

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