Mass General Brigham

PREDICT (Personalized Risk-based Follow-up of Cervical Cancer Screening in Practice), RCT
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Institutional Review Board
Intervention/Interaction Detailed Protocol

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For Intervention/Interaction studies, submit a Detailed Protocol that includes the following sections. If information in a particular section is not applicable, omit and include the other relevant information.

1. Background and Significance

***Cervical cancer remains a public health burden, particularly for underserved populations*.** Cervical cancer mortality in the United States (US) has declined over the past 20 years due largely to improved preventive care and treatment of precancerous lesions.[1] Today, cervical cancer is highly preventable when detected early and managed appropriately. Nevertheless, it continues to be a significant public health concern in the US with 13,960 new cervical cancer cases diagnosed and 4,310 cervical cancer deaths.[2] In addition, an estimated 196,000 cases of high-grade cervical pre-cancer are diagnosed each year.[3] Cervical cancer is most often diagnosed in under-screened individuals or after a failure to follow up on abnormal screening results.[1-3] Racial/ ethnic and socioeconomic disparities in cervical cancer screening, incidence, and mortality persist in the US.[2,4] Even among individuals who receive screening, the benefits are only realized if coupled with timely and appropriate surveillance and diagnostic evaluation. Our work shows that unfortunately many individuals with an abnormal cervical cancer screening result do not receive timely follow-up.[5-8]

***Evolution of cervical cancer screening and management (CCSM)*.** The 2018 US Preventive Services Task Force (USPSTF) screening guidelines recommend 3 strategies to screen for cervical cancer (Papanicolaou [Pap] test alone (with option of reflex human papilloma virus [HPV] testing), Pap/ HPV co-testing, and HPV alone).[9] In 2019, the American Society for Colposcopy and Cervical Pathology (ASCCP) revised guidelines for managing abnormal cervical cancer screening results.[10] The 2019 guidelines reflect the principle of "equal management for equal risks."[11] Algorithms for these guidelines were developed through analyses of 1.5 million observations from the Kaiser Permanente Northern California cohort, a system with strong implementation infrastructure that may not be generalizable to other settings.[11] The 2019 guidelines use information from a patient's current and prior screening and surveillance history to make follow-up recommendations based on their risk of developing cervical squamous intraepithelial neoplasia grade 3 or more severe diagnoses (CIN 3+) in the future. Risk-based guidelines are explicitly designed to maximize benefits of cancer prevention while minimizing harms of over-testing and over-treatment.[10,12] The ASCCP guidelines establish clinical action thresholds recommending immediate colposcopy/ treatment or surveillance

intervals (1, 3 or 5-years) based on the estimated risk of CIN3+ associated with a person's current and historical CCSM results.[10] The complexity of these evidence-based guidelines make it challenging for practitioners to implement in practice. Furthermore, while women with adequate prior screening can stop screening at age 65, many women may not meet exit criteria[13] and "inappropriate exit" may contribute to rising cervical cancer rates and higher stage disease in this age group.[14,15] Roughly 20% of US cervical cancer cases currently occur in women older than 65 years, and primarily affect Black and Hispanic individuals.[2]

***Complexity of implementing of cervical cancer management in clinical practice*.** The need to estimate the risk of developing CIN3+ in the future to determine the appropriate management strategy is complicated and error-prone to implement in clinical practice. The ASCCP guidelines contain hundreds of algorithms to address permutations of age, comorbidity and prior/ current cervical cancer screening history. While the ASCCP has created a phone app to enable practitioners to manually enter results and see the recommended next step, this approach is not feasible for busy primary care practitioners (PCPs) and isn't scalable to manage populations.[16,17] Cervical screening tests/ procedures are often not captured as coded data in electronic health records (EHRs),[18] so they cannot easily be used for risk estimation. Patients who experience barriers to access, including those who identify as Black or Hispanic, those with incomes at or below the poverty threshold, and the uninsured may not receive the full benefits of risk based-management because their prior screening history may be unknown to their current clinical team.[6,19,20] Preliminary analysis of our data from Population-based Research to Optimize the Screening Process (PROSPR) finds that more than a third of patients who received care in 3 diverse healthcare systems, including sites participating in this proposed project, had an unknown cervical cancer screening history prior to the patient's index abnormal test during the study period (unpublished data). As the ASCCP guidelines are a harbinger of other personalized, risk-based algorithms for cancer screening and management, developing systems and strategies to implement these complex guidelines in practice are critical.

Clinical decision support (CDS) is critical to the implementation of cervical screening guidelines. Recognizing the complexity of implementing the CCSM guidelines in clinical practice, the Centers for Disease Control and Prevention's (CDC) Division of Cancer Prevention and Control has developed a CDS tool that provides CCSM guidance using several standard health interoperability standards including Fast Healthcare Interoperability Resources (FHIR).[21] This tool is open-source, and the execution of the ~2000 clinical permutations has been validated. [21] The CDS tool provides practitioners with CCSM recommendations based on the current guidelines from USPSTF and the ASCCP.

While the CDC's CCSM CDS tool transforms USPSTF and ASCCP guidelines into shared, interoperable, and executable algorithms, use in clinical practice requires integration into local infrastructure, most notably the availability of coded data for cervical screening and diagnostic results. We have created and validated coded algorithms to convert text CCSM results into coded data,[8,18] allowing us to integrate the CDS tool. Embedding this open source, interoperable CDS tool in clinical practice settings will support disseminating guideline-recommended care; yet without evaluation of additional strategies it is unlikely that an informatics solution alone will result in timely care for diverse patients in a variety of health care settings.[5,8]

Multilevel barriers to risk-based management recommendations. Responsibility for comprehensive screening and follow-up falls to the ordering practitioner, typically a PCP. Unfortunately, few PCPs/ primary care practices have systems to implement personalized risk assessment or promote follow-up.[16,22] PCPs face the challenge managing populations of patients and coordinating care with involved specialists. The transition from screening to diagnostic evaluation often requires a transfer of role/ responsibility between primary and

specialist care.[23,24] For example, colposcopy should follow "high risk" abnormal Pap or HPV screening results to detect early cervical cancers and to detect and treat precancerous lesions before they progress to cancer.[10]

Patient barriers often begin with not being informed about how and when they will be notified of test results. Patients may not understand the importance of a result or have difficulty negotiating the process for obtaining recommended follow-up. Patient barriers such as language, literacy, financial resources, anxiety, logistical challenges such as transportation and scheduling, and knowledge and beliefs about tests and treatments have been shown to result in delays in follow-up of abnormal screening results.[25-28]

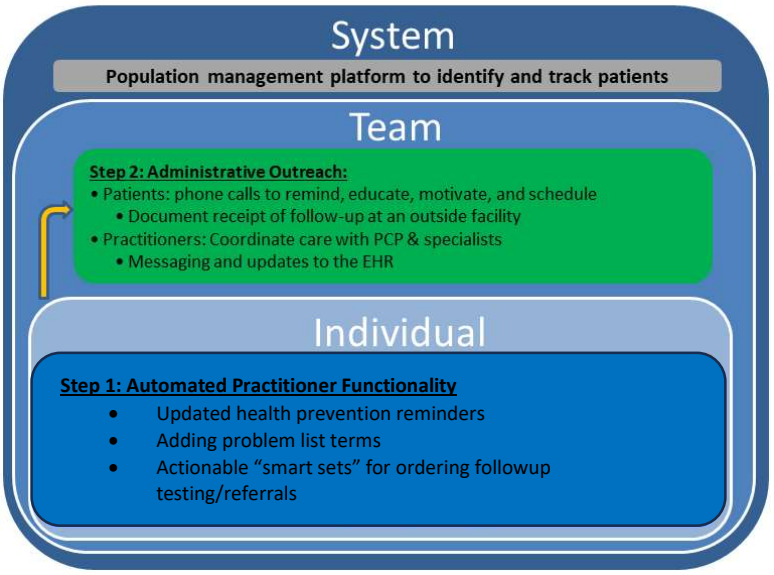
While patients and practitioners may take **individual** responsibility, effective CCSM requires that the patient and PCP function effectively with practice staff and relevant specialists who together comprise a **care team**. The World Health Organization defines a team as "a distinguishable set of two or more people who interact dynamically, interdependently and adaptively towards a common and valued goal, who have been assigned specific roles or functions to perform, with specialized and complementary knowledge and roles, and act as a collective unit."[29] Effective team function can benefit the patient (improved outcomes and satisfaction), PCP and specialist (greater role clarity and job satisfaction), and health system (efficient resource use).[30] Individuals and care teams function within the context of a **health system**, with unique leadership, culture and policies. Systems include infrastructure to support care through health information technology (IT), which can help or hinder the individual and team functions. Systems adopt various approaches to measure and incentivize care that may directly or indirectly influence the follow-up of abnormal screening results.[31]

Summary and potential impact of proposed study. Cancer screening and management guidelines are moving from a "one size fits all" approach to one that is tailored to an individual. CCSM is the first example of a guideline that incorporates longitudinal screening history to personalize risk assessment. While a personalized approach offers the promise of enhancing the balance of benefits vs. harms of screening and management, this ideal can only be realized through strong systems to support care delivery. Without IT tools that integrate personalized algorithms with care delivery, more errors of judgement may occur if practitioners and patients are confused about appropriate next steps. We hypothesize that delivering risk based CCSM to all eligible individuals will require: 1) using a generalizable CDS tool that is validated and open source to implement the ASCCP recommendations; 2) leveraging a system level health IT platform to present risk-based, personalized recommendations; and 3) offering a stepped care approach that individually engages patients and PCPs; and 4) enhances team-functioning, with increasing intensity over time (**Figure 1).** Accordingly, we propose to develop, implement, and rigorously test **PREDICT (Personalized Risk-based Follow-up of Cervical Cancer Screening in Practice)** within 4 primary care practice networks.

A. INNOVATION AND SCIENTIFIC PREMISE

Our scientific premise builds from conceptual models,[32-36] guideline-recommended CCSM, a disseminable informatics approach, and our prior work both on cancer screening and the implementation of pragmatic trials in care settings. We will evaluate the effectiveness and implementation of our intervention, including: 1) visit-based delivery of CCSM reminders to patients and practitioners; and 2) population outreach and practitioner support for scheduling follow-up care. We will deploy the intervention across distinct primary care networks and patient populations.

Figure 1. Multilevel Intervention Components of PREDICT



Our intervention content and strategy of leveraging technology to generate multiple approaches to outreach and engagement is innovative. We will evaluate methods of delivering guideline-recommended care, comparing visit- and population-based approaches. To maximize engagement, we will useinnovative health IT to integrate with patients' EHR records.[8]

Our intervention delivery is highly scalable. By using an open source CDS tool, our approach is broadly disseminable. We propose to integrate the CDC CCSM tool using national data standards (described in **Section C4**), endorsed by the 21st Century Cures Act Final Rule to support seamless and secure access, exchange, and use of electronic health data.[37]

2. Specific Aims and Objectives

Specific Aim 1: To evaluate the *effectiveness* of the multilevel system, team and individual components of PREDICT vs. standard care by conducting a 3-arm cluster randomized controlled trial of individuals who are due for cervical cancer screening and management.

Specific Aim 2: Guided by Evaluation (RE-AIM QuEST) and Determination (CFIR) frameworks, we will assess the reach, adoption, implementation and maintenance of PREDICT. To evaluate the implementation of PREDICT within the 4 networks and to inform and facilitate the dissemination of the intervention beyond the participating networks.

3. General Description of Study Design

PREDICT components include: **1)** system redesign to deliver CCSM recommendations to a population of eligible individuals (build and integration of system already approved in MGB Protocol#2024P000973 **2)** support individual patient and practitioner engagement, and **3)** enhances team coordination through an efficient "stepped care" approach. This will be compared to standard care by the patient's care team using a 3-arm, pragmatic randomized design (with randomization at the clinic level) that will allow us to examine the marginal and cumulative effectiveness of the intervention components.

The study will be conducted in four primary care networks that are part of Mass General Brigham [MGB]: two affiliated with academic medical centers (Brigham and Women's Hospital [BWH] and Massachusetts General Hospital [MGH]), and two affiliated with community hospitals (Newton Wellesley Hospital [NWH] and North Shore Medical Center [NSMC]): (**Table 1**)

Table 1: Characteristics of the Four Participating Primary Care Networks

	Primary Care Practices	Community Health-Centers	Community-based clinics	Hospital-based clinics	No. of PCPs	No of Adult Patients (Black, Latino, Medicaid)
Academic Medical Centers						
BWH	15	2	11	2	213	152,000 (15%, 22%, 17%)
MGH	15	4	10	1	233	164,000 (8%, 17%, 20%)
Community Hospitals						
NWH	4	-	4	-	34	34,000 (<5%, <5%, 8%)
NSMC	13	-	13	-	93	98,000 (<5%, <5%, 13%)

We will perform a 3-arm cluster RCT with randomization done at the primary care practice-level, across the 4 participating practice networks. We have chosen this level of randomization to reduce the risk of cross-arm contamination; it would also be logistically complicated for the practices to have different patients randomized to different intervention components. Patients followed by gynecologists will receive intervention components based on the randomization to the patient's PCP practice. Randomization will be stratified based on: (1) primary care network, (2) practice size (e.g., number of women 21-70 years), and (3) percent insured by Medicaid or dual eligible. Prior RCTs with randomization at the practice level have resulted in good balance of patient and practitioner characteristics across arms.[8,38-42] The 3-arm design is summarized in **Figure 2** and will allow us to compare "standard care" (Arm 1) to two intervention arms that represent the sequential addition of: only the systems level components that provide visit-based reminders to individual patients and practitioners (Arm 2), and the addition of the team-level population outreach and practitioner support (Arm 3). Given our stepped care approach, this randomization scheme will allow us to compare the cumulative addition of each level of intervention to standard care as well as the marginal effect of each additional level to the prior group.

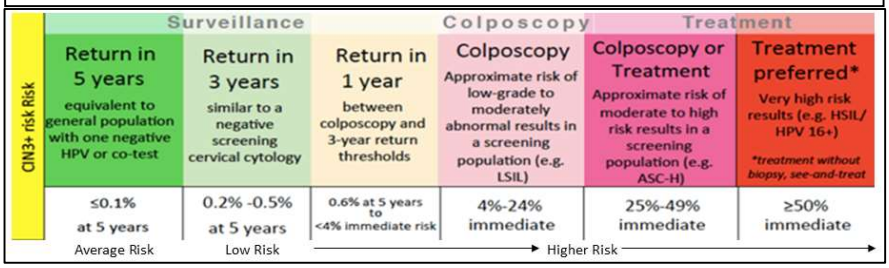
Figure 2: Practices randomly assigned to 1 of 3 arms

Control Arm 1	Intervention Arm 2	Intervention Arm 3
Standard Care	*Standard Care*	*Standard Care*
	Visit Based Reminders	Visit Based Reminders
		Population Health Outreach

4. Subject Selection

Inclusion criteria:
Individuals who:
1) have a cervix and are 21-70 years old. The inclusion of those up to age 70 is intended to identify individuals whose prior history does not meet screening exit criteria,[13] and would warrant surveillance or diagnostic care even though women with adequate prior screening can stop at age 65.
2) receive care at a participating primary care practice (i.e. PCP team visit within the past 3 years),
3) have had a Pap and/ or HPV test within the past 3.5 years, and
4) have a CCSM result that suggests a 5-year risk of developing CIN3+ that warrants surveillance at 1 or 3 years, diagnostic colposcopy, or treatment (Figure 3)

Figure 3: Summary of Risk-Based Clinical Action Thresholds



Personalized individual risk will be assessed by applying algorithms based on CDC's CDS tool.. The need for follow-up will be determined by the lack of an appropriate clinical test, diagnostic procedure or treatment as documented in the EHR within the specified time. Since the Pap and/ or HPV tests used by the CDS tool were done by an MGB-affiliated provider, we anticipate that most follow-up will also occur with the MGB system.

Exclusion criteria: Individuals who: 1) were diagnosed with cervical cancer/ CIN3+ prior to the most recent screening Pap or HPV test; 2) have had their cervix removed; or 3) are not English or Spanish-speaking.

This trial is testing a "care enhancement." We are requesting a waiver of informed consent given the large number of subjects distributed over 47 primary care practices. Randomization will be done at the practice level and individual patients will not be approached for recruitment. The outcomes for the main trial will be assessed using data from the electronic health record.

(See Study Procedures section 6 for more information)

5. Subject Enrollment

The trial is testing a "care enhancement" and is minimal risk; we are requesting a HIPPA waiver given the large number of subjects distributed over 47 primary care practices.The HIPAA waiver is for the data collection to meet the aims of the research, not just for recruitment. Due to the way our IT system is configured, we anticipate that we could review up to 20,000 patient charts study-wide. Not all of the patient charts reviewed will be deemed eligible. All patients will remain under the care of their primary care team and the intervention components will be delivered in addition to those individuals who are overdue for follow-up. **PCPs and specialists will not perform recruitment; this will be done centrally through the automated population based system that applies the 2019 ASCCP guidelines to Pap or HPV results for eligible patients in participating PCP practices**

6. STUDY PROCEDURES

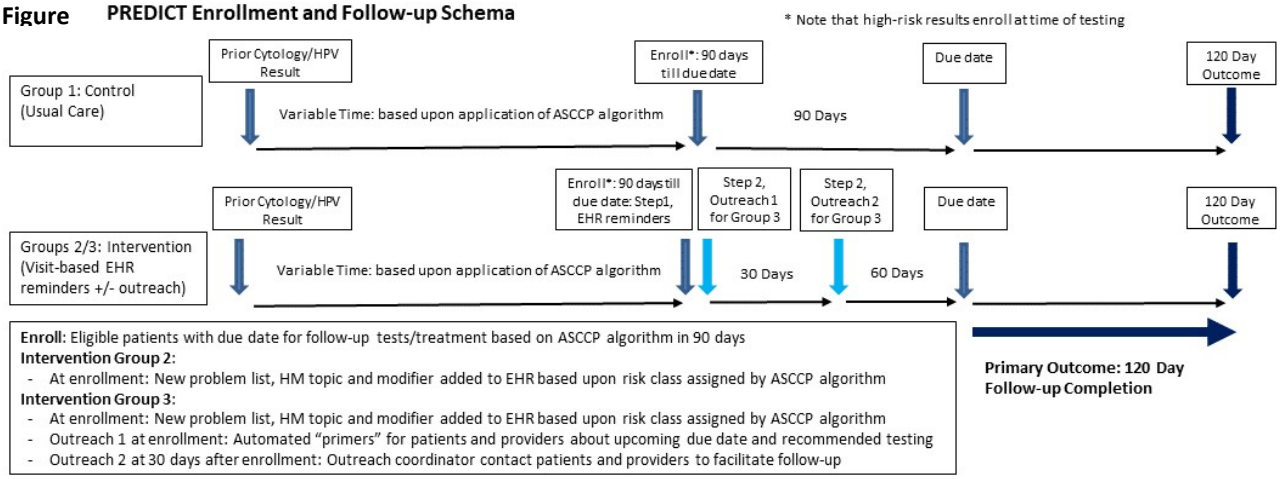
Control Arm (Standard Care only) patients will receive the usual care provided by their PCP, practice, and/or specialist. For eligible women 21-65 years, reminders to perform routine cervical cancer screening are set at a default of 3 years across MGB and can be manually modified by a practitioner to 1 or 5 years (or no testing) based on clinical judgement. Pap/ HPV results are returned to the ordering practitioner in the lab results section of each patient's EHR and in an "In-basket" (i.e., all results of any type, normal or abnormal, are sent into this queue). The interpretation of the results and notification of the patient is at the discretion of the practitioner. Since the ASCCP guidelines are currently only available on an app that is not linked to EHR data, few practitioners manually obtain the required information and input it into

the app to determine the patient's risk. From the "in-basket", the ordering practitioner may choose, at their discretion, to send a letter to the patient, document a phone call, and/ or order additional testing. If the ordering practitioner is not the PCP, the PCP often does not receive any additional information (i.e., at the discretion of the ordering practitioner).

Though individual practices may have standard procedures to communicate and manage results, this process is highly variable and there are no systems in place beyond the initial result communication.

Intervention Arm Components. PREDICT will include multilevel components that address individual (patient, practitioner), team, and system-level barriers These will be tested using the 3-arm design that allows assessment of the sequential addition of these components. This design will also evaluate changing the responsibility for "opportunistic" follow-up, typically by the practitioner or patient at the time of a visit, to a systematic, multilevel approach, examining the

Figure **PREDICT Enrollment and Follow-up Schema**



cumulative and marginal effects of each subsequent level of intervention. In addition to the multilevel components, the individual- and team-level engagement algorithm will take a "stepped care" approach with increasing level of intensity of engagement

Step 1 will start 90 days before the date an individual is due for follow-up ("due date"), at the time of enrollment, based on the patient's personalized risk score (**Figure 4**). For example, Step 1 for a patient with a 5-year CIN 3+ risk of 0.6% in a practice randomized to an intervention arm would automatically have a 1-year surveillance follow-up reminder set in the EHR. In these intervention practices, practitioners could access this information when in the patient's EHR or when the patient views the reminder in their patient portal. For practices randomized to Arm 3, Step 2 would begin with a patient being sent a reminder letter, 90 day prior to the due date via the patient portal or mailed if no portal account (*Outreach 1*). If needed, four weeks later a phone call from the outreach coordinator reminds patients of the follow-up date if scheduled or helps establish follow-up (*Outreach 2*). The coordinator could also place an order for a referral and send a reminder to the practitioner to sign it if appropriate. The study database will include have been made, and the outcome of those efforts.

Figure 5: Practices Randomly Assigned to 1 of 3 Arms

Control Arm 1	Intervention Arm 2	Intervention Arm 3
Standard Care	*Standard Care*	*Standard Care*
	Visit Based Reminders	Visit Based Reminders
		Population Health Outreach

Intervention components in Arm 3 will differ for individuals recommended for 3-year surveillance and for individuals 65 years and older who have prior abnormalities that would warrant additional surveillance or diagnostic management. In Arm 3, individuals recommended for 3-year surveillance will only receive *Outreach 1* reminder letters (the study will have insufficient resources to make phone calls). Since individuals 65 years and older who have prior abnormalities that would warrant additional surveillance or diagnostic management are more likely to have other comorbid conditions that may affect recommended follow-up, study coordinators will message practitioners prior to performing patient outreach

7. Risks and Discomforts

The potential risks to subjects include loss of confidentiality of healthcare data. Study staff will follow careful protocols to minimize these risks. The co-investigators will emphasize the importance of maintaining confidentiality in training all study staff. All study data will be coded with unique study identification numbers. Electronic data will be stored within the MGB firewalls, will be password protected, and will be protected by anti-virus software. Only study staff will have access to study data on shared file areas.

8. Benefits

While a personalized approach offers the promise of enhancing the balance of benefits vs. harms of screening and management, this ideal can only be realized through strong systems to support care delivery. Without IT tools that integrate personalized algorithms with care delivery, more errors of judgement may occur if practitioners and patients are confused about appropriate next steps.

Participants in practices randomly assigned to the intervention arms may benefit by receiving a timely follow-up of their abnormal cancer screening test results. Patients in control practices will receive usual care under the direction of their primary care provider. If the intervention is effective, more timely follow-up of abnormal cancer screening test results could lead to earlier detection, treatment, and cure of the cancers studied in this proposal. In the future, all patients could benefit from the knowledge produced by this study through the dissemination of similar care systems.

9. Statistical Analysis

Our primary analysis will be intention-to-treat (ITT). All eligible, enrolled patients will be part of the ITT cohort. We expect that a small number of patients may change primary care practices within our systems. These individuals will be evaluated according to their initial practice's intervention status. The primary analysis model will be a random effects logistic regression, implemented through the SAS Glimmix procedure. Timely follow-up (yes/no) will be the patient-level outcome and random effects for practice and practitioner will allow for exchangeable correlation between patients within the same practice and patients seen by the same practitioner. The primary fixed predictors will be 2 indicator variables representing the 2 intervention arms and we will use a global likelihood ratio test to compare the 3 study arms.

Results will be presented as adjusted follow-up rates, with 95% confidence intervals, calculated using marginal standardization. Secondary analyses will model time-to-follow-up, using a clustered proportional hazards regression to examine whether follow-up occurs as quickly as possible.

Sample Size/Power. Our primary goal is to enroll 7,500 high risk patients. This design will provide 90% power to detect an 8.4% improvement in the follow-up rate for an intervention arm compared to our control

10. Monitoring and Quality Assurance

The PI will be responsible for monitoring and assuring the validity and integrity of the data and adherence to the IRB-approved protocol. Although we do not anticipate any direct adverse events from this study, we will promptly report any such adverse events to the IRB and halt the study until such potential adverse effects are addressed. Applicable DF/HCC policy (REGIST-101) will be followed. Summary accrual information will be reported for 24 months.

11. Data and Research Material Sharing

A) Sending Data/Materials to Research Collaborators outside Mass General Brigham

All work with patient data will take place behind the MGB firewall. No data will be sent to external collaborators.

B) Receiving Data/Materials from Research Collaborators outside Mass General Brigham

All work with patient data will take place behind the MGB firewall. No data will be sent to external collaborators.

12. Privacy and Confidentiality

- ☒ Study procedures will be conducted in a private setting.
- ☒ Only data and/or specimens necessary for the conduct of the study will be collected.
- ☒ Data collected (paper and/or electronic) will be maintained in a secure location with appropriate protections such as password protection, encryption, physical security measures (locked files/areas)
- ☐ Specimens collected will be maintained in a secure location with appropriate protections (e.g. locked storage spaces, laboratory areas)
- ☒ Data and specimens will only be shared with individuals who are members of the IRB-approved research team or approved for sharing as described in this IRB protocol.
- ☒ Data and/or specimens requiring transportation from one location or electronic space to another will be transported only in a secure manner (e.g. encrypted files, password protection, using chain-of-custody procedures, etc.)

- ☒ All electronic communication with participants will comply with Mass General Brigham secure communication policies.
- ☒ Identifiers will be coded or removed as soon as feasible and access to files linking identifiers with coded data or specimens will be limited to the minimal necessary members of the research team required to conduct the research.
- ☒ All staff are trained on and will follow the Mass General Brigham policies and procedures for maintaining appropriate confidentiality of research data and specimens.
- ☒ The PI will ensure that all staff implement and follow any Research Information Service Office (RISO) requirements for this research.
- ☐ Additional privacy and/or confidentiality protections

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