

From: [Shelton, Helen \(sheltohn\)](#)
To: [Shelton, Helen \(sheltohn\)](#)
Subject: ARS IM Regulatory Updates - Sometimes change is good!
Date: Thursday, April 8, 2021 10:29:02 AM

From: IM Regulatory <IMRegulatory@uc.edu>

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Subject: ARS IM Regulatory Updates - Sometimes change is good!

2020 brought so many changes, and some of them have even been really good!

What's new in ARS IM Regulatory?

Our unit is now fully staffed:

- Helen Shelton – Regulatory Manager
- Amber Crowther – Regulatory CRP
- Lisa Arustamyan – Regulatory CRP
- Romana Saeed – Regulatory CRP
- Jessica Truong – Regulatory CRP

In an effort to help expedite study start-ups during a time of remote working conditions, our team has taken an active role in using Complion to its full capacity. We have been able to help research teams:

- Start and collect signatures on delegation logs using the Complion system
- Send, collect, and maintain training documentation within the Complion system
- Streamline and manage Regulatory Monitoring Visits by utilizing our eReg Complion binders for all new studies, and many older studies that have been converted to our eReg system

The feedback we have received from monitors on the Complion system has been extraordinary!

[Information for Researchers utilizing IM Regulatory Services](#)

UC COIs and Complion

Effective December 14, 2020, the institution rolled out the ability for us to track Conflicts of Interest within the Complion system.

What does this mean to researchers?

If a study has a Complion Study Binder that the IM Regulatory team is managing for you, you will no longer have to complete, sign, and send back a COI form to your regulatory CRP. This is true for new study start-ups and annual reviewal submissions to the IRB.

Now, you will receive a notification within Complion to read a UC document titled 'Financial Disclosure Form'. This form asks the same questions that the former COI document asked regarding your financial interests in relation to the study you are working on. If you can answer no to all the questions asked, you will simply sign the form electronically in the Complion system certifying that you have disclosed that you have no relationships described in the document. If your answer is yes to any of the questions asked on this form, ***DO NOT SIGN OFF***. In the same form, there will be contact information for the regulatory CRP assigned to this study that you should reach out to, and they will send you a fillable COI form to disclose your financial relationship.

NOTE: For older studies that are still in a paper binder Investigator Site File (ISF or Reg binder), the former way will still be used – emailing COIs out to the team, and collecting completed forms.

****For those not using IM Regulatory services**, this new institutional policy is available to your team too if you are using the Complion eReg system to house your regulatory binders. If your team needs additional guidance on how to implement the new process, we are here to help! Just send an email to

IMRegulatory@uc.edu

DocuSign

IM Regulatory Services has also implemented the use of DocuSign for the ease of signing off on many Regulatory documents where allowable by the study sponsors. Again, this helps to expedite processes, streamline startups and hopefully free up some time for our clinical teams to do clinical work!

What do you we need from you?

- Please make sure you include your IM Regulatory CRP on any scheduling of monitoring visits at the time of scheduling.
- Please look for Complion emails. Please log in and read/sign off on documents sent to you. Paper training logs and delegation logs are becoming a thing of the past, but the need for these items are still essential to research. Using Complion will help all of us do things more efficiently and more effectively, but it will require you to sign in a timely manner.
- Look for DocuSign emails from the Regulatory team and again, read/sign off on those regulatory documents in a timely manner as well.

If you have any questions, concerns or comments please email IMRegulatory@uc.edu. We hope these changes and new processes help our Researchers and clinical teams to continue doing ground breaking research!

Due to the Coronavirus COVID-19, effective Monday, March 16, 2020 the University of Cincinnati will be conducting the majority of its business via virtual options until further notice. Email will be the most efficient form of communication and will be addressed between normal business hours M-F 9:00-5:00.

H. Gina Shelton

Clinical Research Manager, Regulatory

Internal Medicine Academic Research Services (ARS)

University of Cincinnati College of Medicine

231 Albert Sabin Way, ML 0551

Medical Sciences Building, Room 6111

Cincinnati, OH 45267-0542

513-558-7183

sheltohn@ucmail.uc.edu

[ARS Staff Contact Information](#)

[ARS Regulatory Tools and Templates](#)