

## Study Start-Up Checklist

Study Title:  
PI:  
Sponsor:

| Study Details: |                         |
|----------------|-------------------------|
| Study type:    | Industry-Sponsored      |
| Departments:   | Radiation Oncology only |
| SOC:           | Standard of Care        |

| Completed                    | Task  | Date Completed | Comments |
|------------------------------|---|----------------|----------|
| <b>Approval Process</b>      |   |                |          |
|                              | Research Proposal: Study Request Survey                                 |                |          |
|                              | • Protocol & Budget Allocation Outline                                  |                |          |
|                              | Attend RadOnc Clinical Trials Committee Meeting                         |                |          |
|                              | • Approved by Radiation Oncology  |                |          |
|                              | Attend Multidisciplinary Disease Team Meeting                           |                |          |
|                              | • Approved by Multidisciplinary Disease Team                            |                |          |
| <b>Management Decision</b>   |   |                |          |
| <b>Study Design Planning</b> |   |                |          |
|                              | Contract (from Sponsor)   |                |          |
|                              | Protocol (from Sponsor)   |                |          |
|                              | Budget (from Sponsor)   |                |          |
|                              | Informed Consent Form   |                |          |
| <b>Submission Process</b>    |   |                |          |
|                              | CTO Submission  |                |          |
|                              | • CTO Approval  |                |          |
|                              | PRMC Feasibility Submission   |                |          |
|                              | • PRMC Approval   |                |          |
|                              | DSMC Submission   |                |          |
|                              | • DSMC Approval   |                |          |
|                              | IRB Submission  |                |          |
|                              | • IRB Approval  |                |          |
|                              | IRB Approval Submitted to CTO   |                |          |
| <b>Contract Execution</b>    |   |                |          |
|                              | Contract Signature  |                |          |
| <b>Study Initiation</b>      |   |                |          |
|                              | PRS Account   |                |          |
|                              | ClinicalTrials.gov Registration   |                |          |
|                              | Site Initiation Visit   |                |          |
|                              | Systems Set Up (ARC, Data Collection, Payment Invoicing, Core Services) |                |          |
| <b>Recruitment</b>           |   |                |          |
|                              | Columbia's RecruitMe Website Posting                                    |                |          |
|                              | HICCC Clinical Trials Website Posting                                   |                |          |

Key:  PI