**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:

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| **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):

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| **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):

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| **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):

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| **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):

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| **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:

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| --- | --- | --- | --- |
| **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:

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| **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:

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

# financial / contract:

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| --- | --- | --- | --- |
| **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):

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| --- | --- | --- | --- |
| **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:

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| --- | --- | --- | --- |
| **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:

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| **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:

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| --- | --- | --- | --- |
| **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**