HUMAN SUBJECTS RESEARCH NEWSLETTER
COMMITTEES ON HUMAN RESEARCH
SERVING THE UNIVERSITY OF VERMONT
AND FLETCHER ALLEN HEALTH CARE
SUMMER 2014

Committee Name Change

The Behavioral Committee has recently changed its name to the Committee on Human Research in the Behavioral and Social Sciences (CHRBSS). This suggestion was made by our researchers and faculty and better depicts the types of research that the Committee reviews. We will work our way through all of our documents to reflect that change where appropriate.

Qualitative Research Changes

We have updated our Research Manual to include Section 7.F. which specifically addresses Qualitative Research. Researchers should reference this section as they are developing their research protocol. In addition, we have combined our Qualitative Research Protocol form and the Common Protocol Cover form into one form. This decrease redundancy and provides for a more streamlined submission process.

Summary of Changes to our Research Manual

Changed the name of the Behavorial Committee to the Committees on Human Research for the Behavorial and Social Sciences throughout the manual.

Manual Sections

3. Contacts – updated with a new associate chair for CHRBSS
4. Determination if Project is Considered Research and If Research Involves Human Subjects (revised)
7.F. Review of Qualitative Research (new)
8.A.1.j.2. Plans for Recruitment/Retention Investigator Self-Experimentation (new)
Subject Payments (revised)
8.A.2. Qualitative Research Protocol (revised)
8.B.3. Oral Translation with Short Form Consent Document (revised #3)
8.B.5. Waiver of Informed Consent, Alteration of Informed Consent, or Waiver of Documentation UVM Waivers Cannot be Used at Other Institutions (new)
12.A.3. Expanded Access of Investigational Drugs (also sometimes referred to as compassionate use) (revised)

Appendices

H. Standards and Language for Studies Involving MRI (substantially revised)
J. Guidance on Engagement in Research (new)
K. Types of Research (new)
L. Pregnancy Testing in Minors (new)
M. Certificates of Confidentiality (new)

Fletcher Allen HealthCare Research Subject Registrations

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. All patients who signed consent prior to January 1, 20014 who's research participation is still ongoing must be registered by January 1, 2015.

For more information please see announcement from FAHC here. The subject Registration Form can be found here.

Completed forms must be submitted to "**Registration – Research Studies" Outlook Mailbox (registrationresearchstudies@vtmednet.org) or FAX to 847-4179.**

ClinicalTrial Registration Requirements

ClinicalTrials.gov is a publicly available registry and results database of federally and privately supported clinical trials conducted in the United States and around the world. The purpose of ClinicalTrials.gov is to disclose to the public key information about clinical trials that are currently available or that have been conducted.

Federal laws and regulations as well as editors of prominent medical journals require registration of clinical trials. To meet this requirement you must register prior to any subject enrollment, provide updates every 6 months, report any serious adverse events, and submit a final report. Definitions, requirements and instructions can be found here at http://www.uvm.edu/~irb/ClinicalTrialRegistryInstruction.pdf.

Changes to Key Personnel Process

The IRB has recently discovered that the key personnel change process may be placing investigators at risk for noncompliance with their protocol rosters. The IRB has been accepting key personnel submissions, whether it coincides with a new protocol submission or subsequent change to the roster, regardless of whether all the key personnel have completed the required training.

We have been holding approvals until all key personnel have completed the training. This process results in the PIs believing everything to be in order with a key personnel change when it is not.

To avoid future instances of this confusion, effective immediately, we have changed our process to add just those individuals who have completed their training. Individuals who have not completed their training will not be approved nor will they be entered into our system. For example, if you wish to add 5 people to a protocol and only 3 have completed training, you will receive approval for those three along with a note that the other 2 have not been added to the project.

It is then the PIs responsibility to submit a new key personnel change form to add those individuals to the protocol once the training requirement has been met.

Subject Reimbursement

Research subjects who are eligible for reimbursement from the research study **through UVM** are required to provide personal information such as name, address and social security number in order that they are paid. In addition to cash, this includes gifts, tokens and gift certificates. The payment threshold for collecting a person's social security number has been changed from $25.00 to payments equal to or less than $100.00. Additionally, if a total number of payments within one year are expected to be greater than $600.00, the social security number is required at the time of their first visit only. These changes went into effect as of 1/14/14. See "New Payment FAQs" on the procurement website for additional information and detail about processing subject payments.

Research subjects who are eligible for reimbursement from the research study **through FAHC** have to provide their social security number at the first visit regardless of the amount of payment. FAHC assigns a unique ID upon the first payment visit and uses that ID going forward to reimburse subjects.

In both cases all correspondence should be sealed in an envelope and marked confidential.

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