

UW Medicine

July 31, 2008

TO: Clinical Department Directors
UW Medicine

FROM: Bruce Ferguson *Bruce*
CFO, UW Medicine

SUBJECT: CLINICAL RESEARCH STAFF TRAINING PROGRAM & JOB
DESCRIPTION LANGUAGE

UW Medicine will implement a comprehensive training curriculum for staff involved in clinical research beginning in September 2008. The curriculum is designed for clinical research nurses, research study coordinators, and other staff who work with faculty in conducting clinical research. We will offer several different tracks designed to match the various levels of involvement staff have in the administration of clinical Research. **Please note that this training is mandatory.**

This training is not required for faculty but they are more than welcome to attend. We want faculty to know about this required training so that they understand why their staff will be gone for these training sessions.

The timeline/action items are as follows:

1. Beginning the week of July 21, 2008: Clinical Department Directors review the lists of staff names from the CRBB repository of trainees given to you by Julie Reid. You will need to identify those staff that will need the full training versus those that will only need a subset of the curriculum. Please return an updated, accurate list of trainees for your department to CRBB no later than August 4, 2008. In addition:
 - Let staff know that training registration and attendance is mandatory, but required modules will vary based on job function.
 - Let faculty know that their clinical research staff will need to take required training.
2. August 4, 2008: CRBB begins direct notification of all staff involved in clinical research regarding his/her training requirements and schedule. All current staff involved in clinical research will be expected to sign up for training as soon as possible but no later than September 15, 2008.
5. September 1 - December 31, 2008: Training sessions for all current staff involved in clinical research takes place. This training must be completed by December 31, 2008.

6. Beginning August 1, 2008: The following steps will be implemented as part of the hiring process:

- All new job descriptions for staff working in clinical research involving human subjects will be modified to include the following language:

"This position will work with clinical research involving human subjects within UW Medicine and therefore clinical Research Study Coordinator (RSC) training is required. The training requirement for this position includes UW Medicine-specific as well as general training."

- The language will be included in the end of the duties and responsibilities sections of the job descriptions, just above the 'Required Skills' section of the classified job description and the 'Required' section of the Professional Staff Positions.
- Job descriptions that have duties that will require contact with clinical research involving human subjects will be put onto UW Hires and posted on the UW employment website with the new language included just above the 'Requirements' section of UW Hires, and will also include the sentence, "Applicants selected for this position who have not already completed this training will be required to complete this training within 90 days of hire."
- Each department director/designee will be responsible for alerting his/her Employment Specialist of the new language to ensure proper notification on the Recruitment Announcement.
- When a final candidate is selected and accepts the employment offer, HR will send a Confirmation of Hire to the Hiring Official/Designee. The Hiring Official/Designee will be responsible for notifying CRBB that a new research staff member has been hired who requires training.
- Department Director/Designee will review the training matrix, determine which Track the new hire belongs in and communicate that to CRBB.
- The expectation is that all newly hired study staff will need to complete training within 90 days of hire.
- For all current staff working in clinical research involving human subjects, this new language needs to be added to their job descriptions. This language should be added on, or soon after, September 1. Once you add this language to the bottom of the current job description, please give this new job description to your employee so that they know of this new expectation. All staff, new and current will be required to take the training that will be offered from 9/3/08 through 12/31/08.

Note: Institutional ownership of the RSC general training and all RSC training tracking, etc will need to be reviewed after 12/31/08 as well as going forward.

Thank you in advance for your effort, collaboration, and support of this strategic initiative.

Cc: Diane Merz
Andria Pierson
Julie Reid

UW SCHOOL OF MEDICINE RESEARCH STUDY COORDINATOR TRAINING REQUIREMENTS

Revised: 7/31/2008

MODULE	COURSE TITLE	TRAINING TRACK		NEW OR EXISTING CURRICULUM	APPROX LENGTH	PROVIDED BY	TRACKED BY
		Track I Study Coordinator, RN	Track II Non-Study Coordinator (office assistant, secretary, budget manager, etc.)				
GCP2	Good Clinical Practices (GCP) August - December 2008	REQUIRED	RECOMMENDED**	New	120 min	SOM/RGE	CRBB
GCP1	Good Clinical Practices (GCP) Online	REQUIRED*	RECOMMENDED**	Existing	300 min	CITI	CITI & CRBB
CRB1	UW Medicine Clinical Research Overview	REQUIRED	REQUIRED	New	90 min	CRBB	CRBB
CRB2	Clinical Research Budgeting, Billing and Financial Management	REQUIRED	RECOMMENDED	New	120 min	CRBB	CRBB
CRB3	Documenting, Coding and Billing Clinical Research Services	REQUIRED*	REQUIRED	Both	120 min	CRBB	CRBB
HSD1	Human Subjects Online	REQUIRED	RECOMMENDED	Existing		CITI	HSD
HIP1	HIPAA Online	REQUIRED	REQUIRED	Existing		COMPLIANCE	COMPLIANCE
	Fundamentals of Conducting Clinical Trials I and II	RECOMMENDED	RECOMMENDED	Existing	120 min	RGE/THS	RGE
	Certificate Program in Clinical Trials	RECOMMENDED	RECOMMENDED	Existing	9 months	UW EXTENSION	UW EXTENSION

*Note: Prior completion fulfills requirement. Please contact "Tracked by" department for confirmation of prior attendance.

**Note: Either GCP1 or GCP2 is recommended.

Definition of Audience

Study Coordinator, RN:

These are defined as classified and professional staff job classifications. They are the Study Coordinators and Research RNs hired in departments who hold these titles

Non-Study Coordinators:

These are staff such as fiscal or secretary who may make phone calls for P.I.s or study coordinators/RNs or may help with the budgets for