Clinical Trial Checklist

The purpose of this checklist is to inform NINDS program staff and grantees of the necessary steps and documentation needed for starting a clinical trial.

Prior to Award:		Yes	No	N/A
1.	The grants management specialist (GMS) should receive from the PI: (Number 1, a-d below)			
1a.	Human subjects training certification for key study personnel. http://cme.cancer.gov/clinicaltrials/learning/humanparticipant-protections.asp	☐	☐	
1b.	List of all participating sites & their Federal-wide assurance numbers (FWAs). If there are foreign sites, PI should notify the GMS, and provide the list of international centers. The GMS will prepare the paperwork required for foreign clearance through Fogarty	☐	☐	☐
1c.	IRB approvals from all participating sites: (a restricted award can be issued if approvals are pending for many sites)	☐	☐	
1d.	Target Enrollment Form: (program staff should contact the PI if the table was not included in the grant application) http://grants.nih.gov/grants/funding/phs398/enrollment.pdf	☐	☐	
2.	PI should respond to summary statement concerns, i.e. scientific & budgetary issues, which should also be sent to the Program Director (PD).	☐	☐	☐
3.	Any unacceptable codes for human subjects or gender/minority inclusion noted by reviewers should be resolved, and appropriate documentation (with PI and Business Official signatures) should be provided to the PD.	☐	☐	☐
4.	Resolve budget issues: PI should submit a revised budget (if necessary) to the GMS, or a justification for expenses if IRG cuts have been recommended.	☐	☐	☐
5.	If applicable, the PI should provide Investigational New Drug/Investigational Device Exemption IND/IDE info (# or letter of exemption) to the GMS.	☐	☐	☐
6.	If applicable, the letter of agreement from drug or device company donating study supplies should be sent to the GMS.	☐	☐	☐
	The Clinical Trials group will review the clinical study and determine the level of safety monitoring needed: http://www.ninds.nih.gov/funding/research/clinical_research/data_safety_monitoring.htm			
7.	Is an independent medical monitor (IMM) needed? *If yes, see questions # 7, a-d.* http://www.ninds.nih.gov/funding/research/clinical_research/data_safety_monitoring.htm#independent	☐	☐	☐
7a.	If yes, has this expense been included in the budget?	☐	☐	☐
7b.	If not, has the revised budget been sent to program staff/GMS?	☐	☐	☐

7c.	Has the CV or biosketch been provided?	☐	☐	☐
7d.	Has the NINDS program official approved the selection of the IMM?	☐	☐	☐
8.	Is a Study Monitoring Committee (SMC) needed? *If yes, see question # 8, a-c.* http://www.ninds.nih.gov/funding/research/clinical_research/data_safety_monitoring.htm#committee	☐	☐	☐
8a.	If yes, have costs of operating the committee, preparing safety reports, and compensation for the SMC members been included in the budget? (If not, the revised budget should be sent to program staff/GMS.)	☐	☐	☐
8b.	Have the CV's or biosketches of the proposed SMC members been provided?	☐	☐	☐
8c.	Has the NINDS program official approved the nominations of the SMC members?	☐	☐	☐
9.	Is a Data & Safety Monitoring Board (DSMB) needed? *If yes, see question # 9, a-c.* http://www.ninds.nih.gov/funding/research/clinical_research/data_safety_monitoring.htm#board	☐	☐	☐
9a.	Has the PI been notified and information provided describing the PI's responsibilities in working with the DSMB?	☐	☐	☐
9b.	Have costs of preparing DSMB reports and travel for key study personnel to attend DSMB meetings been included in the budget? (If they have not been included, the revised budget should be sent to program staff/GMS.	☐	☐	☐
9c.	Will the assistance of a Clinical Trials (CT) group member be needed to run the DSMB?	☐	☐	☐
10.	If this project will be converted to a cooperative agreement, notify the GMS, and prepare a memo & terms of award for conversion to a U01 mechanism (CT group/Frances Yee have a U01 conversion template). http://www.ninds.nih.gov/funding/research/clinical_research/conversion.htm	☐	☐	☐
11.	Have any investigator conflicts of interest been reported to the NINDS Grants Management Officer (GMO) as required by NIH policy? http://grants2.nih.gov/grants/policy/emprograms/overview/ep-coi.htm	☐	☐	☐
12.	For Phase III Clinical Trials: (See # 12, a-c)			
12a.	Has the PI included plans for gender/minority subanalyses? http://grants.nih.gov/grants/funding/phs398/instructions2/p2_inclusion_women_minorities.htm	☐	☐	☐
12b.	Has an updated version of the MOP/study protocol been submitted to the CT Group?	☐	☐	☐
12c.	Has the PI included futility analyses for the trial? http://www.ninds.nih.gov/funding/research/clinical_research/Terms_II.htm	☐	☐	☐

	PD or CT group will notify the GMS of appropriate terms of award for clinical trials that should be attached to the Notice of Grant Award			
Prior to Study Enrollment/Post-award:				
1.	Have the study protocol/MOP (including case report forms) and informed consent form been finalized?	☐	☐	☐
2.	Has IRB approval been obtained from all the clinical sites? If applicable, has the GCRC/CRC approval been obtained?	☐	☐	☐
3.	Has NINDS or the IMM/SMC/DSMB reviewed and approved the study protocol/MOP?	☐	☐	☐
4.	Has the PI provided a recruitment plan (i.e., verification of patient eligibility per site) and timeline for the trial? http://www.ninds.nih.gov/funding/research/clinical_research/quality_assurance_guidelines.htm Definition of recruitment plan: http://www.ninds.nih.gov/funding/research/clinical_research/glossary.htm	☐	☐	☐
4a.	If yes, have the recruitment plan and study timeline been reviewed and deemed appropriate by the CT Group?	☐	☐	☐
5.	Has the trial met the International Committee of Medical Journal Editors (ICMJE) registration requirements by registering the protocol at clinicaltrials.gov? Investigators should go to the NINDS clinical research website for information on this requirement (http://www.ninds.nih.gov/funding/research/clinical_research/clinicaltrials_required_registration.htm)	☐	☐	☐
6.	Have study drug/device issues been resolved (e.g. adequate supply, distribution, etc.)?	☐	☐	☐
7.	Have FDA issues (if any) been resolved?	☐	☐	☐
8.	For multi-site clinical trials, has the investigator training meeting taken place?	☐	☐	☐
9.	If the trial is multi-site, presents high risk to participants, or if there are other major concerns, has KAI conducted a site visit? http://www.ninds.nih.gov/funding/research/clinical_research/assistance.htm	☐	☐	☐
10.	Have the DSMB and NINDS approved the initiation of the study?	☐	☐	☐