



EFS EXPRESS

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Site Saves Time and Effort, and Reduces Patient Burden, with Screening Consent Form

Site: [Cardiology Research at Columbia University Irving Medical Center](#)

Site Type: Academic medical center

Device Type: Tricuspid and mitral valve devices

Many interventional vascular therapy EFSs in [Cardiology Research at Columbia University Irving Medical Center](#) involve tricuspid and mitral valve devices. The inclusion/exclusion criteria for these studies rely heavily on the patient's anatomy, lengthening the typical screening and enrollment process and adding to the burden of sick patients who want to participate in research.

"Our team was spending a lot of time consenting patients who were screen failures, and having to bring them back to screen them for another study. These are sick, mostly elderly patients, many of whom travel into the city from 50 miles away or more. It's not great for them to have to come back in again," says Lauren Privitera, MS, MPH, director of Cardiology Research at Columbia University Medical Center.

That's why the Center for Interventional Vascular Therapy in Cardiology Research developed a [screening consent form](#) for interventional vascular studies that allows researchers to send standard of care CT scans and laboratory results to the sponsor for eligibility evaluation. At first, EFS sponsors were reluctant to allow researchers to use the IRB-approved Informed Consent and HIPAA Authorization form. But after Privitera described the form at an MDIC meeting on the [EFS Patient Informed Consent Form template](#), one sponsor even mentioned allowing use of the screening consent form in its EFS protocol.

While the [screening consent form](#) was designed for all interventional vascular therapy clinical trials, it has been especially helpful in EFS studies. Privitera estimates that using the form saves about two weeks on each tricuspid or mitral valve device EFS patient enrollment. It's also much more efficient for the research team, which is consenting fewer ineligible and more eligible patients for these studies. Just as important is minimizing the burden on sick patients of participating in EFSs. "Using the screening consent form has worked out really well for our team and our patients," says Privitera.

[Columbia University Irving Medical Center](#) was also part of the working groups that developed the [MDIC EFS Master Clinical Trial Agreement](#) (MCTA) template and the [MDIC EFS Patient Informed Consent Form template](#) and participated in MDIC's [EFS Budgeting Best Practices Workshop](#). Using the MCTA, leaders in cardiology research have been able to cut the amount of time needed to finalize an EFS contract from about 45 days to about 30 days. "That's been a huge help to us," says Privitera. Also, Columbia University is a member of the MDIC-EFS Pilot Network.

Through her personal involvement in MDIC, Privitera has increased her understanding of sponsor needs and learned about best EFS practices at other sites. She also gained access to useful EFS tools from other sites.

Privitera would be glad to answer questions about the use of the screening consent form. You can contact her at lp2183@cumc.columbia.edu.

MDIC Templates Used: [EFS Master Clinical Trial Agreement](#)

Columbia Template Used: [Screening Consent Form: Informed Consent and HIPAA Authorization](#)

MDIC thanks Lauren Privitera, MS, MPH, director of Cardiology Research at Columbia University Irving Medical Center, for sharing the site's EFS Success Story.

Have an EFS success story? In support of our 2020 Strategic Priorities, we want to publish success stories to help further the mission and vision of this project. If you would like to share, please send us an e-mail at efspilot@mdic.org with your contact information and 2-3 sentence summary of your project/story and we will contact you to set up a time to discuss further. Success stories may be written up and published in the EFS Express and across general MDIC channels and industry channels.

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