|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | Questions are followed by answer fields. Use the ‘Tab’ key to navigate through. Replace Y/N or Yes/No fields with your answer. | | | |
| NT Health Registry Feasibility Assessment Tool | | | | |
| Completion of this Feasibility Form is a prerequisite to any formal progress on proposed Clinical Registries | | | | |
| **Registry Title:** | | |  | |
| **Principal Investigator:** | | |  | |
| **Unit Name:** | | |  | |
| **Potential Benefits of Registry:** | | |  | |
| 1. Sponsor / CRG | | | | Yes, No, N/A |
| 1.1 | | Is this a Pharmaceutical Sponsored Registry? | | Choose an item. |
| 1.2 | | Is this a Collaborative or Investigator Led Registry? | | Choose an item. |
| 1.3 | | Is there a commitment from a Sponsor to fully fund this Registry? | | Choose an item. |
| 1.4 | | Is this a multi-site Registry? | | Choose an item. |
| 1. Resources | | | | Yes, No, N/A |
| 2.1 | | As the PI do you have adequate time to commit to this Registry and fulfil all ongoing obligations? | | Choose an item. |
| 2.2 | | Does your Trial Co-ordinator/Clinical Team have adequate time to commit to this Registry and fulfil all ongoing obligations – including data entry? | | Choose an item. |
| 2.3 | | Do you have access to funding sources to cover any shortfall in Registry sponsor/partner payments? | | Choose an item. |
| 1. Population | | | | Yes, No, N/A |
| 3.1 | | Total number of patients expected to be recruit at this site, over how many years? | | #patients  #years |
| 3.2 | | How many patients potentially do you see each year that would meet the eligibility criteria? | | #patients |
| 3.3 | | How many patients per week will be screen? | | #patients |
| 3.4 | | How many patients per week will be recruited? | | #patients |
| 3.5 | | How many additional visits from standard of care will be required? | |  |

|  |  |  |  |
| --- | --- | --- | --- |
| 1. Protocol | | | Yes, No, N/A |
| 4.1 | Are there competing registries within NT Health? | | Choose an item. |
| 4.2 | Is this Registry similar to previous registries conducted at this site? | | Choose an item. |
|  | If so, were the previous registries successfully completed? (i.e. recruitment target met and no major problems) | Comment: | |
| 4.3 | Will this registry improve the safety and quality of care that TEHS provides? | | Choose an item. |
| 4.4 | Have you assessed the Registry database? | | Choose an item. |
|  | * If so, does it require the collection of retrospective data? | | Choose an item. |
| 4.5 | How many hours per patient will be required for data entry? | |  |
| 4.6 | Are there other considerations which would increase complexity of the Registry? | Comment: | |
| 4.7 | Is adequate governance processes in place to protect confidentiality, allow for participant withdrawal and procedures for secondary use access? | | Choose an item. |
| 1. Procedures | | | **Yes, No, N/A** |
| 5.1 | Will coordination with other departments/services be required for study visits or procedures? | | Choose an item. |
| 5.2 | Is support from Pathology required for services above standard of care? | | Choose an item. |
| 5.3 | Is support from Medical Imaging required for services above standard of care? | | Choose an item. |
| 5.4 | If an inpatient study, will ward/clinic staff need to be involved? | | Choose an item. |
| Staff | | | **Yes, No, N/A** |
| 6.1 | Do you as PI have adequate time to devote to the protocol and ethics? | | Choose an item. |
| 6.2 | Are qualified staff available? | | Choose an item. |
| 6.3 | Is the workload manageable? | | Choose an item. |
| 6.4 | Is adequate clinic and office space available? | | Choose an item. |

|  |  |  |  |
| --- | --- | --- | --- |
| 1. Approval | | |  |
| **PI Signature:** |  | **Date / / FEASIBLE ☐ NOT FEASIBLE ☐** | |
| **Research Governance Office Signature:** |  | **Date / / FEASIBLE ☐ NOT FEASIBLE ☐** | |
| **Business Manager Signature:**  **(if applicable)** |  | **Date / / FEASIBLE ☐ NOT FEASIBLE ☐** | |
| End of form | | | |