

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
 - Sponsor biography
- 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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