CRISP

Connecting Providers with Technology to Improve Patient Care

Research Request Checklist

April 2023

Request Type	***Documentation Required***	***Responsible Party***
☐ *Administrative Data for Research*	☐ Research Data Request Form (Appendix A)	*Researcher / Requesting Organization*
	☐ IRB Approval ***OR*** ☐ Waiver (Appendix B)	*Researcher / Requesting Organization*
	☐ Payment of Fee (Appendix I)	*Researcher / Requesting Organization*
☐ *IRB-Approved, Patient Consented Research (CRISP Clinical Data ONLY)*	☐ Research Data Request Form (Appendix A)	*Researcher / Requesting Organization*
	☐ IRB Approval (Appendix B)	*Researcher / Requesting Organization*
	☐ Signed Data Use Agreement (Appendix E)	*Researcher / Requesting Organization*
	☐ Panel of Consented Patients (Appendix F)	*Researcher / Requesting Organization*
	☐ Approval from Data Governance Committee (Appendix H)	*CRISP*
	☐ Payment of Fee (Appendix I)	*Researcher / Requesting Organization*
☐ *IRB-Approved, Patient Consented Research (CRISP Clinical Data and HSCRC Case Mix Data)*	☐ Research Data Request Form (Appendix A)	*Researcher / Requesting Organization*
	☐ IRB Approval (Appendix B)	*Researcher / Requesting Organization*
	☐ HSCRC Approval (Appendix C)	*HSCRC*
	☐ Signed Data Use Agreement (Appendix E)	*Researcher / Requesting Organization*

	☐ Panel of Consented Patients (Appendix F)	*Researcher / Requesting Organization*
	☐ Approval from Data Governance Committee (Appendix H)	*CRISP*
	☐ Payment of Fee (Appendix I)	*Researcher / Requesting Organization*
☐ *Combining CRISP Patient Identifiers and Geocoding Data with HSCRC Case Mix Data*	☐ Research Data Request Form (Appendix A)	*Researcher / Requesting Organization*
	☐ IRB Approval (Appendix B)	*Researcher / Requesting Organization*
	☐ HSCRC Approval (Appendix C)	*HSCRC*
	☐ Signed Data Use Agreement (Appendix E)	*Researcher / Requesting Organization*
	☐ Panel of Consented Patients (Appendix F)	*Researcher / Requesting Organization*
	☐ Approval from Data Governance Committee (Appendix H)	*CRISP*
	☐ Payment of Fee (Appendix I)	*Researcher / Requesting Organization*
☐ *Linking and Enhancing Multiple External Data Sets*	☐ Research Data Request Form (Appendix A)	*Researcher / Requesting Organization*
	☐ IRB Approval (Appendix B)	*Researcher / Requesting Organization*
	☐ HSCRC Approval (Appendix C)	*HSCRC*
	☐ Other Data Set Owner Approval (Appendix D)	*Data Set Owners*
	☐ Signed Data Use Agreement (Appendix E)	*Researcher / Requesting Organization*
	☐ Panel of Consented Patients (Appendix F)	*Researcher / Requesting Organization*

	☐ Proof of Data Governance Agreement among Researchers (Appendix G)	*Researcher / Requesting Organization*
	☐ Approval from Data Governance Committee (Appendix H)	*CRISP*
	☐ Payment of Fee (Appendix I)	*Researcher / Requesting Organization*

Appendix A
Research Data Request Form

CRISP Research Data Request Form

Version 2.1 – Last Updated 12/2023

Section A: Research project demographic summary

1. **Name of CRISP Participating Organization** (must signer of the CRISP Participation Agreement)**:**	
2. **Title of study:**	
3. **Collaborating institutions, if any:**	
4. **Initial Submission Date:**	
5. **Principal Investigator:** Name: Title: Email:	Address: City, ST, ZIP: Link to Bio:
6. **Co-investigator(s)** (include email, title, phone, affiliation and, as available, link to bio):	
7. **Clinical Delegator** A member of the research team must have current clinical assess to CRISP services (e.g., ENS, Query Portal, etc.) in order to delegate access to these tools to a member of the research team. This person can be someone other than the PI: Name: Title:	Address: City, ST, ZIP: Email:
8. **Research Administrator / Primary Contact:** Name: Title:	Address: City, ST, ZIP: Email:
9. **Financial Point of Contact** (for invoicing): Name: Title:	Address: City, ST, ZIP: Email:
10. **Funding:** Funding status:	

Total project funding: $ Funding sources:
11. **Planned or actual study start date:** **Planned study end date:**
12. **Data request start date:** **Data request end date:**
13. Study Location(s):
14. **Number of subjects anticipated (sample size):**
15. **CRISP use case supporting this study:**

Section B: Study information

15. **Summary description of study objectives, methodology, and population / sample size** (Details will be provided in the submitted supporting documentation. Max 500 words.):
16. **Describe how CRISP data will be used to support the study:**

17. **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:

Section C: Type and frequency of data requested

18. *Check all that apply:*

☐ **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.

- Frequency of panel submission containing additions, deletions or changes:
- Data submission method:
- Other Method:
- Check if information on the research subjects' participation in this study should be blocked from appearing to other CRISP users (in the CRISP Portal or in other data feeds).

☐ **We would like access to the CRISP Portal** – provides the ability to search study participant information through a web-based portal throughout the duration of the study.

- Number of users to access data (each user must have separate credentials):

☐ **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

- Number of users to access data (each user must have separate credentials):

☐ **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:

☐ Master Patient Index linking across facilities

☐ Geocode data at the Census Block level

☐ Geocode data at the Census Block Group level

☐ Geocode data at the Census Tract level

☐ **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.)

Section E: Required Documentation

(see attachments)

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: _____ Date signed:

For CRISP use only:
Request #:
Data cost estimate:
Approval status (by Research Subcommittee):
Describe provisional approval or revision requirements as needed:

Signed by:

_____
Chair, CRISP Research Subcommittee
Date:

Please complete this form in its entirety.
Missing information will delay the review process.

Overview

CRISP is a regional health information exchange serving Maryland, the District of Columbia, and health care providers throughout the Chesapeake region. In 2016, the participants in the CRISP HIE approved research as a permitted use of data flowing through CRISP. This form is the first step for researchers to request access to data available through CRISP. **Data requests can only be submitted from an organization that has signed the CRISP Participation Agreement.** Upon approval, CRISP can provide researchers conducting studies access to a rich set of clinical information for Maryland patients available from organizations participating in CRISP's health information exchange. Before submission, research requests must have been approved or reviewed by an established Institutional Review Board (IRB) from a CRISP participating organization.

CRISP currently supports research under three approved use cases. Over time, we intend to expand the uses we can support. Please follow the links to find the documents related to each use case and the services we provide to support each use case:

- Use Case for IRB-Approved, Patient-Consented Research – Approved November 8th, 2016
    - Encounter Notification Service (ENS) – After the researcher securely submits a panel of consented research subjects to CRISP, patients are matched to our Master Patient Index (MPI). Each time a patient has an encounter with a hospital, emergency department or ambulatory facility sharing encounter data with CRISP, the researcher will receive real-time notices of the encounter, admission or discharge via a browser-based too
    - CRISP InContext or Clinical Information– After the researcher securely submits a panel of consented research subjects to CRISP, the researcher can query each individual patient and access all the available clinical content from more than 280 data sources including all acute care hospitals in Maryland and DC, laboratories, radiology centers, long-term care facilities, ambulatory providers, and others. Researcher activities on the portal are monitored and audited to ensure that only consented patients are accessed.
- Combining CRISP Patient Identifiers and Geocoding Data with HSCRC Case Mix Data for Research – Approved March 8th, 2017
    - HSCRC Case Mix with CRISP Patient Identifiers and Geocodes – The Health Services Cost Review Commission (HSCRC) provides researchers access to various de-identified case mix data sets on Maryland hospital charges and clinical information. CRISP manages the case mix data and can combine the CRISP MPI and census block level geocodes to the data based on the patient's last known address. Adding the MPI links data on an individual patient across facilities. To obtain access to the Case Mix data, researchers must first submit a request to HSCRC, which will evaluate it and work with CRISP to determine whether this request also needs to be completed. HSCRC and CRISP work together to review, approve and fulfill these requests.
- Linking and Enhancing Multiple Data Sets Using CRISP IDs and Geocodes – Approved November 21st, 2017
    - This use case serves as a generalized version of the earlier HSCRC Case Mix use case for multiple data sets. All data providers must approve the use of their identifiable data in the study and the patients who are contained in the CRISP MPI will be matched across data sets with CRISP serving as a trusted third party to blind researchers and data providers from linking any data to which they are not already privileged.

We currently do not offer bulk data sets on cohorts of subjects, but are developing this capability. If you have a research need that we cannot currently accommodate, you are still welcome to inquire and explain your need to us. We will not be able to approve such requests until our current capabilities have been expanded, but it helps us plan our priorities for expanding our research capabilities. Before submitting this form, we encourage you to contact us to describe your research project so we can give you an informal assessment of how it aligns with our current offerings. Please contact research@crisphealth.org. Include a brief description of your study and the data you are seeking from CRISP.
When complete, please submit this form as an unsigned PDF to research@crisphealth.org. We will review it to make sure it is complete, then return it to you for your electronic signature.

Next steps

Review Process

Once the data request form is submitted, it is reviewed internally at CRISP for completion and technical feasibility. The review process should take 30-45 days from the time the request is submitted (longer if additional information is required or if we receive an unexpected volume of requests). The requestor will be contacted for any further clarifications needed and will be notified if the request cannot be approved at that time.
If all information is available, the Principal Investigator may be invited to present the research study to the CRISP Research Subcommittee, which will then deny, approve or request revisions to the data use request. If the request is approved, the Principal Investigator will be contacted by CRISP with steps to start the implementation process.

Data Access Fees

CRISP will charge data requestors a fee for data access in a cost recovery fashion to ensure the sustainability of our support for research. These fees are subject to change and the costs below should be used as guidance. The pricing model includes a 4% annual rate adjustment. Upon review, CRISP will provide an estimate of these costs and inform the Principal Investigator. As a guideline, we charge a blended rate of $155 per hour for custom data prep and extraction services; $85 per hour for credentialing and data access set up; $125 per hour for account management. For requests involving basic access to the CRISP Portal or the Encounter Notification Service, please use the following estimates for budgeting and for grant requests. The cost estimator tool is available at https://crisphealth.org/information-for-researchers/:

Initial Set Up, Annual Maintenance, and Close Out

All approved data requests require a $1,875 set up fee to covers the initial data request review, approval and processing; initial user training, and accounting services. The annual maintenance fee of $1,250 per year (including the first year, covers annual project review, ongoing customer support services and annual audit. The project closeout fee of $1,875 covers final audit, final review, reporting and project closeout.

Patient/Subject Panel Set-Up

All data requests involving access to the CRISP CRISP Portal or the Encounter Notification Service require the submission of a panel of subjects that include identifiers for matching to the CRISP master patient index. Initial panel setup is $340. Subsequent panels, if needed (to add or delete subjects from the cohort),

are $170 each. For more frequent panel updates, we can provide more detailed methods for submitting panel changes.

Credentialed User Set-Up

Each individual accessing either the CRISP CRISP Portal or the Encounter Notification Service must be credentialed and verified by CRISP. This process involves establishing identification and professional credentials. Users must be sponsored by a signatory of the Participation Agreement. CRISP will charge $170 for each credentialed researcher who will be accessing CRISP data.

CRISP CRISP Portal Access

Credentialed users can request access to the CRISP CRISP Portal based on a specific patient panel. Access is $170 per user per year.

CRISP ENS PROMPT Access

Credentialed researchers can request access for approved uses to the CRISP Encounter Notification Service Proactive Management of Patient Transitions (ENS PROMPT) website based on a specific patient panel. Access is $170 per user per year.

Direct Secure Email Account

CRISP can offer a secure email solution – Direct – for exchanging sensitive data such as PHI between CRISP and the researcher (for subject panel uploads and the like). If the researcher would like to use Direct and does not already have an established Direct account, CRISP can provision one for $315 per year. Data can also be exchanged via secure FTP and other means.

CRISP Research Initiative Cost Estimator

A draft tool is available at https://www.crisphealth.org/resources/research-and-quality-improvement/ to estimate the cost of a specific research project. A snapshot of the estimator tool is below.

More information on the CRISP Research Initiative is available at https://www.crisphealth.org/resources/research-and-quality-improvement/ and details for researcher are available at https://www.crisphealth.org/resources/research-and-quality-improvement/ . For specific questions not addressed on the website, please contact research@crisphealth.org. When complete, please submit this form to research@crisphealth.org.

Appendix B-1

IRB Approval or Waiver Documentation

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

Appendix B-2

IRB Approval or Waiver Documentation

IRB-approved protocol

Appendix B-3

IRB Approval or Waiver Documentation

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 breech 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

Appendix B-4

IRB Approval or Waiver Documentation

IRB-approved consent form(s), 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.

Appendix C
HSCRC Application and Approval

APPLICATION FOR ACCESS TO THE CONFIDENTIAL HSCRC STATEWIDE HOSPITAL DISCHARGE INPATIENT AND OUTPATIENT DATA FILES THROUGH THE CHESAPEAKE REGIONAL INFORMATION SYSTEM FOR OUR PATIENTS (CRISP).

This application pertains to the Statewide Confidential Hospital Discharge Data Sets (Inpatient) and Hospital Outpatient Data Sets (Outpatient), collected by the Health Services Cost Review Commission ("HSCRC") under COMAR 10.37.06 and COMAR 10.37.04, respectively, accessed through the Chesapeake Regional Information System for our Patients (CRISP).

Background

As part of its broad disclosure responsibilities, the HSCRC provides limited access to confidential, patient- level datasets for **research, surveillance and evaluation purposes only**. The HSCRC releases the inpatient and outpatient data that has been collected and deemed final by the HSCRC. These data files are available by fiscal or calendar year three (3) months after the end of a quarter; however, the timing availability is subject to change.

Please note: cases that meet the criteria for federal regulation 42 CFR Part 2 (Confidentiality of Substance Use Disorder Patient Records)[1] or records for patients who opt out of sharing data will not be included in the approved request, unless the applicants received written verified consent to receive this information from the patients participating in the project.

[1] Federal Regulation 42 CFR Part 2 (Confidentiality of Substance Use Disorder Patient Records) imposes restrictions upon the disclosure and use of substance use disorder patient records that are maintained in connection with the performance of any Part 2 program. The regulations in this part prohibit the disclosure and use of patient records unless certain circumstances exist. For more information: https://www.samhsa.gov/about-us/who-we-are/laws- regulations/confidentiality-regulations-faqs

In order to complete the application for access to the Datasets**, a formal letter (on YOUR company/institution letterhead)** of request must be submitted to the HSCRC and contain, in detail, the information required in Sections 1 and 2 below. The following conditions apply to all users of the Data:

The Data shall be used in compliance with Maryland Code Ann. Health-General Article Section 4-101 et. seq.;

- The Data shall be used in compliance with HSCRC statutory provisions, Health General Article, Section 19-201 et. seq., COMAR 10.37.04 and COMAR 10.37.06;
- The Data shall be used only for the purposes approved by the Commission;
- Results of analysis and reports that are based on the Data must be submitted to the Commission for review prior to public release;
- Other restrictions and conditions may apply as deemed appropriate by the Commission.

All requests for the Data are reviewed by the HSCRC Review Board (the "Board"). The review process may take up to **30 days** from submission of a complete letter of request with supporting materials to the Board for consideration. The Board reserves the right to require additional information to determine whether access to the Data should be granted to the requesting Organization. The applicant may be contacted by the Board to discuss its application. The Board makes the final decisions on the release of the Data at its monthly meeting.

All approved applicants will be required to file annual progress reports with the Commission describing any modifications to the goals, design or timeline of the project; also describe data handling procedures, and other unanticipated events related to the confidentiality or disclosure of the Data.

If the project involves research of any kind, all requests must be reviewed by the Institutional Review Board (IRB), a unit within the Maryland Department of Health (MDH), to ensure that the rights, safety, and dignity of human subjects are protected. Please complete the IRB Application at: https://health.maryland.gov/oig/irb/Pages/IRB.aspx and submit it with your application to the HSCRC.

Please send the completed application, IRB application, and a signed copy of the Data Use Agreement to:

Health Services Cost Review Commission Email:

hscrc.data-requests@maryland.gov

- Identify the Organization that is requesting data access. Include the following information for the Organization.
  - Name and Title of Representatives
  - Name of Organization
  - Mailing Address
  - Telephone and Fax Numbers
  - E-mail address
- Describe the purpose for which the data are requested. Please include the proposal with the application.
- Identify the Data Custodians ("Custodians") for the Organization. The Custodian is responsible for ensuring the privacy and security of the Data, including establishment and maintenance of security arrangements to prevent unauthorized use. All individuals who will have direct access to the raw Data, analytics files, or output with cells sizes less than 11 need to be listed as a Custodian. The Data requested must not be physically moved, transmitted or disclosed in any way from or by the site of the Custodian other than as provided in this Agreement, without prior written approval from HSCRC, unless such movement, transmission or disclosure is required by a law.
- Explain the qualifications of the individuals who will be performing the analyses with the Data. Specify any experience using sensitive medical information, whether staff received HIPAA training, and funding source(s).
- State the public benefit of the proposed research analysis. **Please be specific,** as this is a crucial component of the Commission's review for access to the Data.
- Identify the risks to individuals, the public, or other entities, such as specific institutions for the proposed research or analysis.
- Identify the estimated time frame for completion of the project, including the timeframe for publication. If the project takes longer than the estimated time frame, you will need to resubmit your application and receive written approval to continue to use the Data.
- List and describe proprietary interests in this research, if applicable.
- List the **specific** confidential data elements required and justify why each is required. Confidential variables will not be included without sufficient justification.
- Complete the **MDH IRB Application** (https://health.maryland.gov/oig/irb/Pages/IRB.aspx) and submit it with an approval letter or waiver from an external Institutional Review Board (IRB), if applicable.
- Read and sign **Appendix 1: HSCRC Confidential Data Use Agreement**;
- Complete **Appendix 2: Requested Confidential Datasets**.

The Data Management Plan Questionnaire includes four parts. Please describe the actions that will be taken to address the protections specific to this confidential data request. The safeguards that are described should be reasonable and appropriate based on the Organization's environment in which the research, surveillance or evaluation is conducted.

Please note that the explanation should fully describe the protections that are in place. The HSCRC expects that some of the safeguard descriptions in response to a step may overlap with another step. Additionally, many of the questions below may already be addressed in the Organization's Data Management Plan; however, please fully answer each question and not just refer to the data management plan.

A. PHYSICAL POSSESSION AND STORAGE OF The DATA FILES

1. Who will have the main responsibility for organizing, storing, and archiving the Data for the Organization? Please provide name(s) and job title(s).
2. Provide details about who and how the Organization will notify HSCRC of any project staffing changes.
3. Describe how the Organization maintains a current inventory of the Data files being accessed (identify how the agency tracks users and the data being accessed per project).
4. Describe the Organization's training programs that are used to educate staff on how to protect HSCRC data files.
5. Explain the infrastructure (facilities, hardware, software, other) that will access the Data.
6. Describe the policies and procedures regarding access to the Data.
7. Explain the Organization's system or process to track the status and roles of the research team.
8. Describe the Organization's physical and technical safeguards used to protect the Data (e.g., explain the safeguards used to protect user ids/passwords, and only download statistical results, etc.).

B. DATA SHARING, ELECTRONIC TRANSMISSION, DISTRIBUTION

9. Describe the Organization's policies and procedures regarding the sharing, transmission, and distribution of the Data.
10. Please describe any systems used to track the Data at the Organization (if applicable).
11. Describe the policies and procedures the Organization has developed for the physical removal, transport, and transmission of the Data.
12. Explain how the Organization will tailor and restrict access privileges to the Data based on an individual's role on the research team (HSCRC users shall include language to ensure they only request

access to the minimum amount of data necessary for completion of their project. Additionally, if a user has access for multiple projects, language shall be included to specify that the user will only access the data files specific to each DUA).

13. Explain the use of technical safeguards for data access (which may include password protocols, log-on/log-off protocols, session time out protocols, and encryption for data in motion and data at rest).
14. Are additional entities involved in analyzing the Data provided by the HSCRC? If so, please indicate how the analyst of those entities will access the Data:

    ☐ VPN connection

    ☐ Will travel to physical location of the Data at requesting Organization

    ☐ Request that a copy of the Data be housed at second location

    ☐ Other: Please describe other mechanisms for accessing the Data.

15. If an additional copy of the Data will be housed in a separate location, please describe how the Data will be transferred to this location. (Also, please include the information on the Organization's database management under the appropriate subsections of the database management plan.)

C. DATA REPORTING AND PUBLICATION

16. Who will have the main responsibility for notifying HSCRC of any suspected incidents wherein the security and privacy of the Data may have been compromised?
17. Please describe and identify the Organization's policies and procedures for responding to potential breaches in the security and privacy of the Data.
18. Explain how the Organization's data management plans are reviewed and approved.
19. Explain whether and how the Organization's data management plans are subjected to periodic updates during the DUA period.

D. COMPLETION OF RESEARCH TASKS AND DATA DESTRUCTION

20. Describe the Organization's process to notify HSCRC when the project is complete and access is no longer needed.
21. Describe the Organization's policies and procedures for notifying HSCRC if a current HSCRC user is no longer working on the project (particularly if a project involves multiple users).
22. Describe policies and procedures the Organization uses to inform HSCRC of access changes when staff member's participation in the research project is terminated, voluntarily or involuntarily.

23. Describe the Organization's policies and procedures to ensure the original Data are not used following the completion of the project.

This Data Use Agreement ("Agreement") pertains to the above request for the Data. The Data are considered protected health information (PHI). The undersigned gives the following assurances with respect to the Data. _____ (the "Organization") considers the security and confidentiality of PHI as a matter of high priority. Any and all members of the Organization (or individuals acting on behalf of the Organization) having access to patient medical files and information contained in the Data will be held responsible for safeguarding and maintaining strict confidentiality. In order to be granted access to PHI, unconditional agreement to the following standards is required of the Organization:

1. Will attest that all users of the Data received training in the protection of sensitive and private information;
2. Will not attempt to use or permit others to use the Data to learn the identity of any person included therein;
3. Will require all users of the Data within the Organization, as well as any subcontractor, representative, or agent of the Organization who uses the Data, to sign an agreement assuring full compliance with this data use agreement. The Organization will keep these signed agreements and make them available to the HSCRC during normal business hours and upon receipt of prior written notice;
4. Will maintain a data security plan for any subcontractor employed by the Organization which adequately addresses the requirements contained herein;
5. Will not release or permit others to release any information that identifies persons, directly or indirectly;
6. Will not release or publicize or permit others to release or publicize statistics where the number of observations in any given cell of tabulated data is less than or equal to ten (10);
7. Will not release or permit others to release the Data or any part of it to any person who is not a member of the Organization or its subcontractors, without the prior written approval of the HSCRC;
8. Will ensure that any subcontractors accessing the Data will use the Data only for the purposes identified above and will destroy the Data once the project is complete per #18 of this DUA;
9. Will not attempt to link or permit others to attempt to link the hospital stay records of the persons in the data set with personally identifiable records from any source, without prior written authorization from the HSCRC;
10. Will not disclose confidential records identified by the CRISP algorithm as being related to Substance Abuse treatment or disorders in accordance with the Federal Regulation 42 CFR Part 21 (provided that the Organization received written verified consent from the patients to receive this information), unless the Data has been de-identified and the purpose is for research only;

11. Will only use the Data for the purposes identified in the Application for Access to Confidential HSCRC Statewide Hospital Discharge Data and will acknowledge in all reports based on these Data, either by direct cite (where space and/or publication guidelines permit), or by inclusion in a list of data contributors available upon request that the source is the HSCRC;
12. Will not further distribute the Data (at a patient-level and/or code level) to other entities outside of Maryland without advanced written approval from the HSCRC.
13. Will include in all reports produced based on these Data that contain 3M Grouper code-level data, the following written notice: **"THIS REPORT WAS PRODUCED USING PROPRIETARY COMPUTER SOFTWARE CREATED, OWNED AND LICENSED BY THE 3M COMPANY. FURTHER DISTRIBUTION OF REPORTS THAT CONTAIN PATIENT AND/OR CODE LEVEL DATA IS NOT PERMITTED WITHOUT ADVANCED WRITTEN APPROVAL BY 3M. ALL COPYRIGHTS IN AND TO THE 3MTM SOFTWARE (INCLUDING THE SELECTION, COORDINATION AND ARRANGEMENT OF ALL CODES) ARE OWNED BY 3M. ALL RIGHTS RESERVED."**
14. Will not use the Data for purposes of penetration or vulnerability studies to test whether patients in the dataset can be identified using variables contained in the Data;
15. Will allow the HSCRC staff or agent thereof to inspect the offices of the Data user, during normal business hours and upon prior written notice, to ensure compliance with this Data Use Agreement;
16. Will ensure that the transmission of PHI is in full compliance with the Privacy Act2, Freedom of Information Act3, HIPAA4, and all other State and federal laws and regulations, as well as all Medicare regulations, directives, instructions, and manuals;
17. Will give the HSCRC written notice immediately or as soon as reasonably practicable upon having reason to know that a breach, as defined below has occurred;

Any unauthorized use of the Data by the Organization, including its members, shall constitute a breach of this Agreement. Any breach of security or unauthorized disclosure of the Data by the subcontractors of the Organization shall constitute a breach of this Agreement. Any violation of State or federal law with respect to disclosure of the Data by the Organization, including but not limited to, the HIPAA, shall constitute a breach of this Agreement. Notwithstanding the breaches specifically enumerated above, any other failure by the Organization or business associates, including its contractors, subcontractors or providers to comply with the terms and obligations of this Agreement shall constitute a breach of this Agreement. Any breach of the Data by a third-party will promptly: (i) be the subject of contractual termination or other action, as determined by the Organization and (ii)

[2]**The Privacy Act of 1974**, a United States federal law, establishes a Code of Fair Information Practice that governs the collection, maintenance, use, and dissemination of personally identifiable information about individuals that is maintained in systems of records by federal agencies. For more information: https://www.justice.gov/opcl/privacy-act-1974

[3]**The Freedom of Information Act (FOIA)** generally provides that any person has the right to request access to federal agency records or information except to the extent the records are protected from disclosure by any of nine exemptions contained in the law or by one of three special law enforcement record exclusions. For more information: https://foia.state.gov/learn/foia.aspx

[4]**The Health Insurance Portability and Accountability Act of 1996** (HIPAA) sets national standards for patient rights with respect to health information. The Privacy Rule protects individually identifiable health information by establishing conditions for its use and disclosure by covered entities. For more information: http://www.hhs.gov/ocr/hipaa or http://privacyruleandresearch.nih.gov

be reported to the HSCRC within two (2) business days of the day the Organization becomes aware of the third-party violation.

Any alleged failure of the Organization to act upon a notice of a breach of this Agreement does not constitute a waiver of such breach, nor does it constitute a waiver of any subsequent breach(es);

In the event that the HSCRC reasonably believes that the confidentiality of the Data has been breached, the HSCRC may: investigate the matter, including an on-site inspection for which the the Organization shall provide access; and require the Organization to develop a plan of correction to ameliorate or minimize the damage caused by the breach of confidentiality and to prevent future breaches of data confidentiality. In the event of a breach of this Agreement, the HSCRC may seek all other appropriate remedies for breach of contract, including, but not limited to, termination of this Agreement, disqualification of the Organization from receiving PHI and PII from the HSCRC in the future, and referral of any inappropriate use or disclosure to the Maryland Office of the Attorney General, or the appropriate individual or entity;

At its sole cost and expense, the Organization shall indemnify and hold the HSCRC, its employees and agents harmless from and against any and all claims, demands, actions, suits, damages, liabilities, losses, settlements, judgments, costs and expenses (including but not limited to attorneys' fees and costs), whether or not involving a third-party claim, which arise out of or relate to the Organization, or any of its subcontractors' or agents use or disclosure of Data that is the subject of this Agreement. The Organization shall not enter into any settlement involving third-party claims that contain an admission of or stipulation to guilt, fault, liability or wrongdoing by the HSCRC or that adversely affects the HSCRC's rights or interests, without the HSCRC's prior written consent.

18. Will provide a Certification of Data Destruction to the HSCRC once the source data are destroyed and the project is completed;
19. Will retain these data files for a maximum of 5 years.

This Agreement will remain in effect for the duration of the time in which the data is retained. However, this Agreement may be terminated by the HSCRC at any time, and for any reason.

If this project described above is not completed within a five-year timeframe, the applicant must submit a new application for the continued use of the data associated with this request.

The signatures below indicate agreement to comply with the above-stated requirements. All persons within the Organization must fully comply with this agreement. Failure to comply with the provisions specified herein may result in civil and/or criminal penalties in accordance with state law and policy.

Organization #1: (THE ORGANIZATION)

My signature indicates agreement to comply with the above-stated requirements. I understand that failure to comply with the provisions specified herein may result in civil and/or criminal penalties in accordance with state law and policy.

Signed:_____Date:

Print Name:_____Title:

Address:

City:_____State:_____Zip Code:

Phone:_____E-mail Address:

HSCRC Representative

Signed:_____Date:

Print Name:_____Title:

Appendix D
Approval of Other Data Owners

Appendix E
CRISP Data Use Agreement

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 230, Columbia, MD 21046 and **DATA RECIPIENT** ("Data Recipient"), located at **ADDRESS**, (each a "Party" and, collectively, the "Parties") for the purpose of supporting the research study **NAME OF STUDY** ("Research Study") approved by the CRISP Research Subcommittee on **April 30, 2019** under the approved use case, **Combining CRISP and HSCRC Case Mix Data**. 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 **PA SIGNER**. 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:
Program Director, CRISP Research Initiative
7160 Columbia Gateway Drive
Suite 100
Columbia, MD 21046

If to Data Recipient:

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 **DATE**.

For CRISP	**For DATA RECEIPIENT**
_____	_____
Name: Craig Behm	Name: _____
Title: Chief Executive Officer	Title: _____
Date: _____	Date: _____

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. Changes to approved users can be made by the Principal Investigator or Delegator listed below.

Approved Research Study:

Approving Participating Organization:

Principal Investigator:

PI Title:

PI Contact Email:

Approved Users:

Add/ Delete/ Modify/ Unchanged	Name	Title	Email	Delegator or Delegate	CRISP Verified*

**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.*

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: _____

Attachment E – Fee Schedule

FY 2024 Revised Research Rates

Service	Cost	=
Base Data Service – Portal Access or Data Insights Extract	$20,000	
HSCRC Data Matching	$5,000	
Addi&#65533;onal Data Pulls / Longer Portal Access (with same variables and cohort)	$5,000 / request	
Addi&#65533;onal Data Pulls / Longer Portal Access (with different variables and cohort)	$10,000 / request	
Non-Standard Data Matching (i.e., researcher provides addi&#65533;onal data sets that CRISP matches to Data Insights Extract)	Star&#65533;ng at $20,000, increasing based on complexity	
	Subtotal	
	(-) 50% Discount for Maryland-Based Entities	
	(+) 15% overhead cost (for security and other operating costs)	
	Total:	

Note: Costs do not include the cost of other datasets, including HSCRC data.

Appendix F
Directions for Patient Panel Submission

CRISP Patient Panel Checklist

Section 1: Account and POC Information

Account Name: -

Date:

Point of Contact Name (ENS/Panel Lead): -

Phone #:

Email: -

Which CRISP Services are you interested in?:

☐ Clinical Data (If checked, disregard Section 4) ☐ ENS notifications ☐ ENS notifications + Clinical Data

Section 2: Patient Panel – General Information

The patient panel that you submit informs many aspects of CRISP services/infrastructure including:

- Encounter Notifications (ENS): Informs CRISP of your active patients so we can notify you of hospital events.
- Care Team: CRISP is able to display your organization as a part of a patient's active Care Team.
- User Audit: Under CRISP policy, users may only search for actively managed patients, as dictated by the patient panel. Frequent searching for patients that are not on your panel may result in a security flag.

To ensure that CRISP accurately reflects your active patient roster, please send your patient panel at least every 90 days.

Failure to submit timely panels may result in termination of user access to CRISP services.

Section 3: Patient Panel – Submission

Medical Record Number/Unique Patient ID:

☐ Participant-specific MRN

☐ Hospital/System MRN (If checked, please specify which hospital/system):

_____

How will you submit your patient panels?

☐ Self-Service Panel Loader (recommended) – please indicate max of 2 submitters on bulk load sheet	☐ SFTP ☐ CRISP hosted ☐ Participant hosted
☐ Secure email ☐ CRISP Direct secure email (CRISP will provide credentials) – please indicate max of 2 submitters on bulk load sheet	☐ ADT/SIU feed to CRISP

What kind of panel will you be submitting? **Please disregard if you checked ADT/SIU feed above

☐ Overwrite (Each panel will overwrite the last) • If you checked Self-Service Panel Loader, you must submit an Overwrite panel	☐ Delta (You will only send Add/Update/Delete rows)

Section 4: ENS Alerts – Delivery to CRISP Participant

ENS Trigger Alerts	Notification Delivery
All users will receive notifications for the following trigger events: • Admission, Discharge, and Transfer messages for ED, Inpatient, and Outpatient settings • Users will be able to filter for specific alert types in ENS PROMPT	ENS PROMPT for all users, as indicated on the corresponding User Bulk Upload Sheet.
If you have a specific request or use case outside of the default settings above, contact your account representative.	

FOR INTERNAL USE ONLY: ENS team, please confirm that the following items have been completed:

☐ **SUD status** ☐ **ENS Recipient Objects created** ☐ **Source Code sent to outreach**

Appendix G
Proof of Data Governance Agreement among Researchers

Appendix H
Approval from Data Governance Committee

[Attach relevant Minutes.]

Appendix I
Fee Schedule

FY 2024 Revised Research Rates

Service	Cost	=
Base Data Service – Portal Access or Data Insights Extract	$20,000	
HSCRC Data Matching	$5,000	
Addi&#65533;onal Data Pulls / Longer Portal Access (with same variables and cohort)	$5,000 / request	
Addi&#65533;onal Data Pulls / Longer Portal Access (with different variables and cohort)	$10,000 / request	
Non-Standard Data Matching (i.e., researcher provides addi&#65533;onal data sets that CRISP matches to Data Insights Extract)	Star&#65533;ng at $20,000, increasing based on complexity	
	Subtotal	
	(-) 50% Discount for Maryland-Based Entities	
	(+) 15% overhead cost (for security and other operating costs)	
	Total:	

Note: Costs do not include the cost of other datasets, including HSCRC data.