HUMAN SUBJECTS RESEARCH NEWSLETTER
COMMITTEES ON HUMAN RESEARCH
SERVING THE UNIVERSITY OF VERMONT
AND FLETCHER ALLEN HEALTH CARE

SPECIAL NOTICE
JUNE 9, 2011
FOR ALL NEW HUMAN SUBJECT SUBMISSIONS

The 2010 Affiliation Agreement between the University of Vermont (UVM) and Fletcher Allen Health Care (FAHC) now requires approval of a billing plan for all protocols utilizing FAHC resources regardless of whether they are UVM or FAHC studies. See attached notice.

The IRB's Role

To assist the FAHC Compliance Department with identifying which protocols are required to have billing plans, we have added a new question to our common protocol cover form in Section 4 as indicated below.

Fletcher Allen Health Care (FAHC) Compliance Coverage Analysis and Billing Plan Approval

j. Will this study involve any FAHC patients or any equipment, facilities, supplies or personnel of FAHC, whether standard of care or protocol-driven, such as laboratory, pharmacy, imaging, EKGs, or other diagnostic or therapeutic items or staff?

Yes ☐ No ☐

If the answer to any part of the above question is Yes, the FAHC Compliance will need to approve a billing plan prior to the release of IRB approval. For more information, please reference "Research Billing Compliance" on the Fletcher Allen Health Care website. For additional questions, call Denise Quint in the Fletcher Allen Integrity and Compliance department at 847-9482.

If you have answered yes to this question, the IRB will notify the FAHC Compliance Department who will in turn be in touch with the Principal Investigator (PI) or Contact to determine what type of billing plan is required. If a study-specific billing plan is not required, a "standard" billing plan will be approved.

Development of the billing plan and the IRB review of the protocol will be simultaneous. After all of the IRB review issues have been addressed, "standard" billing plan protocols will be released to the PI/Contact. For the "study-specific" billing plans, the protocol approval materials will be forwarded to the FAHC Compliance Department where they will be held until the study-specific billing plan is complete. The IRB will notify the PI/Contact when the protocol approval materials are forwarded to the FAHC Compliance Department. All questions regarding the billing plan are to be forwarded to compliance@vtmednet.org.

Once the FAHC Compliance Department approves the study-specific billing plan, they will release the approval materials to the protocol Contact.

****This applies to all new human subjects protocols. Failure to use the revised Common Protocol Cover form, which includes the new billing question, will result in delay of IRB review.****

6/8/2011

Dear Colleagues,

As you all know compliance with billing requirements for routine clinical services is a very important component of our clinical research activity. The 2010 affiliation agreement among Fletcher Allen, UVM and the UVM Medical Group requires that principal investigators engaged in clinical research activities obtain approval of a "billing plan" for Fletcher Allen-related studies before enrolling study subjects. The Fletcher Allen Compliance Department is actively working with the Office of Clinical Trials Research and the Research Protections Office to streamline the process for coverage analysis and billing plan approval. For IRB submissions on or after July 1, 2011 that involve Fletcher Allen patients or resources, the Fletcher Allen Compliance Department will contact you once you have submitted a protocol to the IRB. Fletcher Allen Compliance and the IRB will perform their reviews concurrently. Final IRB approval will be released after Fletcher Allen Compliance has approved a billing plan. Fletcher Allen has arranged for outside resources to ensure the volume of studies needing review does not exceed our capacity to complete the reviews in a timely manner. If we determine that revisions to our process are necessary, we will certainly consider that as we move forward.

While we seek to avoid additional administrative burdens, it is vitally important that billing related to clinical trials is done correctly. Research billing is recognized as a risk area for hospitals by the HHS Office of the Inspector General (OIG). Other academic medical centers have paid millions of dollars in settlements with the federal government in recent years due to research billing improprieties, and health care reform has added significant funding for government audits and investigations of government program billing. We appreciate your understanding and cooperation with this initiative. Additional information is available through the following link: http://www.fletcherallen.org/services/administrative/integrity_compliance/research_billing_compliance.html. Please contact the Fletcher Allen Compliance Department at 847-7726 or compliance@vtmednet.org if you have any questions.

Thank you for your assistance in facilitating this policy.

Sincerely,

Paul

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Ira

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