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.

February 2011

Regarding Study Billing Coverage Analysis Tables

- Please remember that these tables are required for **ALL** Full Committee IRB-HSR & Expedited IRB-HSR studies with NCI CIRB approval.
- *Their purpose is to help ensure Medicare compliance and to reduce billing errors.*
- The Coverage Analysis should include all study **and** standard of care procedures within a protocol that could potentially generate a billable Medical Center (MC) or Health Services Foundation (HSF) charge, with a clear billing designation (i.e., Patient / Study).
- If the procedure does not generate a billable MC/HSF charge (i.e. urine pregnancy test kits that are processed on-site via kits provided by the sponsor), the table or footnotes must

explain this. **(See attached resource table of billable vs. non-billable charges & sample table.)**

- **Remember: If a procedure is considered "Standard of Care" but is being paid for by the Sponsor, it may NOT be billed to the subject or insurance.**

***IF YOU HAVE A CLINICAL TRIALS AGREEMENT*: To ensure timely approval:**
Please send Jen Crosby, in the School of Medicine Clinical Trials Office, the necessary documents, upon request, to create a Study Billing Coverage Analysis draft. If you do not have budget documentation (or don't know who has it), you may be able to request the pending CTA from your Contract Negotiator at the Office of Grants and Contracts.

- The purpose of reviewing your budget is *not* to check your math or to inquire about how much you're budgeting for each procedure. We are looking to see what procedures the sponsor reimburses for.
- Once the table is completed, it has to be reviewed and signed by the PI and CTO reviewer. The CTO reviewer will scan and forward the document, along with your budget documentation to the Office of Grants & Contracts (Either your Contract Negotiator, or if unknown, Andrew Breen & Katherine Boswell).

The documents needed for review OR building the table include:

- Study Protocol (sponsor's protocol is best)
- IRB Consent
- Budget or pending Clinical Trials Agreement
- Pending documents are acceptable

- A copy of the Study Billing Coverage Analyses will always be kept at the Clinical Trials Office. If for some reason you misplace your document, feel free to contact us & we will send you a copy.
- **See attached example of a Coverage Analysis table.**

Helpful hints for Jen:

- Anything you might know off the top of your head (i.e., study team does the phlebotomy, all the labs are sent out, study drug is provided, etc.)
- Who your Contract Negotiator is.
- If there are certain Arms UVA is not participating in.

If you have any questions or need any help in this process, please call Jen Crosby at 3-5350 or email her at jac8tr@virginia.edu. She will be happy to help you.

March 2011

Subject: Clinicaltrials.gov

The FDA has recently announced that, effective March 7, 2012, the consent forms for studies regulated by the *FDA (any study involving the use of a drug, device or biologic for research purposes)* must have an additional statement in the consent form. (The new statement is **NOT** required for any study opened prior to effective date.)

If you are part of a multi-site trial, the sponsor will notify you if this sentence needs to be added to your consent forms.

Our IRB-HSR has added this new sentence to the consent form template for new studies. It states:

"A description of this clinical trial will be available on *http:// www.ClinicalTrials.gov*, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time."

Remember:

- According to U.S. Public Law (as well as the policy of most major journals), it is the sponsor's responsibility to register all applicable clinical trials on the clinicaltrials.gov website.
- That means that *for NIH trials, investigator initiated trials, etc., it is the Principal Investigator's responsibility to post the trial on the site prior to the first subject enrollment*.

"Applicable clinical trial", for purposes of the registration, is defined as a trial to which human subjects are "prospectively assigned to intervention or comparison groups to study the cause-and-effect relationship between a medical intervention and a health outcome".

If you have questions on what trials require registration or how to register your trials, please contact Lori Elder (lje5u@virginia.edu; 924-8570).

April 2011 with Additional Tip

Regarding Sharing of Patient / Subject Data with an Outside Entity

You may not share health information with any HIPAA identifier (PHI) of a research subject outside of the UVa HIPAA covered entity via email, fax, phone, etc. unless the subject has signed consent allowing the disclosure, or the IRB has approved a waiver of consent for sharing this information. The UVa HIPAA covered entity includes the hospital, Health System, School of Medicine, School of Nursing, Health Services Foundation, and Office of the Vice President for Research.

Example: you want to query a sponsor about a potential subject's inclusion into a study. You may only include such information as 'white 35 year-old female'.
No initials, name, Med Record #, date of birth, any date of service, etc.
(The information that is sent may not identify the individual in any way.)

STOP, THINK and BE CAREFUL-

- This is sensitive health information, and we need to be very careful to protect it
- Also remember that there are significant monetary fines for loss or misuse of PHI

The IRB will be presenting a Chat Hour on this topic: June 22 12-1300 PHS Classroom A and June 29 0830-0930 Morton

HIPAA Identifiers

1. Name
2. All geographic subdivisions smaller than a state, including street address, city, county, precinct, zip code, and their equivalent geocodes, except for the initial three digits of the zip code if, according to the current publicly available data from the Bureau of the Census: (1) The geographic unit formed by combining all zip codes with the same 3 initial digits contains more than 20,000 people and (2) The initial 3 digits of a zip code for all such geographic units containing 20,000 is changed to 000.
3. All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older. *[This means you may record the year but not record the month or day of any date related to the subject if the subject is under the age of 89. In addition if the subject is over the age of 89 you may not record their age and you may not record the month, day or year of any date related to the subject]*
4. Telephone numbers
5. Fax numbers
6. Electronic mail addresses
7. Social Security number
8. Medical Record number
9. Health plan beneficiary numbers

10. Account numbers
11. Certificate/license numbers
12. Vehicle identifiers and serial numbers, including license plate numbers
13. Device identifiers and serial numbers
14. Web Universal Resource Locators (URLs)
15. Internet Protocol (IP) address numbers
16. Biometric identifiers, including finger and voice prints
17. Full face photographic images and any comparable images
18. Any other unique identifying number, characteristic, code that is derived from or related to information about the individual (e.g. initials, last 4 digits of Social Security #, mother's maiden name, first 3 letters of last name.)

Please note:

When a previously enrolled research subject ***becomes*** a prisoner, the Principal Investigator must notify the IRB immediately. The PI (and sponsor) must determine if the subject will remain in the study or be dropped from participation. If the prisoner/subject is to remain in the study, then the IRB will need to promptly review the protocol in accordance with the requirements of 45CFR46 subpart C if the Principal Investigator wishes to have the prisoner subject continue to participate in the research**.** Modification to the protocol may be required in order to protect the prisoner/subject. Some issues to consider:

1. Is the subject placed in danger by stopping study intervention "cold Turkey"?
2. What training or information might the prison officials need in order to continue the study in that setting?
3. What additional study processes might need to be in place to ensure subject safety?

IF at a follow-up visit or phone call, it is discovered that a subject was in prison during part of the study, and is now out of prison; and the subject is to remain in the study, the study team should submit a Protocol Violation reporting the participation of a prisoner in a study that was not approved for the enrollment of prisoners.

For more detailed information about conducting research with prisoners, go to the IRB Website: (http://www.virginia.edu/vpr/irb/hsr/for_researchers.html) and click on 'IRB-HSR Research Guidance'

June 2011

One of our coordinators found the following information:

If the sponsor wants the site to dispose of the study drug:

Call Environmental Health and Safety; Biosafety at 982-4911. They will provide a "white bucket".

You can put the study med in the bucket and complete the paperwork that they provide.

Call them back when you are finished: they will pick up and incinerate the bucket and provide you with documentation of the completed process for your records.