SUO-CTC PROJECT REVIEW, APPROVAL, AND INITIATION PROCESS

Project Review and Approval

1. Research concept/protocol presented to SUO-CTC member by Industry sponsor:
   - SUO-CTC member refers contact or Industry sponsor to the SUO-CTC Director of Research Services in the central office

2. CTC/Sponsor operational discussion:
   - SUO-CTC Director of Research Services secures CDA between Sponsor and SUO-CTC
   - SUO-CTC Director of Research Services facilitates discussion with sponsor’s team to provide a general overview:
     - Protocol synopsis including patient population, site requirements and accrual targets
     - Scope of services available from CTC
     - Initial assessment of services required for project
     - Related fees associated with services
   - SUO-CTC and sponsor determine feasibility of collaboration and establish timeline for next steps

3. Coordination of Project Review by SUO-CTC office:
   - Determines organ site committee interest to pursue concept/project
   - Coordinates receipt of documents for review from sponsor
     - Presentation materials (as available):
       - Protocol synopsis or concept sheet
       - Protocol draft
       - Informed consent
       - Draft budget
       - Other supporting documents
   - Disseminates materials to the organ site committee members
   - Schedules review via appropriate meeting venue; live or conference call, with or without sponsor as needed

4. Organ site sub-committee review:
   - Committee review to consider:
     - Clinical merits of the trial
     - Capabilities of member sites to conduct study
     - Capabilities of member sites to accrue patients
     - Current or planned protocols that may compete with efficient patient recruitment
   - Provide feedback and make recommendations, as appropriate, regarding:
     - Project/Protocol scientific merit
     - Project feasibility for success through SUO-CTC
     - Collaboration with the sponsor
   - Approve project, as appropriate:
     - Secure approval from the SUO-CTC Board of Directors
     - Secure approval from the SUO Executive Committee
   - Expenses incurred for the review are the responsibility of the sponsor, as appropriate and necessary

Project Initiation:

5. Service agreement finalized:
   - SUO-CTC office develops a draft of proposed services and gains agreement from the sponsor
   - SUO-CTC office reviews services with appropriate organ site committee members
   - SUO-CTC office and sponsor finalize scope of services and execute contract

6. Site Identification:
   - Organ Site Committee recommends sites for participation or a full membership ‘call for sites’ is initiated via secure website
   - Member complies with CDA to view protocol overview and related study materials
   - Feasibility Questionnaires completed from interested investigators
   - Feasibility Questionnaires data compiled and provided to sponsor

7. Site recommendations:
   - SUO-CTC office reviews site data and feasibility questionnaire data with sponsor
   - Full list of interested sites with contact information provided to the sponsor
   - Final selection and feasibility of the sites remains at the discretion of the sponsor

For more information contact:
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