**POPULATION SCIENCE STUDY START-UP CHECKLIST**

This form was designed for use for any Population Science study, not just those conducted in the Division of Population Science.

JT#: Click or tap here to enter text.

iRIS ID#: Click or tap here to enter text.

Instructions: Please use the checklist throughout the study start-up phase of the trial.

# PRE-MDG:

|  |  |  |  |
| --- | --- | --- | --- |
| **TASK:** | **COMPLETE:** | **N/A:** | **DATE COMPLETED:** |
| Confirm site selection by Sponsor  |[ ] [ ]  Click or tap here to enter text. |
| Enterprise Wide: Confirm Sponsor Approval for Multi-Site |[ ] [ ]  Click or tap here to enter text. |
| Confirm final protocol  |[ ] [ ]  Click or tap here to enter text. |
| Identify Appropriate MDG and Communicate with MDG PM for Submission  |[ ] [ ]  Click or tap here to enter text. |

## Multi-site start-up:

|  |  |  |  |
| --- | --- | --- | --- |
| **TASK:** | **COMPLETE:** | **N/A:** | **DATE COMPLETED:** |
| Notify Multi-site IIT Project Manager |[ ] [ ]  Click or tap here to enter text. |
| Gather sub-site contacts, location, and PI information |[ ] [ ]  Click or tap here to enter text. |
| Determine if there is a need for an IRB reliance agreement  |[ ] [ ]  Click or tap here to enter text. |
| Complete Multi-site Clinical Study Review form and submit to JCRI |[ ] [ ]  Click or tap here to enter text. |
| Confirm multisite language in protocol for MDG, PFC and PRMC approval |[ ] [ ]  Click or tap here to enter text. |
| Set date for sub-Site SIVs |[ ] [ ]  Click or tap here to enter text. |
| Obtain sub-Site delegation of Authority logs |[ ] [ ]  Click or tap here to enter text. |
| After SIV, distribute slides and currently approved protocol to all attendees |[ ] [ ]  Click or tap here to enter text. |
| Set date of activation and obtain sub-site activation email |[ ] [ ]  Click or tap here to enter text. |

# multidisciplinary disease group (mdg):

|  |  |  |  |
| --- | --- | --- | --- |
| **TASK:** | **COMPLETE:** | **N/A:** | **DATE COMPLETED:** |
| Submit to MDG and Present at Scheduled Meeting |[ ] [ ]  Click or tap here to enter text. |
| Confirm MDG Approval, if Regional Research Sites (RRS) are included, obtain approval from RRS MDGs |[ ] [ ]  Click or tap here to enter text. |
| Obtain Disease Map and Priority Form  |[ ] [ ]  Click or tap here to enter text. |

# protocol feasibility committee (pfc):

|  |  |  |  |
| --- | --- | --- | --- |
| **TASK:** | **COMPLETE:** | **N/A:** | **DATE COMPLETED:** |
| Identify Protocol Coordinator |[ ] [ ]  Click or tap here to enter text. |
| Identify Data Manager |[ ] [ ]  Click or tap here to enter text. |
| Complete PFC Submission Form to PFC PM |[ ] [ ]  Click or tap here to enter text. |
| Prepare and Send PFC Submission Packet |[ ] [ ]  Click or tap here to enter text. |
| Present Protocol at Assigned Meeting |[ ] [ ]  Click or tap here to enter text. |
| Confirm PFC Approval |[ ] [ ]  Click or tap here to enter text. |
| Complete Radiology Feasibility (if applicable) |[ ] [ ]  Click or tap here to enter text. |
| Verify Data Monitoring Expectations / Plan per Site |[ ] [ ]  Click or tap here to enter text. |

# protocol review and monitoring committee (prmc):

|  |  |  |  |
| --- | --- | --- | --- |
| **TASK:** | **COMPLETE:** | **N/A:** | **DATE COMPLETED:** |
| Confirm Receipt of Radiology Manual (if applicable) |[ ] [ ]  Click or tap here to enter text. |
| Confirm Approval Radiology Feasibility (needed for IRB submission) (if applicable) |[ ] [ ]  Click or tap here to enter text. |
| Confirm Regulatory Coordinator |[ ] [ ]  Click or tap here to enter text. |
| Prepare and Submit PRMC Forms and Protocol |[ ] [ ]  Click or tap here to enter text. |
| Obtain PRMC Approval |[ ] [ ]  Click or tap here to enter text. |

# institutional review board (irb):

|  |  |  |  |
| --- | --- | --- | --- |
| **TASK:** | **COMPLETE:** | **N/A:** | **DATE COMPLETED:** |
| Review Informed Consent  |[ ] [ ]  Click or tap here to enter text. |
| Identify the IRB of Record for the trial (Jefferson or other)* If Jefferson is the lead, obtain reliance documentation for each site
 |[ ] [ ]  Click or tap here to enter text. |
| Confirm Receipt of IRB Approval / Protocol Training from Regulatory |[ ] [ ]  Click or tap here to enter text. |

# laboratory:

|  |  |  |  |
| --- | --- | --- | --- |
| **TASK:** | **COMPLETE:** | **N/A:** | **DATE COMPLETED:** |
| Confirm Receipt of Lab Materials (i.e., test tubes, etc.) |[ ] [ ]  Click or tap here to enter text. |
| Confirm Sample Mailing Procedures |[ ] [ ]  Click or tap here to enter text. |

# data:

|  |  |  |  |
| --- | --- | --- | --- |
| **TASK:** | **COMPLETE:** | **N/A:** | **DATE COMPLETED:** |
| If IIT: Create Database (REDCap) |[ ] [ ]  Click or tap here to enter text. |
| Establish Data Transfer and Use Agreement (DTUA) as needed |[ ] [ ]  Click or tap here to enter text. |
| Establish Data Sharing Methods |[ ] [ ]  Click or tap here to enter text. |
| Create Progress Notes |[ ] [ ]  Click or tap here to enter text. |
| Create Source Documents |[ ] [ ]  Click or tap here to enter text. |

# miscellaneous:

|  |  |  |  |
| --- | --- | --- | --- |
| **TASK:** | **COMPLETE:** | **N/A:** | **DATE COMPLETED:** |
| Arrival of Sponsor Equipment (EKG machine, BP cuff, etc.) |[ ] [ ]  Click or tap here to enter text. |

# financial / contract:

|  |  |  |  |
| --- | --- | --- | --- |
| **TASK:** | **COMPLETE:** | **N/A:** | **DATE COMPLETED:** |
| Confirm grant / account number was assigned |[ ] [ ]  Click or tap here to enter text. |
| Confirm contract is fully executed |[ ] [ ]  Click or tap here to enter text. |
| Establish Professional Services Agreement (if applicable) |[ ] [ ]  Click or tap here to enter text. |
| Confirm ClinCard account is set up and ClinCards received |[ ] [ ]  Click or tap here to enter text. |

# site initiation visit (siv):

|  |  |  |  |
| --- | --- | --- | --- |
| **TASK:** | **COMPLETE:** | **N/A:** | **DATE COMPLETED:** |
| Schedule SIV |[ ] [ ]  Click or tap here to enter text. |
| Create SIV slides if necessary |[ ] [ ]  Click or tap here to enter text. |
| Send SIV Confirmation and Agenda (Study Team, Nursing, Regulatory, IDS) |[ ] [ ]  Click or tap here to enter text. |
| Confirm SIV was completed |[ ] [ ]  Click or tap here to enter text. |

# study personnel documentation:

|  |  |  |  |
| --- | --- | --- | --- |
| **TASK:** | **COMPLETE:** | **N/A:** | **DATE COMPLETED:** |
| JeffTrial Staff List is Current |[ ] [ ]  Click or tap here to enter text. |
| Delegation of Authority Log(s) are signed and filed |[ ] [ ]  Click or tap here to enter text. |
| Financial Disclosure Certification Forms for all Investigators are signed and filed |[ ] [ ]  Click or tap here to enter text. |
| Protocol Training e-mails are sent and filed |[ ] [ ]  Click or tap here to enter text. |
| Current (within 2 years) signed and dated CVs are on file for all staff |[ ] [ ]  Click or tap here to enter text. |
| Current medical licenses are on file for all relevant staff |[ ] [ ]  Click or tap here to enter text. |
| Protocol training logs are signed and filed |[ ] [ ]  Click or tap here to enter text. |

# activation:

|  |  |  |  |
| --- | --- | --- | --- |
| **TASK:** | **COMPLETE:** | **N/A:** | **DATE COMPLETED:** |
| Confirm Ready to Activate Internally (all boxes are checked for each site) |[ ] [ ]  Click or tap here to enter text. |
| Send Activation Email (if Enterprise Wide: Clinical Lead per site) |[ ] [ ]  Click or tap here to enter text. |
| Update the JeffTrial Record to “OPEN TO ACCRUAL” |[ ] [ ]  Click or tap here to enter text. |
| Finalize any Patient Identification needs with IS&T or CROE (Community Research Operations and Enrollment) |[ ] [ ]  Click or tap here to enter text. |

# enterprise wide specifics:

|  |  |  |  |
| --- | --- | --- | --- |
| **TASK:** | **COMPLETE:** | **N/A:** | **DATE COMPLETED:** |
| JeffTrial Personnel Update (per location) |[ ] [ ]  Click or tap here to enter text. |
| JeffTrial Committees / Meetings Update (per site) – ongoing/site |[ ] [ ]  Click or tap here to enter text. |
| Document All Site Numbers for Each Site |[ ] [ ]  Click or tap here to enter text. |

**Completed by:**

**Printed Name Signature Date**