u> Email: <u>kharrazi@jhu.edu</u>		Address: <u>624 N Broadway</u> City, ST, ZIP: <u>Baltimore MD 21205</u> Phone: <u>443 287 8264</u>
9. Funding: Funding status: <u>Funded</u> Funding sources: <u>NIMH (National Institute of Mental Health)</u>		Total project funding: \$ <u>~490,000</u>
10. Planned or actual study start date: <u>May 1, 2019</u>	Planned study end date: <u>May 1, 2019</u>	
11. Study Location(s): <u>State of Maryland</u>		
12. Number of subjects anticipated (sample size): <u>Maryland Residents (Population-level study)</u>		
13. CRISP use case supporting this study: <u>Linking Multiple Data Sets</u>		



Section B: Study information

14. Summary description of study objectives, methodology, and population / sample size (Details will be provided in the submitted supporting documentation. Max 500 words.):

The proposed study will conduct population-level analysis on data from multiple sources to address suicide research gaps by understanding the risk factors for, and the burden of, suicide among those seen in structured healthcare settings. The analysis will link clinical data such as hospital discharges, insurance claims, and electronic health records to discover the type, severity, and timing of suicide predictors in the Mid-Atlantic region. The project will also offer essential benchmarks and measures for providers and payers to reduce suicide events in their systems.

The project will seek data from the following sources:

Population-level:

- HSCRC Case Mix data
- MHCC claims data
- Medicaid data from Hilltop

Suicide cases:

- Completed suicides from Maryland Examiner's Office
- EHR data from Johns Hopkins and Sheppard Pratt hospitals
- VHA
- Anne Arundel Medical Center
- Peninsula Regional Medical Center

15. Describe how CRISP data will be used to support the study:

CRISP's role will be to serve as a data manager, including three core services:

- Data Linker: Just as we currently do for the HSCRC case mix data, CRISP will run the demographic information for each received data set into CRISP's Master Patient Index (Initiate), then create a hashed (a masked version of the) Enterprise ID so that the data could be linked to other data sets that are part of the study without exposing the CRISP ID or making the identifier useful for any other purpose.
- Data Scrubber: CRISP will remove the demographic information from the data set and replace it with the hashed EID.
- Data Enhancer: Just as we do with the HSCRC Case Mix data, CRISP will add geocodes to the data at a Census Tract, Census Block or Census Block Group level based on the subject's address so that the researchers can look at the geographic distribution of the data. CRISP will then securely transfer the de-identified data sets to the researchers for analysis.

16. Describe how the data request meets policy requirements under permitted uses of CRISP data and authorizes CRISP to allow the researcher access to the requested data sources. If there is not a current research data use case that has been approved, please describe the general use under which your data request would fall (e.g., request for a limited set of deidentified data to identify condition prevalence, etc.). Describe how this study would provide benefit to CRISP participants, their affiliates, or the residents of the region CRISP serves. Please see the [CRISP website](#) and the [Participation Agreement material amendment for research memo](#) for more information:

CRISP's use case for Linking and Enhancing Multiple External Data Sets Using CRISP IDs and Geocodes for Research was approved by the CRISP Clinical Advisory Board on 21 November 2017. JHSPH will obtain permission from the data holders described above to link the data in a de-identified manner using CRISP as a trusted third party for creating hashed linkages among the data sets. This methodology aligns with the described requirements for supporting the use case.



Section C: Type and frequency of data requested

17. Check all that apply:

<p><input checked="" type="checkbox"/> We will submit panels of demographic information of enrolled patients/subjects in research study – required for studies involving specific individuals who have consented to participate.</p> <ul style="list-style-type: none">• Frequency of panel submission containing additions, deletions or changes: One Time• Data submission method: Other Method (Describe)• Other Method: <u>We will receive data sets via SFTP, JHUBox or Direct depending on the source.</u> <p><input checked="" type="checkbox"/> Check if information on the research subjects' participation in this study should be blocked from appearing to other CRISP users (in the Clinical Query Portal or in other data feeds).</p>
<p><input type="checkbox"/> We would like access to the Clinical Query Portal – provides the ability to search study participant information through a web-based portal throughout the duration of the study.</p> <ul style="list-style-type: none">• Number of users to access data (each user must have separate credentials): _____
<p><input type="checkbox"/> We would like to receive Encounter Notification Service (ENS) alerts – provides real-time notifications when study participants are admitted, discharged, or transferred to, from, or within a hospital and other care settings</p> <ul style="list-style-type: none">• Number of users to access data (each user must have separate credentials): _____
<p><input checked="" type="checkbox"/> We would like CRISP to link data to HSCRC Case Mix Data – you must first submit a data request to HSCRC for evaluation. Check the CRISP data requested (if selecting geocodes, select the least granular level of aggregation required for your study:</p> <ul style="list-style-type: none"><input checked="" type="checkbox"/> Master Patient Index linking across facilities<input checked="" type="checkbox"/> Geocode data at the Census Block level<input type="checkbox"/> Geocode data at the Census Block Group level<input type="checkbox"/> Geocode data at the Census Tract level
<p><input checked="" type="checkbox"/> Other data request (Describe in detail in question 15 or an additional attachment the data set or data access you are requesting and the timeframe (start and stop dates, frequency of data release, etc.) of the data request. Note that CRISP may not currently have the capability of fulfilling the request as described.)</p>

Section E: Required documentation

The following documentation is required for the data request to be reviewed. Please submit this documentation with the data request form. Note that the Institutional Review Board (IRB) must meet the requirements in [COMAR 10.25.18.02\(31\)](#) and [subsection .10](#).

- IRB approval letter for the study (*or a waiver of patient authorization letter from the IRB in accordance with HIPAA if the disclosure will not involve patient consent*). This approval should demonstrate that the IRB was informed or made aware of the study's access of patient data through CRISP.
- IRB-approved protocol.



- IRB-approved data security plan that describes whether protected health information (PHI) or personally identifiable information (PII) will be obtained and, if so, how it will be stored and transferred. This plan should describe the researcher's plan for secure data transfer, storage, and management, user access and credentialing, data retention and destruction policies, and data breach or data loss management policies. Plan must provide information about how the organization binds all members (i.e., organizations, individual staff) of research team to specific privacy and security rules in using sensitive data files. Provide the names of the security plan documents included with this data use request.
- IRB-approved consent form(s), if applicable, including a statement that the participant explicitly allows their information to be accessed through CRISP for the research. The statement should describe the methods of obtaining explicit, fully informed, opt-in consent. The following suggested language is acceptable for inclusion in a subject consent form:

By participating in this study, you agree that researchers may receive copies of any of your medical treatment and test records that are available through the Chesapeake Regional Information System for our Patients (CRISP). CRISP is a health information exchange that supports the sharing of patient health information among health care providers such as doctors, hospitals, laboratories, radiology centers, and other health care providers or facilities in Maryland, the District of Columbia, and other parts of the Mid-Atlantic region. More information about CRISP, including information about your right to decline to make your medical records available through CRISP, can be found at www.crisphealth.org. You understand that, if you choose to opt out of CRISP, CRISP will no longer be able to provide data for the purpose of this research study.

18. List of supporting documentation. Provide the document names of all supporting documents included with this data request.

IRB approval letter or waiver: IRB Approval letter

IRB-approved study protocol: IRB approved study protocol

IRB-approved data security plan: IRB approved data security plan

IRB-approved consent form: Not applicable

Other supporting documents (document names and descriptions):

Health Services Cost Review Commission (HSCRC) and Office of the Chief Medical Examiner (OCME) approval documents

Section F: Research update

- Researchers must submit a copy of the IRB approval renewal notice within 30 days of receipt from the IRB anytime the IRB approval is about to expire until the research study is closed.
- Researchers must notify CRISP immediately in the event of personnel changes requiring the addition or removal of credentialed users of CRISP data. Under no circumstances may individual credentials be passed from one individual to another. All users accessing CRISP data must be individually credentialed.
- A signed Certificate of Data Destruction will be required upon conclusion of the study (if applicable).



Section G: Signature

By submitting this data request form, the Principal Investigator is acknowledging that the information provided is accurate to the best of his or her knowledge. He or she also understands that individuals accessing CRISP data will need to sign a data use agreement. **DO NOT SIGN INITIAL SUBMISSION.** CRISP will review your data request and return it to you for signature after review for completeness.

PI signature: *Hadi Kharrazi*
Hadi Kharrazi (May 1, 2019)

Date signed: May 1, 2019

For CRISP use only:

Request #: 2018-03

Data cost estimate: \$80,000

Approval status (by Research Subcommittee): Approved

Describe provisional approval or revision requirements as needed:

Data sources may be added from among those listed in the IRB-approved plan as the data use agreements are finalized. Further CRISP approval will be needed only for data sources not currently listed in the research plan.

Signed by:

Christopher Chute
Christopher Chute (May 1, 2019)

Chair, CRISP Research Subcommittee

Date: May 1, 2019









JHU Suicide Outcomes - CRISP Research Data Request - APPROVED - 2019-04-30

Final Audit Report

2019-05-01

Created:	2019-04-30
By:	Ross Martin (ross@360degreeinsights.com)
Status:	Signed
Transaction ID:	CBJCHBCAABAA4Pi8Zpsk9GapxNnfZ6VePvFtvhO0ye7y

"JHU Suicide Outcomes - CRISP Research Data Request - APPROVED - 2019-04-30" History

-  Document created by Ross Martin (ross@360degreeinsights.com)
2019-04-30 - 5:47:59 PM GMT- IP address: 100.36.81.55
-  Document emailed to Hadi Kharrazi (kharrazi@jhu.edu) for signature
2019-04-30 - 5:49:28 PM GMT
-  Document viewed by Hadi Kharrazi (kharrazi@jhu.edu)
2019-04-30 - 5:49:31 PM GMT- IP address: 128.220.160.1
-  Document e-signed by Hadi Kharrazi (kharrazi@jhu.edu)
Signature Date: 2019-05-01 - 11:31:01 AM GMT - Time Source: server- IP address: 162.129.44.19
-  Document emailed to Christopher Chute (chute@jhu.edu) for signature
2019-05-01 - 11:31:02 AM GMT
-  Document viewed by Christopher Chute (chute@jhu.edu)
2019-05-01 - 11:31:04 AM GMT- IP address: 128.220.160.1
-  Document e-signed by Christopher Chute (chute@jhu.edu)
Signature Date: 2019-05-01 - 2:32:20 PM GMT - Time Source: server- IP address: 162.129.251.19
-  Signed document emailed to Christopher Chute (chute@jhu.edu), Hadi Kharrazi (kharrazi@jhu.edu) and Ross Martin (ross@360degreeinsights.com)
2019-05-01 - 2:32:20 PM GMT



Attachment B – Data Management Plan

The proposed population-level data warehouse will contain data sources with different denominators and temporal coverages. For example, hospital discharge summaries, and the all-payer insurance claims almost represent the entire Maryland population; however, the EHR data will represent a select number of health systems representing a smaller population (and in some cases only the patients who have died by suicide). Outcomes of interest will be suicide death (OCME data), attempt, ideation, and near-death suicide events (mainly EHR free text), and MVA non-suicidal fatal accidents (EHR, control group). Predictors of interest will be demographics, clinical (e.g., diagnoses, medications, procedures, interventions and treatment, utilization, and service-level event), behavioral, social, and environmental variables.

The data warehouse will launch with retrospective data sources, representing a range of dates in the past. At regular intervals, the database will be infused with new OCME decedent data to be matched to the CRISP MPI and other sources. The publically available, aggregated data sources will be linked at the census tract level.

Note that the research team will not receive protected health information (PHI) from the data custodians as CRISP will act as the mediator for data aggregation while anonymizing the data. Also, human subject research only applies to living patients thus records for individuals who died by suicide will be treated differently. CRISP is linking all data and we will only receive limited PHI (dates, YOB, Census block group info). The study will use retrospective limited patient data.

1. **Personally Identifiable Information (PII):**

Please identify the Personally Identifiable Information (PII) that you may be obtaining and using in your study:

Name, signature, initials, or other identifiable code	<input type="checkbox"/>
Geographic identifier: address, GPS location, etc.	<input checked="" type="checkbox"/>
Dates: birth, death, clinical service, discharge, etc.	<input checked="" type="checkbox"/>
Contact information: phone numbers, email address, etc.	<input type="checkbox"/>
ID: Social Security Number, driver's license number, etc.	<input type="checkbox"/>
Health record identifiers: medical record, insurance plan number, etc.	<input type="checkbox"/>
Account numbers	<input type="checkbox"/>
Device identifiers: e.g., implants	<input type="checkbox"/>
Internet identifiers: IP address, social media accounts	<input type="checkbox"/>
Biometric identifiers, including finger and voice prints	<input type="checkbox"/>
Audio recordings	<input type="checkbox"/>
Video or full face photographic images	<input type="checkbox"/>
Genomic/genetic data	<input type="checkbox"/>



Any other unique identifying number, characteristic, or code (note: this does not mean the unique code assigned by the investigator to code the data)	<input type="checkbox"/>
Other: Click here to enter text.	<input type="checkbox"/>

2. Data Collection:

Collection of data for a research study can take on many forms. It can be as simple as gathering the data with pen and paper or developing an on-line adaptive survey that changes based on the participant's answers. Regardless of the method, PII for the purposes of identifying the participants will most likely be collected. Once collected, the raw data should go through a de-identification process to further protect PII.

In what form will you access, receive, and/or store PII?

1. **Hard Copy/Paper:** Yes No

If yes, please answer the following:

1. If applicable, how will the data be stored securely during transfer?
2. Will the data be secured in a locked cabinet or room? Yes No
3. If study IDs/Codes are used, will they be stored separately from the study data? Yes No
4. Will the hard copy/paper be destroyed after data abstraction and cleaning are complete?
Yes No

If No, when do you plan to destroy the hard copies?

5. **Electronic:** Yes No

If yes, please answer the following:

1. Will the data be collected/stored on a portable device (laptop, mobile phone, tablet, PDA) protected by encryption? Yes No
2. Will study participants use personally owned devices or study-provided devices? N/A
Personally owned Study provided
3. Is the application/website used for data collection being developed in-house (Hopkins) or by a 3rd party vendor?
In-house 3rd party



If 3rd party, provide the name of vendor and URL:

Identify Mobile Ecosystem (check all that apply) Apple Google Website

4. Will the data be stored on a local secure server (@JHSPH/on-site) or in the Cloud/Web?

Secure Server Cloud/ Web

5. Will it be encrypted? Yes No

6. Will you be backing up your data? Yes No

7. **Audio Recording:** Yes No

If yes, please answer the following:

1. Will you store the audio recording securely in a locked cabinet/room until transcription is complete?

Yes No

2. Will you use a transcription service that requires strong security protections to PII? If the PII comes from JHH/JHHS, you must use an approved vendor.

Yes No

3. Will the audio recording be destroyed after transcription? Yes No

If no, why not?

1. **Photograph/Video:** Yes No

If yes, please answer the following:

1. Will the photographs/videos be stored securely in a locked cabinet or room? Yes No

2. Will the photograph/video be destroyed? Yes No

If yes, when?

3. **PII De-Identification of Data Used for this Study:**

When will you destroy the PII and/or the code linking the PII with the study ID?

Three years after this study ends we will destroy the PII. CRISP, a HIPAA protected entity, will maintain the code linking the PII for future projects.

4. **Data Storage and Analysis:**

One of the keys to protecting PII is the proper use of tools to share and conduct your analysis. JH and JHSPH offers several options for you to consider. Please select the



system that you plan to use to protect your study data by clicking the box. Consult JHSPH IT for assistance if needed.

- JH Virtual Desktop**: The Hopkins Institute for Clinical and Translational Research (ICTR) provides a virtual Windows desktop (SAFE Desktop). It includes productivity software such as Microsoft Word and Excel, as well as statistical software, including SAS, Stata, R, R Studio, and Python. 100 GB of storage space is provided.
- JHSPH SharePoint and File Shares**: These systems provide a managed and secure platform for your research project. They also provide a built-in encrypted backup solution.
- JHSPH RedCAP**: These are departmentally managed applications. RedCAP is an application designed for collaborative research projects.
- JHSPH HPCC**: High Performance Computing Cluster (HPCC: <https://jhpce.jhu.edu/>) can provide the high capacity computing required for very large data sets.
- JHBox**: Johns Hopkins Box (JHBox) is a secure cloud-based file sharing service which enables people to collaborate and share information and may be accessed through any device: desktop, laptop, phone, or tablet with appropriate permissions. JHSPH IT recommends that investigators not use JHBox as a primary storage location, but use it instead for initial data collection, sharing results, and other collaborative information with the research team.
- Independent Departmental Servers and Systems**: These servers are typically managed by departmental or research team IT staff. Because these servers are not centrally managed by JHSPH IT, all documentation regarding data security protections will need to be provided by the owner/administrator of the server. This responsibility may fall to the data owners (PI).
- Other**: Please provide details regarding any other systems being utilized. Examples may include servers and applications located at another university participating in your study or a 3rd party web-based application.

5. **Other Data Security Measures:**

Please review the following questions. This additional information will be utilized to assist in the development of a comprehensive Data Security plan. This would include the systems used to analyze the data, data security contacts and additional requirements.

1. During the analysis phase, do you plan to use computer systems that are not managed by JHSPH or JH? Yes No
If yes, please explain:
2. Do you have a designated person on your research team other than the PI who is the technical contact for a Data Security plan? Yes No
If yes, please provide a contact name:
3. Does your sponsor have other specific data security requirements for the study data? Yes No



If possible, please explain:

Please add any other information that you believe is relevant to data security.

4. **Certificate of Confidentiality:**

All NIH studies include Certificate of Confidentiality protections with the grant; the consent form must include the C of C language provided in our template. Other funders may obtain C of C protections through NIH. (<https://humansubjects.nih.gov/coc/index>)

Does the study have Certificate of Confidentiality protections?

Yes No

5. Will you use clinical data of 500 records or more from Johns Hopkins Hospital and its affiliates?

Yes No

If yes, please complete the JHM Data Security Checklist available on the JHSPH IRB website: www.jhsph.edu/irb and upload a copy of the checklist to the "Miscellaneous" section.



CRISP

Connecting Providers with Technology to Improve Patient Care

Attachment C – CRISP Research Initiative Data Use Agreement – Authorized Researchers

The following individuals are approved for access to CRISP data under the data use agreement described below:

Approved Research Study: Addressing Suicide Research Gaps: Understanding Mortality Outcomes (JHU Suicide Outcomes)

Approving Participating Organization: Johns Hopkins University on behalf of its School of Medicine

Principal Investigator: Hadi Kharrazi, MD, PhD

PI Title: Assistant Professor

PI Contact Email: kharrazi@jhu.edu

Data Use Agreement Effective Date: 1 May 2019

Approved Users:

Add/Delete/Modify/Unchanged	Name	Title	Email	Delegator / Delegate	CRISP Verified*
Unchanged	Paul Nestadt, MD	Assistant Professor	pnestadt@jhmi.edu	Delegator	Yes
Unchanged	Hadi Kharrazi, MD, PhD	Assistant Professor	kharrazi@jhu.edu	Delegate	Yes
Unchanged	Tom Richards	CPHIT Technology Director	tom.richards@jhu.edu	Delegate	Yes

*CRISP Verified: User identity has been verified; user has signed an end user agreement; user has completed required training; and user is otherwise eligible to access the data types requested.

Approved by:

Name: Ross Martin, MD, MHA

Title: Program Director, CRISP Research Initiative

Date: 1 May 2019



CRISP Research Initiative End User Agreement

CRISP has a Participation Agreement with each data-contributing organization that accesses or submits data. The Participation Agreements include specific provisions governing the use of data and include business associate agreements. This End User Agreement is intended to supplement the organization-focused Participation Agreement by enumerating important protections in the use of data for research purposes. Each individual accessing CRISP tools and services for an approved research use must complete and sign this form. Direct questions to research@crisphealth.org.

I will use the information made available through CRISP exclusively for the purposes specified in the specific data request listed below as approved and will not access or use the data provided for any other purpose – including any other research or clinical use – unless approved through another approval process.

- I understand that, to use CRISP data for clinical purposes, I must obtain separate credentials from CRISP for that purpose.
- I will protect the data provided by CRISP in accordance with the approved privacy and security plan submitted to CRISP with the data request.
- I will not access CRISP services if I become no longer employed/contracted by my participating organization.
- I have watched the [Clinical Query Portal Training Video](#) (if accessing portal).
- I have watched the [ENS PROMPT Training Video](#) (if accessing ENS PROMPT).

End Users will be permitted to access CRISP services as described in the approved data use request during the period of the study. A more complete explanation of the protections and allowable uses of data CRISP holds on behalf of participants is in the [CRISP Participation Agreement and associated Policy Documents](#). If unsure as to a use, please contact CRISP. This Research End User Agreement is entered into between CRISP and the End User, who is using the system on behalf of an approved research case on behalf of the institution listed below, which is a CRISP participant and signatory of the CRISP Participation Agreement.


End User Printed Name: Tom Richards

End User Title: CPHIT Technology Director

End User Email: tom.richards@jhu.edu

Participating Organization/Study Sponsor: Johns Hopkins Hospital on behalf of its School of Medicine

Name of Approved Study: JHU Suicide Outcomes

End User Signature: 

Date: May 2, 2019



Attachment D – Certificate of Data Destruction

To be filled out and signed by Data Recipient and returned to CRISP upon completion of the study conducted under this data use agreement unless prohibited by law.

The undersigned hereby certifies that all copies of the following data files provided to _____ by CRISP on _____.

Description of files destroyed:

Method of destruction (shredding, overwriting, etc.):

Date of destruction:

Data destroyed by:

Principle Investigator signature: _____



CRISP

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Attachment E – Fee Schedule

The following summary shows the annual fees associated with this data use agreement. The CRISP Research Initiative operates under a cost recovery model. CRISP will invoice the Data Recipient upon execution of the Data Use Agreement and annually thereafter through the duration of the contract. Terms are Net 30.

CRISP Initiative for Enabling Research - Cost Estimator - FY2018															
Study Name: JHU Suicide Outcomes		Study Duration in years (7 max):	1	Annual rate increase after year 1:	4%	Calendar Year Start Date:	2018	Overhead Rate:	10%	2020	2021	2022	2023	2024	Total Cost
Research Service	Cost per Hour / Unit (blended)	Hours per Service Request	Cost per Service Request (CY2018)	Number Required per Year	Total Number Required	2018	2019	2020	2021	2022	2023	2024	Total Cost		
1st-Year Setup	\$ 125.00	15	\$ 1,875.00	One Time	1	\$ 1,875.00								\$ 1,875.00	
Ongoing Yearly Maintenance	\$ 125.00	10	\$ 1,250.00	Yearly	1	\$ 1,250.00	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ 1,250.00	
Project Closeout	\$ 125.00	15	\$ 1,875.00	One Time	1	\$ 1,875.00	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ 1,875.00	
User Credentialing (initial set up per user)	\$ 85.00	2	\$ 170.00	4	4	\$ 680.00								\$ 680.00	
Patient/Subject Panel - (initial set up)	\$ 85.00	4	\$ 340.00	One Time	1	\$ 340.00								\$ 340.00	
Patient/Subject Panel - Panel Submission	\$ 85.00	2	\$ 170.00	One Time	1	\$ 170.00	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ 170.00	
CRISP Query Portal Access (per user per year)	\$ 85.00	2	\$ 170.00	0	0	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	
ENS PROMPT Access (per user per year)	\$ 85.00	2	\$ 170.00	0	0	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	
Direct Secure Email Account (per year for panel upload)	\$ 315.00	1	\$ 315.00	One Time	1	\$ 315.00	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ 315.00	
Additional custom data prep hours	\$ 155.00	1	\$ 155.00	Variable	350	350	0	0	0	0	0	0	0	350 hour(s)	
Additional credentialing and data access hours	\$ 85.00	1	\$ 85.00	Variable	11	11	0	0	0	0	0	0	0	11 hour(s)	
Additional account management hours	\$ 125.00	1	\$ 125.00	Variable	88	88	0	0	0	0	0	0	0	88 hour(s)	
Project Notes:	Addressing Suicide Research Gaps: Understanding Mortality Outcomes. PI: Hadi Kharrazi funded by NIH (NIMH). Will invoice for \$40,000 on signing and submit a final invoice for other total effort on project completion.														
Total Custom Hours \$:						\$ 66,185.00	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ 66,185.00	
Subtotals:						\$ 72,690.00	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ 72,690.00	
Overhead:						\$ 7,269.00	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ 7,269.00	
Totals:						\$ 79,959.00	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ 79,959.00	







JHU Suicide Outcomes - CRISP Research DUA - For CRISP Signature

Final Audit Report

2019-06-04

Created:	2019-05-31
By:	Ross Martin (ross@360degreeinsights.com)
Status:	Signed
Transaction ID:	CBJCHBCAABAAmFg5J3tO0FdkNRBJf-c5Hjp3qgISfL81

"JHU Suicide Outcomes - CRISP Research DUA - For CRISP Signature" History

-  Document digitally presigned by Michael McGrath (mcgra11@jhu.edu)
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