**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?
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| * + - 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: