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