CRISP

Connecting Providers with Technology to Improve Patient Care

CRISP Research Data Request Form

Version 1.7 – Last Updated 10/30/19

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: _____ Address: _____
   Title: _____ City, ST, ZIP: _____
   Email: _____ Phone: _____
   Link to Bio: _____

6. **Co-investigator(s)** (include email, title, phone, affiliation and, as available, link to bio):

7. **Research Administrator / Primary Contact:**
   Name: _____ Address: _____
   Title: _____ City, ST, ZIP: _____
   Email: _____ Phone: _____

8. **Financial Point of Contact** (for invoicing):
   Name: _____ Address: _____
   Title: _____ City, ST, ZIP: _____
   Email: _____ Phone: _____

9. **Funding:**
   Funding status: _____ Total project funding: $_____
   Funding sources: _____

10. **Planned or actual study start date:** _____ **Planned study end date:** _____

11. **Study Location(s):** _____

12. **Number of subjects anticipated (sample size):** _____

13. **CRISP use case supporting this study:** Other Not Yet Approved

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

Section C: Type and frequency of data requested

17. *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: Self-Loading (As Needed)
- Data submission method: CRS Pre-Post Panel
- Other Method: _____

☐ 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).

☐ **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.

- 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 ☐ CRS Pre-Post Report ☐ Custom Report

☐ 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

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 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.

☐ 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.

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

IRB approval letter or waiver: _____

IRB-approved study protocol: _____

IRB-approved data security plan: _____

IRB-approved consent form: _____

Other supporting documents (document names and descriptions):

_____

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: _____

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 several 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 tool, ENS PROMPT.
    - Clinical Query Portal – 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.

Other use cases are described on the CRISP website at https://crisphealth.org/services/crisp-research-initiative/. 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 Dr. Ross D. Martin, Program Director, Research and Transformation, at ross.martin@crisphealth.org or 202-697-3077. 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.

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

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. The fees listed below are for FY2020. 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 Clinical Query 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 Clinical Query 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 Clinical Query 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 Clinical Query Portal Access

Credentialed users can request access to the CRISP Clinical Query 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://crisphealth.org/information-for-researchers/ to estimate the cost of a specific research project. A snapshot of the estimator tool is below.

CRISP Initiative for Enabling Research - Cost Estimatimator - FY2018											
Study Name: Enter Name Here	Study Duration in years (5 max):	3		Annual rate increase after year 1:	4%	Start Date:		Overhead Rate:	10%		
Research Service	Cost per Hour / Unit (blended)	Hours per Service Request	Cost per Service Request (First Year)	Number Required per Year	Total Number Required	Year 1	Year 2	Year 3	Year 4	Year 5	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	3	$ 1,250.00	$ 1,300.00	$ 1,406.08	$ -	$ -	$ 3,956.08
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	3	3	$ 510.00					$ 510.00
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	Quarterly	12	$ 680.00	$ 707.20	$ 735.49	$ -	$ -	$ 2,122.69
CRISP Query Portal Access (per user per year)	$ 85.00	2	$ 170.00	3	9	$ 510.00	$ 530.40	$ 551.62	$ -	$ -	$ 1,592.02
ENS PROMPT Access (per user per year)	$ 85.00	2	$ 170.00	3	9	$ 510.00	$ 530.40	$ 551.62	$ -	$ -	$ 1,592.02
Direct Secure Email Account (per year for panel uploads)	$ 315.00	1	$ 315.00	Yearly	3	$ 315.00	$ 327.60	$ 340.70	$ -	$ -	$ 983.30
Additional custom data prep hours	$ 155.00	1	$ 155.00	Variable		0	0	0	0	0	$ -
Additional credentialing and data access hours	$ 85.00	1	$ 85.00	Variable	0	0	0	0	0	0	$ -
Additional account management hours	$ 125.00	1	$ 125.00	Variable	0	0	0	0	0	0	$ -
					Subotals:	$ 5,990.00	$ 3,395.60	$ 5,460.50	$ -	$ -	$ 14,846.10
					Overhead:	$ 599.00	$ 339.56	$ 546.05	$ -	$ -	$ 1,484.61
					Totals:	$ 6,589.00	$ 3,735.16	$ 6,006.55	$ -	$ -	$ 16,330.71

More information on the CRISP Research Initiative is available at https://crisphealth.org/services/crisp-research-initiative/ and details for researcher are available at https://crisphealth.org/information-for-researchers/. For specific questions not addressed on the website, please contact Dr. Ross D. Martin, Program Director for Research and Transformation at CRISP at ross.martin@crisphealth.org. When complete, please submit this form to research@crisphealth.org.