Dear Colleagues:

We are pleased to announce we now have the ability to link research patient data in GE to electronic medical records in PRISM. This will enable us to enhance patient safety, make PRISM a more robust data resource for researchers, and bring us into compliance with research billing regulations.

What is changing?

As of January 1, 2014 researchers and research staff will need to complete a registration form for any Fletcher Allen patients executing a new consent form to participate in a research study. Completed forms must be sent to FAHC Registration. Registration staff will enter this information into GE, which will then transfer to the patient's record in PRISM. Active research participants currently enrolled in clinical research need to be registered through this process no later than January 1, 2015. Research participants who are not registered Fletcher Allen patients, or when the research subject's only participation is through online, web-based, or phone surveys, as well as in person interviews or paper questionnaires do not need to be registered.

Please note that, at this time, research study titles will not be visible in the electronic medical. However, we are actively working with the IRB to include additional study information in the EMR in the future as a patient safety measure.

Why are we doing this?

We're embarking on this change for three major reasons:

1. Patient safety will be enhanced because we'll be able to see in PRISM when our patients are enrolled in clinical studies. Having a complete picture of a patient's activities across our institution enables us to provide the safest, most appropriate care.

2. We will be able to enhance our ability to leverage the EMR as source for future research endeavors.

3. CMS requires that some (but not all) clinical trials claims have an accompanying National Clinical Trial Registry number. All research claims must be billed as research – not clinical care. Billing research costs in any other way is considered fraudulent, and significant fines have been levied against other major AMCs for billing research incorrectly. Some have been banned from doing future research. This workflow will enhance our ability to be in compliance billing for research studies.

What is expected of me?

As of January 1, 2014 researchers and research staff will need to complete a registration form for any Fletcher Allen patients executing a new consent form to participate in a research study. This form is available at:

Completed forms must be submitted to "**Registration – Research Studies" Outlook Mailbox (registrationresearchstudies@vtmednet.org) or FAX to 847-4179.** We appreciate your support of this important initiative, and look forward to the opportunities it will provide to enhance research activities at

Fletcher Allen and UVM. Moving forward, the IRB will be working with the IT Research Subcommittee to ensure that all appropriate protections of human research subjects are in place as we better utilize the EHR to support research.

Please contact us if you have any questions.

Sincerely,

Ira Bernstein, MD
Senior Associate Dean for Research, UVM College of Medicine

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