

## **Utilizing OnCore Capabilities to Automate Annual Continuation Review Submissions to PRMC**

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### **1. Background**

Siteman Cancer Center's Protocol Review and Monitoring Committee (PRMC) reviews all active cancer research studies on an ongoing basis by assessing progress at regular intervals. Study teams must submit their continuation review/annual documentation within the OnCore Clinical Trials Management System (CTMS), to include the Institutional Review Board (IRB) application (or proof of approval from external IRB) along with a completed PRMC Continuation Review (CR) Request Form, at the time of IRB approval of the continuing review. Missing and late annual renewal submissions represent noncompliance and can be a challenging obstacle to overcome without quality control mechanisms in place to assure ongoing capture of research activity. The Siteman PRMC Office, in collaboration with the Cancer Center Informatics (CCI) team, has employed the capabilities of the OnCore CTMS to develop new automation processes to address this challenge: creation of an auto-populated PRMC CR Request Form and distribution of automated email notifications to research teams.

### **2. Goals**

Our goal is to streamline the submission process for annual renewals of cancer-relevant research studies, thereby decreasing submitter burden and increasing compliance of timely submissions. We will accomplish these goals by automating the completion of continuation review forms within OnCore and generating automatic email reminders for study teams when an annual renewal is due to PRMC.

### **3. Solutions and Methods**

The Siteman PRMC and CCI teams have been developing an automated CR Form, which will mimic and replace the current manually-completed form, whereby OnCore CTMS auto-populates the majority of required information directly into the form for PRMC submission and review. To assist with improving compliance rates for annual CR submissions, we have also implemented over the past year automatic, repeated email notifications to study teams via OnCore to cue that a CR is due for submission. The automated CR Form has been pilot tested with six seasoned regulatory coordinators who routinely provide submissions via OnCore and will be rolled out to all cancer center submitters in Spring 2020.

### **4. Outcomes**

Since implementing the CR email reminder system in early 2019, the Siteman PRMC Office experienced a 47% increase in the number of CR submissions received (number of submissions approved between January – June, 2019 = 109 and number approved between July – December, 2019 = 229).

The pilot testers have provided very positive feedback regarding the new CR Form and reminder system.

- Less time is spent by the submitters collating the information needed for a CR.
- With large volumes of studies managed by each coordinator, the email reminders have greatly assisted with managing their workflows and preventing late submissions.

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- The reminders are reaching study teams who are not as accustomed to submitting via OnCore, thus facilitating educational opportunities for the PRMC Coordinators to train novice submitters who conduct either a minimal amount of studies or primarily non-oncology research.

## **5. Lessons Learned**

Future directions include:

- Expanding the automated process to incorporate PRMC change review/modification submissions.
- Potentially automating PRMC initial study submissions via OnCore interfacing with the electronic IRB system to capture pertinent data for the PRMC application.