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**Checklist for Study Feasibility Assessment**

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| --- |
| *Instructions:* |
| * *In the* ***STATUS*** *column, write [****√****] if the element is available or can be fulfilled; [****X****] if the element is not available or cannot be fulfilled; [****NA****] if the element is not applicable.*
* *In the* ***COMMENT*** *column, comment as appropriate.*
 |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Protocol Title:** <*Insert title*> |  |  |  | **Protocol Number:**<*Insert number*> |
| **Study Site:** <*Insert site*> |  |  |  | **Date of assessment:**<*dd/mm/yyyy*> |
| **Potential Investigator (PI):** <*Insert name>* |  |  |  | **PI’s Contact Number:** <*Insert contact*> |
| **ELEMENTS** | **STATUS** | **COMMENT** |
| **Part 1 – Scientific, Technical & Ethical Elements** |
| 1. Investigator(s) has sufficient qualification, training and medical practice experience.
 |  |  |
| 1. Protocol is compliant with local regulations for registration in NMRR and with requirements of investigator’s site.
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| 1. Subject eligibility criteria are realistic and well defined in the protocol.
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| 1. The comparator investigational product is available in investigator’s site (if required).
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| 1. The protocol is consistent with GCP guidelines.
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| **Part 2 – Subject** |
| 1. Study population targeted for in this protocol is available at investigator’s site.
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| 1. Investigator’s institution has competing clinical studies, targeting the same population.
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| 1. Investigator has capacity to recruit the required number of appropriate subjects, within the established time limits.
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| 1. The number of potential subjects outside investigator’s site can be recruited according to protocol and type of advertisement (if necessary).
 |  |  |
| 1. There are protocol requirements which have an impact upon the consent of subjects to participate in the study.
 |  |  |
| 1. Acceptable tests or treatments period.
 |  |  |
| **Part 3 – Personnel Availability** |
| 1. Investigator has sufficient time to personally examine and treat subjects.
 |  |  |
| 1. Investigator has sufficient time to supervise the research team.
 |  |  |
| 1. Investigator has sufficient time to ensure that the data recorded in the case report forms and all other required reports are accurate, complete, legible and submitted rapidly to the sponsor/ sponsor-investigator.
 |  |  |
| 1. Investigator has sufficient time to interact with the sponsor, sponsor-investigator and the research team.
 |  |  |
| 1. Investigator have sufficient time to properly conduct and complete the study appropriately within the established timeframe.
 |  |  |
| **Part 4 – Resources** |
| 1. Investigator can delegate some of the medical aspects of the study to sub-investigators.
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| 1. Investigator can delegate a number of significant aspects of the study to coordinators.
 |  |  |
| 1. Investigator can rely on support of a sufficient number of qualified employees for the anticipated duration of the study.
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| 1. Technical and professional personnel required are available for the study.
 |  |  |
| 1. Availability of budget and financial contract for the research team.
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| **Part 5 – Facilities and Equipment** |
| 1. There is sufficient working space required for study personnel.
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| 1. There is space required for subject recruitment and follow-up.
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| 1. There is space to securely store subjects’ study records and clinical study material.
 |  |  |
| 1. All materials necessary for the study is available on-site.
 |  |  |
| 1. Protocol-required specific medical materials are available on-site.
 |  |  |
| 1. There is available space for storage of the investigational product.
 |  |  |
| 1. There is available local laboratory facilities or other services necessary for the requirements of the protocol
 |  |  |
| 1. There is space required for monitoring, auditing or inspecting.
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