**Radiology Study Feasibility Assessment**

This Checklist is to be used to review both internally and externally proposed studies. See SOP# RAD003.

Study Short Title/Topic: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Person Proposing: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Department: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

PI initiated or Sponsored? \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Safety Assessment**

|  |  |
| --- | --- |
| * + - Have Radiology faculty performed procedure(s) before? |  |
| * + - Safety and efficacy established? What other publications exist? Is there an Investigator’s Brochure? |  |
| * + - Is the research a reasonable benefit for the patient without compromising care? |  |
| * + - Is the research scanning time excessive? Longer than SOC? If yes, is it justified? |  |
| * + - Required agent FDA approved for the indication? |  |
| * + - Are the appropriate supplies/samples proposed? |  |

**Financial Assessment**

|  |  |
| --- | --- |
| * + - If PI initiated: what organizations/NIH mechanisms/existing funds might support this? |  |
| * + - Have the budget details and contract been provided to the CTO/SponPro? Do they include department fees as approved by CTO/SponPro? |  |
| * + - Is cost-sharing required for personnel? Are dept waivers required for services? |  |
| * + - Where will payment be deposited? Does PI keep residual or return to funder? |  |
| * + - What will research cover and what is SOC? |  |

**Overall Design Assessment**

|  |  |
| --- | --- |
| * + - How will participants be identified? |  |
| * + - Is a routine dictation needed or special measurement (i.e. RECIST 1.0, 1.1, Lugano) |  |
| * + - Staff to send test images, de-identified CD, CRF, etc. |  |
| * + - Does a study-specific protocol need to be created/saved on the scanner so that each study patient has the same protocol run each time? |  |
| * + - Following each scan, does data need to be FTP’s to sponsor? |  |
| * + - Customized CRFs needed? |  |
| * + - What is the timeframe of the study? |  |
| * + - Are the study windows appropriate? |  |
| * + - How will we recruit? Are we likely to recruit enough subjects? |  |
| * + - Customized Request Form needed to be completed by the PI and submitted to the CTO? |  |

**Resource Assessment**

|  |  |
| --- | --- |
| * + - Do we have the faculty and staff time to devote? |  |
| * + - Who would be involved? What role? |  |
| * + - Does it fit within overall department plan and department research plan? |  |
| * + - Publication possibilities? |  |
| * + - How does this contribute to body of literature? What *new* question is being addressed? |  |

Notes: