June 2006

Notes-to-File

A Note-to-File is a tool to explain some discrepancy in the conduct of a research study or to clarify a decision made in regards to some aspect of the study.

It is important that it not become a device to allow a research investigator or coordinator to ignore protocol or to allow lax conduct of a study.

The tool should only be used when a discrepancy occurs or it is felt that a more thorough clarification is needed - it is not a device to allow the discrepancy.

July 2006

For research personnel who send Screening Logs outside UVa

Per the IRB-HSR: HIPAA regulations require that if a subject has NOT signed consent, you may not send any identifiers, including initials, with the screening log.

If you are required to send a screening log to an outside sponsor, and it does include any identifiers, then tracking of this disclosure must be done with Medical Records (Health Information Services).

For information about tracking, the IRB requests that you contact them directly.

August 2006

Reminder about Confidentiality Agreements:

When providing education to clinic, unit staff, or any other ancillary personnel regarding a study:

- Remember to be clear that, not only does the confidentiality agreement apply to subject/patient data, it also applies to information about the study itself.
- No information about the study should be discussed outside UVA. That information is Proprietary and Confidential.

September 2006

Reminder Regarding Study Document Retention:

Regardless of whether or not a study falls under FDA or NIH regulations:
In order to satisfy the HIPAA regulations for study document retention, you need to maintain your records for a minimum of 6 years following the completion of the study.

Do be aware that FDA regulations may require that documents be maintained longer than the 6 years.

If you have any questions, contact the SOM Clinical Trials Office (924-8530).

October 2006

All Notes to File, corrections made to data, as well as any other notation made to a study record, MUST be signed, or initialed, and dated by the person making the notation/correction.

This allows for an easy-to-see chronological audit trail. (Remember: after a few months, you may not remember exactly why you made the change, so some note explaining any change to data might be helpful.)

November 2006

Grants, and the studies funded by them, must BOTH be approved by the IRB.

As soon as the Investigator is notified that his grant will be funded, (s)he should go to the IRB website and download the Grant Information Form and the Grant Application Summary. http://www.virginia.edu/vprgs/irb/hsr_submit_grant.html

These forms must be submitted to the full board of the IRB for approval.
For help, contact Terry Ryan in the IRB-HSR.(982-1855)

December 2006

When creating your study budget:

Don't forget to include those items that fall outside the Grants/Billing process request form such as Tissue Procurement Facility, Investigational Pharmacy, Research MRI, IRB charges, etc. They all generate charges that you need to incorporate into your budget, but will not be included on the Grants/Billing request form.