NAME OF STUDY

FULL LIST OF POTENTIAL TOPICS – TO BE TARGETED FOR EACH NEW TRIAL

9:00 AM  Introductions and General Roles                Petra Kaufmann, MD
9:15 AM  Grants Management                                      GMB rep
  • Grants Management Specialist
  • Just in Time materials needed (human subjects training, Performance site information, foreign site clearance process)
  • Common site contract issues
9:45 AM  Scientific/Protocol Discussion , Scientific PD
  • Protocol Synopsis
  • Consent template review (sample and data sharing, ct.gov req)
  • Overall study timeline, enrollment completion target
  • Medication supply
  • Data Management – data system, CRF, common CDE, data sharing/archiving
  • Manuals: Operations, Statistical Analysis
  • Study Policies – site termination, publication, close out plan
  • FDA Guidance on Suicidality monitoring - PI confirmation about need for plan
10:45 AM  BREAK
11:00 AM  Administrative Discussion ,Admin PD
  • Human Subject Code 44- resolution plan
  • Clinical Trial terms of award, milestone restrictions
  • Budget review, Annual Progress Reports, Plan for Admin Continuation/ Feasibility
  • Process to request carryover, release milestones, add sites, other reporting
  • Interest in Certificate of Confidentiality Louise Ritz, OCR- GMB Liaison
  • ClinicalTrials.gov requirements
11:30 AM  DSMB Discussion , DSMB Liaison
  • Overview of NINDS DSMB Guidelines,
  • Scheduling, planning, reporting
  • DSMB general membership
  • Table templates available
  • Ancillary study review process
  • Addition of new sites – DSMB consideration
11:45 AM  Recruitment and Retention Planning and Reporting Jamie Roberts, Recruitment Specialist
  • Recruitment plan, accrual goals, enrollment strategies, reporting
  • Study website, NINDS Clinical Trials Spotlight (introduce Shannon Garnett)
  • Recruitment and Reporting of Women and Minorities Crina Frincu, OCR Program Analyst
NOON  Remaining Issues

OPTIONAL AFTERNOON SESSIONS:  ___CDE Planning ___Recruitment Planning