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SUO-CTC's Seven Steps to Streamlined Site Selection

1. Research concept/protocol presented to SUO-CTC member by Industry sponsor

At the discretion of the SUO-CTC member, the Industry sponsor is directed to the SUO-CTC Director of Research Services in the central office.

2. CTC/Sponsor operational discussion

- SUO-CTC Director of Research Services facilitates discussion with sponsor's team to provide a general overview:
 - Protocol/project review process
 - 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

- CTC office assesses organ site committee interest to pursue concept/project
- CTC office secures CDA between Sponsor and SUO-CTC
- CTC office coordinates receipt of documents for review from sponsor
 - Presentation materials (concept sheet, protocol draft, informed consent etc)
 - Sponsor biography
 - Other supporting documents including proposed per patient and site budgets
- CTC office disseminates documentation to the organ site committee members
- Schedules review via appropriate meeting venue (live or conference call and with or without sponsor as needed)

4. Organ site sub-committee review

- Committee will review protocol and supporting documents considering
 - 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 regarding
 - Project/Protocol
 - Collaboration with the sponsor
- Recommendation for approval to the SUO-CTC Board of Directors as appropriate
- Expenses incurred for the review are the responsibility of the sponsor, as appropriate and necessary

IF ACCEPTED

5. Sponsorship agreement finalized

- SUO-CTC office develops a draft of proposed Services and gains agreement from the sponsor
- Proposed Services Agreement is reviewed for consensus with appropriate CTC member(s)
- SUO-CTC office discusses final scope of services and fees with sponsor
- SUO-CTC finalizes agreement/contract for signature

6. Call for sites via SUO-CTC secure website – call remains open 7-10 business days

- Members are notified of call for sites and directed to secure website
- Member complies with CDA to view protocol overview
- Website updated with feasibility requirements including: protocol summary, investigational agent, treatment regimen, patient selection criteria, patient evaluation criteria, duration of study, budget, sponsor etc.
- Members respond to SUO-CTC office by submitting a letter of interest

7. Site recommendations provided

- SUO-CTC office will confirm eligibility and short-list the interested sites for the sponsor
- Final list, of interested sites and contact information for each, is forwarded to the sponsor within three weeks of the call date
- Final selection and feasibility of the sites remains at the discretion of the sponsor