

30 March 2023

To whom it may concern,

I am very pleased to write this letter of support for UVA Records & Information Management Office for the NAGARA Program Excellence Award. We have a long and productive history with them that has solved so many of our records management mysteries.

I came back from vacation in 2015 to find that the closed study file boxes that we, in the Investigational Drug Pharmacy, had gotten ready to move to storage off-site were unable to be sent and, even worse, they asked up to tell them which records could be destroyed immediately. They said our records were very old and couldn't/shouldn't be stored permanently. While I knew that they should not be stored indefinitely, I had no path to determine which records could/should be destroyed.

This thought that I had been nagging me for so many years had become real - I had to face the 120+ boxes full of closed studies from the 1980s numbering more than 1800. I'll admit that I've had sleepless nights wondering how I – or anyone else - would be able to figure out what to do with the boxes of studies that we had the titles of but for which we had no contacts and no idea about retention timelines.

As luck would have it, one of our study coordinators stopped by and mentioned this new office at UVA called Records & Information Management (RIM) that was set up to, well, manage records just like this. I did not have any idea what kind of records they managed and was only mildly optimistic because no one seemed to know what to do with study closed records. To add to that, we were storing pharmacy records separately from the investigator teams which set us up to function as silos.

I looked up the office and found Caroline Walters name. I sent her an email and, later we spoke on the phone. I could not believe what I was hearing. She described everything I needed – and more. She could not only organize and store the study information relating to sponsor and contacts AND connect our records with the study investigator's records, but she would also manage contacting the sponsors after they had determined retention time to get authorization for destruction. WOW!

After hearing all of this, I went out and bought lottery tickets. I just felt so lucky. While I did not win the Virginia Lottery, I did win the records management lottery. That was more than enough for me. I slept well that night.

To begin, Caroline set me up with her team to figure out a way to transition all of our records to URMA for tracking. As part of this Caroline's team helped us find a storage facility for our physical records that was approved by the University and who would store our study documents until UVA RIM contacted them for destruction.

At the same time, they set up a spreadsheet to direct us to what needed to be used as input for the old studies to have them tracked. This took quite a while on our end and her team worked with us to make sure we were on track. Once we submitted the spreadsheet to RIM, they input them into URMA. Then they instructed us on how to process the boxes for shipment to the storage facility. This whole process took about a year.

One of the challenges we had for the team is that we had many files (studies) in a box. Their standard is one study with many files in one box. So, we were opposite of what their system was set up to manage at that point. That did not seem to cause a problem for them and they figured out a way to accommodate our needs. I bought more lottery tickets.

Once the physical records process was complete, the RIM crew began to work with us in the same way for our electronic documents. While the physical ones are what we focus on most, Caroline explained that the e-records are also records that must be managed the same way. As our office is trending toward being a paper-light office, this process will become more and more important to us.

Caroline and her team were steadfast, supportive and extremely knowledgeable with regard to how this must be done to ensure compliance with regulations. The competence of this crew is unquestionable. Given our distress about having to destroy these records without the correct documentation, this kind of knowledge was reassuring to us. The path they set up for us to follow was and is very clear and understandable. There is no mystery because there are regulations. Any question I asked, Caroline sent me rock-solid regulations to support the decisions made by her office.

In addition, the office provides educational webinars to help us continue to guide us to organize our records in a more retrievable format – proper naming of files, accessibility, and more. I am attending one of those today!

I cannot recommend any office or team more highly than I recommend UVA's Records & Information Management Office for the NAGARA Program Excellence Award. With all of the challenges our team presented, nothing was a showstopper. Our entire team is grateful for their patience, follow-through and continued support.

Sincerely,

A handwritten signature in black ink, appearing to read 'ABA', with a long, sweeping horizontal line extending to the right.

Amy P. Adams, PharmD, CCRP
Lead Pharmacist, Investigational Drug Service
UVA Health