|  |  |  |
| --- | --- | --- |
| **ITCC Site Feasibility Checklist** | | |
| **Ethics, Legal  and Regulatory Capabilities** | * Does the organisation participate in the single ethical review process and accept HREC approval from others? |  |
| * Is there a Research Governance Office (RGO) to process a submission for local approval and do they have capacity to work through the required steps (legal, contractual)? |  |
| * Is there staff who can work on the application to submission and undertake ongoing reporting requirements? |  |
| * What are the overall approval timelines and have there been any previous difficulties meeting those timelines? |  |
| * Are there specific regulatory requirements for the organization (e.g. Catholic wording or other specific text to be included in master PICF, fees for RGO amendments, other local committees that need to review/approve the study etc.)? |  |

|  |  |  |
| --- | --- | --- |
| **ITCC Site Feasibility Checklist (cont.)** | | |
| **Medical** | * Who are likely Principal Investigators (PIs) and what is their specialty and relevant clinical trial experience (i.e. as PI, Sub or Co-Investigator)? |  |
| * Palliative care service, comment on inpatient, consultative and outreach service, number of patients per year, disease profile. |  |
| * Relationships with other clinicians such as oncology, respiratory, general medicine, aged care. |  |
| * Can suitable participants be approached from these other clinics, and will there be support? |  |
| * General interest in research from others, openness to introducing other treatment patterns, readiness and acceptance of background and comparative therapy. |  |
| * Information on the study specific population (in terms of stage of disease, protocol-based definition of study disease and population). |  |
| * Can estimate of the likely recruitment numbers on a per annum basis be provided? |  |

|  |  |  |
| --- | --- | --- |
| **ITCC Site Feasibility Checklist (cont.)** | | |
| **Operational** | * Is the patient population likely to have characteristics that compete with any other studies? |  |
| * Are there any cultural imperatives in relation to the study design or the tools used? |  |
| * How might such issues be dealt with? |  |
| **Site demographics** | * Does the organisation have prior experience in clinical trials, and prior experience in conducting similar studies? |  |
| * Are study coordinators, pharmacists, and nurses available to participate? |  |
| * If applicable, are staff available to collect study assessments, including on weekends? If study assessments are required over the weekend, what arrangements might be required? |  |
| * Does the site have staff with sufficient training and capacity to perform the role of site principal investigator, sub-investigator and study nurse? |  |
| * Are there any pre-existing competing studies that may impact on recruitment, such as similar patient population or competing with investigator or study staff time? |  |

|  |  |  |
| --- | --- | --- |
| **ITCC Site Feasibility Checklist (cont.)** | | |
| **Site infrastructure** | * Specific availability of office space, secure storage and filing, computing and photocopying equipment. |  |
| * Availability of study staff via telephone and mobile phone |  |
| * Is there IT infrastructure with internet capacity and user support? |  |
| * Is there the capacity to visit patients at home for follow-up? |  |
|  | * If applicable, availability of protocol specific equipment (specify) |  |
|  | * If applicable, availability of adequate and secure Investigational Product storage |  |
| **Quality** | * Whether sites have undergone sponsor/ independent site audits in the past. |  |
| * Previous experience with clinical trial audits, and if so, were any concerns raised. |  |
| * Are there any training requirements identified for any person on the team? |  |