**PROTOCOL FEASBILITY REVIEW**

The purpose of the Protocol Feasibility Review Process is to meet National Cancer Institute (NCI) expectations in assessing protocol feasibility and prioritization at the Winship Cancer Institute (WCI) at Emory University. The feasibility review will involve a thorough assessment and proactive review of the protocol by representatives from applicable WCI resource areas to determine operational requirements and enrollment barriers. Individuals participating in the feasibility review will document and provide their assessment to the Research Manager. A feasibility review must occur prior to Disease Team (DT) protocol approval and Protocol Review and Monitoring Committee (PRMC) submission. The results of this review will be shared with the PRMC.

**INSTUCTIONS**

Please reference the Protocol Intake Form to complete sections below.

Please complete form for all trials (*interventional and non-interventional).*

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| 1. **PATIENT ACCRUAL & PI WORKLOAD**

**(Completed by Research Manager & PI)** |
| **Patient Population Seen at Center (Cancer Registry data):** | *CY 2017* |  | *CY 2018* |  | *CY 2019* |  |  |
| **Overall Target Accrual Goal:**  |  | **Current Overall Accrual** *(if available)***:** |  | **Center Primary Accrual Completion Date:** |  |
| **Center Total Accrual Goal:** |  | **Center Annual Accrual Goal:** |  | **Participating Sites Accrual Goal (Grady or VA, other per Study Intake Form):** |  |
| **Center Accrual Duration (months):** |  |  **Total # of Trials by PI** (actively accruing and patients in follow-up): |  | **Total # of Accruing Trials by PI:** |  |

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| 1. **CLINICAL OPERATIONS CONSIDERATIONS**

**(Completed by Research Manager)** |  |  |
|  | **YES** | **NO** | **NA** | **UNK** | **Comments** |
| Has the Disease Team (DT) protocol acuity (OPAL) score been assigned? Please describe. | [ ]  | [ ]  | [ ]  | [ ]  | **DT OPAL Score \_\_\_\_\_\_** |
| Does the DT expect staffing to be adequate and experienced to conduct the trial once opened?If no, please review/discuss with Assistant Director, Clinical Research Staff, and be prepared to discuss with DT. | [ ]  | [ ]  | [ ]  | [ ]  |  |
| Are personnel required to conduct special procedures or efficacy measures? | [ ]  | [ ]  | [ ]  | [ ]  |  |
| Does the DT anticipate any staffing challenges in operationalizing this protocol at participating sites? *(Consider response to “Participating Site Accrual Goal” question in section A above)* | [ ]  | [ ]  | [ ]  | [ ]  |  |
| Additional Comments |  |
| **Clinical Operations Considerations Assessment** |
| **Completed by Research Manager** | **Low****(**no feasibility challenges) | **Moderate****(**some feasibility challenges) | **High****(**many feasibility challenges) | **Comments** |
| What impact do the responses above have on feasibility? | [ ]  | [ ]  | [ ]  |  |

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| 1. **REGULATORY CONSIDERATIONS**

**(Completed by Regulatory Team)** |  |  |
|  | **YES** | **NO** | **NA** | **UNK** | **Comments** |
| Is current staffing adequate and experienced to complete a timely study start-up process? | [ ]  | [ ]  | [ ]  | [ ]  |  |
| Is current staffing adequate and experienced to maintain ongoing regulatory activities once the trial is activated? | [ ]  | [ ]  | [ ]  | [ ]  |  |
| Is the Sponsor using a central IRB? | [ ]  | [ ]  | [ ]  | [ ]  |  |
| Will the Sponsor make IRB submissions on behalf of the site?  | [ ]  | [ ]  | [ ]  | [ ]  |  |
| Does the Sponsor expect the study to be excessively monitored? If yes, please explain in comments. | [ ]  | [ ]  | [ ]  | [ ]  |  |
| Additional Comments |  |
| **Regulatory Considerations Assessment** |
| **Completed by Regulatory Team** | **Low****(**no feasibility challenges) | **Moderate****(**some feasibility challenges) | **High****(**many feasibility challenges) | **Comments** |
| What impact do the responses above have on feasibility? | [ ]  | [ ]  | [ ]  |  |

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| 1. **FINANCIAL CONSIDERATIONS**

**(Completed by Research Manager)** |  |  |
|  | **YES** | **NO** | **NA** | **UNK** | **Comments** |
| Will the Sponsor reimburse trial participants? | [ ]  | [ ]  | [ ]  | [ ]  |  |
| Does Disease Team have financial resources to support the trial if it is unfunded or underfunded? | [ ]  | [ ]  | [ ]  | [ ]  |  |
| If sponsor study budget is available, will the Sponsor pay for pre-study activities if the study is not activated at Winship due to contractual issues? | [ ]  | [ ]  | [ ]  | [ ]  |  |
| If sponsor study budget is available, does the sponsor expect the study to be audited by a regulatory body and are audit preparation costs factored into the study budget? | [ ]  | [ ]  | [ ]  | [ ]  |  |
| Are special equipment or supplies required and provided by the Sponsor? | [ ]  | [ ]  | [ ]  | [ ]  |  |
| Additional Comments |  |
| **Financial Considerations Assessment** |
| **Completed by Research Manager** | **Low****(**no feasibility challenges) | **Moderate****(**some feasibility challenges) | **High****(**many feasibility challenges) | **Comments** |
| What impact do the responses above have on feasibility? | [ ]  | [ ]  | [ ]  |  |

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| 1. **QUALITY AND TRAINING CONSIDERATIONS**

**(Completed by Research Manager and Quality Management Team)** |  |  |
|  | **YES** | **NO** | **NA** | **UNK** | **Comments** |
| Is current staffing adequate and experienced to support the quality and education necessary for trial conduct? | [ ]  | [ ]  | [ ]  | [ ]  |  |
| If monitoring off-site, are there appropriate resources in place?  | [ ]  | [ ]  | [ ]  | [ ]  |  |
| If this is a multi-site trial with a Winship PI serving as the main study PI, are appropriate monitoring resources in place?  | [ ]  | [ ]  | [ ]  | [ ]  |  |
| Additional Comments |  |
| **Quality and Training Considerations Assessment** |
| **Completed by Quality Management Team** | **Low****(**no feasibility challenges) | **Moderate****(**some feasibility challenges) | **High****(**many feasibility challenges) | **Comments** |
| What impact do the responses above have on feasibility? | [ ]  | [ ]  | [ ]  |  |

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| 1. **ENROLLMENT CONSIDERATIONS**

**(Completed by Research Manager & PI)** |  |  |
|  | **YES** | **NO** | **NA** | **UNK** | **Comments** |
| Are the inclusion & exclusion criteria reasonable to meet the accrual goal?  | [ ]  | [ ]  | [ ]  | [ ]  |  |
| Does the washout period impact enrollment? | [ ]  | [ ]  | [ ]  | [ ]  |  |
| Does age impact enrollment? | [ ]  | [ ]  | [ ]  | [ ]  |  |
| Will duration of participation impact enrollment? | [ ]  | [ ]  | [ ]  | [ ]  |  |
| Will the frequency of visits impede participation or scheduling? | [ ]  | [ ]  | [ ]  | [ ]  |  |
| Will the frequency of dosing impact enrollment or scheduling? | [ ]  | [ ]  | [ ]  | [ ]  |  |
| Could procedural discomfort to the study participant impact participation or participant compliance? | [ ]  | [ ]  | [ ]  | [ ]  |  |
| Do we have access to the right patient population? *(See section A for accrual considerations.)* | [ ]  | [ ]  | [ ]  | [ ]  |  |
| Additional Comments |  |
| **Enrollment Considerations Assessment** |
| **Completed by Research Manager** | **Low****(**no feasibility challenges) | **Moderate****(**some feasibility challenges) | **High****(**many feasibility challenges) | **Comments** |
| What impact do the responses above have on feasibility? | [ ]  | [ ]  | [ ]  |  |

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| 1. **PROTOCOL CONSIDERATIONS**

**(Completed by Research Manager & PI)** |  |  |
|  | **YES** | **NO** | **NA** | **UNK** | **Comments** |
| Are there competing trials? If so, are there enough eligible patients to support this trial? Provide justification for competing trials. *(See section A for accrual considerations.)* | [ ]  | [ ]  | [ ]  | [ ]  |  |
| Is the protocol similar to previously conducted studies? If so, were the previous studies successfully completed? | [ ]  | [ ]  | [ ]  | [ ]  |  |
| Does the study require research specific EKGs? | [ ]  | [ ]  | [ ]  | [ ]  |  |
| Is specialized equipment required? Is there appropriate training and space for the equipment. If yes, please comment.  | [ ]  | [ ]  | [ ]  | [ ]  |  |
| Will special procedures require evaluations or testing outside of regular clinic hours? | [ ]  | [ ]  | [ ]  | [ ]  |  |
| Are frequent and/or severe Adverse Events expected? | [ ]  | [ ]  | [ ]  | [ ]  |  |
| Does the staff/study team require special training on the protocol? (i.e., procedural, biosafety concerns) | [ ]  | [ ]  | [ ]  | [ ]  |  |
| Have you successfully worked with this Sponsor in the past? | [ ]  | [ ]  | [ ]  | [ ]  |  |
| Additional Comments |  |
| **Additional Protocol Considerations Assessment** |
| **Completed by Research Manager** | **Low****(**no feasibility challenges) | **Moderate****(**some feasibility challenges) | **High****(**many feasibility challenges) | **Comments** |
| What impact do the responses above have on feasibility? | [ ]  | [ ]  | [ ]  |  |

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| 1. **ANCILLARY SERVICES CONSIDERATIONS**

**(Completed by Research Manager. If yes, verify resources are available with applicable ancillary committees/representatives.)** |
| **Imaging Resources**  | **YES** | **NO** | **NA** | **UNK** |  |  |
| **Comments** |
| Are there special imaging requirements? | [ ]  | [ ]  | [ ]  | [ ]  |  |
| Additional Comments |  |
| **In-Patient Unit Resources** | **YES** | **NO** | **NA** | **UNK** |  |  |
| **Comments** |
| Will in-patient resources be required? | [ ]  | [ ]  | [ ]  | [ ]  |  |
| Additional Comments |  |
| **Phase I Unit Resources** | **YES** | **NO** | **NA** | **UNK** |  |  |
| **Comments** |
| Will Phase I Unit resources be required for any length of time?*Please contact Phase I lead if resources are required.*  | [ ]  | [ ]  | [ ]  | [ ]  |  |
| Additional Comments |  |
| **Discoveries and Developmental Therapeutics Resources** | **YES** | **NO** | **NA** | **UNK** |  **Comments** |
| Will Discoveries and Developmental Therapeutics resources be required for any length of time? | [ ]  | [ ]  | [ ]  | [ ]  |  |
| Additional Comments |  |
| **Laboratory Resources** | **YES** | **NO** | **NA** | **UNK** |  |  |
| **Comments** |
| Will special laboratory equipment and personnel be adequate to conduct the protocol? | [ ]  | [ ]  | [ ]  | [ ]  |  |
| Are extended hours required? | [ ]  | [ ]  | [ ]  | [ ]  |  |
| Additional Comments |  |
| **Ophthalmology Resources** | **YES** | **NO** | **NA** | **UNK** |  |  |
| **Comments** |
| Are there special ophthalmology requirements? | [ ]  | [ ]  | [ ]  | [ ]  |  |
| Additional Comments |  |
| **Outpatient Resources** | **YES** | **NO** | **NA** | **UNK** |  |  |
| **Comments** |
| Are there special outpatient requirements? | [ ]  | [ ]  | [ ]  | [ ]  |  |
| Additional Comments |  |
| **Research Pharmacy Resources** | **YES** | **NO** | **NA** | **UNK** |  |  |
| **Comments** |
| Are there special research pharmacy requirements? | [ ]  | [ ]  | [ ]  | [ ]  |  |
| Additional Comments |  |
| **Pathology Resources** | **YES** | **NO** | **NA** | **UNK** |  |  |
| **Comments** |
| Are there special pathology requirements? | [ ]  | [ ]  | [ ]  | [ ]  |  |
| Additional Comments |  |
| **Cardiology**  | **YES** | **NO** | **NA** | **UNK** |  |  |
| **Comments** |
| Are there special cardiology requirements? | [ ]  | [ ]  | [ ]  | [ ]  |  |
| Additional Comments |  |
| **Dermatology**  | **YES** | **NO** | **NA** | **UNK** |  |  |
| **Comments** |
| Are there dermatology requirements? | [ ]  | [ ]  | [ ]  | [ ]  |  |
| Additional Comments |  |
| **Audiology**  | **YES** | **NO** | **NA** | **UNK** |  |  |
| **Comments** |
| Are there audiology requirements? | [ ]  | [ ]  | [ ]  | [ ]  |  |
| Additional Comments |  |
| **Other Ancillary Department: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** | **YES** | **NO** | **NA** | **UNK** |  |  |
| **Comments** |
| Are there special protocol requirements that need consideration? | [ ]  | [ ]  | [ ]  | [ ]  |  |
| Additional Comments |  |
| **Ancillary Services Considerations Assessment** |
| **Completed by Research Manager** | **Low****(**no feasibility challenges) | **Moderate****(**some feasibility challenges) | **High****(**many feasibility challenges) | **Comments** |
| What impact do the responses above have on feasibility? | [ ]  | [ ]  | [ ]  |  |

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| **SIGNATURES** |
|  |  |  |
| Research Manager Signature |  | Date |
|  |  |  |
| Principal Investigator Signature |  | Date |