February 2010

We have had a couple of questions, lately, regarding Surrogate Assent

I sent the following questions to one of our UVA lawyers, Beth Hodsdon: (without naming the study, I will mention that it could be of benefit to the subject)

"A coordinator has a potential subject who is in a coma. They want to enroll him in a study. His sister is coming in today and will meet with the coordinator. However, she informed the coordinator that the man has a friend who has Power of Attorney. I suspect that this is not Medical Power of Attorney, but if it is - does that supersede the sister's ability to sign as surrogate?"

Beth's answer:

Under Virginia law the POA will trump the family's decision-making only if it is both a medical POA and it specifically gives authority for the appointed surrogate to enroll the person in a research study. (If it comes down to examining the POA, I'd be glad to look at it if that would help.)

"Now – my second part to this: the family is not local. Do we have to start with spouse, parents, etc. before we can work with the sister?"

Beth's answer:

If the POA isn't relevant, then we go through the state law hierarchy of decision-makers: a guardian if there is one; if not, spouse; if none (or if legally separated), then parent(s); if none, then sibling(s).

I also checked with Eileen, in the IRB. If the sister says the parents are deceased, then she may sign. However, if the parents can be reached, we need to start with them. If they say "No", then it is no. (we are assuming there is no spouse, but if there is, then she precedes the parents on the list of surrogates (see Beth's answer to part 2))

The full list of who may sign as surrogate as per Title 21; Part 50.3 Definitions:

"Family member means any one of the following legally competent persons:

- spouse;
- parents;
- children (including adopted children);
- brothers, sisters, and spouses of brothers and sisters;

and any individual related by blood or affinity whose close association with the subject is the equivalent of a family relationship."

March 2010

Lately, it has been noted that Version Control can be a significant issue:

Remember that you need to change the version date on any protocol and consent whenever changes are made to the document.

This is an easy thing to overlook, but can have real consequences when you are ready to make your next modification or when a monitor or auditor is reviewing your paperwork.

Also please remember to save a **clean copy** of each version of the **approved documents**, both electronically and in hard copy.

It is very important to name, maintain, and store electronic files in a systematic fashion so that others on the team, especially new team members who may take over for you, can find and access the files. For example: do not store study files on personal hard drives

June 2010

I had 2 suggestions for a TIP for this month. I liked them both, so…….

1) Please remember that, if your project has a contract or a letter of indemnification, **you may not begin your study *(including recruitment)* until the contract and/or letter has been signed by all parties.**

2) It is generally the coordinator who handles the Grant Billing Process: completing the Grant Pricing Request Form (with Kathy Richardson).
Once your study is up and running, it is the responsibility of the study team (most usually the coordinator) to monitor trial finances.
This will include invoicing sponsors (if applicable), keeping track of payments and billing, and making sure financial contractual obligations are being met on the sponsor side as well as the site side.
It also includes reconciling the account summary that is sent from Patient Financial Services and HSF.

July 2010

One very good thing about our Coordinator Group is that, when someone gets an answer for something, it benefits us all.

If anyone ever needs to know how to get meal vouchers at the hospital cafeterias for outpatient subjects – here is the process and the person to contact:

Contact Ann Counts or Kim Harriman via email or phone.
Ann: ac3p 4-2696 Kim: khh8b 4-2287

They will need to know what you would like to say on the voucher, authorized signature, amount, and the PTAEO to be charged. Also, you are only billed for the amount spent. Change is not given back on vouchers to subjects, so most departments go with a $6.00 - $7.50 meal voucher (though this is not an absolute, if you need more).
Ann and/or Kim would like to have at least 24 hour notice.

August 2010

Privacy is the right of persons not to share information about themselves.

Confidentiality is the obligation to keep private information that has been collected from being shared with others.

From our NetLearning Mandatory Training Module for 2010:

As of 2009, **individual employees can be convicted of criminal violations** if they intentionally and wrongfully disclose protected patient health information (PHI). This is in addition to existing Health System policies by which an employee may be subject to termination of employment for a violation of confidentiality and reported to a licensing board if a licensed professional. HR Policy #707

What do I do?

1. Access only the information you need to perform your job. Be aware that the Medical Center *records and examines activity* on information systems that contain or use electronic protected health information (e-PHI).

2. Employees who have job-related access to the electronic medical record system may access their own PHI electronically (MC Policy #0163). This does *not* extend beyond your own medical record – i.e. you may not access electronic records of any other person regardless of any legal or family relationship, or the person's permission.

3. Protect PHI by utilizing safeguards and following policies. For example, log off of computers when done, and dispose of confidential documents in approved recycling bins.

4. Be aware that Facebook and other **social websites are** *not* **secure**; therefore, posting patient information on these websites is NOT permitted! Consult MC Policy #0202 regarding limits on acceptable internet and intranet uses of de-identified patient information.

5. Report at once any known or alleged, apparent or potential violations of confidentiality of PHI to **both** your manager and the Corporate Compliance and Privacy Office. Prompt action may reduce exposure to governmental penalties.

6. Always use fax cover sheets with a confidentiality notice when sending patient information within or outside the UVA Medical Center.

To summarize:

As UVA employees, HIPAA allows us to view Personal Health Information (PHI) ONLY as it applies to our research role.

It is NOT carte blanche to look at any records we may want to view.

October 2010

REMINDER:

If you are working with the Investigational Pharmacy for your study:

you MUST forward a copy of all approved, modified protocols (**both** the sponsor and the IRB protocol) to them.

They are required to have a copy of the most current version of both protocols.

Second October 2010 Tip

Certification of Adult Subject Capacity to Consent for Research

IRB-HSR # _____

Protocol Title: _____

Subject name *Printed*: _____

Primary Capacity Assessment
Based on my personal examination, I certify that the above-named subject is unable to understand the nature, extent, risks/benefits, alternatives, or possible consequences of inclusion into the proposed human subject research study or is unable to convey his/her understanding in any way.

Comments:_____

_____ _____ _____
Principal Investigator Principal Investigator Date/time
or Designee Or Designee
Printed Signature

Secondary Capacity Assessment
T*he Secondary Capacity Assessment is not required if the subject is unconscious or experiencing a profound impairment of consciousness due to trauma, stroke, or other acute physiological condition*.

_____ _____ _____
Physician /Clinical Psychologist Physician /Clinical Psychologist Date/time
Printed Signature
This person may not be a member of the study team.

Certification of Adult Capacity to Consent to Research

This subject has regained capacity to consent.

_____ _____ _____
Principal Investigator Principal Investigator Date/time
or Designee Or Designee
Printed Signature

January 2011

URMA is designed to help manage and organize both physical and electronic records held at UVa.

Step 1: Identify the Records Administrators and Coordinators for your department. There can be more than one person assigned to each of these roles. Once identified, you can create accounts for these individuals in URMA. *You cannot use URMA without having an account*.

* Records Administrator: This person can authorize the destruction or transfer of your departmental records.

* Records Coordinator: This is the person who knows where records are kept, works with departmental records frequently, and is the contact for questions related to your departmental records. (This, most likely, is YOU)

Step 2: Organize Your Records

Step 3: Start Entering Information in URMA

For a tutorial, and to start the process, go to http://www.virginia.edu/recordsmanagement/urma/urma.html.

How this will HELP you:

- Once you have the study information entered into URMA you can print labels for your archiving boxes. After your boxes are stored, (Records Management is working on a central location - YEAH!) you can let Caroline Walters and Lori Kressin take it from there.
- No more spending days trying to find the sponsor contact to allow you to destroy documents. Our wonderful Records Management folks take that task off your shoulders!
- So go to the above website to get signed on, get your studies entered, and you'll be set. Then – I suggest – when Caroline has her next class - attend for more information and/or updates. There are also URMA specific training classes that will look in greater depth at how to use this application.

BUT – please be aware that URMA is still being refined, so some pages and requested information will be changing. Your entered information will be automatically moved, though, as the site changes.