CRISP
*Connecting Physicians With Technology
to Improve Patient Care in Maryland*

Chesapeake Regional Information System for our Patients

Use Case: Using CRISP to Support IRB-Approved, Patient-Consented Research

For Submission to Clinical Committee for Approval: Last updated 09/15/2016

Overview

CRISP can provide researchers conducting studies that track a specific group of subjects over time with a streamlined way to access a rich set of clinical information available from organizations participating in CRISP's health information exchange. This use case specifically supports researchers conducting IRB-approved research in which subjects (or their authorized agents, on their behalf) have agreed to participate in the study.

Background and Value

CRISP is connected to and receives data from all acute care hospitals in Maryland and DC as well as a number of radiology centers, long-term care facilities, ambulatory practices, and other participants in the CRISP service area. The clinical information these facilities share with CRISP is made accessible in real time to participating health care providers through multiple CRISP services. Examples of CRISP services that researchers could leverage include, but are not limited to:

- **Clinical Query Portal**: CRISP has the ability to provide researchers with access to the CRISP Clinical Query Portal, through which researchers can search for clinical information on research subjects throughout the duration of the study, streamlining the process of medical abstraction for the permitted purpose of the study.
- **Encounter Notification Service (ENS)**: CRISP has the ability to provide researchers with real-time notifications when research subjects are admitted, discharged, or transferred to, from, or within a hospital and other care settings within the CRISP service area. This service could reduce the burden on study participants and researchers to report and record encounters and increase the accuracy of research data.
- **Data Extracts**: CRISP has the potential to extract data from aggregated data sources for subjects participating in IRB-approved, patient-consented studies. This capability has not yet been built, but would be included in this use case as a more effective mechanism for delivering tailored data sets for specific research purposes.

Other CRISP services may become available to researchers in the future and could provide additional information or methods of data delivery, provided the data falls under the allowable uses within current CRISP Participation Agreements and Data Use Agreements.

Use Case Description

This service would allow researchers conducting IRB-approved, subject-consented studies to leverage CRISP services for the enrolled individuals. The use case would begin with subject attribution, or matching a patient in the CRISP database to a researcher. The researcher would provide to CRISP a list of enrolled subjects for whom the researcher would like to access CRISP data, along with periodic updates to reflect additions to or deletions from the cohort. When requested, the researcher would have to show that each subject is enrolled in the research study, and has provided explicit, fully informed, opt-in consent sufficient for CRISP to share information about medical encounters with the researcher by permitting access to CRISP data sources. The process for opting-in is described in the Opt-In Applicability section.

Researcher responsibilities

The researcher would have several responsibilities to participate in this service:

- Provide documentation of IRB-approved study, including the name of the entity requesting the data; name of the IRB board; name and role of principal investigator and any co-investigators; details about the purpose of the study and study protocol; the start and end date of the study; and a description of how the data request meets policy requirements and authorizes CRISP to allow the researcher access to the requested data sources to obtain the individual's information.

- Provide a panel of enrolled study participants, along with ongoing updates for additional and deletions from the panel.

- Demonstrate adequate safeguards to ensure confidentiality of source data, prevent re-disclosure that would identify an individual, and prevent re-release of source data through signing a Data Use Agreement in a CRISP-approved form.

- Provide acknowledgement of the use of CRISP data in publications resulting from its use.

- Reimburse CRISP's chargeable costs and expenses.

CRISP responsibilities

CRISP would have the following responsibilities:

- Review and approve data access requests in accordance with CRISP's governance process.
- Provide researchers with educational materials related to the CRISP service and opt-out processes for study participants.
- Establish secure mechanisms for researcher access to CRISP data for consented study participants, including credentialing researchers to gain access to CRISP data.
- Provide boilerplate language that accurately describes the data provided for the study for use in publication.

Permitted Purpose Category

Permitted purpose #4, Research.

Opt-In Applicability

Unlike most of CRISP's services, individuals would have to explicitly opt-in to allow their information to be accessed through CRISP for this research use case through the study's patient consent process.

Researchers would be responsible for obtaining consent from each study participant whom the researcher included on his or her roster of individuals sufficient to allow the researcher to review the individual's information through CRISP. If a study participant previously opted out of participation in the CRISP HIE, the participant's clinical data would not be available to the researcher unless the participant opts back into CRISP.

The following language would be acceptable to include in a participant authorization document to support access to CRISP data:

> 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.

Approval:

This Use Case Policy has been approved by the Clinical Advisory Board.

_____   11/8/16
Chairperson   _____
                                       Dated