The Case for a Designated Clinical Research Educator

Maraty Gray, BA, CCRP; Rebecca Selle, BS, CCRP; Betty Oleson, BSN, RN, CCRP; James Thomas, MD, PhD - Medical College of Wisconsin

Purpose

In a busy clinical trials office with more than 80 staff members, it may be daunting to onboard new staff with the goal of ensuring continued education of current regulations and best practices related to clinical research. This proves particularly challenging given that it is rare that new staff have any previous clinical research experience or a high level of relevant knowledge. Consistency in training (i.e., internal processes and expectations, best practices, etc.) is often also a hurdle. By having designated Clinical Research Educators (CREs), MCW's Cancer Center Clinical Trials Office has been able to provide uniform training across specialties leading to improved adherence to performance expectations and consistent best practices across teams.

Methods and Materials

The cancer center CREs provide ongoing education to staff through an onboarding program, which is tailored by position; monthly education seminars; an annual symposium and other specific trainings, as applicable. Methods of teaching include didactic methods, as well as hands-on learning and simulation. The educators also create tools and checklists with the goal of developing uniform intra-department processes. Another unique duty of a cancer center CRE is to assist in distributing and developing learning opportunities that meet continuing education requirements for staff maintaining professional research certifications. This reduces a major burden for staff members (finding applicable courses, obtaining funding/reimbursement, dedicating travel time, etc.), and provides all staff with continued learning opportunities. The CREs also assist staff in preparation for audits and the development of Corrective and Preventative Action Plans.

Results

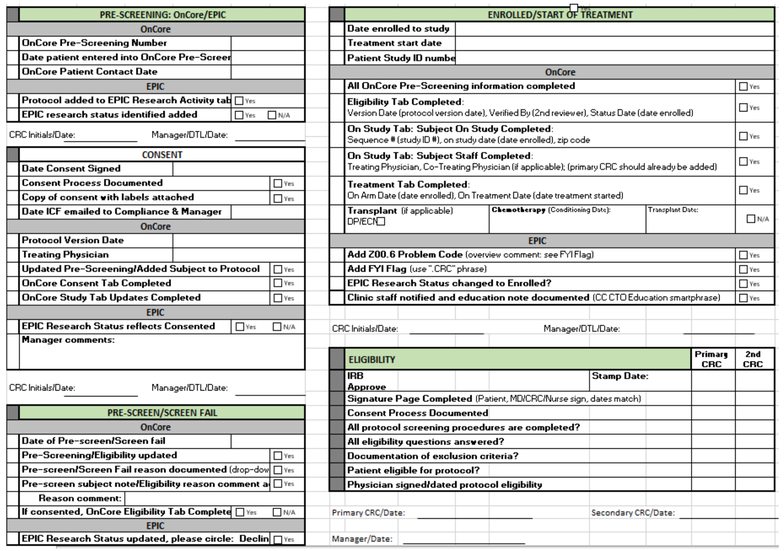
Utilizing dedicated CREs has had a positive impact in the MCW Cancer Center Clinical Trials Office in many areas. For example, during the orientation phase, new staff feel supported by having a main contact and they experience a much smoother and consistent onboarding process when CREs coordinate a majority of the process. This simultaneously decreases the onboarding burden of our experienced staff and reduces variations in training. In addition, audit outcomes have improved significantly as departmental standards and best practices have been developed and enforced. This includes fewer major and minor findings and auditors praising the consistency of documentation practices. The monthly educational opportunities developed by CREs have made it easier for staff to obtain educational credits and maintain their research certifications. Educators also have become resources to our entire department beyond the onboarding process by developing standard operating procedures and guidelines, and providing day-to-day assistance as needed (i.e., troubleshooting, facilitating questions regarding internal processes, required trainings, etc.).

Conclusions & Discussion

The implementation of CREs has proven to be a successful model for the MCW Cancer Center Clinical Trials Office. Other departments have sought out the CREs as resources for their own staff training and education. Our CREs also have collaborated on campus-wide education initiatives. Having designated educators has promoted a consistent culture of clinical research best practices within the MCW Cancer Center Clinical Trials Office.

Acknowledgements

Special thanks to Ms. Carrie O'Connor for her technical writing assistance on this poster.



PRE-SCREENING: OnCore/EPIC	
OnCore	
OnCore Pre-Screening Number	
Date patient entered into OnCore Pre-Screer	
OnCore Patient Contact Date	
EPIC	
Protocol added to EPIC Research Activity tab	☐ Yes
EPIC research status identified added	☐ Yes ☐ N/A

CRC Initials/Date: _____ Manager/DTL/Date: _____

CONSENT	
Date Consent Signed	
Consent Process Documented	☐ Yes
Copy of consent with labels attached	☐ Yes
Date ICF emailed to Compliance & Manager	
OnCore	
Protocol Version Date	
Treating Physician	
Updated Pre-Screening/Added Subject to Protocol	☐ Yes
OnCore Consent Tab Completed	☐ Yes
OnCore Study Tab Updates Completed	☐ Yes
EPIC	
EPIC Research Status reflects Consented	☐ Yes ☐ N/A
Manager comments:	

CRC Initials/Date: _____ Manager/DTL/Date: _____

PRE-SCREEN/SCREEN FAIL	
OnCore	
Date of Pre-screen/Screen fail	
Pre-Screening/Eligibility updated	☐ Yes
Pre-screen/Screen Fail reason documented (drop-dow	☐ Yes
Pre-screen subject note/Eligibility reason comment a	☐ Yes
Reason comment:	
If consented, OnCore Eligibility Tab Complete	☐ Yes ☐ N/A
EPIC	
EPIC Research Status updated, please circle: Declin	☐ Yes

ENROLLED/START OF TREATMENT			
Date enrolled to study			
Treatment start date			
Patient Study ID numbe			
OnCore			
All OnCore Pre-Screening information completed			☐ Yes
Eligibility Tab Completed: Version Date (protocol version date), Verified By (2nd reviewer), Status Date (date enrolled)			☐ Yes
On Study Tab: Subject On Study Completed: Sequence # (study ID #), on study date (date enrolled), zip code			☐ Yes
On Study Tab: Subject Staff Completed: Treating Physician, Co-Treating Physician (if applicable); (primary CRC should already be added)			☐ Yes
Treatment Tab Completed: On Arm Date (date enrolled), On Treatment Date (date treatment started)			☐ Yes
Transplant (if applicable) DP/ECP☐	Chemotherapy (Conditioning Date):	Transplant Date:	☐ N/A
EPIC			
Add Z00.6 Problem Code (overview comment: see FYI Flag)			☐ Yes
Add FYI Flag (use ".CRC" phrase)			☐ Yes
EPIC Research Status changed to Enrolled?			☐ Yes
Clinic staff notified and education note documented (CC CTO Education smartphrase)			☐ Yes

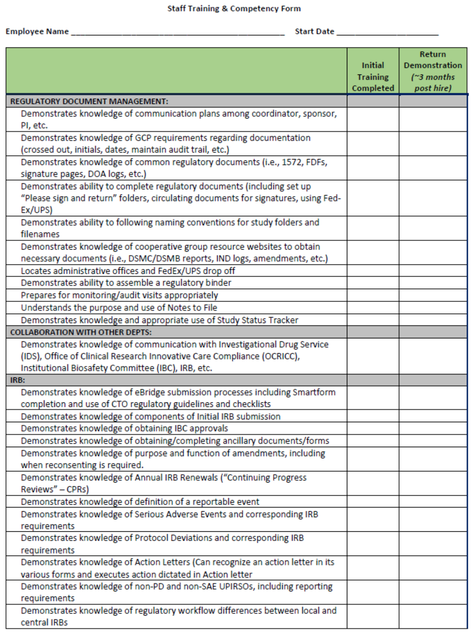
CRC Initials/Date: _____ Manager/DTL/Date: _____

ELIGIBILITY		Primary CRC	2nd CRC
IRB Approve	Stamp Date:		
Signature Page Completed (Patient, MD/CRC/Nurse sign, dates match)			
Consent Process Documented			
All protocol screening procedures are completed?			
All eligibility questions answered?			
Documentation of exclusion criteria?			
Patient eligible for protocol?			
Physician signed/dated protocol eligibility			

Primary CRC/Date: _____ Secondary CRC/Date: _____

Manager/Date: _____

Figure 1: Checklist for new subject screening and enrollment reflecting internal workflows

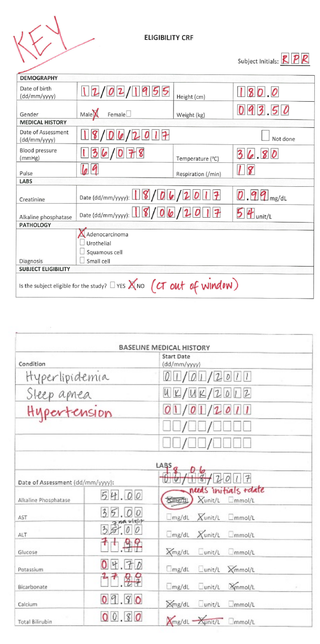


Staff Training & Competency Form

Employee Name _____ Start Date _____

	Initial Training Completed	Return Demonstration (~3 months post hire)
REGULATORY DOCUMENT MANAGEMENT:		
Demonstrates knowledge of communication plans among coordinator, sponsor, PI, etc.		
Demonstrates knowledge of GCP requirements regarding documentation (crossed out, initials, dates, maintain audit trail, etc.)		
Demonstrates knowledge of common regulatory documents (i.e., 1572, FDFs, signature pages, DOA logs, etc.)		
Demonstrates ability to complete regulatory documents (including set up "Please sign and return" folders, circulating documents for signatures, using Fed-Ex/UPS)		
Demonstrates ability to following naming conventions for study folders and filenames		
Demonstrates knowledge of cooperative group resource websites to obtain necessary documents (i.e., DSMC/DSMB reports, IND logs, amendments, etc.)		
Locates administrative offices and FedEx/UPS drop off		
Demonstrates ability to assemble a regulatory binder		
Prepares for monitoring/audit visits appropriately		
Understands the purpose and use of Notes to File		
Demonstrates knowledge and appropriate use of Study Status Tracker		
COLLABORATION WITH OTHER DEPTS:		
Demonstrates knowledge of communication with Investigational Drug Service (IDS), Office of Clinical Research Innovative Care Compliance (OCRICC), Institutional Biosafety Committee (IBC), IRB, etc.		
IRB:		
Demonstrates knowledge of eBridge submission processes including Smartform completion and use of CTO regulatory guidelines and checklists		
Demonstrates knowledge of components of initial IRB submission		
Demonstrates knowledge of obtaining IBC approvals		
Demonstrates knowledge of obtaining/completing ancillary documents/forms		
Demonstrates knowledge of purpose and function of amendments, including when reconsenting is required.		
Demonstrates knowledge of Annual IRB Renewals ("Continuing Progress Reviews" – CPRs)		
Demonstrates knowledge of definition of a reportable event		
Demonstrates knowledge of Serious Adverse Events and corresponding IRB requirements		
Demonstrates knowledge of Protocol Deviations and corresponding IRB requirements		
Demonstrates knowledge of Action Letters (Can recognize an action letter in its various forms and executes action dictated in Action letter		
Demonstrates knowledge of non-PD and non-SAE UPIRSOs, including reporting requirements		
Demonstrates knowledge of regulatory workflow differences between local and central IRBs		

Figure 2: Competency assessment example for regulatory coordinators/specialists



KEY

ELIGIBILITY CRF

Subject Initials: KPR

DEMOGRAPHY
Date of birth (dd/mm/yyyy): 12/02/1955 — Height (cm): 180.0
Gender: Male X Female ☐ — Weight (kg): 043.50
MEDICAL HISTORY
Date of Assessment (dd/mm/yyy): 19/06/2017 ☐ Not done
Blood pressure (mmHg): 136/078 — Temperature (°C): 37.20
Pulse: 64 — Respiration (/min): 17
LABS
Creatinine — Date (dd/mm/yyyy): 19/06/2017 — 0.99 mg/dL
Alkaline phosphatase — Date (dd/mm/yyyy): 19/06/2017 — 54 unit/L
PATHOLOGY
Diagnosis: X Adenocarcinoma ☐ Urothelial ☐ Squamous cell ☐ Small cell
SUBJECT ELIGIBILITY
Is the subject eligible for the study? ☐ YES X NO (CT out of window)

BASELINE MEDICAL HISTORY

Condition	Start Date (dd/mm/yyyy)
Hyperlipidemia	01/01/2011
Sleep apnea	06/06/2012
Hypertension	01/01/2011
	☐☐/☐☐/☐☐☐☐
	☐☐/☐☐/☐☐☐☐

LABS

Date of Assessment (dd/mm/yyyy):	19/06/2017 (uses initials rule)	
Alkaline Phosphatase	54.00	X unit/L ☐ mmol/L
AST	50.00	☐ mg/dL X unit/L ☐ mmol/L
ALT	57.00	☐ mg/dL X unit/L ☐ mmol/L
Glucose	114.00	X mg/dL ☐ unit/L ☐ mmol/L
Potassium	04.20	☐ mg/dL ☐ unit/L X mmol/L
Bicarbonate	27.00	☐ mg/dL ☐ unit/L X mmol/L
Calcium	01.50	X mg/dL ☐ unit/L ☐ mmol/L
Total Bilirubin	00.50	X mg/dL ☐ unit/L ☐ mmol/L

Figure 3: Answer keys to exercises for data entry, documentation, and eligibility

Onboarding Curriculum

All Staff

General topics (Weeks 1-2)

- ❑ Oncology and clinical trials basics
- ❑ General workflows and ancillary services
- ❑ The flow of a new study (e.g., Confidentiality Disclosure Agreements, Disease Oriented Team, Scientific Review Committee, DSMC, etc.)
- ❑ Training for the Clinical Trial Management System and other applicable software/databases
- ❑ Anatomy of a protocol and source documentation
- ❑ Documentation per GCP, FDA regulations, and internal expectations
- ❑ Review department Standard Operating Procedures and guidelines
- ❑ Preceptor assignment
- ❑ Shadowing opportunities (e.g., Translational Research Unit, Investigational Drug Services (IDS), research lab staff, etc.)

Clinical Research Assistants, Coordinators, and Nurses

Weeks 2-3

- ❑ Electronic Medical Record training including oncology specific workflows
- ❑ IRB reporting
- ❑ Informed consent process
- ❑ Workflows for subject screening, enrollment, and study visits
- ❑ Workflows with ancillary departments (e.g., compliance, imaging, lab, IDS, etc.)

Regulatory Coordinators and Specialists

Weeks 2-3

- ❑ New study submission process including:
  - ❑ IRB submission
  - ❑ Workflows with ancillary departments (e.g., safety committees, budget and contract team, compliance, etc.)
  - ❑ Informed Consent Form preparation
  - ❑ Execution of essential documents
  - ❑ Guidance in working with sponsors and Clinical Research Organizations
- ❑ IRB submissions of amendments, annual reviews, and reportable events

Competency Evaluations

4-6 months into employment

- ❑ Review a subject shadow chart or regulatory binder completed by new staff
- ❑ Assess independence and proficiency of workflows and tasks covered during onboarding

Figure 4: Abbreviated onboarding curriculum checklist

Contact

Maraty T. Gray, BA, CCRP
Medical College of Wisconsin
mtgray@mcw.edu
www.mcw.edu/Cancer-Center.htm
414-805-8244