**[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)
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| Total accrual goal:* Phase II/III:
	+ ≥ 20 patients (3)
	+ 5-19 patients (2)
	+ < 5 patients (1)
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| 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)
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| Regulatory Considerations * Low (2)
* Moderate (1)
* High (0)
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| Financial Considerations* Low (2)
* Moderate (1)
* High (0)
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| Quality and Training Considerations* Low (2)
* Moderate (1)
* High (0)
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| Participant Enrollment Considerations* Low (2)
* Moderate (1)
* High (0)
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| Additional Protocol Considerations* Low (2)
* Moderate (1)
* High (0)
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| Ancillary Services Considerations* Low (2)
* Moderate (1)
* High or N/A (0)
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| 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 |
|  |  |  |
| 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 |