

# DATA COORDINATING CENTER (DCC) CHECKLIST

**\*\* This checklist can assist NHLBI staff and others when writing review criteria for Funding Opportunity Announcements for DCCs, when evaluating potential DCCs during pre- or post-award site visits and as a tool to begin discussions among all stakeholders when launching a large clinical trial program.**

CLINICAL STUDY/TRIAL OPERATIONS		COMPLETE
<b>A. Program Initiation for Success</b>		
1	Identify DCC staff and their roles within the program.	<input type="checkbox"/>
2	Develop a plan that would facilitate frequent communications and interactions with all stakeholders upon commencement of a study to facilitate setting realistic goals and sharing study management ideas and strategies.	<input type="checkbox"/>
3	Identify strategies to motivate, reward and recognize all stakeholders.	<input type="checkbox"/>
4	Identify the space, staff and equipment to be used for the project and ensure that they are suitable for the project's activities.	<input type="checkbox"/>
5	Identify staff or committed collaborators with subject matter, clinical trial methodology and statistical analysis expertise as needed to conduct the study.	<input type="checkbox"/>
<b>B. Communication</b>		
1	Develop a plan that highlights lines of communication and authority and establishes accessible and secure methods of communication (e.g., conference calls, SharePoint, websites, email, paper records, newsletters) among collective project staff.	<input type="checkbox"/>
2	Develop a plan to ensure that a public website remains current and includes an adequate description of the study or studies (e.g., protocol, manual of operations, contact information), as appropriate.	<input type="checkbox"/>
3	Determine how internal/administrative websites with password access for different bodies (e.g. Steering Committee, Data and Safety Monitoring Board, DCC staff) will be used for communication purposes and maintained.	<input type="checkbox"/>
4	Have a plan for making project plan documents accessible to appropriate study staff.	<input type="checkbox"/>
<b>C. Administrative Coordination</b>		
1	Identify fixed and variable costs at the start of the study, strategies for constraining or reducing costs and potential areas where there may be insufficient funds.	<input type="checkbox"/>
2	Establish a plan for monitoring costs on a scheduled basis.	<input type="checkbox"/>
3	Determine appropriate payments for the study.	<input type="checkbox"/>
4	Outline a plan to administer payments to sites and other units as appropriate that will foster compliance with study objectives.	<input type="checkbox"/>
5	Facilitate and arrange logistics for in-person meetings and conference calls and identify staff responsible for meeting coordination (e.g., planning, note taking, and distribution of minutes and reports for meetings).	<input type="checkbox"/>
<b>D. Study Planning and Management</b>		
1	Provide expert assistance in protocol design and analysis plans, and feasibility assessments.	<input type="checkbox"/>
2	Outline recruitment plans for identifying, screening and enrolling subjects.	<input type="checkbox"/>

3	Have a plan to assess protocol feasibility and demonstrate that recruitment goals are realistic using available data on the target population from registries or prior studies to the extent possible.	<input type="checkbox"/>
4	Establish processes for tracking ancillary studies and changes/approvals by the Protocol Review Committee, Data and Safety Monitoring Board (DSMB) and Institutional Review Board (IRB).	<input type="checkbox"/>
5	Establish procedures for negotiation of third party agreements.	<input type="checkbox"/>
<b>E. Publication and Presentation Development</b>		
1	Establish, document, and follow processes for manuscripts and presentations tracking, preparation, review, communication and submission (including interaction with pharmaceutical and device collaborators as appropriate).	<input type="checkbox"/>
2	Provide leadership in coordination of and analysis for publications and presentations including establishing timelines for preparation and submission of primary and secondary manuscripts.	<input type="checkbox"/>
<b>DATA MANAGEMENT</b>		<b>COMPLETE</b>
<b>A. Global and Data Security</b>		
1	<p>Develop and document a data security plan with appropriate security processes and procedures (regardless of data capture approach).</p> <ul style="list-style-type: none"> <li>a. Develop a plan using the National Institute for Standards and Technology Special Publication 800-18 guidance on appropriate topic areas and include a plan of action and milestones that would address security plan vulnerabilities.</li> <li>b. Develop a plan for disaster recovery that meets project needs for availability, confidentiality, and data/application location.</li> <li>c. Identify available security expertise to work on the project as needed.</li> <li>d. Develop a plan and assign responsibilities for Information Technology (IT) security at each site or core lab, if data are to be uploaded.</li> </ul>	<input type="checkbox"/>
<b>B. Data Systems</b>		
1	Utilize data dictionaries (meta data) that describe the formatting and descriptive contents of uploaded data for all systems (including clinical site systems) and provide appropriate expertise.	<input type="checkbox"/>
2	Ensure data management systems comply with privacy and accessibility regulatory requirements and/or Public Laws (e.g. Section 508 amendment to the Rehabilitation Act, Privacy Impact Assessment, Title 21 CFR Part II, Privacy Act, Health Insurance and Portability and Accountability Act (HIPAA etc.).	<input type="checkbox"/>
3	Test, validate, and optimize data capture systems to provide immediate feedback on user errors logic errors, and out-of-range data, including across-form consistency.	<input type="checkbox"/>
4	Develop a system to track biospecimens, when appropriate, and maintain the link between the biospecimens and the study data incorporating appropriate QC samples.	<input type="checkbox"/>
<b>C. Randomization</b>		
1	Have the ability to support web-based allocation (when needed), touch-tone allocation, and email notifications.	<input type="checkbox"/>
2	Limit access to randomization sequences/algorithms, code, and validation programs to as few individuals as practical.	<input type="checkbox"/>

3	Provide flexibility in the randomization system to allow for permuted block or other adaptive randomization procedures.	<input type="checkbox"/>
4	Check eligibility electronically prior to permitting randomization, where possible.	<input type="checkbox"/>
<b>D. Reporting</b>		
1	Provide timely feedback to sites including real-time reporting on items like forms completion, missed visits, data entry issues and point-in-time reporting on items like performance reports and comparisons among sites.	<input type="checkbox"/>
2	Provide reports for clinical sites on items like upcoming visits and unresolved delinquencies.	<input type="checkbox"/>
3	Collaborate with clinicians and committees to design and develop appropriate reports and establish reporting frequency, including reporting by site, when appropriate.	<input type="checkbox"/>
4	Have a plan for ensuring accurate and reliable analyses.	<input type="checkbox"/>
5	Use graphics for reports and summaries provided to the DSMB, Steering Committee, and others to ensure that large amounts of data can be understood and assessed in an efficient and accurate manner.	<input type="checkbox"/>
<b>E. Analysis</b>		
1	Address primary and secondary analyses in the analysis plan to the extent possible.	<input type="checkbox"/>
2	<p>Establish a mechanism to process requests for secondary/ancillary analyses not addressed in the analysis plan.</p> <ul style="list-style-type: none"> <li>a. Require that requests for analyses contain a scientific question/hypothesis, and lists of variables, time points and proposed comparisons.</li> <li>b. Establish a plan to set priorities for analyses by a group that includes DCC representation and takes into account the total Full Time Equivalents of statistical and statistical programming effort dedicated to these tasks.</li> </ul>	<input type="checkbox"/>
<b>QUALITY CONTROL/QUALITY ASSURANCE</b>		<b>COMPLETE</b>
<b>A. Quality Assurance (QA)</b>		
1	Identify lead QA staff.	<input type="checkbox"/>
2	Create a quality management plan at the start of the program, which focuses on key variables and potential vulnerable areas (risk based approach).	<input type="checkbox"/>
3	Have written programs for training study monitoring staff.	<input type="checkbox"/>
4	Provide study staff (DCC and clinical sites) with pertinent ongoing training including documentation of proficiency (protocol certification, Human Subjects Training, Ethics Training, IT Security, data capture etc.) and establish timelines/triggers for retraining at appropriate intervals.	<input type="checkbox"/>
5	Have well documented site monitoring plans. (As appropriate, use statistical programs, in-house data monitoring and conference calls. Consider alternative methods to on-site monitoring such as webinars, electronic review of forms).	<input type="checkbox"/>
6	Establish assessment tools, with study leadership, to evaluate the DCC and the clinical sites.	<input type="checkbox"/>
7	Identify metrics for clinic evaluations (e.g. protocol deviations/violations, late forms, recruitment rates, missing data, data entry accuracy etc.).	<input type="checkbox"/>

8	Provide plans to validate statistical programming which will ensure reproducibility and accuracy of results.	<input type="checkbox"/>
9	Develop and implement a biospecimen QA/QC program for central laboratories and/or biorepositories.	<input type="checkbox"/>
<b>B. Quality Control (QC)</b>		
1	Identify lead QC staff.	<input type="checkbox"/>
2	Maintain QC procedures and schedules.	<input type="checkbox"/>
3	Provide QC reports in a timely manner.	<input type="checkbox"/>
4	Outline a plan for testing key protocol processes and procedures (simulating study visits, forms completion with sham data etc.).	<input type="checkbox"/>
5	Have processes documented for establishing and reviewing DCC Standard Operating Procedures, checklists and tools.	<input type="checkbox"/>
6	Address and document responses and corrections to identified problems.	<input type="checkbox"/>
7	Document and follow procedures for identifying and correcting possible data errors.	<input type="checkbox"/>
8	Document and follow procedures for quantifying measurement errors in key variables.	<input type="checkbox"/>
9	Document and follow procedures for handling protocol deviations/violations. Evaluate the QC program regularly, making adjustments as needed based on feedback from the clinical sites and monitors.	<input type="checkbox"/>
10	Introduce statistical monitoring to examine aggregate data and identify potential site variations.	<input type="checkbox"/>
11	Conduct process reviews during the study to ensure that the study is implemented appropriately at study sites and procedures at DCC are robust.	<input type="checkbox"/>
<b>HUMAN SUBJECTS PROTECTION/REGULATORY AFFAIRS</b>		<b>COMPLETE</b>
<b>A. Human Subject Protections</b>		
1	Have a system is in place to track the human subjects' protection training of appropriate study staff.	<input type="checkbox"/>
2	Collaborate with investigators to create and distribute the consent document template(s).	<input type="checkbox"/>
3	Ensure that the IRB-approved informed consent forms at clinical sites have required elements and are factually correct (including back-translation of documents written in languages other than English).	<input type="checkbox"/>
4	Review consent documents for signatures and use of the IRB date stamped form during site visits.	<input type="checkbox"/>
5	Develop a well-defined reporting process for adverse events (AE) and unanticipated problems (as defined by OHRP) that is defined precisely and is in compliance with local IRB requirements, 21 CFR 312.32 for Investigational New Drugs (IND), 21 CFR 812.150 for Investigational Device Exemptions (IDE), and International Conference on	<input type="checkbox"/>

	Harmonisation Regulations E2A, as applicable. Implement a plan to report safety analyses and report AEs to the Data and Safety Monitoring Board (DSMB) in a format that highlights trends or signals.	
6	Support human subjects' data and biospecimen repository and regulatory activities, as appropriate. For programs collecting, processing, assaying, storing or distributing biospecimens, ensure that systems are in place to maintain subject confidentiality and to track subject informed consent.	<input type="checkbox"/>
<b>B. FDA Related Regulatory Requirements</b>		
1	Identify and make available expert regulatory staff involved in IND/IDE management for assistance and advice on IND/IDE regulations and preparation for inspections.	<input type="checkbox"/>
2	Establish a process for preparing and managing IND/IDE reports and other requirements.	<input type="checkbox"/>
<b>C. OHRP Related Regulatory</b>		
1	Verify center(s) Federal-wide Assurance status when the DCC is responsible for site selection.	<input type="checkbox"/>
2	As appropriate, develop an online regulatory documents library that accepts site submissions and produces reports and email alerts about outstanding or expired documents, specifically IRB annual approvals.	<input type="checkbox"/>