**Application to Conduct a Multi-Center Clinical Trial   
under a University-based IND or IDE**

Initial Application  Revised Application

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| 1. **GENERAL INFORMATION** |
| **Date of Submission: December 4, 2020** |
| 1. **Sponsor’s Name, Address and Contact Information (e-mail and phone number):** |
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| 1. **Clinical Trial Title (as listed on the front cover of the clinical protocol):** |
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| 1. **Source(s) of Funding:** |
| **INSTRUCTIONS FOR FIELD 3:** Provide all sources of monetary funding, including any entity that will provide investigational product. If grant funded, provide the grant number. |
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| 1. **Number of Anticipated Sites** that will conduct the trial under the University-based Sponsor-investigator held IND/IDE**:** |
| **NOTE:** Addition of any sites after ECS-HSR approval is received requires the submission of a revised application to IIS. |
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| 1. **Clinical Trial Site Principal Investigators (PIs) Names and Addresses where administration of the investigational product will occur:** |
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| 1. **Justification for Site(s) unable to submit their own IND/IDE Application to FDA** |
| **INSTRUCTIONS FOR FIELD 6:** Provide a detailed rationale for each external site that is unable to submit their own IND/IDE application. All options must be explored and exhausted before consideration will be given to allow the trial to be conducted at an external site under a University-based IND/IDE application. |
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| 1. **SPONSOR RESPONSIBILITIES** |
| 1. **Provide the Sponsor’s procedures and requirements for selecting investigators qualified by training and experience as appropriate experts to investigate the drug/device. [21 CFR Parts 312.53 & 812.43]**   **NOTE:** It is strongly recommended that the Sponsor perform a search of the Inspection Classification Database to confirm a potential investigator has never been issued an Official Action Indicated (OAI) letter. <https://www.accessdata.fda.gov/scripts/inspsearch/> |
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| 1. **Provide the sponsors procedures for collection, review and maintenance of essential documents. [21 CFR Parts 312.53 & 812.43]** |
| **NOTE:** Essential documents include: Form FDA 1572 or Statement of Investigator, investigator CVs, medical licenses, completed financial disclosure forms, clinical laboratory ranges, clinical laboratory certificates, delegation of authority log, protocol and IB signature pages, IRB approval and documentation of protocol training. |
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| 1. **Provide the Sponsor’s procedure for disseminating the Investigator’s Brochure and Clinical Protocol (drugs) or Investigational Plan and Report of Prior Investigations (devices) to the external sites. [21 CFR Parts 312.55 & 812.45]** |
| **INSTRUCTIONS FOR FIELD 9:** Describe when these documents will be provided to external sites and how the Sponsor will ensure that the documents have been received and reviewed by the external site Investigators. |
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| 1. **Provide the Sponsor’s procedures for distribution and control of the investigational product. [21 CFR Parts 312.53 & 812.43]** |
| **INSTRUCTIONS FOR FIELD 10:** Describe how the Sponsor will ensure that the investigational product is only shipped to investigators participating in the investigation. To include how accountability will be managed at the external site(s). |
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| 1. **Provide the Sponsor’s procedures for informing site investigators of new observations and/or reports in a timely manner. [21 CFR Parts 312.55 & 812.45]** |
| **INSTRUCTIONS FOR FIELD 11:** Describe how the Sponsor will communicate with external sites about new observations and reports particularly with respect to adverse effects and safe use (i.e., newly identified risks). To include how often and in what format information will be provided. |
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| 1. **Provide the Sponsor’s procedures for review of ongoing investigations at the external site and investigator compliance with the investigator agreement and protocol procedures. [21 CFR Parts 312.56 & 812.46]** |
| **INSTRUCTIONS FOR FIELD 12:** Describe how the Sponsor will handle an investigator not complying with the signed investigator agreement, when he/she will review and evaluate the evidence relating to the safety and effectiveness of the drug or device as it is reported by the external site investigators, and the plan should the drug or device be found to present an unreasonable and significant risk to subjects. |
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| 1. **Provide the Sponsor’s procedure to ensure adequate record keeping and record retention at the external sites. [21 CFR Parts 312.57 & 812.140]** |
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| 1. **INSTITUTIONAL REVIEW BOARD OVERSIGHT** |
| 1. **Will individual IRBs or a single IRB be used? (If a single IRB will be used, skip to #18)** |
| **NOTE:** Federal funding requires multi-center trials use a single IRB. Although use of a single IRB is not required for non-federally funded trials, it is highly recommended that the single IRB mechanism be explored to streamline the regulatory approval and reporting processes among participating sites. |
| Individual IRB  Single IRB |
| 1. **For individual IRBs, describe how the Sponsor will ensure the clinical protocol is updated appropriately based on comments received from participating local IRB review.** |
| **INSTRUCTIONS FOR FIELD 15:** The description should include which sections of the protocol and ICF template cannot be modified without first obtaining Sponsor approval. Discuss when the clinical protocol and ICF template changes will be submitted to the University of Pittsburgh HRPO and distributed to approved participating sites. |
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| 1. **For individual IRBs, how will the Sponsor ensure external sites obtain timely IRB approval of protocol amendments and continuing review?** |
| **INSTRUCTIONS FOR FIELD 16:** Discuss what actions will be taken by the Sponsor should a site not obtain IRB approval within required timeframes. |
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| 1. **For individual IRBs, how the Sponsor will ensure external sites are meeting IRB requirements for reporting serious adverse events, non-compliance, or other unanticipated events involving risk to subjects.** |
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| 1. **EXTERNAL SITE ACTIVATION** |
| 1. **Describe the resources needed to conduct the trial and the process for determining that a potential site has the appropriate resources and facilities to properly conduct the trial.** |
| **INSTRUCTIONS FOR FIELD 18:** Examples include: a viable patient population, designated research personnel, list of competing trials, designated treatment facility, laboratory equipment, freezers, etc. |
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| 1. **Provide Sponsor confirmation by signing below that the Sponsor will be present either an in-person or virtually for the Site Initiation Visit (SIV).** |
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| 1. **Describe the content and format of the SIV.** |
| **INSTRUCTIONS FOR FIELD 20:** Provide the complete list of information presented during the SIV and by whom. Describe the format for the visit, required attendees, and how the information will be provided to anyone who is unable to attend. List any documents that will be collected from the external site during the SIV. Include a description of the sponsor’s involvement in the SIV. |
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| 1. **Describe the required elements that must be satisfied before an external site will be activated for enrollment.** (Examples include:Collection and acceptance of all essential documents, proof of Good Clinical Practice and Human Subjects Protections training, completed SIV, and an executed contract) |
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| 1. **Under what circumstances will a site’s ability to enroll be suspended or terminated?** |
| **INSTRUCTIONS FOR FIELD 22:** Include the actions that would need to be taken at the participating site to re-instate the ability to accrue. |
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| 1. **DETAILED MONITORING PLAN** |
| 1. **Who will be responsible for monitoring the conduct and progress of the clinical trial at external sites?** |
| University of Pittsburgh Center for Clinical Trials and Data Coordination (CCDC)  Contract Research Organization (provide the name of the CRO and attach the Scope of Work that will be included in the contract):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Other (please explain and provide the Scope of Work): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| 1. **What specific qualifications will the Sponsor or CRO require for the selection of a qualified monitor (qualified by training and experience)?** |
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| 1. **Estimated number of hours per month that will be spent on monitoring activities across all sites (to include study start up and ongoing monitoring of the clinical trial activities)?** |
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| 1. **How many monitors will be assigned to the external sites?** |
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| 1. **If the sponsor or monitor is requesting permission to periodically perform remote monitoring, please describe the process for how source documents containing confidential information will be transmitted for review.** |
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| 1. **At what intervals will monitoring occur?** |
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| 1. **Under which circumstances will the frequency of monitoring visits be increased or decreased?** |
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| 1. **What format of Case Report Forms (CRFs) will be used?** |
| Paper-based CRFs  Electronic CRFs\*  \*Attach confirmation that the Electronic Data Capture system is 21 CRF Part 11 compliant. |
| 1. **What percentage of informed consents will be monitored?** |
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| 1. **What percentage of subject records will be monitored for eligibility?** |
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| 1. **What percentage of subject records will be monitored for protocol compliance?** |
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| 1. **What specific study documentation, including essential documents, will be monitored?** |
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| 1. **How will queries for missing data and data discrepancies be handled with the external site?** |
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| 1. **Provide Sponsor confirmation, by signing below, that all monitoring visit reports will be provided to the external sites within 2-4 weeks of the conclusion of the visit. Participating PI and Sponsor signature will be obtained, and the signed report provided to IIS within 6-8 weeks of the conclusion of the visit.** |
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| 1. **In the event a PI response is required to respond to a monitoring visit report, how long will he/she be given to respond?** |
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| 1. **Provide the Sponsor’s plan for PIs that do not respond to a monitoring visit report within the required time.** |
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| 1. **Provide the Sponsor’s plan for reviewing external monitoring visit reports and the PI response.** |
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| 1. **REQUIRED ATTACHMENTS** |
| **Copy of the Investigator Brochure or Device Description and Report of Prior Investigations.** |
| **Copies of the Case Report Forms that will be utilized across all sites, and if electronic CRFs will be used a certification that the electronic data capture system is 21 CFR Part 11 compliant.** |
| **If biologic specimens (blood, serum, tissue, saliva, stool, etc.) will be collected for correlative or exploratory research purposes, the collection, packaging, and shipping instructions.** |
| **If a CRO will be utilized, the Scope of Work that will be included in the contract.** |
| **Additional relevant attachments:** |

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Printed Name of Person Completing the Application Date

**I certify that the information provided within this application is true and accurate.**

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Printed Name of Sponsor

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Sponsor Signature Date