February 2008

Please Remember:

It is required that you follow your protocol precisely as written and approved by the IRB. You may not deviate from the protocol without first obtaining approval from the IRB.

For example: If you find that anyone on the research team has deviated from the protocol as written, you may need to:
1) either submit a protocol violation(s) (as per IRB definitions and procedures) and then follow the protocol as written, OR
2) submit a protocol violation(s) (as per IRB definitions and procedures) and then submit a modification to the IRB, so that your protocol better matches your intent.

In the interim – while your modification is being written, submitted, reviewed, and approved, you must follow the current, approved protocol as it is written.

March 2008

Notes – to - File

We've talked about them before - not using them as a "get out of jail free" card, but there is an article in the March Applied Clinical Trials issue about this.

"When used properly, a Note-to-File (NTF) can be a positive practice. A useful NTF has the following parts: 1) A problem identified, 2) a procedural change identified for preventing recurrence, 3) and the initiation of that procedure."

Apparently, some sites are being cited by the FDA for writing multiple NTFs, but without taking any corrective action.

As an auditor, the author reports having worked with coordinators who write "trivial NTFs and place them in Regulatory Binders…instead of developing good recordkeeping practices". Notes-to-File can be useful tools to demonstrate that an error has been identified by the research staff, but as emphasized in the article, a note without the corrective action identified and initiated may cause more trouble.

*For those who would like to view the article, it is in Applied Clinical Trials, Volume 17, Number 3, March 2008. The author is Carl Anderson, Senior Consultant; Biologics Consulting Group, Inc.
If you can't access it and want a copy, let me know and I can fax it to you (its just one page). You can reply directly to me at kgd@virginia.edu.

Karen Davenport

April 2008

Regarding compensation for study subjects:

- All study subjects must provide the study team with a SS# or TIN # (Tax Identification Number) or they cannot be compensated for being in the study.
- They may enroll if they wish, but may not be paid.
- This includes payment by gift card if >$50.
- Regarding illegal immigrants or those with certain types of visas: it is a violation of federal law to pay anyone without a proper SS or TIN #

May 2008

Following the Brown Bag session we had on April 18 regarding Medicare billing updates:

For Category B study devices:

- The operative or procedure note MUST include a statement that the procedure was part of a clinical trial to ensure accurate coding and reporting to Medicare and insurance companies.

Please note: for those of you who missed the session – never fear – there will be more opportunities to hear this information. We will be offering this again – probably several times.

June 2008

For those of you who may not yet be aware of it, there have been some significant changes to the definition of "Protocol Violation".

A Protocol Violation is no longer only an event over which the Investigator has control. **Any** unapproved deviation from the protocol, or GCPs, or the IRB policies is considered a Protocol Violation: whether or not it is intentional and whether or not it is under the control of the Investigator.

One other item of note: if you happen to have an event that meets the definitions of a Serious Adverse Event, and a Protocol Violation, and an Unanticipated Problem, you only need to report it once.
The algorithm for reporting is: SAE, then Protocol Violation, then Unanticipated Problem.

Please refer to the IRB website: http://www.virginia.edu/vprgs/irb/maintain.html for more explicit instructions.

July 2008

The IRB-HSR requires that you send your new ***investigator-initiated*** protocol submissions to Lori Elder in the SOM Clinical Trials Office if:

- you think your study may require an ***investigator-held*** IND (Investigational New Drug)
    - if your proposed study will use an FDA approved drug for a new indication, using different dosing, using a different route of administration, and/or using a different formulation
    - if your study will use an unapproved drug and is not being conducted under a sponsor's IND
    - if your study will use an herbal or dietary supplement
- you think your study may require an ***investigator-held*** IDE (Investigational Device Exemption) submission to the FDA
    - if your study will utilize a non-US marketed medical device
    - if your study will utilize a US marketed medical device for a new indication
- your study is an investigator-initiated multi-site study for which the UVa Principal Investigator will be the lead PI

Please note, the SOM Clinical Trials Office is only required to review the study if it is investigator initiated. If the study is being conducted under a sponsor's IND or IDE, a review by the SOM CTO is not required.

Contact Lori as soon as possible, even if you only have a draft protocol. ***She can help you determine the need for an IND / IDE, assist in the submission process, and ensure processes are in place to ensure compliance with regulations governing investigator-held INDs / IDEs / multi-site studies.***

Lori can be reached at lje5u@virginia.edu or 924-8570.

August 2008

Just a couple of reminders:

1) Remember that you may not make any handwritten changes of any kind to the approved informed consent form. That includes changes to the payment section.

2) You must save your study documents for at least 6 years following the close of your study with the IRB – per HIPAA. BUT – if your study is industry or federally funded, you may need to save your documents for a much longer period. Always check with your sponsor before destroying any study documents.

See the following IRB website for further clarification:

http://www.virginia.edu/vprgs/irb/hsr/recordkeeping.html

September 2008

- If you receive notification from a sponsor (such as a letter or email) that instructs you to change a procedure or make some other change to the protocol without a protocol amendment from the sponsor, notify the sponsor that you will be unable to make this change until you receive an official protocol amendment and obtain IRB approval.

- Per regulation 21CFR Part 312.66, you may **not** make any change to the protocol until you receive documented IRB approval. The only exception, per regulations 21CFR Part 312.66 and 45CFR Part 46.103(b)(4)(iii), is to prevent imminent harm to subjects.

November 2008

These questions have come up, lately:

- Who owns study data?

- If the investigator moves to a new institution, can (s)he take the data?

- What is UVA's policy?

The University of Virginia does own data/specimens, unless the Vice President for Research Office agrees that the investigator may take them with him/her. If that were the case, a Material Transfer Agreement would be used for specimens, and a letter is used for data.

UVA does have a policy on this. It is called "the Notebook Policy". It is referenced in the new faculty exit checklist that was just released by the Provost Office. See the link http://www.virginia.edu/provost/facultyexit.pdf.