Date: February 22, 2016

From: David Horrocks
President of CRISP

To: CRISP Participants

Re: Notice of Proposed Material Amendment to the Participation Agreement for Research

---

Updated to reflect Participant comments – Final Version

Amendment Effective Date: March 24th, 2016

Background

As we have developed CRISP together over the past 7 years of operations, the organization has remained committed to the core principle of incremental and manageable growth. The CRISP Participation Agreement initially included two Permitted Purposes for data use; for *Treatment* and for a *Public Purpose* permitted or required by law. In the case of the latter Permitted Purpose, when only permitted, additional review steps are taken, such as Advisory Board approval of a specific Use Case. Three years ago CRISP worked with Participants through a Material Amendment process to introduce a third Permitted Purpose for *Operations* limited to Care Coordination, Quality Improvement, and Quality Assessment activities. Use Cases or services justified under this third Permitted Purpose must be approved by the CRISP Clinical Advisory Board and the Use Case is then publically posted on the CRISP website.

Since inception stakeholders have been asking when CRISP would begin to support research processes and efforts. The CRISP management team has collaborated with a range of stakeholders from the research community, the CRISP Clinical Advisory Board, the Maryland Health Care Commission, and other CRISP Participants to formulate an approach to support Research Use Cases. We believe now is the right time to introduce a well-defined Research-focused Permitted Purpose.

To that end, CRISP is proposing this fourth Permitted Purpose for research to be added as a material amendment to the Participation Agreement through a modification to the Policies and Procedures. This permitted purpose will be structured in the same way as the third permitted purpose; specific use cases must be approved by the CRISP Clinical Advisory Board and posted to the CRISP website. Additionally, any research use case approved by CRISP must be in accordance with any current or future Maryland Health Care Commission HIE Regulations. The current Permitted Purposes are included below with the proposed material amendment language highlighted in red.

Proposed Material Amendment Language

5. Permitted Purposes
Participants and participant users may access and use data through the CRISP only for permitted purposes, as defined in the Terms and Conditions. Permitted purposes for data use are listed below:

1. For treatment of an individual
2. For a public purpose (see Participation Agreement for definition)
3. For quality assessment and improvement activities, including care coordination, defined in HIPAA as a subset of health care operations activities, when such uses are approved by the CRISP Clinical Advisory Board, and subject to the limitations stated in Section 3.02 b (i) of the Terms and Conditions (see Appendix B for a list of approved quality improvement and care coordination uses).
4. For research designed to develop or contribute to generalizable knowledge and which may or may not require the approval of an IRB. Disclosure of information under this Permitted Purpose shall only be permissible when it appears calculated to provide benefit to CRISP participants or their affiliates and/or to residents of the region CRISP serves, as evaluated by the Clinical Advisory Board and as further described in the Policies and Procedures. For purposes of making decisions concerning this Permitted Purpose number four, The Clinical Advisory Board shall consist of representatives from at least three (3) CRISP Participant entities.

Approved uses under this Permitted Purpose number three (3) and four (4) may be modified or added with the approval of the CRISP Clinical Advisory Board, and such modifications or additions will be treated as non-material amendments to the Policies and Procedures and posted on the CRISP website.

With the approval of the Clinical Advisory Board, specific use cases under Permitted Purpose number three (3) and four (4) may be extended to entities that are covered entities under HIPAA but not full CRISP participants entitled to the other Permitted Purposes upon a finding that such an extension is in furtherance of the mission of CRISP, that the entity has obtained a CRISP Participant sponsor, that entry into a full Participation Agreement with the covered entity is not possible or practical, and that the covered entity will be required to enter into a written agreement with CRISP that protects the interests of CRISP and its participants in the integrity of the CRISP Services and the appropriate use of the information to be provided to the covered entity.

For Permitted Purpose four (4) CRISP shall be permitted to charge the requestor a fee reflecting its direct and indirect costs to provide the requested information. The introduction of a fee structure shall be approved by the CRISP Board, on recommendation of the Finance Advisory Board. Individual Use Cases shall be approved by the CRISP Clinical Advisory Board from time-to-time, which may result in additional required steps for approval under certain Use Cases, for example, IRB approval or review by a CRISP formed Research Committee which includes consumer representation. If the CRISP Board empanels a new Advisory Board or Committee to advise on appropriate uses of data, comprised of at least three (3) participant representatives, as is now the case for existing advisory boards, it shall be permissible for that Advisory Board or Committee to fulfill the role described herein for the Clinical Advisory Board as it relates to the Quality Assessment and Improvement and Research permitted purposes. CRISP shall comply with all applicable legal requirements and shall comply with patient protections required for a Maryland HIE regardless of whether the subject individuals are residents of Maryland. CRISP shall conduct a preliminary review of each request for feasibility as to CRISP and for general compliance with laws before any research request is brought forward for consideration by relevant committees. Requestors will be required to enter into a Data Use Agreement with CRISP, in a CRISP approved form. This Permitted Purpose shall apply to disclosures of information received from participants through the CRISP HIE but in some circumstances may not apply to data sets received by CRISP from state agencies.

Use Case Example

As stated in the proposed material amendment above, any use case justified under the Research Permitted Purpose will require approval from a CRISP Advisory Board. This process is currently relied upon for approving use cases justified under the Permitted Purpose #3 in which use cases are reviewed and approved by the CRISP Clinical Advisory Board. In an effort to offer tangible Use Case scenario, a use case is include as an addendum to this memo.

Materials Amendment Process and Schedule (CRISP Participation Agreement Section 12.04)

The CRISP Participation Agreement and Policies and Procedures define a specific process that must be followed for material amendments to the Participation Agreement. The details of the process and timing are outlined below. This memo serves as the initiation of the material amendment process.

If the amendment is Material, CRISP will:

- Provide notice to Participant in accordance with Section 23.2 and through posting the amendment and its effective date on the CRISP website, in both cases, at least ninety (90) days prior to the effective date of the amendment.
- Allow Participants thirty (30) days from the date of the initial posting of the notice on the CRISP website to submit written comments to CRISP regarding the amendment.

Comments are not Confidential Information and may be posted on the CRISP website (though not required).

- Within forty-five (45) days of initial posting of the amendment, CRISP will convene a meeting at which the Participants will be allowed to present comments or objections or suggestions as to the amendment to CRISP.
- Within sixty (60) days of the initial posting notice of the amendment on the CRISP website, CRISP shall consider and evaluate both written comments received during the comment period and information presented at the meeting and make any revisions to the proposed amendment that are deemed reasonable and necessary by CRISP, after consultation with the Advisory Board.
- If CRISP modifies the proposed amendment, the effective date will be extended by an additional thirty (30) days after CRISP posts the modified amendment on the CRISP Website, without further process or comments.

In all events, CRISP will provide Participant with a follow-up email notification of the final amendment to Participant's Designated Contact and its effective date a reasonable time in advance of the effective date, normally thirty (30) days, upon its determination by CRISP in accordance with this Section 12.04.

Addendum

Research Use Case Example

Use Case Description: Encounter Notifications to Support IRB Approved Research

Overview

A cohort study looks at a population over a defined period of time, such as delivering ADT information about a patient's relevant medical services encounter, in real or near-real time, to a researcher conducting IRB-approved research involving the patient. Patients must explicitly opt-in to participate in the service, and researchers must demonstrate validity of research and patient participation.

Background and Value

CRISP currently receives all ADT (Admit, Discharge, Transfer) messages from every hospital in Maryland. CRISP uses this encounter data to provide value to participants through a variety of services. CRISP's Encounter Notification System (ENS) provides real-time notifications for care coordination and quality improvement purposes when patients are admitted, discharged, or transferred to, from, or within a hospital. Providers and care managers sign up for the service and submit a roster of their active patients whose care they monitor to CRISP, and if one of those patients has an encounter (such as an emergency department admission or discharge), the provider receives a notification. ENS allows providers to better coordinate, follow-up, and track their patients' care and health, and aligns with new payment models that incentivize care coordination.

Researchers who follow a set of patients over time, such as in a cohort study, may also receive value from encounter notifications. Sending automatic alerts of encounter events to researchers could reduce the burden on study participants and researchers to report and record encounters, and increase the accuracy of research data. The effort to CRISP would be limited as CRISP could provide researchers with the same alerts it already sends ENS participants.

Use Case Description

This service would provide encounter notification alerts to researchers conducting IRB-approved ongoing cohort studies, for the individuals enrolled in the research studies. The use case would begin with patient attribution, or matching a patient and a researcher. The researcher would provide to CRISP a list of enrolled patients for whom they would like to receive relevant notifications, updated to reflect additions to or deletions from the cohort. The researcher would have to show that each patient

is enrolled in the research study, and has provided explicit, fully informed, opt-in permission sufficient for CRISP to share information about medical encounters with the researcher. The process for opting-in is described in the Opt-In Applicability section. CRISP and the researcher would work cooperatively establish alerting rules which would dictate which encounter types would generate alerts for the researcher. CRISP would make relevant notifications available to providers through Direct messaging, for which researchers would have to work with CRISP to create a DIRECT account.

Researcher Responsibilities

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

1. 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, ADT data elements requested, 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 release the required data to the Researcher
2. Listing, and updating, the researcher's panel of enrolled patients
3. Direct messaging account
4. Demonstrating 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
5. Paying CRISP's chargeable costs and expenses

CRISP Responsibilities

CRISP would be responsible for managing the service, and coordinating all activities, specifically:

1. Providing researchers with CRISP education materials for study participants
2. Working with researchers to determine appropriate alert rules
3. Working with researchers to set up Direct accounts

Securely delivering encounter notifications in real or near-real time, during the duration of the study and not beyond that time

Permitted Purpose Category

Permitted purpose #4, for Research.

Opt-In Applicability

Unlike most of CRISP's services, individuals would have to explicitly **opt-in** to the sharing by CRISP of their information for research. Researchers would be responsible for obtaining permission (written or electronic) from each study participant who the researcher included on his or her roster of individuals to receive notifications from CRISP and documenting that permission to CRISP. If a study participant previously opted out of participation in the CRISP HIE, the participant would be excluded from ENS alerts to the researcher unless the participant opted back into CRISP. The opt-in for this research would be general in scope and would not be limited to the sharing of information with respect to the research.

Other

- This use case makes no allowance for CRISP to send or provide access to clinical data in CRISP
- CRISP will develop a Data Use Agreement, or an addendum to the existing Agreement, appropriate for researchers who wish to receive notifications under this Use Case.

Approval:

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

_____ _____

Chairperson Dated