**STUDY START-UP CHECKLIST –**

**Clinical team**

**JT#**: Click or tap here to enter text. **PI**: Click or tap here to enter text.

**Sponsor**: Click or tap here to enter text.

**Protocol Title**: Click or tap here to enter text.

**Instructions**: Please use the checklist throughout the study start-up phase of the trial. Note, certain sections contain tasks specific to their trial type and location(s) of trial activation.

# **Pre-Multidisciplinary Group (MDG) Committee Meeting**  COMPLETE **|** N/A **|** Date Completed (if applicable)

1. Confirm CDA was signed by JCRI business operations [x]  [ ]  Click or tap to enter a date.

2. Confirm completion of feasibility questionnaire [ ]  [x]  Click or tap to enter a date.

3. Pharmacy feasibility review (ePRO) [ ]  [ ]  Click or tap to enter a date.

4. Confirm Pre-Site Visit was conducted with sponsor and PI [ ]  [ ]  Click or tap to enter a date.

5. Confirm receipt of finalized protocol [ ]  [ ]  Click or tap to enter a date.

6. Confirm site selection by the sponsor [ ]  [ ]  Click or tap to enter a date.

7. Schedule review for MDG/Regional Research Committee (RRC) meeting (only needs to be reviewed at RRC if site specific PI did not vote at Enterprise Wide (EW) MDG meeting) [Send agenda 48 hours in advance]

 [x]  [ ]  Click or tap to enter a date.

8. Add trial to PDL/tracker [ ]  [ ]  Click or tap to enter a date.

9. Confirm sponsor approval for Multi-Site [ ]  [ ]  Click or tap to enter a date.

Including:

 a. One PI for all sites\* [ ]  [ ]  Click or tap to enter a date.

 b. Confirm and document all site numbers for each site

 [ ]  [ ]  Click or tap to enter a date.

 c. One contract and budget [ ]  [ ]  Click or tap to enter a date.

 d. IP shipment directly to each site [ ]  [ ]  Click or tap to enter a date.

 e. CRA monitoring at each site [ ]  [ ]  Click or tap to enter a date.

 f. Study supplies shipment directly at each site [ ]  [ ]  Click or tap to enter a date.

 g. Availability of non-English translated consents (inclusive of populations at Regional Research Sites (RRS)) [ ]  [x]  Click or tap to enter a date.

 h. Resource guide [x]  [x]  Click or tap to enter a date.

\*PI oversight plan available to share with sponsor

10. Verify if an NCTN Trial with IP shipped from PMB that an investigator at the site has the site as their shipping address *(if needed work with Pam Touchstone to update the shipping address of the investigator on their CTEP account)*

 [ ]  [x]  Click or tap to enter a date.

# **MDG Committee Meeting**  COMPLETE **|** N/A **|** Date Completed (if applicable)

1. Confirm MDG approval from majority of voting members

 [ ]  [ ]   Click or tap to enter a date.

2. Confirm RRS participation [ ]  [ ]  Click or tap to enter a date.

3. Confirm enrollment goal per site [ ]  [ ]  Click or tap to enter a date.

4. Confirm Institutional PI and site PI [ ]  [ ]  Click or tap to enter a date.

5. If RRC did not vote at E-W MDG meeting, PI &/or MDG PM attends RRC MDG and presents trial for vote

 [ ]  [ ]  Click or tap to enter a date.

6. Complete MDG REDCap entry [ ]  [ ]  Click or tap to enter a date.

7. Send MDG approval/disapproval notification e-mail [PI, MDG Leader, RRC Leader, CTO Directors, CTO Regulatory Managers, Budgets/Contracts, Site Lead, Coordinator (if applicable)]

 [ ]  [ ]  Click or tap to enter a date.

8. Create protocol record in JeffTrial (see JeffTrial guidance document)

\*Add key personnel for each site to JeffTrial staff list

 [ ]  [ ]  Click or tap to enter a date.

9. Update JeffTrial with MDG and RRC meeting outcomes (if applicable)

 [ ]  [ ]  Click or tap to enter a date.

10. Submit protocol and MDG approval to JCRI for calendar build

 [ ]  [ ]  Click or tap to enter a date.

11. Identify program assignment and submit for CRLC review and determination

 [ ]  [ ]  Click or tap to enter a date.

12. Finalize MDG meeting minutes and obtain MDG Lead signature

 [ ]  [ ]  Click or tap to enter a date.

13. Complete MDG Priority Form and obtain signature from MDG lead

 [ ]  [ ]  Click or tap to enter a date.

14. Update disease map [ ]  [ ]  Click or tap to enter a date.

# **Protocol Feasibility committee (PFC)**  COMPLETE **|** N/A **|** Date Completed (if applicable)

1. Complete PFC submission form [ ]  [ ]  Click or tap to enter a date.

Including:

1. Identification of primary coordinator [ ]  [ ]  Click or tap to enter a date.
2. Identification of data manager [ ]  [ ]  Click or tap to enter a date.
3. Ancillary department involvement [ ]  [ ]  Click or tap to enter a date.
4. Identification of any specialized study labs and equipment

 [ ]  [ ]  Click or tap to enter a date.

2. Prepare and send PFC submission packet (PFC submission form, pharmacy manual, imaging manual, laboratory manual, protocol)

 [ ]  [ ]  Click or tap to enter a date.

3. Share PFC submission packet with RRC [ ]  [ ]  Click or tap to enter a date.

4. Present protocol at assigned PFC meeting and RRC PFC meeting (if applicable)

 [ ]  [ ]  Click or tap to enter a date.

5. Confirm PFC approval [ ]  [ ]  Click or tap to enter a date.

6. RRS PM: Update JeffTrial with meeting approval details and send PFC approval e-mail (if applicable)

 [ ]  [ ]  Click or tap to enter a date.

7. Complete Radiology Feasibility (if applicable) [ ]  [ ]  Click or tap to enter a date.

8. Complete Institutional Biosafety Committee (IBC) initial submission (if applicable) [ ]  [ ]  Click or tap to enter a date.

9. Complete Value Analysis Committee submission (if applicable)

 [ ]  [x]  Click or tap to enter a date.

# **Pre-IRB Submission (When handled by Research Support Services Reg Ops)** COMPLETE **|** N/A **|** Date Completed (if applicable)

1. Confirm receipt of Radiology Manual [ ]  [ ]  Click or tap to enter a date.

2. Confirm approval from Radiology Feasibility if applicable (needed for IRB submission)

 [ ]  [ ]  Click or tap to enter a date.

3. Confirm IBC approval if applicable (needed for IRB submission) [ ]  [ ]  Click or tap to enter a date.

4. Confirm Value Analysis Committee approval by regulatory if applicable (needed for IRB submission)

 [ ]  [ ]  Click or tap to enter a date.

5. Confirm regulatory coordinator is assigned [ ]  [ ]  Click or tap to enter a date.

6. Confirm submission packet to regulatory (Disease map, PRMC questions, Priority form, Radiology/IBC/Value Analysis Committee approval(s) as applicable)

 [ ]  [ ]  Click or tap to enter a date.

7. For NCTN studies, begin Imaging Radiation Oncology Core (CORE) credentialing if applicable [ ]  [ ]  Click or tap to enter a date.

8. For NCTN Begin surgical credentialing if applicable [ ]  [ ]  Click or tap to enter a date.

9. Confirm list of study staff with regulatory in JeffTrial (for NCTN trials also review DTL)

[x]  [x]  Click or tap to enter a date.

10. Review ICF (check for any inconsistencies and for financials) [ ]  [ ]  Click or tap to enter a date.

11. Confirm if patient reimbursement/payment is provided

 [ ]  [ ]  Click or tap to enter a date.

12. Identify IRB of Record (Jefferson or Central) [ ]  [ ]  Click or tap to enter a date.

1. If Central IRB, find out from sponsor if Jefferson has to submit SAE and/or deviations OR if sponsor will submit on our behalf [ ]  [ ]  Click or tap to enter a date.
2. If Jefferson does not submit, identify sponsor staff responsible and ensure access to central IRB system

[ ]  [ ]  Click or tap to enter a date.

1. Identify reporting requirements of the trial by sponsor and IRB

 [ ]  [ ]  Click or tap to enter a date.

13. Confirm Value Analysis Committee approval if applicable (needed for IRB submission)

 [ ]  [ ]  Click or tap to enter a date.

14. Confirm submission packet to regulatory (Disease map, PRMC questions, Priority form, Radiology/IBC/Value Analysis Committee approval(s) as applicable)

 [ ]  [ ]  Click or tap to enter a date.

15. For NCTN studies, begin Imaging Radiation Oncology Core (CORE) credentialing if applicable [ ]  [ ]  Click or tap to enter a date.

16. Begin surgical credentialing if applicable [ ]  [ ]  Click or tap to enter a date.

# **Pharmacy/Drug** COMPLETE **|** N/A **|** Date Completed (if applicable)

1. Confirm receipt of pharmacy manual [ ]  [ ]  Click or tap to enter a date.

2. Create and submit Beacon Build [ ]  [ ]  Click or tap to enter a date.

3. Confirm IDS & CRC has Interactive Voice Response System (IVRS) access, if needed [ ]  [ ]  Click or tap to enter a date.

4. Confirm how to order study drug [ ]  [ ]  Click or tap to enter a date.

5. Confirm receipt of study drug prior to activation, if applicable [ ]  [ ]  Click or tap to enter a date.

6. For NCTN studies, confirm Pharmaceutical Management Branch (PMB) account & a shipping Investigator is available on site for each site participating site

 [ ]  [ ]  Click or tap to enter a date.

7. Confirm if IP is hazardous, if so, confirm use of Jefferson CSTD [ ]  [ ]  Click or tap to enter a date.

# **iMAGING** COMPLETE **|** N/A **|** Date Completed (if applicable)

1. Confirm receipt of imaging manual [ ]  [ ]  Click or tap to enter a date.

2. Complete Radiology Feasibility Form [ ]  [ ]  Click or tap to enter a date.

3. Confirm access to imaging upload system (eg. Bioclinica, Paraxel, Triad etc.) [ ]  [ ]  Click or tap to enter a date.

4. Confirm radiology approval [ ]  [ ]  Click or tap to enter a date.

# **Laboratory** COMPLETE **|** N/A **|** Date Completed (if applicable)

1. Confirm receipt of lab manual [ ]  [ ]  Click or tap to enter a date.

2. Confirm SKCC-PK-PD & RRS Team can process research labs or if other lab support is needed [ ]  [ ]  Click or tap to enter a date.

3. Confirm storage requirements (eg. Batch shipping) [ ]  [ ]  Click or tap to enter a date.

4. Confirm receipt of lab kits at all sites [ ]  [ ]  Click or tap to enter a date.

5. Confirm completion of PKPD/RRS lab requisition sheets [ ]  [ ]  Click or tap to enter a date.

6. Confirm access to Lab site or portal [ ]  [ ]  Click or tap to enter a date.

7. Confirm tissue request/shipping process/labels [ ]  [ ]  Click or tap to enter a date.

# **Data Management and Coordination** COMPLETE **|** N/A **|** Date Completed (if applicable)

1. If IIT, confirm creation of database (REDCap) [ ]  [ ]  Click or tap to enter a date.

2. If sponsor/NCTN trial, confirm necessary staff have access to Electronic Data Capture system (EDC) [ ]  [ ]  Click or tap to enter a date.

3. If sponsor/NCTN trial, confirm necessary staff have completed EDC training [ ]  [ ]  Click or tap to enter a date.

4. Create progress notes [ ]  [ ]  Click or tap to enter a date.

5. Develop EPIC research progress note [ ]  [ ]  Click or tap to enter a date.

6. Create source documents [ ]  [ ]  Click or tap to enter a date.

7. Confirm imaging portal access [ ]  [ ]  Click or tap to enter a date.

8. Confirm QOL/Questionnaire portal access [ ]  [ ]  Click or tap to enter a date.

9. Create documents for in-service [ ]  [ ]  Click or tap to enter a date.

# **Miscellaneous** COMPLETE **|** N/A **|** Date Completed (if applicable)

1. Confirm access to all applicable protocol systems [ ]  [ ]  Click or tap to enter a date.

2. Upload documents to shared drive (AE log, deviation log, sponsor specific forms for reporting SAE’s, screening and enrollment logs, source documents) [ ]  [ ]  Click or tap to enter a date.

3. Confirm arrival of sponsor equipment for each site participating in Trial (EKG machine, BP cuff, etc.) [ ]  [ ]  Click or tap to enter a date.

4. Confirm equipment functions properly [ ]  [ ]  Click or tap to enter a date.

5. Equipment inspected by BioMed and site-specific engineering departments for other sites

[x]  [ ]  Click or tap to enter a date.

6. Training of staff on operation of equipment [ ]  [ ]  Click or tap to enter a date.

7. Confirm pathology/biopsy request process [ ]  [ ]  Click or tap to enter a date.

# **Financial Contract** COMPLETE **|** N/A **|** Date Completed (if applicable)

1. Confirm Calendar Build is complete in JeffTrial [ ]  [ ]  Click or tap to enter a date.

2. Confirm budget and contract are finalized [ ]  [ ]  Click or tap to enter a date.

3. Verify Clinical Trial Agreement (CTA) is signed by PI [ ]  [ ]  Click or tap to enter a date.

4. Confirm grant/account number was assigned and pushed to EPIC [ ]  [ ]  Click or tap to enter a date.

5. Check contract for competitive or set enrollment (if set enrollment make sure PM monitors accrual and reaches out to regulatory for accrual amendment as needed) [ ]  [ ]  Click or tap to enter a date.

6. Review Visit Payment Tracker (VPT)/set up VPT review and training with JCRI [ ]  [ ]  Click or tap to enter a date.

7. If NCTN trial, check funding page/OPEN system [ ]  [ ]  Click or tap to enter a date.

8. Confirm participant payment account (eg. ClinCard) is set up, payment cards have been received, and staff have been trained to use payment portal and distribute payment cards. [ ]  [ ]  Click or tap to enter a date.

# **Site Initiation Visit (SIV)** COMPLETE **|** N/A **|** Date Completed (if applicable)

1. Schedule SIV with participating sites [ ]  [ ]  Click or tap to enter a date.

2. Create SIV slides (if necessary) [ ]  [ ]  Click or tap to enter a date.

3. Send SIV confirmation and agenda (study team, nursing, regulatory, QAE, IDS, PKPD Lab, etc.) [ ]  [ ]  Click or tap to enter a date.

4. Confirm SIV was completed [ ]  [ ]  Click or tap to enter a date.

5. Schedule in-service with applicable clinical nursing team (eg. Infusion nurses, radiation oncology nurses, inpatient team, etc.) [ ]  [ ]  Click or tap to enter a date.

# **Activation** COMPLETE **|** N/A **|** Date Completed (if applicable)

1. Confirm ready to activate with sponsor (greenlight) for each site and inform regulatory of sponsor greenlight [ ]  [ ]  Click or tap to enter a date.

2. Confirm ready to activate internally (all boxes are checked) for each site [ ]  [ ]  Click or tap to enter a date.

3. Send activation e-mail [ ]  [ ]  Click or tap to enter a date.

4. Confirm regulatory updated JeffTrial record to “open to accrual” [ ]  [ ]  Click or tap to enter a date.

5. Complete in-service/training for nursing staff as needed [ ]  [ ]  Click or tap to enter a date.

6. Confirm trial populates in EPIC for clinicians to choose as a pathway as applicable [ ]  [ ]  Click or tap to enter a date.

**Completed by:**

**Printed Name Signature Date**