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| Protocol Information | | |
| **Date**: | | |
| **Name of PI or Director of DCC** (If Director is other than Principal Investigator)**:** | | |
| **IRB Number:**  **Project Title**: | | |
| **Overview:** This form provides the IRB with information about how the PI will provide oversight for activities at sites external to CHOP as part of a multi-center research studies. A **data-coordinating center (DCC)** supports and coordinates study activities when a clinical study involves more than a single site. The IRB reviews the operations and procedures of the DCC to ensure that the study will be conducted in accordance with Good Clinical Practice Guidelines and approves its procedures. Once the IRB has approved the DCC’s procedures, its activities related to the other sites are reported at the time of continuing review (e.g., the IRB does not require approval for addition of new sites.)  *See IRB website*: https://intranet.research.chop.edu/display/cmtirb/Multicenter+Oversight | | |
| **Components of Study Oversight**  The following trial oversight responsibilities make up the components of a DCC and may be divided between multiple organizations. Complete those sections of this form that pertain to the activities performed by the CHOP component of the DCC. It may be advisable to identify the other organization(s) responsible for the other activities. | | |
| (1) Document Preparation and Distribution  (2) Site Management and Oversight,  (3) Test Article and Materials Distribution, | | (4) Data Management and Statistical Analysis, and (5) Data and Safety Monitoring (6) Central Laboratories or Repository for routine or specialized tests |
| **eIRB** **Related Sections** includeSection 1.03 (1.0) and all of Section 1.04. Attach this form to Section 1.04 (3.0) | | |
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| Data Coordinating Center Organization and Funding | | |
| Study Leadership | | |
| CHOP Investigator is PI  Pharmaceutical Sponsor: | | Non-CHOP Investigator (name and institution): |
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| DCC Organization | | |
| Briefly describe the study organization including the role of the DCC: | | |
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| **DCC Responsibilities** (check all services that apply to the CHOP component of the DCC) | | |
| Document Preparation and Distribution  Site Management and Oversight  Test Article and Materials Distribution | Data Management and Statistical Analysis  Data and Safety Monitoring  Central Clinical, Research Laboratory or Repository | |

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| **Complete only those sections that relate to services that will be supplied by the CHOP component of the DCC.** | | |
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| Document Preparation and Distribution | | |
| 1) **Check all items for which the DCC will have oversight and responsibility**.  Describe (a) the systems for writing, maintaining and amending the protocols, informed consent documents, case report forms and other trial materials that are developed by the DCC and distributed to each collaborating institution. (b) Describe the process for issuing amendments and assuring that the modifications are delivered to institutions in a timely way and are approved by the local IRB. | | |
| Protocol  Informed Consent Template  Advertisement | | Study Manuals  Subject study materials (e.g., diary cards)  Case report forms |
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| Site Management and Oversight | | |
| 2) **Site Management and Oversight** activities include: (a) site qualification and (b) selection and (c) monitoring of site performance during the conduct of a study. The IRB will approve the procedures used by the DCC and expects that the DCC will provide an updated list of participating sites at least annually. | | |
| YES  NO | (a) Will the DCC be responsible or participate in the selection of clinical sites? If “YES”, describe the site selection and qualifying process and attach or reference any SOPs that will be used (if any) applicable to the qualification process. If “NO”, go to the next Section. | |
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| **Site IRB Approval** | (b) Describe the procedures by which the DCC will assure that each site receives IRB approval for the approved study protocol prior to permitting the site to enroll subjects and the process used to assure that each site obtains the informed consent of each subject in compliance with federal regulations. | |
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| **Sites, FWA#s and IRB Authorization Agreements** | (c) Include a listing of all sites and their corresponding FWA#s in **eIRB Section 1.05 (2.0).** If CHOP is the IRB of record for any of the study sites, a copy of the signed executed IRB Authorization Agreement must be attached to **eIRB Section 1.05 (3.0)**. If new sites are added during the course of the approval period, the site listing and IRB Agreements must be updated via an amendment at least annually. | |
| **YES  NO** | (d) Will the DCC be responsible for monitoring sites’ performance of study during the study? If “YES”, describe all processes and systems (including electronic) that will be used as part of site monitoring activities. Attach any SOPs applicable to on-site monitoring. | |
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| By checking the box at left, the PI confirms that the DCC will maintain a copy of each IRB’s initial and subsequent approval letters\* in their files, including for all amendments and continuing reviews. In addition, the PI confirms that they an updated listing of study sites and IRB authorization agreements will be maintained in eIRB, Section 1.05 (2.0) and (3.0). **\*** These letters do not need to be forwarded to the CHOP IRB but must be available upon request. | | |

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| Test Articles and Materials Distribution | |
| 3) Describe the systems in place to control the distribution and accountability of test articles, investigational products and the systems that will assure that the test article is not shipped until the site receives IRB approval. | |
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| YES  NO | (a) Does the test articles require an IND or IDE? If “YES”, describe who holds the IND or IDE and the process for assuring compliance with all applicable FDA requirements. |
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| Data Management and Statistical Analysis | |
| 4) Complete the applicable sections below related to the services to be provided by the DCC. | |
| YES  NO | (a) Will the DCC be responsible for randomization services? If “YES”, describe the randomization system and protections from unblinding.  Describe the process for unblinding a subject in the event of an emergency (if any); if “NO”, go to 4(b) |
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| YES  NO | (b) Will the DCC be responsible statistical analysis? If “YES”, describe the systems in place for performing all required statistical analyses, the operations of the statistical center and the quality control procedures that will assure the fidelity of the results. |
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| YES  NO | (c) Is the DCC responsible for data management? If “YES”, describe the data management systems that are in place that assure (a) the fidelity of the data and (b) that maintain the privacy and confidentiality of private information for each protocol coordinated by the DCC. Also complete section 4(d) below. |
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| YES  NO | (d) Describe the process by which data will be transmitted to the DCC and transferred by the DCC to any other organization that will be responsible for analysis of all or part of the data. |
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| Maintenance of Confidentiality of Data | |
| YES  NO | (5) Will the data transmitted to the DCC contain any of the 18 elements defined by HIPAA as identifiers? **Note**: The DCC is engaged in human subjects research if it receives identifiable private health information from the sites.  If “YES”, describe the procedures and systems in place to minimize the risk of disclosure of PHI and to protect the confidentiality of subjects. |
| **Directions for Completing this Section**  For studies where CHOP is both a site and the DCC, completion of the remainder of this section pertains only to the activities of the DCC and the activities as a site will be completed in eIRB Sections 9.01 – 9.04. | |
| (a) Describe plan for protecting PHI (individually identifiable health information) from disclosure. | |
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| (b) Describe plan to destroy identifiers at the earliest opportunity consistent with the goals of the study, unless there is a clinical justification for retaining them. | |
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| (c) Describe the reasons why the DCC needs to receive PHI as part of this research. | |
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| (d) If PHI must be forwarded to another investigator or laboratory (e.g., central reading of video EEG), provide a justification and certify that the informed consent document includes this discolosure of PHI to prospective participants. | |
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| Data and Safety Monitoring Plan | |
| 6) Describe the overall Data Safety and Monitoring (DSM) plan and safety systems and provide evidence to justify that the DSM plan is appropriate, given the nature of the research involved. | |
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| YES  NO | (a) Will the DCC be responsible for receiving SAE reports?  If “YES”, describe the system and procedures for reviewing the reports in a timely manner, for reporting to the responsible regulatory authority(s) and for distributing those reports as required, to the study sites. |
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| YES  NO | (b) If there is a Data Safety Monitoring Board (DSMB), will the DCC be responsible for coordinating their activities? If “YES”, describe the plans for preparing reports for the DSMB so as to maintain blinding of the trial statistician and for distributing the summary information in a timely fashion to the participating sites. |
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| YES  NO | (c) If there is a DSMB, provide membership contact information for the members, including the members’ disciplines. (attach separate sheet if necessary) |
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| Central Laboratory | |
| 1) Briefly describe the role of the DCC as a central laboratory for routine clinical or research tests (e.g. PK or genetic analysis) or as a repository for future research. Refer to applicable sections of the protocol as appropriate. | |
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