**January 2007**

**Submissions to the GCRC/IRB:**

Happy New Year!
This month the Tip involves an attachment. Helena Estes-Johnson and I put together some simple flow charts to help explain the flow for submitting to the GCRC/IRB. There are separate flow charts for submitting a new study, a status report, and a modification. For those of you who are new, or who only submit to GCRC occasionally, this will, hopefully, be helpful.

Attachment

**February 2007**

**Obtaining Informed Consent for non-English speaking subjects:**

You may Not use the outside translator phone service for obtaining initial research informed consent. You may use the phone service to assist you with study visits, but for obtaining informed consent, a translator must be physically present and must sign the consent form.

The School of Medicine SOPs for conducting human subject research are being updated to reflect this. Due to a transition period during which our website is being updated, moved and modified, the SOP updates are not yet available for viewing.

**March 2007**

**When should you re-consent subjects?**

You should re-consent the subject when there is a *substantive* change that may affect whether or not the subject may wish to continue participation in the study

Examples of when to re-consent may include, but not be limited to:

- Added or deleted procedures or visits
- New risk information provided
- New standard-of-care alternatives

You must use the Addendum format when the study is closed to enrollment (though subjects may still be either on treatment or in follow-up).

**April 2007**

**Register All Study Subjects in Clinic Using the Grant Order Request Form**

The information on the form clearly identifies subjects as having *study services and procedures*.
You may:

- send the Grant Order Request Form to the clinic the day before the study visit
- have the subject bring the Grant Order Request Form with them to clinic
- meet the subject in clinic and have the Grant Order Request Form with you
- add the statement "**Grant Encounter - please route this form to Billing**" at the top of the Grant Order Request

Better communication with registration staff will improve the billing process.
Have any billing questions or problems?

Contact Kathy Richardson, SOM Clinical Trials Office Budget & Billing coordinator at (434)982-4383 or kr3m@virginia.edu

**May 2007**

**Regulatory Documents:**
Regulatory Documents do vary depending on the type of study. However, ALL studies require certain Regulatory Documents:

- All IRB submissions and approvals (also include other approvals such as PRC or GCRC)
- All other IRB correspondence, such as protocol violation reports, change of personnel, protocol modifications, protocol status forms, study closure, etc.
- Signed IRB Investigator Agreement
- All approved versions of the informed consent form
- All reports of Serious Adverse Events
- Signed consent forms (may be filed with the Reg Docs or subject study files)
- Drug or Device accountability forms (if a drug or device is used in your study)
- Though not required, it is recommended that you maintain a Personnel and Responsibilities of Duties form for each study
- Also highly recommended, is a log of all subjects enrolled in your study.

**For Sponsored trials also maintain all versions of the sponsor's protocol, Investigator Brochure (if there is one), and sponsor correspondence.
**For help setting up your Regulatory files call the SOM Clinical Trials Office 4-8574**

**June 2007**

A Couple of Reminders:
Some times it is the simple things we forget, so please remember:

1) When doing an industry study, you must have a fully executed contract before entering your first subject. This is UVA policy.

2) Remind subjects, during the consent process, that if they owe money to the state of Virginia, it will be automatically taken from any study compensation they may receive.
If your subjects have questions, they can call The Virginia Department of Taxation's Set-Off Debt Collection Program at 804-367-8380.

**July 2007**

## Advertising in the C'VILLE

With Melissa gone, I have taken on the advertising through the C'VILLE.

The instructions on the template on the website are not quite accurate anymore.

**Please use the following process:**

- Submit your ad for approval to the IRB
- Fax the approved ad to me (Karen Davenport) at 243-5999
- Send the electronic version of the ad (in the C'VILLE template) to me at kgd@virginia.edu
- When you complete the contact info at the top of the ad template, please also send me the address – UVA Box #_____
- I will forward your ad to Marketing and Communication (Diane Butler) – you do not have to do that

Thank you. If you have questions, you can call me at 4-8574

**August 2007**

### A Radiology Coding Reminder to all Investigators and Study Coordinators

Please be aware that all Radiology procedures performed under a research protocol must have a Radiology Information Management System (**RIMS**) code listed on the Grant Order Request form. **CPT** and **SMS** codes alone are inadequate to identify a specific Radiology procedure. When you obtain or verify CPT/SMS codes for Radiology procedures, be sure to also request the RIMS code that accommodates the specifics of your protocol.

Assistance in obtaining all Radiology coding is available from Tim Ulrich who can be contacted at 924-2782 or tju2s@virginia.edu

**September 2007**

For those of you who are new (and maybe not so new), both of these issues have come up recently:

Please remember:
Prior to submitting **anything** to the IRB: review the IRB website. Templates change, processes change, and it is just easier to check things out **before** you submit rather than having to re-submit.

Also: when reviewing a protocol for procedures and budget building, make sure that the Schedule of Events matches the written text in the body of the industry protocol. Sometimes they don't match, and you have to go back to the sponsor to find out which is correct.

**October 2007**

## When working with the Investigational Pharmacy:

Prior to the initiation of the study, forward the following to Michelle Hobbs and Amy Adams:

1) A copy of the sponsor protocol, if there is one, and the approved IRB protocol
2) A copy of the approved consent
3) The Pharmacy Manual, if there is one, and a copy of the Invest Brochure, if applicable

Once the pharmacy receives the above, the process may vary depending on the type of study, but the main thing to remember is to communicate with Amy and Michelle, and to give them plenty of advanced notice.
The phone number for the investigational pharmacist is 2-1048.

Also - for monitoring visits - if the monitor wants to go to pharmacy, please give Amy and Michelle as much advanced notice as possible.

**November 2007**

## Update from the Shipping Hazardous Materials talk from September 7, 2007

There was some confusion about the Fed Ex plastic ‘overpak’ and what labels go on the plastic and what has to be on the box. Following a discussion with Ericka Pearce, Office of Environmental Health and Safety:

- The box inside the Fed Ex overpak MUST have all of the required labels, including shipper and destination addresses and contact information.
- The Fed Ex overpak has the Fed Ex shipping label attached, and if you are told to *also* put the labels on the overpak, you may do so, but they MUST be on the box.

Old shipping boxes that have “Diagnostic Specimens” or “Patient Specimen” should have those designations marked out completely. A **‘UN3373’** label must be on all boxes shipping Category B specimens, which covers most basic lab samples. If you don’t have the UN stickers, call your lab, and they should be able to send them to you.