January 2009

There has been some confusion noted lately about "safety" vs "efficacy" in clinical trials.

In general: "safety tests" are tests that are done to monitor for side effects while "efficacy tests" are those that monitor how well the drug or device is working.

- Safety tests are things such as: lab tests, VS, EKGs, other 'safety' tests such as radiology, review of AEs/SAEs, etc.
- Efficacy tests would include: pharmacokinetics or scales that are done specifically to see if the drug is effective. For example: cognitive tests for Alzheimer's drugs or HAM-D scales for depression drugs.

February 2009

I was asked to pass this along. Not too many of us use Petty Cash for our subjects, but for those who do, this might be helpful:

- Per UVa Policy, petty cash payments are limited to a maximum of $100 per payment and $599 per calendar year per individual.

- The web site address for this policy is http://www.virginia.edu/finance/polproc/pol/iie2.html

The IRB-HSR has added this tip into their protocol template in order to make research personnel aware of this policy.

March 2009

Personnel and Delegation of Duties forms

When opening a new study, whether it is sponsored or Investigator-initiated (sometimes – particularly if Investigator-initiated):

It is recommended that you complete a Personnel and Delegation of Duties form.

This is not a federally-required form, but it is exceptionally useful in identifying roles – especially if you have a situation where staff rotates through, or no one person or group manages the whole study.

The form, in Word format, is attached. You may amend the duties as best suits your specific study.

April 2009

We had an interesting issue come up recently:

A trial involved a "**new** procedure" which would be performed by UVA physicians. This was not a standard procedure being done in a new way, but a NEW PROCEDURE.
The protocol required an extensive physician training program - with hands on skills and didactic training, etc. as well as proctored procedures here with the first subjects in the study.
But, what it also required was that our physicians be "credentialed" here at UVA by the "Credentialing Committee". (***see 2 attachments***)

There may be different situations in which you need to contact the Clinical Staff Office about credentialing. For instance:

- Your study requires a non-UVA physician to perform a procedure here at UVA
- Your study requires that UVA physicians perform a ***new procedure, technique or treatment modality*** that has never been done at UVA before

Your first step will be to call the Clinical Staff Office at 924-9055 to get help regarding applications and what paperwork you will need.

- In the event there are no approved criteria, the Medical Center shall first determine whether it will allow the new or additional Clinical Privilege.
- Applications for new, or additional Clinical Privileges, must be in writing and submitted by the Applicant as well as by the appropriate Department Chair.
- The Credentials Committee shall determine the conditions and requirements upon which any new or additional Clinical Privileges shall be granted including, but not limited to, how current competence will be demonstrated, any proctoring or other monitoring requirements. The Committee will recommend the requirements to the Clinical Staff Executive Committee (CSEC) for consideration.
- In turn, the CSEC shall make appropriate recommendations regarding new or additional Clinical Privileges to the Medical Center Operating Board for final determination.

(The above taken from Clinical Staff Bylaws; section 6.6
http://www.healthsystem.virginia.edu/internet/clinicalstaff/credentialing.cfm; scroll down to Bylaws of the Clinical Staff)

May 2009

For study participants who may want to donate blood:

If the study involves a drug that is not approved by the FDA, the American Red Cross guidelines state that the study participant may ***not*** donate blood for one year after they take their last dose of study drug.

The following ***is*** allowed:

- Clinical trial participants who are in a non-study drug study (survey, blood draw only (depending on amount drawn for study), etc.)
- Clinical trial participants who have a device implanted – that does not have a drug associated with it.
- Clinical trial participants who are participating in Stage IV studies where the drug is already approved by the FDA for another indication

There are quite a few situations where they defer to their physician for his/her opinion as to whether or not the subjects can donate.

If you or the study subject have any questions call the organization where they donate blood and talk to one of their nurses OR call the American Red Cross at 1-800-GIVELIFE or 1-800-448-3543 and ask to speak to one of their nurses.

June 2009

None submitted

July 2009

Reminder regarding the very important topic of billing:

- All members of the study team need to have an understanding of the study contract's budget language in order to ensure that charges are billed correctly.
- No service or procedure *that is paid for by a sponsor* may be billed to insurance or Medicare, including what might otherwise be considered standard of care. The Informed Consent language in the "Will being in this study cost you any money?" section must be consistent with what is agreed to in the study contract.
- Preparing a Billing Coverage Analysis when beginning a study will identify each expected study charge and how it is to be billed. This must also reflect the study contract's budget language.

Please contact Kathy Richardson, School of Medicine Clinical Trials Office Budget and Billing coordinator, at 982-4383 or kr3m@virginia.edu for assistance with preparing a Billing Coverage Analysis or with any clinical trials budget or billing issues.

August 2009

There is still some confusion about device studies and the Office of Supply Chain Management, so we're re-sending the November TIP: (revised a bit)

Ask yourself: Am I using a device, not currently used at UVA, in our research that is purchased, contracted, donated, or loaned for trial?

- IF the answer is YES: UVa (NOT IRB) policy requires that the device be evaluated by the Office of Supply Chain Management.

- The IRB does need a copy of the application for evaluation, but does not need a copy of the actual approval or an approval number.

For your convenience, the information about obtaining Supply Chain Management evaluation is available on the IRB website (http://www.virginia.edu/vpr/irb/hsr/index.html) and the application called the New Medical Device Request is present under "Forms".

IF your study is already approved by the IRB but you have not obtained Supply Chain Management review, please do so at this time.

- In order to obtain approval; complete the Form, fax a copy to the IRB at 924-2932 and then submit the form to Supply Chain Management. If there are questions on how to complete the form contact their office at 982-3857.

For additional information see the following Hospital Policies:
0076: Medical Devices Evaluation and Monitoring System # 0165: Safe Medical Devices Act Reporting

October 2009

Tips for transporting samples by car

Since some of you need to transport blood and/or urine specimens from your off-site clinic to the central lab at UVA, the following is information provided by Ericka Pearce during her Shipping of Hazardous Materials certification class for our continuing education series:

- Pack specimens, **in a leak-proof primary container**, with enough absorbent material to soak up any spillage

- Put primary containers in a leak-proof package (possibly a leak-proof sealable shipping bag); but a leak-proof zip lock baggie will work
- Securely place everything in a separate closed box – preferably in the trunk of the car
- **If using dry ice – be sure that the container is allowed to vent**
- Have the attached "courtesy letter" with you whenever you transport specimens.

**Please note that it would also be a good idea to always have a box of gloves and/or spill materials (a biohazard/red bag and Cavicide) with you.

Call Ericka Pearce at 982-4911 if you have any questions

*Per Ericka, REMEMBER: this should be for **patient specimens only.** Category B cultures should be shipped by air or packaged as a Category B and transported using a trained and certified courier.*