**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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| ❑ |  | | | | | | |

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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: | | | |  | | | | | | |
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| **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 |