**DISEASE TEAM PROTOCOL ASSESSMENT**

The purpose of the Disease Team (DT) Protocol Assessment is to critically evaluate the scientific value and impact of a study and to meet National Cancer Institute (NCI) expectations in prioritizing clinical studies conducted at Winship Cancer Institute (WCI). The Research Manager and Principal Investigator (PI) may complete the assessment form prior to the DT meeting; however, critical study discussion and finalized scoring should occur at the DT meeting.

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| Scientific Relevance | | | |
| Categories | **Description (points)** | **Score** |
| Innovation  *Does this protocol challenge or have the potential to change the current clinical paradigm by utilizing novel theoretical concepts, approaches or methodologies, or instrumentation/interventions?* | Highly innovative (2) |  |
| Moderately innovative (1) |  |
| Minimally innovative (0) |  |
| Clinical Impact | Phase II-III with practice changing implications (3) |  |
| Phase I-first in class that has potential across multiple tumor types/preclinical data support (2) |  |
| Phase I-III trial with *possible* practice changing implications (1) |  |
| Little or no clinical importance (e.g. post-marketing (phase IV) study) (0) |  |
| Rare or molecularly targeted tumors (0) |  |
| Trial Design and Rationale | Exceptional (2) |  |
| Very good / Satisfactory (1) |  |
| Fair / Poor (0) |  |
| Is the Trial Based on Data from a Winship Affiliated Lab? | Emory/Winship lab (2) |  |
| Cooperative Group (1) |  |
| Other institution (0) |  |

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| Impact on Winship | | | |
| Categories | **Description (points)** | **Score** |
| Source of Protocol | Investigator-Initiated study led by Winship (5) |  |
| Investigator-Initiated study with Winship as a participant site (4) |  |
| Foundation/Consortium with Winship PI involvement in design (3) |  |
| Cooperative group supporting LAPS grant activity (3) |  |
| Industry-Initiated with Winship PI involvement in design (1) |  |
| Industry-Initiated (0) |  |
| Academic Credit | Emory/Winship Investigator-Initiated trial based on Winship-originated science (5) |  |
| Emory/Winship Investigator-Initiated trial, multi-institutional (4) |  |
| Emory/Winship Investigator-Initiated trial (3) |  |
| Trial with likelihood of authorship (Lead PI/high accrual) (2) |  |
| Cooperative group trial with no chance of authorship but associated institutional credit (1) |  |
| Multi-institutional trial with no chance of authorship or credit (0) |  |
| Junior Investigators as PI/Co-PI  *<5 years as faulty member either at Emory/Winship* *or other institution* | Yes (2) |  |
| No (0) |  |
| Focus on women, minorities, or participant enrollment across the lifespan  *(for IITs only)* | Yes (2) |  |
| No (0) |  |
| Focus on Winship’s Catchment Area  (for IITs only) | Yes (2) |  |
| No (0) |  |

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| Feasibility and Operations | | |
| Categories | **Description (points)** | **Score** |
| Competing Trials | No competing trials open in pipeline (2) |  |
| 1 competing trial open or in pipeline over next 6 months (1) |  |
| ≥ 2 competing trials currently open or in pipeline over next 6 months (0) |  |
| PI and study team successfully met target enrollment (100%) on a study enrolling similar patient population within the last 2 years | Yes (2) |  |
| No (0) |  |
| N/A (0) |  |
| Accrual Expectation | Total accrual goal:   * Phase 0/I:   + > 5 patients (3)   + 3-5 patients (2)   + < 3 patients (0) |  |
| Total accrual goal:   * Phase II/III:   + ≥ 20 patients (3)   + 5-19 patients (2)   + < 5 patients (1) |  |
| Feasibility Review Assessment\*  *(conducted prior to DT meeting)*  *Low: no feasibility challenges*  *Moderate: some feasibility challenges*  *High: many feasibility challenges*  *\*Scoring from Protocol Feasibility Review Form* | Clinical Operations Staffing   * Low (2) * Moderate (1) * High (0) |  |
| Regulatory Considerations   * Low (2) * Moderate (1) * High (0) |  |
| Financial Considerations   * Low (2) * Moderate (1) * High (0) |  |
| Quality and Training Considerations   * Low (2) * Moderate (1) * High (0) |  |
| Participant Enrollment Considerations   * Low (2) * Moderate (1) * High (0) |  |
| Additional Protocol Considerations   * Low (2) * Moderate (1) * High (0) |  |
| Ancillary Services Considerations   * Low (2) * Moderate (1) * High or N/A (0) |  |
| TOTAL SCORE | |  |

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| **Overall Impact** | **DT Score** | **Description (points)** | **Action** |
| High | 31-46 | Excellent to Exceptional | Protocol may proceed to PRMC |
| Moderate | 16-30 | Satisfactory to Very Good | Protocol requires strong justification from DT to proceed to PRMC |
| Low | 0-15 | Poor to Fair | Protocol does not move forward. If DT endorses trial, note key discussion points in the comments section below. Protocol must be approved by Associate Director for Clinical Research. |

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| **DT PROTOCOL ASSESSMENT COMMENTS** |
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| **SIGNATURES** | | | |
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| Research Manager Signature |  | Date |
|  |  |  |
| Principal Investigator Signature |  | Date |
|  |  |  |
| Disease Team Chair Signature |  | Date |
|  |  |  |
| Associate Director for Clinical Research Signature  *(Only applicable for Protocol Impact Score of Low (0-15))* |  | Date |