TriHealth
Hatton Research Institute

1. As mentioned in last month's Regulatory Notes, we have a New Study Submission Form (for Hatton Regulatory Document Review for Compliance (DRC), Hatton Administrative Review, and IRB Review) (copy attached). It is required for **all** studies regardless of study type as it contains information needed to help determine risk to the institution/human subjects and to help ensure compliance. Your regulatory coordinator has been trained on how to complete this form; however, Lead Coordinators and/or Managers should double check for accuracy prior to the investigator signing off.

2. In addition to the new submission form, we are streamlining the submission process. One submission will be made by your Regulatory Coordinator Hatton_Admin_Review@trihealth.com with all required documents (see attached requirements by study type). This one submission will be used for DRC and/or Administrative Review as well as your TriHealth IRB submission. Please review the attached sheet – Website – How to Start a New Research Study. The new process is effective starting today. The website is being updated to reflect the new process and I will let you know when it is live.

3. So that everyone is up-to-date on submission status please use "reply all" when responding questions and/or revisions to study documents.

4. Any submission with CITI and/or a CV that is expiring within one month of the submission date will be held for processing until training is completed or the CV is updated.

5. Due to feedback received, we've decided to change the regulatory folder setup for submissions in process. We will be omitting the sub-folders "To be completed", "Ready for Submission" and "Ready to File" and replacing with "Regulatory –Working Documents for Submission" with a sub-folder "Drag and drop final documents for submission here". Once the Regulatory Coordinator is notified that all documents are ready for submission, the folder will be emptied and put in the appropriate Regulatory folder.

6. Just a reminder to notify your Manager upon identifying a potential non-compliance issue. She will notify me, as our Compliance Team representative, and we will discuss the next steps. Please do not go directly to the IRB because then they expect a non-compliance report to be filed and it may turn out that after investigating, that the issue didn't require reporting.

7. Just a reminder that Care Everywhere is for exchange of records by treatment providers at the time they are providing care to a patient. Research does not fall into the definition of treatment and is not available for researcher access. Further, patients must agree to share records through Care Everywhere and their agreement is based on understanding it is for treatment purposes.

8. Please be sure to copy me on requests or issues that pertain to EPIC and Research. I am our Research point of contact and need to understand how your request or issue may impact other departments, the Research Module and our internal processes.