



Jennifer Hixon, CCRP, Regulatory Affairs Manager

How long have you worked at UAMS? I have been with UAMS for 12 years.

What is your favorite part of the job?

I really enjoy working with investigators, research staff, and different departments across campus and at other sites. Obtaining FDA approval for investigator-initiated drug and/or device studies is always interesting because of the variety of proposed ideas. We see so many different diseases (breast, HPV vaccines, pediatric, cancer, stroke, psych, etc.) that my work is never boring.

Are there any challenges?

The field of human subject research is overflowing with challenges. Our focus is on investigator-initiated clinical research. UAMS serves as the sponsor for IND/IDE studies and ORRA fulfills its regulatory roles. There is a lot of communication between our department, investigators and research staff. My job is to help investigators develop a good protocol that the FDA will approve. I routinely monitor studies to ensure subject safety above all, as well as the collection of accurate and reliable data. Everyone in our group strives to assist in overcoming research challenges in the most effective way while maintaining compliance with FDA/IRB regulations.

Human subject research has different regulations and protocols to follow in order to achieve the research goals. Subject safety is always the main focus. Since we all want every clinical research study to be successful, we must stay up-to-date with the FDA regulations.

Often investigators have grant deadlines, so I must prioritize and provide guidance within a specific time-frame.

Our department works with a large variety of people and with different personalities. We strive to work well with everyone in a team. We take this approach to achieve the end goals of the FDA, each research team, and ultimately the success of each study.

ORRA also manages ClinicalTrials.gov for UAMS Investigator Initiated Studies.

How does your research support work interact with other groups?

Investigator-initiated clinical research studies (using FDA regulated products) are reviewed and determine whether a study needs to go to the FDA. Since we handle investigational new drug/device studies, we interact with various groups/departments at UAMS/ACRI/VA. At times, we work with outside corporations providing a study drug or device.

How do you/your group handle problematic issues?

Communication is key.

It is extremely important to me and our department to have good communication with everyone. At times, the type/style of communication varies depending on the day, investigator, and study.

Most of the time, resolution is achieved through email. However, if problematic issues are more complex, we meet to address concerns, brainstorm, and explain the federal rules and

regulations that must be followed.

How many protocols do you work on annually?

We review protocols submitted to the IRB that include a possible investigational drug or device. Every month is unique. In January 2017, ORRA reviewed 19 protocols.

ORRA works with investigators with a human subject research study that requires a study sponsor for their investigational drug or device. We have around 36 drug/device studies that we are sponsoring at the moment. These require reporting and ongoing monitoring.

How about after hours? What do you do for fun?

I was born and raised in Nashville, Tennessee and all of my family still live in that area. I enjoy going home to visit and we always have lots of laughs.

Being at the beach is probably where I am the most relaxed.

My husband and I really enjoy motorcycle riding. We enjoy visiting state parks and hiking or simply going for walks. My fur baby, Murfee (see below) joins us for walks and sometimes my adult step-son will join us for movies or a Travs baseball game.



A local non-profit organization that I am involved in offers dance, music and art lessons for foster and under-privileged children. I also help with an annual summer cereal drive and an annual Christmas party for an orphanage. We make sure every child receives gifts, lunch and can participate in games. We try to make each child feel special while also providing a safe and fun time for them.

What personal skill or hobby don't most people know about you?

I enjoy fishing. I'm not that great at it, but I have the necessary patience and enjoy being out in nature; it is peaceful.

Something most people do not know is that I was the Field Commander (Drum Major) in my high-school band in Nashville, TN. That position required a lot of work and dedication and the experience helped me learn various ways to work with others.

Every morning I choose to be happy and to help people throughout the day wherever possible.