**[Insert DEPARTMENT/DIVISION] PROTOCOL ASSESSMENT**

The purpose of the team Protocol Assessment is to critically evaluate the scientific value and impact of a study expectations in prioritizing clinical studies conducted at Emory University. The [*Department Research Administrator*] and Principal Investigator (PI) may complete the assessment form prior to the Scientific Review; however, critical study discussion and finalized scoring should occur prior to submission of study documents for preaward approval.

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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 an Emory Affiliated Lab? | Emory lab (2) |  |
| Cooperative Group (1) |  |
| Other institution (0) |  |

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| Impact on Department | | | |
| Categories | **Description (points)** | **Score** |
| Source of Protocol | Investigator-Initiated study led by Emory University (5) |  |
| Investigator-Initiated study with Winship as a participant site (4) |  |
| Foundation/Consortium with Emory University PI involvement in design (3) |  |
| Cooperative group supporting grant activity (3) |  |
| Industry-Initiated with Emory University PI involvement in design (1) |  |
| Industry-Initiated (0) |  |
| Academic Credit | Emory Investigator-Initiated trial based on Emory University-originated science (5) |  |
| Emory Investigator-Initiated trial, multi-institutional (4) |  |
| Emory 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* *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 Emory’s Catchment Area  (for IITs only) | Yes (2) |  |
| No (0) |  |

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| Feasibility and Operations | | |
| Categories | **Description (points)** | **Score** |
| Competing Trials @ Emory | No competing trials at Emory open in pipeline (2) |  |
| 1 competing trial open at Emory or in pipeline over next 6 months (1) |  |
| ≥ 2 competing trials currently open at Emory 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\*  *Low: no feasibility challenges*  *Moderate: some feasibility challenges*  *High: many feasibility challenges*  *\*Scoring from Clinical Trial 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** | **Score** | **Description (points)** | **Action** |
| High | 31-46 | Excellent to Exceptional | Protocol may proceed |
| Moderate | 16-30 | Satisfactory to Very Good | Protocol requires strong justification from Investigator to proceed |
| Low | 0-15 | Poor to Fair | Protocol does not move forward. If [*Dept/Div designee or Scientific expert*] 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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| **ASSESSMENT COMMENTS** |
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| **SIGNATURES** | | | |
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| Department Vice-Chair of Research Signature |  | Date |
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| Principal Investigator Signature |  | Date |
|  |  |  |
| Division Team Chair Signature |  | Date |
| Associate Director for Clinical Research  *(Only applicable for Protocol Impact Score of Low (0-15)* |  | Date |