|  |
| --- |
| **PROTOCOL FEASIBILITY SCORE CARD** |

*Directions:* Responses to this form constitute the best estimate of resources and capability to fulfill the study requirements. Complete the form after reviewing the protocol and other available study materials. The scorecard is intended to be used once the Protocol Feasibility Form has been completed. Use the score to guide the decision in pursuing a study.

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | **Category** | **1** | **2** | **3** | **4** | **5** | **Score** | **Weight** | **Total** |
| **IMPLEMENTATION** | **Competing Trials** | 3+ competing trials active or pending over next 6 months |  | 1-2 competing trials active or pending over next 6 months |  | 0 competing trials active or pending over next 6 months |  | 11 |  |
| **Study Population** | Rare population, database search needed, recruitment from external sources |  | Available in other OSU clinics, multidisciplinary collaboration may be needed |  | Readily available in current clinics, current list available |  | 12 |  |
| **Benefit** | No generally-accepted therapeutic benefit to subjects or future populations |  | Some potential direct benefit to subjects in trial or future patients |  | Generally accepted therapeutic benefit to individual subjects or high likelihood of future benefit to subjects/patients |  | 10 |  |
| **Protocol Implementation** | Inadequate resources and new operational procedures needed |  | Additional resources may be needed, operational guidance may be needed |  | Available resources for the complexity of the protocol, coordinating staff able to implement |  | 11 |  |
| **Study Procedure & Data Complexity** | Complex study procedures, development of data collection tools required (e.g. REDCap creation, worksheets) |  | May involve multidisciplinary team procedures or unfamiliar EDCs |  | Experience with procedures and data collection (e.g. commercial EDC), worksheets provided |  | 11 |  |
| **ACADEMIC MERIT** | **PI Involvement & Publication** | Local PI , Little or no likelihood of OSU publication resulting from trial |  | Committee involvement, potential for publication or presentation for PI, Sub-I, or research staff |  | National PI or PI initiated, guaranteed or high likelihood of publication |  | 10 |  |
| **Research Reputation/ Enrollment** | Study has already started or add-on site for a trial, global trial with 100+ sites |  | Possible 1st enroller and/or expected top 50% of all sites, limited sites globally OR investigator initiated trial from another site, including NIH |  | Agreed to be 1st enroller and/or expected top 20% of sites or single site study, investigator initiated trial OR coordinating center for NIH |  | 11 |  |
| **Degree of Innovation/ Scientific Merit** | Little or no new experimental methodology or procedures (e.g. post-market registry, Phase 3 & 4) |  | Some new methodology or procedures (e.g. Phase 2 &3) |  | Novel methodology or clinical procedures (e.g. pivotal or feasibility studies, Phase 1 &2) |  | 12 |  |
| **FISCAL** | **Budget** | Insufficient funding |  | Break-even funding |  | Sufficient funding (all costs covered, plus) |  | 12 |  |
| **TOTAL** | | | | | | | |  | **/500** |
| **%** | | | | | | | | | |