RED RIVER COLLEGE
OF APPLIED ARTS, SCIENCE AND TECHNOLOGY

CLINICAL RESEARCH DACUM

Facilitated by Gene Semchych and Mike Stuhldreier

Dec-02

Practitioners will participate in clinical research according to Good Clinical Practice (GCP) Guidelines and Regulatory requirements, including but not limited to: I.C.H., P.H.I.A., F.I.P.A., R.E.B., H.I.P.A.A., N.I.H., Tri-council, and other regulatory bodies (eg. Health Canada, F.D.A.)

ORGANIZE A	Set and achieve goals A1	Triage A2	Prioritize A3	Direct self A4	Be flexible A5	Be persistent to achieve goals A6	Be precise/concise A7			
COMMUNICATE B	Educate/Teach B1	Communicate verbally B2	Write B3	Determine audience and adjust as necessary B4	Interpret non-verbal communication B5	Listen actively B6	Use interviewing skills B7	Document in detail B8	Use technical/medical terminology and jargon B9	Ask questions B10
SOLVE PROBLEMS C	Think globally C1	Think creatively C2	Identify problem C3	Assess the problem C4	Identify solutions C5	Implement solutions C6	Evaluate solutions C7	Revise strategies C8	Identify resources C9	
MANAGE PEOPLE D	Assign team roles as per qualifications D1	Coordinate activities D2	Monitor team D3	Manage physicians D4	Manage participants D5	Manage industry D6	Develop rapport D7	Inspire cooperation D8	Work independently D9	Work as part of a team D10
ASSESS E	Interview and assess participants for eligibility E1	Review charts E2	Ask questions E3	Determine feasibility E4	Identify budget issues E5	Think critically E6	Assess site E7	Assess investigator E8	Describe the Drug/Investigational Product Research process E9	Describe and identify a variety of research types E10

MAINTAIN SUBJECT FOCUS F	Recognize own limitations F1	Follow guidelines F2	Maintain participant safety F3	Monitor and assess procedures F4	Document adverse events F5	Follow-up on adverse events F6	Document and report and follow-up serious adverse events F7	Advocate F8		
IMPLEMENT RESEARCH PROCESS G	Review protocol G1	Determine feasibility G2	Prepare protocol for ethics submission G3	Implement/participate study specific training G4	Develop S.O.P.s G5	Follow S.O.P.s G6	Implement/evaluate consent process G7	Recruit and retain participants G8	Prepare dangerous goods for transport G9	Follow protocols in detail G10
	Be audit ready G11	Develop consent form G12	Terminate/close study G13	Be accountable G14	Identify H.R. needs for study completion G15	Account for investigational product G16	Design recruitment strategy G17	Conduct clinical procedures as required G18	Communicate results G19	
USE TECHNOLOGY H	Use fax H1	Use phone H2	Send/receive e-mail H3	Use remote electronic data entry H4	Use computer skills H5	Keep current in office technology H6	Use photocopier H7	Use audio-visual aids H8		
CREATE/MAINTAIN PARTICIPANT STUDY RECORDS I	Develop/design source documents I1	Verify source documents I2	Maintain source documents I3	Record everything I4						
ADMINISTRATE J	Complete regulatory documents J1	Prepare and review/revise budget J2	Review and approve clinical trial agreement J3	Complete site information sheets/forms J4	Maintain personnel records J5	Ensure completion of confidentiality agreement J6	Maintain administrative records J7	Maintain study records J8	Archive records J9	Prepare for institutional review J10
ACT PROFESSIONALLY K	Maintain confidentiality K1	Show empathy K2	Practice diplomacy K3	Promote positive image K4	Show dedication K5	Maintain certification/ registration K6	Learn continuously K7	Focus on customer K8	Practice/exhibit professional ethics K9	Exhibit a professional work ethic K10