**SITE SELECTION VISIT CHECKLIST**

**Part A: Preparation for Visit**

|  |  |
| --- | --- |
| Sponsor: |  |
| Sponsor Contact: | Name: | Phone: |
|  | Title:  | Fax: |
|  |  | E-mail: |
|  |
| ❑ | Visit Date Confirmed – Anticipated Date: |
| ❑ | Study documents circulated to site staff for review (e.g., protocol, investigator brochure) |
| ❑ | Site attendees available and confirmed |
| ❑ | Meeting room booked (AV requirements; refreshments) |
| ❑ | Applicable departments aware of visit during tour of facilities |
| ❑ | Dates confirmed: |
|  | REB Meeting Date: |  | Deadline: |  |
|  | Date: |  | Deadline: |  |
|  | CTC Meeting Date: |  | Deadline: |  |
|  | Date: |  | Deadline: |  |
| Documents Compiled: |
| ❑ | CV of QI and copy of current medical license |
| ❑ | CVs of key site personnel |
| ❑ | SOP index  |
| ❑ | Blank examples of source documentation  |
| ❑ | Estimated recruitment potential for patient population  |
| ❑ | Evidence of previous clinical trial experience (e.g., generic list of trials previously conducted without breaching company confidentiality). List: |
| Other Documents (list): |
| ❑ |  |
| ❑ |  |
| ❑ |  |

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|  |  |  |  |  |
| Signature of Person Completing Form |  | Name |  | Date |

**Part B:** **Site Selection Visit Summary**

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| --- | --- | --- | --- |
| **Sponsor:** |  | **Date of Visit:** |  |
| **Sponsor Contacts:** |  |
| **Name** | **Phone**  | **Fax**  | **E-mail** |
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|  |  |  |  |
|  |  |  |  |
| **Protocol Number:** |  |
| **Protocol Title:** |  |
| **Attendees** - Sponsor: |  |
|  |
| **Attendees** - Site: |  |
|  |
| **Summary of Meeting** (append agenda) – key points discussed: |
| **Items Reviewed**: |
| ❑ | Protocol |
| ❑ | Investigational product |
| ❑ | Study monitoring plans |
| ❑ | Data management plans |
| ❑ | Study timelines (dates): |
| Anticipated regulatory approval date: |  |
| Anticipated overall study start date: |  |
| Anticipated site study start date: |  |
| Anticipated investigator meeting date: |  |
| Anticipated accrual end date: |  |
| Anticipated Notification of Site Selection: |  |
| ❑ | Publication Policy  |

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| **Tour of Facilities** |
| ❑ | Pharmacy |
| ❑ | Investigational drug storage area |
| ❑ | Laboratory |
| ❑ | Examination rooms  |
| ❑ | Clinics  |
| ❑ | Treatment area (specify) |
| ❑ | Monitor work area |
| ❑ | Other (specify) |
| ❑ | Other (specify) |
| ❑ | Other (specify) |

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| ❑ | **Action Items** (list): |
|  | 1. Include who is responsible for the action and due date
 |
|  |  |
| ❑ | **Follow-Up Required** (specify): |
|  |  |
|  |  |

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| **Outcome:** |
| ❑ | Site selected to conduct the study |
| ❑ | Site agrees to conduct |
| ❑ | Site declined (reason): |
| ❑ | Sponsor declined (reason): |

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| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| Signature of Person Completing Form |  | Name |  | Date |